Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

National Cancer Control Programme

National Quality Assurance Framework for Radiation Oncology in Ireland

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Preface

Radiation is a critical component of modern cancer therapeutics. It harnesses the physical and biological characteristics of ionizing radiation to cure, assist in curing or to palliate symptoms of cancer. There is often a narrow therapeutic index, and the technology to deliver this treatment is highly complex. This mandates an overarching programme that ensures patient safety and quality of care that meets national best practice guidelines and international evidence and standards.

The National Programme for Quality in Radiation Oncology outlines a paradigm to achieve this goal – both nationally and at local facility levels. It covers critical areas such as infrastructure; equipment; workforce; safety-incidence-learning; governance; evidence-based guidelines; key performance indicators and minimum datasets. The National Quality Assurance Framework for Radiation Oncology in Ireland is compliant with relevant statutory requirements.

One of the most important priorities is the patient, and in particular, their outcome from radiation treatment in terms of tumour control, side effects and their own perception of their quality of life and other outcomes. These are the fundamental metrics of the success and quality of a treatment for the fundamental stakeholder, the patient.

This programme of work was a significant under-taking, and the considerable work of the National Radiation Oncology Working Group of the National Cancer Control Programme (NCCP) is acknowledged with gratitude. Particular mention is made of Ruth Ryan, who with the assistance of Dr Niamh O'Callaghan and Ms. Louise Murphy, largely enabled this project to come to fruition. Multidisciplinary care should be the cornerstone of cancer care, patients should have access to high quality care staffed by appropriate specialists. These specialists are an essential part of improving and refining our cancer services.

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National Clinical Lead for Radiation Oncology, National Cancer Control Programme

Statement of Purpose and Need

Quality, its assurance and its improvement are all fundamental to good practice in any area of health. This principle is expressed in the legislation underpinning the Health Information and Quality Authority (HIQA), and is corroborated by key national health bodies such as the Department of Health, the Quality Improvement Division of the Health Service Executive (HSE), The Medical Exposure Radiaiton Unit (MERU), the Medical Council and others.

The Director of the NCCP therefore requested the National Clinical Lead for Radiation Oncology to develop a national programme for quality in radiation oncology. This work was developed by the National Radiation Oncology Working Group of the NCCP.

Such a programme for quality brings radiotherapy in Ireland into line with other developed countries such as Canada, Australia and the USA – all of which retain publicly available national guidance for quality in radiation oncology.

The National Cancer Strategy 2017 – 2026 (Department of Health (DoH), 2017), in recommendations 34 to 37, clearly stipulates the requirements for:

- A clearly defined framework for patient quality and safety,
- National healthcare quality indicators for cancer,
- Guidelines for cancer care in line with NCEC, and
- Focused patient experience surveys.

This programme fulfils these requirements for radiotherapy at an apt time. It also provides the opportunity to incorporate a standardized system across all the radiotherapy centres, promoting consistency and equality for patients regardless of where they live.

There are two broad dimensions to the national quality programme:

The first pertains to national standards that emanate centrally from NCCP and other bodies. These include National Treatment Guidelines, National Key Performance Indicators and the National Minimum Dataset among others. They must be consistent and contextualised with an evidence base, as well as the relevant statutory and regulatory bodies.

The second dimension for the quality programme is the local radiotherapy facility, and the requirements it must meet to ensure quality and safety of patients. This involves a suite of indicators, explanations of each, facility documentation required to confirm they are being adhered to, along with an assessment and scoring system to facilitate future accreditation activities as they evolve through the designated national bodies.

It is hoped that this programme will enable evidence-based consistent practice in radiotherapy nationally, with the focus on patients, their outcomes and the continuous cycle of improving them.

National Context and Relevant Legislation

The **Health Service Executive** was established under the Health Act 2004 to use the resources available to it in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public. Quality Improvement Division of the HSE was established in 2015 to support the development of a culture that ensures improvement of quality of care is at the heart of all services that the HSE delivers. It has a substantial repository of reports, papers and tools to achieve its function, one of the key ones being The Framework for Improving Quality (HSE - Quality Improvement Division, 2016).

The **National Cancer Control Programme (NCCP)** is a directorate within the Health Service Executive (HSE) which manages, organizes and delivers cancer control on a whole population basis. The National Cancer Control Programme (NCCP) was established in 2007 to implement the National Cancer Strategy 2006 with the aim to reduce cancer incidence; to reduce cancer mortality and morbidity; and to improve the quality of life of people living with cancer (Department of Health and Children (DoHC), 2006). The role and remit is expanded in the National Cancer Strategy 2017- 2026 (Recommendation 44 inter alia). The NCCP is responsible for the development of radiotherapy services; its Director chairs the National Programme for Radiation Oncology Board. The Director also sits on the Radiation Oncology Working Group, which develops policy, strategic, operational and other reports for the NCCP. This programme for quality was produced by the Working Group at the request of the NCCP Director.

The **National Cancer Strategy** 2017 – 2026 makes specific recommendations for radiotherapy nationally, including: the expansion of public sector radiation oncology facilities in Dublin, Cork and Galway In line with the National Plan for Radiation Oncology; a planned National Programme of Equipment Refreshment and Replacement; development of a health technology assessment function, and for the NCCP to manage the recruitment of appropriate levels of specialised staff for this treatment modality (Department of Health (DoH), 2017). Other recommendations relevant to radiotherapy include outcomes data from the National Cancer Registry (NCRI); promotion of research; development of clear frameworks for quality and safety, quality healthcare indicators and guidelines for cancer care in conjunction with the National Clinical Effectiveness Committee (NCEC).

The **NCEC** was established by the Minister for Health in September 2010, and is supported by the Clinical Effectiveness strand of the National Patient Safety Office (NPSO) in the Department of Health. The NCEC has national remits for clinical guideline methodology, clinical audit and education and training – all of which are components of a programme for quality. The NPSO has published guidance on Building a Culture of Patient Safety (2011) – a report of the Commission on Patient Safety and Quality Assurance (DoHC, 2008).

A clearly defined statutory framework exists for Radiation Protection of patients. The recommendations of the International Centre for Radiation Protection (ICRP) are embedded in the European Atomic Energy Community Treaty (EURATOM), which in-turn issues directives that are transposed in national laws by member states (Council Directive 2013/59/Euratom, 2013). For radiation protection of patients, Medical Exposure Directive 97/43 EURATOM was transposed into Irish law through Statutory Instruments SI 478 (2002) / 303 (2007) and 459 (2010). The legislation gives effect to the National Radiation Safety Committee, which advises the Minister of Health and Department of Health and the CEO of the HSE. The Medical Exposure Radiation Unit (MERU) is the executive, administrative and advisory unit for the National Radiation Safety Committee and regulates patient radiation protection practices in radiological facilities, both private and public. Any programme for quality must be compliant with the stipulations set down by MERU.

The **Health Information and Quality Authority**, under section 8(1)b of the Health Act (2007) the Authority has the function of setting standards on the safety and quality of health and social care services. Under section 8(1) c of the Health Act 2007, the Authority has the function to monitor compliance with standards and to advise the Minister for Health and the HSE accordingly. These National Standards were approved by the Minister for Health on 16 May 2012. The Authority also retains a function under section 8(1) f to operate accreditation programmes in respect of services, and to grant accreditation to any of them meeting standards set or recognised by the Authority. Any Programme for Quality must therefore be concordant with the National Standards, and ideally provide the basis for a putative accreditation process if the Authority were to seek one.

Healthy Ireland was launched by the Taoiseach and Minister for Health in 2013, and is the national framework for action to improve the health and wellbeing of the people of Ireland. It takes a whole-of-Government and whole-of-society approach to improving health and wellbeing and the quality of people's lives. The Health and Wellbeing Programme in the Department of Health has responsibility for strategic planning and co-ordination of the implementation of the Framework actions. Also established was a multi-stakeholder Healthy Ireland Council to provide a national advisory forum to support the implementation of the Framework across sectors. The central role of the Healthy Ireland framework is observed in the recommendations of the National Cancer Strategy 2017 – 2026 (Department of Health (DoH), 2017).

Methodology

The National Cancer Strategy (2017) recommends that "The NCCP will develop, publish and monitor a programme of national quality healthcare indicators for cancer care, involving both process and outcome measures, in line with international standards."

The principal objective of developing this quality assurance framework is to improve the quality of care received by patients. The other primary objectives are improvement of patient outcomes, and improvements in the consistency and standard of care.

This framework document is not by definition a policy, procedure, protocol or guideline. However the *HSE National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs)* was used as guidance for development of this document (National PPPG Steering and Project Groups, 2016).

The framework is based on the best research evidence in conjunction with clinical expertise. A research question and search terms were developed and approved by representatives of the National Radiation Oncology Working Group in the National Cancer Control Programme (NCCP). The following bibliographic databases were searched using keywords implicit to the question (Please see Appendix H Search Methodology for more detail):

- Pubmed,
- Cumulative Index for Nursing and Allied Health Literature (CINAHL),
- Embase and the
- Cochrane database were searched along with
- a number of societies and training bodies' web pages.

The full search strategies are available upon request.

The quality indicators were developed and agreed upon by the National Radiation Oncology Working Group. The discursive sections outlining the rationale for the quality indicators where further discussed by the national group. It was agreed that each speciality and/or professional group would focus on current peer review papers that support the quality indicators. Any additional work that was provided by this working group are referenced and included in the Bibliography.

Guidelines deemed eligible for review were critically appraised using Appraisal of Guidelines Research and Evaluation (AGREE) II criteria (Brouwers et al., 2010).

Section 1 - The NCCP National Framework

1.0 The NCCP's roles and responsibilities

The Department of Health's National Cancer Strategy (2017-2026) oultine that adoption of a programmatic approach to cancer control is recommended internationally in order to harness the necessary policy responses, ensure equity of access to services and ultimately deliver improved outcomes for patients (Department of Health (DoH), 2017). The NCCP works with the Department of Health, the Health & Wellbeing Directorate of the HSE, Hospital Groups, community healthcare organisations and training, accreditation and professional bodies to achieve these aims. The NCCP provides leadership across the continuum of cancer care. It promotes the provision of high quality evidence-based care to optimise outcomes and patient experience. The functions, work areas and achievements of the NCCP since its establishment have been documented in its seven year report, published in 2014.

The overall strategic input and impact of the NCCP will continue to be in the following areas:

- Leading on the implementation of cancer policy and on the development of cancer services including in the areas of prevention and survivorship;
- Defining evidence-based guidelines and practice in cancer care;
- Commissioning and monitoring service provision;
- Leading on the implementation of capital projects to ensure optimum patient access to diagnostics and treatment; and
- Developing programmes to promote best practice in cancer care, including workforce planning and education/training programmes.

1.1 Oversight and performance review

The NCCP will continue its strong oversight of cancer services, including monitoring the provision of services against agreed performance criteria as set out in the HSE Performance and Accountability Framework.

The NCCP will support best practice and the service level agreements with the hospital groups will provide a mechanism to address suboptimal performance issues. An audit mechanism is essential to support the evidence base for the provision of services, including the provision of specialist services in designated cancer centres (Appendix B Audit) .

The NCCP has significant authority over cancer control services in the public sector in order to ensure that they are in line with national policies and international best practice. This includes the authority to direct the discontinuation of any services that are not in line with agreed policy, or that do not meet required standards.

1.2 Developing a mechanism for prioritising new developments in cancer care

New developments in cancer care are emerging rapidly. It is essential that a robust, evidence-based mechanism for assessing, evaluating and prioritising the implementation of these new developments is put in place, taking into account the potential benefit to patients in terms of quality of life and outcomes and also ensures that it makes the best possible use of available resources.

2.0 National Clinical Guidelines

The National Cancer Strategy (2017-2026) (Department of Health (DoH), 2017) recommendation 37 states that:

"The NCCP will develop further guidelines for cancer care in line with National Clinical Effectiveness Committee (NCEC) Standards. Audits will also be developed in accordance with the NCEC Framework for National Clinical Audit."

This National Clinical Guidelines are developed to improve the standard and consistency of clinical practice in line with the best and most recent scientific evidence available. To date the NCCP have published four national clinical guidelines. They focus on the diagnosis, staging, and treatment of specific tumour sites, they focus on areas of clinical practice:

(i) Known to be controversial or uncertain,
(ii) Where there is identifiable practice variation,
(iii) Where there is new or emerging evidence,
(iv) Where guidelines have potential to have the most impact.

Radiation oncology along with surgery and medical oncology forms the cornerstone of cancer treatment. Each guideline to date addresses cllinical questions in radiation oncology and provides recommendations.

The National Radiation Oncology Working Group are currently developing clinical guidelines specifically for radiation oncology. The clinical areas being addressed were prioritised by the Working Group, clinical consultant supervisors have been assigned to tumour sites with research being carried out by Specialist Registrars, and support is being provided by the NCCP. This work is currently underway. It is anticipated that national centres would adhere to national guidelines.

3.0 National Key Performance Indicators (KPI) suites

Key Performance Indicators (KPIs) are required to measure how the health system is delivering on the objectives for improvements in cancer care outlined in this Strategy. They are essential to monitor the impact of the various elements of cancer control across the patient pathway.

The KPIs include internationally comparable clinical outcome measures, as these are the ultimate test of whether the system has performed for patients. Other indicators, such as those focused on process and activity, are required to provide signals in areas such as system performance and capacity. KPIs will also be used to focus attention on variations in performance, e.g. against the targets or between organisations, regions and populations. The information arising can inform decision making in areas such as policy and resource allocation.

The current National KPIs for radiation oncology measures:

- Number and percentage of patients receiving radical treatment for all cancers who commenced treatment within 15 working days of being deemed ready to treat by the Radiation Oncologist.

The National Radiation Oncology Working Group has identified further development of national KPIs as a priority. This work is currently underway.

4.0 National Minimum Dataset for radiotherapy

The National Radiation Oncology Working Group has identified the stages of a radiotherapy patient journey and a national minimum dataset for radiotherapy available in Appendix F Minimum Dataset

The health system currently captures a large amount of data in a myriad of electronic and manual formats. Some of the information can be used to measure cancer trends, record cancer system activity, improve system performance and, to an extent, shape policies to improve cancer control.

Qualitative and quantitative data are available on some population and lifestyle issues, and there are limited data on patient experience of treatment and palliative care. Further data can be captured by surveys and research projects.

The lack of an integrated information system across the entire health service is the major obstacle in providing accessible and shareable management information to measure performance and to inform future policy.

The multiplicity of data collection sources do not, in general, collect data in a uniform manner with agreed datasets, shared definitions or standardised coding and classification. In addition, while much data are available from sources such as the National Cancer Registry (NCR) or Hospital In-Patient Enquiry (HIPE), it is not evident that these are being systematically, serially and consistently interrogated to generate information that can drive policy.

In the context of an overall approach to management of information and information technology across the HSE, it must be a priority to improve collaboration between the collectors and the users of cancer data, such as the NCR, the NCCP, the National Screening Service (NSS), individual hospitals and Hospital Groups, the Department of Health and researchers. It will also be essential to have a clear legal and administrative framework for the collection, sharing and reporting of cancer data.

Section 2 - Local Facilities Quality Indicators

The facility quality indicators should serve as guidance towards meeting National standards..
The table of quality indicators is collated below. A discursive narrative of these points follows.

Patient Outcomes and the Quality Improvement Cycle		**MERU KPI**	**HIQA NS**
1	Tumour-control outcomes are recorded in patients receiving radical courses of radiotherapy.		2.8
2	Toxicities, acute and late, are recorded using validated instruments.		2.8
3	Patient reported outcomes, satisfaction, complaints, concerns and feedback are recorded.		1.8 2.8 3.1
4	The Radiation Treatment Programme has a Quality Improvement Cycle, which audits the above data and other KPI's for deficits in comparison to accepted benchmarks, addresses the deficit and re-measures the outcomes.		2.8 2.2.3 3.7 8.1
5	The Radiation Treatment Programme provides written, visual or online educational materials about radiation treatment planning, delivery, side-effects and follow-up to patients and their families.		1.4
6	The programme has documented informed-consent policies, in line with national standards and legislation, including specific guidelines for women and men of child-bearing age.	5	1.5
7	The programme offers patients information and participation on available national and international clinical trials that have been examined by the competent ethics body. The programme monitors the percentage of patients enrolled on clinical trials.		2.1
National Guidelines and Key Performance Indicators			
8	As part of justification, the radiation treatment programme utilizes national radiation planning and treatment guidelines and protocols. The rationale for non-adherence to guidelines is documented in individual cases.		2.1 5.11
9	The Radiation Treatment Programme has a system that monitors and effects compliance with the national KPI's for Radiation Oncology defined by the NCCP.		1.2 5.11
10	Patients have their case discussed at an appropriate multi-disciplinary meeting as part of the justification process for a radiation treatment.		2.3

Governance Structures		MERU KPI	HIQA NS
11	The Radiation Treatment Programme has clearly defined its reporting structure, and the responsibilities of all personnel (including suitable delegate) and committees, to ensure accountability for the quality and safety of care it provides, and the resources used to achieve this. The links with local, group and national health bodies are clearly defined.		3.6 5.1 5.2 7.1
12	There is an identified head of the Radiation Treatment Programme, a radiation oncologist, to whom all staff report regarding all aspects of the programme with suitable managerial and financial support.		5.1 5.6
13	There is a strategic plan, with facility-agreed timeframe (not greater than 5 years), that identifies on-going development and resource needs of the facility in order to maintain or improve the service provided, and that is consistent with group and national policies and requirements. Resource needs include infrastructure, equipment, workforce and models of service.		2.6 2.7 5.4 7.2
14	Documented management decisions, policies and procedures incorporate and support care delivered in accordance with the guidelines and requirements of the relevant national and international healthcare and statutory bodies including the NCCP, HIQA, HSE, DOH, MERU, and Irish Medical Council, and European Union.		5.1 5.5
	Workforce		
15	Core personnel, including Medical Physics Expert(s), Radiation Protection Experts (Advisors), Radiation Safety Officer, Practitioner(s), Lead Practitioner, have their roles and responsibilities clearly defined in line with national and European legislation – particularly with regard to radiation safety, justification and optimisation.		
16	There is a workforce plan to ensure sufficient numbers, mix and skills of staff to ensure patients are treated within national laws, guidelines and standards of care.		6.1
17	The programme ensures that all staff have the necessary qualifications, credentials, certifications and licenses; and successfully complete appropriate, accredited continuous professional development programmes; and are fully trained in radiation protection, optimisation and new techniques		6.2 6.3 6.4
18	Evidence of time and funding during working hours allocated to education, research and development, administration and quality assurance and improvement activities.		6.4

Radiation Treatment Quality Assurance		MERU KPI	HIQA NS
19	Compliance with technical quality control, policies and procedures is monitored and audited by a Radiation Treatment Quality Committee (RTQC).		5.8
20	The RTQC is responsible for the program's Quality Improvement Cycle, which conducts audits, assesses deficits in outcomes against benchmarks, and addresses the deficits and reassesses/ audits again.	6	5.8
21	The RTQC has documented terms of reference that meet all the requirements for composition, committee chair, meeting frequency, accountabilities and keeping of minutes.	6	5.7 5.8
22	The RTQC has a blame-free process for personnel to access the committee and to report concerns about radiation treatment quality or safety.		3.6 5.7
Safety, Incidents and Learning			
23	There is a radiation safety programme that fulfils the national and EU legislative requirements, in terms of personnel, their roles and responsibilities, training, and equipment.		3.1 3.3
24	There is a Radiation Safety Committee, whose membership and terms of reference meet NRSC guidelines. Minutes and records are kept of meetings, record of attendance, recommendations and actions taken.	1	
25	The programme, through a defined group, undertakes a proactive assessment of risk, preferably using an accepted methodology. It incorporates lessons learnt retrospectively into this proactive assessment process.		
26	The Radiation Treatment Programme has written policies and procedures that address the reporting, investigation, action, documentation, and monitoring of radiation treatment incidents. These are compliant with local, group and national requirements.	3	3.1 3.2 3.3 5.8
27	Radiation incidents are integrated (using an appropriate system) into a feedback, learning and improvement cycle for staff, consistent with National, EU and HSE policies on clinical incidents and learning.	3	3.1 3.2 5.8
28	The programme has a policy of open disclosure with regard to safety incidents, in line with national legislation and guidance.	1	
29	The facility has patient pregnancy protocols, compliant with MERU guidelines, which inter alia record a) pregnancy status throughout all procedures; b) decision and justification to treat while pregnant; c) incidents of inadvertent foetal exposure; d) waiver form and procedure.	4	

Data Management, Protection and Datasets		MERU KPI	HIQA NS
30	Each patient record contains the Minimum Dataset, as defined by the NCCP for radiation treatment.		2.5
31	All treatment planning data is retained sufficient to recreate the original treatment plan for a given patient.		
32	All treatment verification data is retained for 25 years, in order for them to be reconstructed in a clinically meaningful way if required.		
33	All equipment, calibration, dosimetric and planning system data is recorded and traceable. This includes all equipment service records, Quality Assurance records and replacement due dates.	2	
34	All patient data is kept in accordance with the General Data Protection Regulation (GDPR), national statutes regarding Data Protection and HIQA National Standards for information governance.		8.2
35	All paper and electronic records are managed in compliance with HSE Medical Records policy and HIQA National Standards for the management of healthcare records.		8.3
Planning Peer Review and Quality Controls			
36	Contouring of targets and organs-at-risk is guideline based, and reviewed at a departmental peer-review planning meeting along with the treatment plan technique, dosimetry and DVHs for radical or re-treatment case.		3.1.2
37	Site specialization is encouraged amongst radiation oncologists, with appropriate mix to allow peer-review and cross cover.		
38	The radiation treatment prescription meets all criteria outlined in Irish recommendations, to deliver treatment addressing dose prescription, site and laterality, patient identification and authorisation.		3.1.4
39	Radiotherapy treatment plans, dose calculations, and patient set-up data are independently reviewed prior to beginning treatment in all cases.		3.1.4
40	There are identification procedures that: a) Verify patient identity and, b) Match the patient to their treatment prescription and plan prior to each treatment session.		
41	There are policies and procedures to monitor patients with pacemakers/defibrillators or implantable devices during radiation treatment.		3.1.4

Radiation Treatment		MERU KPI	HIQA NS
42	There are identification procedures that **a**) Verify patient identity and, **b**) Match the patient to their treatment prescription and plan prior to each treatment fraction.	5	3.1.4 3.1.6
43	A visual monitoring system is in place for the observation and monitoring of patients during treatment.		3.1.4 3.1.6
44	Documented use of a verification system that incorporates equipment interlocks on out-of-tolerance treatment parameters and include clear instructions on the management of overrides.		3.1.4 3.1.6
45	There is assessment of image based verification in accordance with facility treatment management guidelines		3.1.4 3.1.6
46	Patients are reviewed during radiation treatment in accordance with facility patient management guidelines.		1.1.5 2.2.4 3.1.4
47	When radiation treatment is being delivered, a Radiation Oncologist and a Medical Physicist are present at the radiation treatment facility or capable of responding within a time limit set by a programme		3.1.4
48	There are policies and procedures guiding the planning and safe delivery of emergency radiation treatment		3.1.4 3.1.6
49	New types of treatment are justified in advance, before being generally adopted: staff are fully trained in all aspects of new techniques		
Equipment and Dosimetry			
50	Documented quality assurance programme for radiation therapy equipment and systems that includes all tests, their frequencies and tolerances; a protocol for managing test failures, non-compliances or equipment/system failures including action levels, reporting requirements and action taken		3.1.6
51	Records of equipment uptime and downtime should be maintained. Delays of treatment and unscheduled breaks in treatment should be recorded		3.1.6
52	Records of acceptance tests and commissioning data for all radiotherapy equipment, new treatment techniques and new methods of dose calculations. Commissioning is independently reviewed, and checked with measurements (as necessary) by a qualified individual (usually a medical physicist) who was not involved in the commissioning.		3.1.6

Equipment and Dosimetry (cont.)		MERU KPI	HIQA NS
53	For new equipment, all personnel involved with its calibration, operation, or maintenance are appropriately trained		3.1.6
54	Documented audit of radiation treatment machine calibration or dosimetry at least annually, as well as documentation: 1) that the facility has successfully participated in an external dosimetric intercomparison conducted with a non-affiliated organisationally separate service within the last two years and which has been reviewed and actioned as appropriate, and 2) that the facility has successfully participated in a level III dosimetric intercomparison within the last five years and which has been reviewed and actioned as appropriate.		3.1.6
55	Documented dosimetry that includes: • Derivation of all factors • Independent check of clinical dosimetric data by a medical physicist		3.1.6
56	At least one check of all monitor units, exposure time or dwell time calculations for each treatment plan.		3.1.6
57	Records of traceability of all radiation equipment calibrations including documentation of independent checking		3.1.6
58	Equipment for monitoring radiation and for use in responding to emergency situations		3.1.6
59	The programme has clear documented policies and procedures for the control of radionuclides and radioactive sources that comply with national and EU legislation.		
60	An up to date inventory of all equipment is maintained		
61	A copy of the facility RPII licence is on display	2	

2.0 Patient Outcomes and Quality Improvement Cycle

The landmark paper from the Institutes of Medicine outlined the key components of a Care System required to deliver quality clinical care to patients, accompanied by 10 rules for re-design to achieve this (Institute of Medicine Committee on Quality of Health Care in, 2001). One of the central components was Outcomes, which were required to be safe and effective. The IOM subsequently developed a cancer-specific document for quality in cancer care, which specified surveillance for recurrences during the survivorship phase, as well as prevention and management of long-term and late effects during this and other phases of the patient journey through their cancer history (Institute of Medicine of the National Academies, 2013). These central tenets of quality are also central to the HIQA National Standards for Safer, Better Healthcare approved by the Irish Minister for Health in May 2012 (HIQA, 2012). These standards include Patient-Centred Care and Support, along with Effective and Safe Care.

It follows from the above that no clinical enterprise can validate the effectiveness or safety of its treatments for patients without recording the relevant outcomes. In the case of radiotherapy this includes tumour control endpoints, as well as early and evolving side effects data. Validated, internationally-accepted instruments exist for recording these, as well as quality of life (e.g. CTCAE, EORTC QOL) (US Deptartment of Health and Human Services, 2010, EORTC Quality of Life Department). This background generates the first 2 indicators of quality:

No.	Quality Indicators
1.	Tumour-control outcomes are recorded in patients receiving radical courses of radiotherapy.
2.	Toxicities, acute and late, are recorded using validated instruments.

Additionally, there is increasing evidence in medicine for the validity of Patient Reported Outcomes, and their correlation with objective endpoints (Bottomley et al., 2016, Wilson et al., 2015, Basch, 2017). This also reinforces the patient-centred focus of quality recommended by IOM and HIQA, and represents a pragmatic way to accrue relevant outcome data. In addition, patient satisfaction, complaints and concerns provide important means for treatment units to enhance the patient experience irrespective of their treatment outcomes. The National Cancer Strategy includes this in Recommendation 35, in line with HIQA's standard approach for the National In-Patient Acute Care Patient Experience Survey (Health Information and Quality Authority (HIQA)). This gives rise to the 3rd indicator of quality:

Recommended evidence or quality indicators include:

No.	Quality Indicators
3.	Patient reported outcomes, satisfaction, complaints, concerns and feedback are recorded.

There is evidence, originating from industry, that cyclical review in processes reduces errors, defects and waste (Sokovic, 2010). Methodologies from industry have been adopted in healthcare [11], and have been utilized in radiotherapy (Chera et al., 2012, Pawlicki et al., 2012). The HSE Quality Improvement Division outlines an approach in its Framework for Improving Quality in our Health Service (Health Service Executive - Quality Improvement Division, 2016). Several methodologies exist, ranging from simpler (PDSA/PDCA cycle) through to less simple (Lean-VSM-5S) to more

complicated (Six Sigma – DMAIC). All have been used in healthcare, and the key criterion is that a selected system is used proficiently and consistently by people who are comfortable and competent in its delivery. This gives rise to the 4th indicator of quality:

Recommended evidence or quality indicators include:

No.	Quality Indicators
4.	The Radiation Treatment Programme has a Quality Improvement Cycle, which audits the above data and other KPI's for deficits in comparison to accepted benchmarks, addresses the deficit and re-measures the outcomes.

Patients require information about their treatment and future care-plan, as contained in Recommendation 40 of the National Cancer Strategy (Department of Health (DoH), 2017). This is consistent with many theme of IOM and HIQA, particularly rules of re-design 2 and 3 of the IOM; and National Standard 1 of HIQA. Recommendation 42 emphasizes the shared care protocols spanning hospital and primary care settings. These give rise to the 5th quality indicator:

Recommended evidence or quality indicators include:

No.	Quality Indicators
5.	The Radiation Treatment Programme provides written, visual or online educational materials about radiation treatment planning, delivery, side-effects and follow-up to patients and their families.

Consent for treatment is well established in Irish case law, and recognised under the Irish Constitution –as well as in international and European rights law. It is required for all radiotherapy treatments. Guidance is given by the HSE National Consent Policy 2013 (National Consent Advisory Group, 2013), and MERU oversees the implementation of this within the context of the specific statutory instruments underpinning radiation safety and protection in Ireland (Medical Exposure Radiation Unit, 2013). HIQA references consent in national standard 1.5, while the Irish Medical Council provides guidance for doctors (Medical Council of Ireland, 2016). Protection around pregnancy must comply with MERU section 4 and the relevant legislation. Specific considerations are required around patients and their wishes regarding their fertility (Pereira and Schattman, 2017). This gives rise to the 6th quality indicator:

Recommended evidence or quality indicators include:

No.	Quality Indicators
6.	The programme has documented informed-consent policies, in line with national standards and legislation, including specific guidelines for women and men of child-bearing age.

Clinical trial participation in radiation oncology has a number of potential benefits, including improved patient access to modern treatment paradigms and techniques; improved patient outcomes; exposure of staff and departments to improved techniques under external benchmarked

supervision and standards; and overall improved departmental quality as referenced below (The Faculty of Radiation Oncology et al., 2011).

There is increasing evidence of improved patient outcomes from participation in clinical trials compared with non-involved patients in non–small-cell lung, breast, colorectal, and testicular cancers (Chua et al., 2010). Internationally, high accrual activity to clinical trials has been used as an example of a goal of an exemplary clinical research site, with the recommendation to accrue at least 10% of patients to medical oncology clinical trials (Armstrong, 2005). The Scottish Cancer Taskforce National Cancer Quality Steering Group recently published recommendations of a target of 15% for the proportion of patients with cancer who are consented for a clinical trial (Scottish Cancer Taskforce National Cancer Quality Steering Group, 2014). This gives rise to the 7th quality indicator:

No.	Quality Indicators
7.	The programme offers patients information and participation on available national and international clinical trials that have been examined by the competent ethics body. The programme monitors the percentage of patients enrolled on clinical trials.

3.0 National Guidelines and Key Performance Indicators

3.1 Guidelines

HIQA highlight the importance of using best available national and international evidence and ongoing evaluation of service-user outcomes to determine the effectiveness of the design and delivery of care and support (HIQA, 2012 - Theme 2: Effective Care and Support).

All radiation treatment programmes should have policies and procedures for clinical care, treatment planning and delivery (Canadian Partnership for Quality Radiotherapy, 2015). These policies and procedures are to be reviewed at least every two years, revised as necessary, and readily available to staff as reference material (Canadian Partnership for Quality Radiotherapy, 2015).

No.	Quality Indicators
8.	As part of justification, the radiation treatment programme utilizes national radiation planning and treatment guidelines and protocols. The rationale for non-adherence to guidelines is documented in individual cases.

3.2 Key Performance Indicators

The radiation treatment program should monitor patient wait times in relation to national, and/or professional guidelines (Canadian Partnership for Quality Radiotherapy, 2015). The radiation treatment program should report wait times to local, and/or national organisations as required (Canadian Partnership for Quality Radiotherapy, 2015).

The National Cancer Strategy KPI No. 16 sets a target of a 90% compliance in patient commencing treatment within 15 working days of being deemed ready to treat by 2017 (Department of Health, 2017).

The National Radiation Oncology Working Group has identified further development of national KPIs as a priority. This work is scheduled to commence in 2018.

Recommended evidence or quality indicators include:

No.	Quality Indicators
9.	The radiation treatment programme has a system that monitors and effects compliance with the national KPI's for Radiation Oncology defined by the NCCP.
10.	Patients have their case discussed at an appropriate multi-disciplinary meeting as part of the justification process for a radiation treatment.

4.0 Governance Structures

4.1 Governance structures

HIQA Standards states that service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare (HIQA, 2012 - Theme 5: Leadership, Governance and Management). They aslo state Service providers actively support and promote the safety of service users as part of a wider culture of quality and safety (HIQA, 2012 - Standard 3.6). This is in accordance with the Canadian Partnership for Quality Radiotherapy Quality indicators that state within the radiation treatment program, there are clearly defined accountabilities for the quality of care that is delivered to patients (Canadian Partnership for Quality Radiotherapy, 2015). These are defined through the program's reporting structure and through the responsibilities of all staff directly involved in delivering care (Canadian Partnership for Quality Radiotherapy, 2015).

Recommended evidence or quality indicators include:

No.	Quality Indicators
11.	The radiation treatment programme has clearly defined its reporting structure, and the responsibilities of all personnel (including suitable delegates) and committees, to ensure accountability for the quality and safety of care it provides, and the resources used to achieve this. The links with local, group and national health bodies are clearly defined.

A head of the Radiation Treatment Programme should also be identified who should be a Consultant Radiation Oncologist (Canadian Partnership for Quality Radiotherapy, 2015).

Recommended evidence or quality indicators include:

No.	Quality Indicators
12.	There is an identified head of the Radiation Treatment Programme, a radiation oncologist who is the lead practitioner (with suitable managerial and resource support),, to whom all staff report regarding all aspects of the programme.

4.2 Strategic Plan

The National Cancer Strategy (2017) recommends that:

"The NCCP, working with other Directorates in the HSE and with the Department of Health, will develop a rolling capital investment plan, to be reviewed annually, with the aim of ensuring that cancer facilities meet requirements."

"In line with the National Plan for Radiation Oncology, public sector radiation oncology facilities in Dublin, Cork and Galway will be expanded to meet patient demand and a planned National Programme of Equipment Refreshment and Replacement will be implemented across the Strategy period."

The use of resources and the way resources are planned, managed and delivered are an important part of delivering safe and high quality care and support (HIQA, 2012 - Standards 7.1, 7.2, 2.6, 2.7) The strategic plan should ensure the department has sufficient and appropriate equipment, infrastructure and staff to deliver patient care in line with national and international guidelines and key performance indicators.

Recommended evidence or quality indicators include:

No.	Quality Indicators
13.	There is a strategic plan, with facility-agreed timeframe (not greater than 5 years), that identifies on-going development and resource needs of the facility in order to maintain or improve the service provided, and that is consistent with group and national policies and requirements. Resource needs include infrastructure, equipment, workforce and models of service.

Facilities governance, policies and procedures' should incorporate the intent of the National Healthcare Charter (Health Service Executive and Department of Health, 2012). Methods of obtaining direct feedback from patients are therefore vital in informing the quality improvement process (The Faculty of Radiation Oncology et al., 2011).

The technical quality of care and patient outcome should be evaluated, compared to benchmarks for best practice, and acted upon accordingly (The Faculty of Radiation Oncology et al., 2011).

Recommended evidence or quality indicators include:

No.	Quality Indicators
14.	Documented management decisions, policies and procedures incorporate and support care delivered in accordance with the guidelines and requirements of the relevant national and international healthcare and statutory bodies including the NCCP, HIQA, HSE, DOH, MERU, Irish Medical Council and European Union.

5.0 Workforce

All personnel with direct or indirect responsibility for the provision of radiation treatment should be appropriately educated, trained, qualified, and competent (Canadian Partnership for Quality Radiotherapy, 2015, An Bord Altranais, 2008, Medical Exposure Radiation Unit, 2013).

The workforce should be managed to deliver safe, quality care (The Faculty of Radiation Oncology et al., 2011, HIQA, 2012 - Standard 2.3). Staffing numbers should be established to safely meet planned patient care capacity (The Faculty of Radiation Oncology et al., 2011). National, local and professional staffing guidelines should be adhered to where available (Canadian Partnership for Quality Radiotherapy, 2015).

Recommended evidence or quality indicators include:

No.	Quality Indicators
15.	Core personnel, including Medical Physics Expert(s), Radiation Protection Experts (Advisors), Radiation Safety Officer, Practitioner(s), Lead Practitioner, have their roles and responsibilities clearly defined in line with national and European legislation – particularly with regard to radiation safety, justification and optimisation.
16	There is a workforce plan to ensure sufficient numbers, mix and skills of staff to ensure patients are treated within national laws, guidelines and standards of care.

HIQA Standards for Workforce state that service providers plan and organise their services to ensure there are enough staff with the necessary qualifications, skills and experience to deliver safe high quality care to service users at all times (HIQA, 2012 - Theme 6: Workforce). This in line with recommendation #16 and #50 of the National Cancer Strategy (2017).

Recommended evidence or quality indicators include:

No.	Quality Indicators
17.	The programme ensures that all staff have the necessary qualifications, credentials, certifications and licenses; and successfully complete appropriate, accredited continuous professional development programmes; and are fully trained in radiation protection, optimisation and new techniques

The National Cancer Strategy (2017) made the following recommendation with regard to continous professional development of the workforce:

> "The NCCP and the National Cancer Research Group will examine mechanisms to ensure that newly appointed cancer consultants and Advanced Nurse Practitioners have protected time to pursue research interests in their new posts."

Recommended evidence or quality indicators include:

No.	Quality Indicators
18.	Evidence of time and funding during working hours allocated to education, research and development, administration and quality assurance and improvement activities.

6.0 Radiation Treatment Quality Assurance

HIQA standards for Leadership, Governance and Management state that service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare (HIQA, 2012 - Standards 5.7 and 5.8). In accordance with this, the radiation treatment program should have a comprehensive quality assurance program that encompasses all aspects of radiation treatment planning and delivery that directly or indirectly impacts patient care with, at a minimum, the following components (Canadian Partnership for Quality Radiotherapy, 2015):

1. A Radiation Treatment Quality Assurance Committee (RTQAC)
2. Detailed written policies and procedures for all quality assurance activities in the program
3. A process for the retention of documents pertaining to quality assurance activities.

The RTQAC (Canadian Partnership for Quality Radiotherapy, 2015):

- Should be comprised, at a minimum, of a Radiation Oncologist, a Medical Physicist, and a Radiation Therapist with operational responsibility for quality assurance in the radiation treatment program. Other suggestions include a nursing representative, data manager and safety and quality officer.
- Is chaired by a Radiation Oncologist, Medical Physicist or Radiation Therapist
- Is a standing committee that meets at regular intervals − no fewer than four times per year. Each department should also have regular operational meetings at more frequent intervals.
- Reports to the head of the radiation treatment program and/or other committees or groups with responsibility for quality within the radiation treatment program, cancer program, or organisation.

Its duties and responsibilities are to oversee the dissemination, implementation, auditing and monitoring of this quality assurance framework. Section 6 Clinical Audit of the 'Patient Radiation Protection Manual' outlines a summary of the requirements for Clinical Audit in Radiological Practice and a guide to the implementation of structures and processes for an effective audit cycle (Medical Exposure Radiation Unit, 2013 - Section 6: Clinical Audit).

Facility governance acknowledges and supports safe practice, quality improvement, innovation and the safe and considered introduction of new technologies (The Faculty of Radiation Oncology et al., 2011, HIQA, 2012 - Standard 3.6). An appropriate committee/management structure to monitor and manage the quality of health care being delivered should be in place (The Faculty of Radiation Oncology et al., 2011).

There should also exist a mechanism for staff to access the RTQAC to report concerns about radiation treatment quality (Canadian Partnership for Quality Radiotherapy, 2015).

Recommended evidence or quality indicators include:

No.	Quality Indicators
19.	Compliance with technical quality control, policies and procedures is monitored and audited by a Radiation Treatment Quality Committee (RTQC).
20.	The RTQC is responsible for the programme's Quality Improvement Cycle, which conducts audits, assesses deficits in outcomes against benchmarks, addresses the deficits and reassesses audits again.
21.	The RTQC has documented terms of reference that meet all the requirements for composition, committee chair, meeting frequency, accountabilities and keeping of minutes .

No.	Quality Indicators
22.	The RTQC has a blame-free process for personnel to access the committee and to report concerns about radiation treatment quality or safety.

7.0 Safety, Incident and Learning

7.1 Safety

The radiation treatment program should have a radiation safety program to oversee the safe use of radioactive devices and materials in compliance with relevant legislation and regulations (Canadian Partnership for Quality Radiotherapy, 2015, HIQA, 2012 - Standards 3.1, 3.2, 3.3 and 3.6). Written policies and procedures should also exist (Canadian Partnership for Quality Radiotherapy, 2015).

It is necessary to have a Radiation Safety Committee (RSC - a Statutory Committee) whose members, meeting frequency and records are compliant with the EPA Office of Radiological Protection. The RSC should ensure compliance with Council Directive 2013/59/Euratom (2013), also known as the Basic Safety Standards which cover the radiation safety of public, patients and workers. The MERU 'Patient Radiation Protection Manual' details the Governance and Structure of a Radiation Safety Commitee (Medical Exposure Radiation Unit, 2013 - Section 1: Governance and Workforce):

In line with MERU and the Basic Safety Standards, a qualified individual is designated as having primary responsibility for all aspects of radiation safety in the treatment programme – a Radiation Safety Officer (Canadian Partnership for Quality Radiotherapy, 2015). With respect to matters of radiation safety, the Radiation Safety Officer reports to the organisation's CEO and/or other individuals, committees, or groups with responsibility for safety within the cancer program or organisation (Canadian Partnership for Quality Radiotherapy, 2015). The Radiation Safety Officer reports as necessary, and at least annually, to the cancer program or organisation quality committee or equivalent on matters pertaining to radiation safety in the radiation treatment program (Canadian Partnership for Quality Radiotherapy, 2015).

All staff in a facility should receive regular radiation safety training at a level appropriate to their job description (Canadian Partnership for Quality Radiotherapy, 2015). It is recommended that participation be monitored as part of performance evaluation (Canadian Partnership for Quality Radiotherapy, 2015).

Recommended evidence or quality indicators include:

No.	Quality Indicators
23.	There is a radiation safety programme that fulfils the national and EU legislative requirements, in terms of personnel, their roles and responsibilities, training, and equipment.
24.	This is overseen by a Radiation Safety Committee, whose membership and terms of reference meet NRSC guidelines. Minutes and records are kept of meetings, record of attendance, recommendations and actions taken.
25.	The programme, through a defined group, undertakes a proactive assessment of risk, preferably using an accepted methodology. It incorporates lessons learnt retrospectively into this proactive assessment process.
26.	The radiation treatment program has written policies and procedures that address the reporting, investigation, action, documentation, and monitoring of radiation treatment incidents. These are compliant with local, group and national requirements.
27.	Radiation incidents are integrated (using an appropriate system) into a feedback, learning and improvement cycle for staff, consistent with National, EU and HSE policies on clinical incidents and learning.

7.2 Radiation Treatment Incident Management

HIQA's Standards for Safe Care and Support states that service providers should effectively identify, manage, respond to and report on patient-safety incidents (HIQA, 2012 - Theme 3: Safe Care and Support). The radiation treatment program should monitor, investigate, act upon, document, and report radiation treatment incidents that occur at any point in the radiation treatment process from decision-to-treat through completion of treatment delivery (Canadian Partnership for Quality Radiotherapy, 2015). Risk assessments must be carried out for all techniques and new equipment.

Radiation treatment incidents need to be identified and the appropriate action taken as per MERU guidance (Medical Exposure Radiation Unit, 2013, Medical Exposure Radiation Unit, 2017, HIQA, 2012 - Standard 5.8).

The radiation treatment program should take action to prevent critical radiation treatment incidents from recurring and should report critical radiation treatment incidents to local, national, and/or international organisations as required (Canadian Partnership for Quality Radiotherapy, 2015).

The radiation treatment program should participate in the incident reporting framework prescribed by MERU and their own hospital group. Promoting open reporting and providing feedback to staff on incident data and investigations are vital components of a successful incident management system.

A management plan for radiation safety should be in place, defining responsibilities and delegations of all persons involved with radiation exposures and management of radiation safety (The Faculty of Radiation Oncology et al., 2011). All staff must be made aware of their role in radiation protection (The Faculty of Radiation Oncology et al., 2011). New staff must undergo the appropriate level of radiation protection education. Regular radiation protection courses and specific training must be in place.

A register of equipment, staff and safety notifications relating to radiation safety, ensuring notification and communication as required by the regulatory authority should be maintained (The Faculty of Radiation Oncology et al., 2011).

Appropriate equipment and resources should be available for radiation survey measurement in both routine checks and emergency situations (The Faculty of Radiation Oncology et al., 2011).

Regular review of all radiation safety procedures, the radiation management plan and physical verification to confirm continuing radiation safety should also take place (The Faculty of Radiation Oncology et al., 2011).

Recommended evidence or quality indicators include:

No.	Quality Indicators
28.	The programme has a policy of Open Disclosure with regard to safety incidents, in line with national legislation and guidance.
29.	The facility has patient pregnancy protocols, compliant with MERU guidelines, which inter alia record a) pregnancy status throughout all procedures; b) decision and justification to treat while pregnant; c) incidents of inadvertent foetal exposure; d) waiver form and procedure.

8.0 Data Management, Protection and Datasets

Service providers should have effective arrangements in place for information governance and management of healthcare records (HIQA, 2012 - Standards 8.2 and 8.3). Patient records should include demographic data, medical and social history, assessment, consultation notes and treatment record, clinical correspondence including referrals, the prescription and plan, test results and diagnostic staging studies and other administrative details such as health insurance status, billing, consent and legal correspondence (The Faculty of Radiation Oncology et al., 2011). Other information that assists in safe patient management includes emergency contacts, next of kin and required support services (The Faculty of Radiation Oncology et al., 2011, HIQA, 2012 - Standard 2.5).

Recommended evidence or quality indicators include:

No.	Quality Indicators
30.	Each patient record contains the Minimum Dataset, as defined by the NCCP for radiation treatment.

Sufficient radiation treatment information should be retained to allow the treatment plan to be reconstructed as a means of estimating the radiation dose delivered to tumour targets or normal tissues (Canadian Partnership for Quality Radiotherapy, 2015).

Recommended evidence or quality indicators include:

No.	Quality Indicators
31.	All treatment planning data is retained sufficient to recreate the original treatment plan for a given patient.
32.	All treatment verification data is retained for 25 years, in order for them to be reconstructed in a clinically meaningful way if required.

Ensuring security and appropriate retention of patient records and databases (as per Data Protection (Amendment) Act 2003 (Ireland, 2003)) is important (The Faculty of Radiation Oncology et al., 2011). The National Hospital Office has a Code of Practice for Healthcare Records Management – Retention and Disposal schedule (NHO Healthcare Records Management Steering Committee, 2007).

Recommended evidence or quality indicators include:

No.	Quality Indicators
33.	All equipment, calibration, dosimetric and planning system data is recorded and traceable. This includes all equipment service records, quality assurance records and replacement due dates.
34.	All patient data is kept in accordance with the General Data Protection Regulation (GDPR), national statutes regarding Data Protection and HIQA National Standards for information governance.
35.	All paper and electronic records are managed in compliance with HSE Medical Records policy and HIQA National Standards for the management of healthcare records.

9.0 Planning, Peer Review and Quality Control

9.1 Planning Procedures

The radiation treatment program, as part of the multidisciplinary cancer program, uses the Tumour Node Metastasis (TNM) tumour staging system or another valid staging system where indicated, to aid in prognostication, multidisciplinary treatment planning, and the analysis and reporting of outcomes (Canadian Partnership for Quality Radiotherapy, 2015).

Radiation treatment prescriptions should also be regularly audited by peer review (The Faculty of Radiation Oncology et al., 2011).

Widely endorsed among radiation oncologists, peer review has several dimensions (Brundage et al., 2013). These include case conference review of treatment decision-making, peer-to-peer review of planning contours and team meetings where representatives from multiple disciplines (e.g. physicians, therapists, physicists and nurses) review proposed treatment plans (Cancer Quality Council of Ontario, 2017).

Planning and treatment guidelines should be followed and the radiation treatment programme should have processes for selecting and regularly reviewing guidelines to be sure that they reflect current research and best practice information, including a process to decide among conflicting guidelines or multiple recommendations (Canadian Partnership for Quality Radiotherapy, 2015).

Treatment planning protocols should be documented, accessible to staff and endorse evidence-based best practice (The Faculty of Radiation Oncology et al., 2011). External and internal immobilisation methods and equipment should be fit for purpose (The Faculty of Radiation Oncology et al., 2011). Planning and imaging procedures localise, delineate and define target volumes and organs at risk, as well as enabling treatment verification (The Faculty of Radiation Oncology et al., 2011). There should also be a clearly defined process for authorising a course of treatment or any change to a previously authorised course of radiation treatment (Canadian Partnership for Quality Radiotherapy, 2015).

All radiation treatment plans administered with adjuvant or curative intent, and other plans where there is a significant potential for adverse patient outcome if tumour targets and/or normal structures are treated inappropriately, should undergo Radiation Oncologist peer review of volumes and dosimetry ideally before the start of treatment in all cases, or if not possible, before 25% of the total prescribed dose has been delivered (Canadian Partnership for Quality Radiotherapy, 2015).

Site specialisation is encouraged in line with the NCCP Workforce Plan for Radiation Oncology. Every radiation treatment plan, dose calculation, and patient set-up should be reviewed independently by a second professional (Radiation Oncologist, Medical Physicist, or Radiation Therapist as appropriate) prior to beginning treatment. There should exist a written procedure describing the minimum checks to be performed (Canadian Partnership for Quality Radiotherapy, 2015) (HIQA 3.1.2 3.1.4).

Recommended evidence or quality indicators include:

No.	Quality Indicators
36.	Contouring of targets and organs-at-risk is guideline based, and reviewed at a departmental peer-review planning meeting along with the treatment plan technique, dosimetry and DVHs for radical or re-treatment case.
37.	Site specialisation is encouraged amongst radiation oncologists, with appropriate mix to allow peer-review and cross cover.

No.	Quality Indicators
38.	The radiation treatment prescription meets all criteria outlined in Irish recommendations, to deliver treatment addressing dose prescription, site and laterality, patient identification and authorisation.
39.	Radiotherapy treatment plans, dose calculations, and patient set-up data are independently reviewed prior to beginning treatment in all cases.
40.	There are identification procedures that a) Verify patient identity and, b) Match the patient to their treatment prescription and plan prior to each treatment session.
41.	There are policies and procedures to monitor patients with pacemakers/defibrillators or implantable devices during radiation treatment.

10.0 Radiation Treatment

10.1 Treatment Delivery

HIQA Standards for Safe Care and Support states that a service focused on safe care and support is continually looking for ways to be more reliable and to improve the quality and safety of the service it delivers (HIQA, 2012 - Standards: 3.1.4 and 3.1.6). This includes outcome goals that are clearly defined when planning care for individual service users (HIQA, 2012 - Standard: 2.2.4). In line with MERU, verification procedures should be in place to minimise the risk of incorrect patient, incorrect dose and anatomical treatment misplacement (The Faculty of Radiation Oncology et al., 2011, Medical Exposure Radiation Unit, 2013).

Patients are positively identified using at least two patient-specific characteristics before any treatment or service is provided. Patient-specific identifiers include name, date of birth, medical record number, and photographs (Canadian Partnership for Quality Radiotherapy, 2015). Section 5 Patient Protocols of the 'Patient Radiation Protection Manual' states that each department should have a protocol in place where this applies (Medical Exposure Radiation Unit, 2013 - Section 5: Patient Protocols).

It should be possible to observe patients during radiation delivery and monitor according to need. Some patient groups may require more intense observation, ancillary support equipment and trained personnel (e.g. those on receiving concurrent chemotherapy, paediatric patients, those with pacemakers or similar or other special needs) (The Faculty of Radiation Oncology et al., 2011).

Recommended evidence or quality indicators include:

No.	Quality Indicators
42.	There are identification procedures that a) Verify patient identity and, b) Match the patient to their treatment prescription and plan prior to each treatment fraction.
43.	A visual monitoring system is in place for the observation and monitoring of patients during treatment.

Patients are reviewed for their fitness to continue and for their psychosocial needs throughout a course of treatment (The Faculty of Radiation Oncology et al., 2011) by a radiation oncologist or qualified designate (Specialist registrars, advanced nurse practitioners, clinical nurse specialists) (Canadian Partnership for Quality Radiotherapy, 2015). HIQA's standards for Person-Centred care and Support state that person-centred care and support places service users at the centre of all that the service does this includes flexibility to respond to the changing needs and preferences of service users where this can be achieved safely, effectively and efficiently (HIQA, 2012 - Standard: 1.1.5).

A Radiation Oncologist and a Medical Physicist should be present at the radiation treatment facility or readily available and capable of responding within an appropriate time limit set by the radiation treatment program, whenever any radiation treatment is delivered (Canadian Partnership for Quality Radiotherapy, 2015).

The radiation treatment program should also have defined policies and procedures guiding the planning and delivery of emergency radiation treatments of patients and does not compromise any of the usual quality and safety measures that apply to the routine treatment of patients (Canadian Partnership for Quality Radiotherapy, 2015).

Recommended evidence or quality indicators include:

No.	Quality Indicators
44.	Documented use of a verification system that incorporates equipment interlocks on out-of-tolerance treatment parameters and include clear instructions on the management of overrides.
45.	There is assessment of image based verification in accordance with facility treatment management guidelines.
46.	Patients are reviewed during radiation treatment in accordance with facility patient management guidelines.
47.	When radiation treatment is being delivered, a Radiation Oncologist and a Medical Physicist are present at the radiation treatment facility or capable of responding within a time limit set by a programme.
48.	There are policies and procedures guiding the planning and safe delivery of emergency radiation treatment.
49.	New types of treatment are justified in advance, before being generally adopted: staff are fully trained in all aspects of new techniques

11.0 Equipment and Dosimetry

11.1 Radiation Therapy Equipment

Healthcare should be provided in a physical environment which supports the delivery of high quality, safe, reliable care and protects the health and welfare of service users (HIQA, 2012- Standard: 2.7)
Safe and effective management of Radiation Therapy Equipment should be in accordance with legislative requirements, national policy, national guidelines where they exist, and best available national and international evidence (HIQA, 2012 - Standard: 3.1.5).

Radiation treatment equipment includes radiation treatment planning and delivery equipment and all major accessories used in the radiation treatment program (Canadian Partnership for Quality Radiotherapy, 2015). Specifically, this includes all teletherapy and brachytherapy treatment devices, treatment simulation devices, treatment planning computer systems, electronic information systems that are integrated with the above equipment and calibration and quality assurance devices used in relation to the above equipment (Canadian Partnership for Quality Radiotherapy, 2015).

Section 2 Radiology Equipment, Licence and Reports of the MERU 'Patient Radiation Protection Manual' states that service providers should have processes in place to identify and manage risks associated with radiological equipment to minimise the risk of harm to patients (Medical Exposure Radiation Unit, 2013 - Section 2: Radiology Equipment, Licence and Reports).

The National Cancer Strategy (2017) recommends that "In line with the National Plan for Radiation Oncology, public sector radiation oncology facilities in Dublin, Cork and Galway will be expanded to meet patient demand and a planned National Programme of Equipment Refreshment and Replacement will be implemented across the Strategy period."

11.2 Responsibility for Equipment Quality Control

A Radiation Treatment Quality Assurance Committee (RTQAC) monitors quality control activities and indicators of equipment performance (Canadian Partnership for Quality Radiotherapy, 2015).

11.3 Equipment Quality Control Procedures

There should also be a preventative maintenance program for radiation therapy equipment that ensures safety, reliability, reproducibility and accuracy (The Faculty of Radiation Oncology et al., 2011). In order to assess the ongoing performance of all radiation therapy equipment used in treatment planning and delivery there should be an ongoing quality control programme as part of the overall quality assurance programme (The Faculty of Radiation Oncology et al., 2011).

Quality control procedures describing the tests to be performed, frequency of testing, qualifications of those testing, tolerances associated with any measurement and procedures to be followed in the event a test fails or a measurement falls outside an allowed tolerance should be in place (Canadian Partnership for Quality Radiotherapy, 2015). These need to be based upon best available evidence and published practice guidelines.

11.4 Emergency Procedures

There are clearly defined procedures to be followed in the event of acute failure of equipment or systems that could affect patient, staff, or public safety (Canadian Partnership for Quality Radiotherapy, 2015).

Recommended evidence or quality indicators include:

No.	Quality Indicators
50.	Documented quality assurance programme for radiation therapy equipment and systems that includes all tests, their frequencies and tolerances; a protocol for managing test failures, non-compliances or equipment/system failures including action levels, reporting requirements and action taken.

11.5 Introduction of New Equipment

Qualified, trained and experienced staff should specify requirements of new radiation therapy equipment (The Faculty of Radiation Oncology et al., 2011). New radiation therapy equipment, and any modification to same, should be installed, acceptance tested and commissioned for clinical use by qualified personnel (i.e Medical Physicst Expert (MPE)) (The Faculty of Radiation Oncology et al., 2011, Medical Exposure Radiation Unit, 2013 - Section 1: Governance and Workforce). MPE should take responsibility for the commissioning program (The Faculty of Radiation Oncology et al., 2011). This should clearly define: any baseline values for quality assurance and system operation; the scope of tests to be performed with respect to their intended clinical use; the staff groups to be involved; and the risk assessment for component or system failure and for the introduction of any treatment technique (The Faculty of Radiation Oncology et al., 2011). All commissioning programmes and results should be subject to review either internally or externally before clinical introduction (peer review).

Recommended evidence or quality indicators include:

No.	Quality Indicators
51.	Records of equipment uptime and downtime should be maintained. Delays of treatment and unscheduled breaks in treatment should be recorded.
52.	Records of acceptance tests and commissioning data for all radiotherapy equipment, new treatment techniques and new methods of dose calculations. Commissioning is independently reviewed, and checked with measurements (as necessary) by a qualified individual (usually a medical physicist) who was not involved in the commissioning.
53.	For new equipment, all personnel involved with its calibration, operation, or maintenance are appropriately trained.

11.6 Equipment Obsolescence

Equipment or software that is unable to provide the functionality required for modern, standard-of-care patient treatment is defined to be obsolescent and is targeted for replacement with contemporary equipment or software (Canadian Partnership for Quality Radiotherapy, 2015).

11.7 External Dosimetry Audit

An independent machine dosimetry audit should be conducted on an annual basis (Canadian Partnership for Quality Radiotherapy, 2015). It is necessary to have an independent calibration check done with the introduction of any new linac or treatment device. After that the quality assurance or quality control process should ensure consistent performance.

Recommended evidence or quality indicators include:

No.	Quality Indicators
54.	Documented audit of radiation treatment machine calibration or dosimetry at least annually, to include documentation: 1) That the facility has successfully participated in an external dosimetric intercomparison conducted with a non-affiliated organisationally separate service within the last two years and which has been reviewed and actioned as appropriate, and 2) That the facility has successfully participated in a level III dosimetric intercomparison within the last five years and which has been reviewed and actioned as appropriate.

11.8 Dosimetry

Dose measurement ensures compliance of the dose delivery with the treatment prescription (The Faculty of Radiation Oncology et al., 2011). All radiation dose measurements must be traceable to a national standard if available, otherwise to an internationally recognised standard (The Faculty of Radiation Oncology et al., 2011, Canadian Partnership for Quality Radiotherapy, 2015).

Dosimetry equipment that conforms to the requirements of a specified dosimetry code of practice must be used (The Faculty of Radiation Oncology et al., 2011).

The calibration of the radiation dose delivered by all treatment units should be consistent with dosimetry codes of practice recommended by national regulatory authorities (The Faculty of Radiation Oncology et al., 2011).

Medical physicists must provide the data required for treatment planning, regularly verify their integrity and define the methodology to be used for patient dose calculations (The Faculty of Radiation Oncology et al., 2011).

All new or modified treatment devices that affect dose calculation must have their calibration factors determined by a Medical Physicist Expert (MPE) (The Faculty of Radiation Oncology et al., 2011).

All clinical dosimetric data should be verified by a MPE and independently checked against existing acceptance and commissioning data (The Faculty of Radiation Oncology et al., 2011). Responsibility for treatment planning systems, dose calculations and radiotherapy planning optimisation lies with the MPE. In line with BSS, all calculations of dose to a patient should be performed and independently checked by medical physicists or radiation therapists trained and experienced in specific planning calculation methods (The Faculty of Radiation Oncology et al., 2011). Where independent monitor unit calculation is impractical, measurement may replace an independent check (The Faculty of Radiation Oncology et al., 2011).

There is a system for independent verification of dose delivery to individual patients (The Faculty of Radiation Oncology et al., 2011).

11.9 Dosimetric Intercomparison

It is advised that the radiotherapy facility participates in dosimetric intercomparisons of at least one photon beam and one electron beam every two years (The Faculty of Radiation Oncology et al., 2011). Inter-comparisons include at least one level III dosimetric intercomparison every five years using a treatment scenario relevant for the particular centre (The Faculty of Radiation Oncology et al., 2011).

Recommended evidence or quality indicators include:

No.	Quality Indicators
55.	Documented dosimetry that includes: • Derivation of all factors • Independent check of clinical dosimetric data by a medical physicist
56.	At least one check of all monitor units, exposure time or dwell time calculations for each treatment plan.
57.	Records of traceability of all radiation equipment calibrations including documentation of independent checking.
58.	Equipment for monitoring radiation and for use in responding to emergency situations.
59.	The programme has clear documented policies and procedures for the control of radionuclides and radioactive sources that comply with national and EU legislation.
60.	An update inventory of all equipment is maintained
61.	A copy of the facility RPII licence is on display

Appendix A Risk Management

The EU Basic Safety Standards (Council Directive 2013/59/Euratom, 2013) gives direction regarding accidental and unintended exposures in the context of medical exposure. Article 63, Part (b) states "*the quality assurance programme includes a study of the risk of accidental or unintended exposures*". This is the prospective aspect of risk management: its scope can include equipment, processes, human and organizational factors and the external environment. Parts (c), (d), (e) and (f) give direction on the retaining of appropriate systems for the record keeping and analysis of events, arrangements for notification and the dissemination of information learned from events. This is the reactive or retrospective component of risk management. Note: risk is not confined solely to accidental or unintended exposure.

The document EC RP N^{o} 181 (2015a) lists the aims of the overall integration of these two components of risk management, namely:

- to identify hazards and failures
- to evaluate the consequences of a hazard and/or failure,
- to define the likelihood and severity of those hazards/failures in order to calculate the associated risks and to prioritize prevention efforts,
- to define how to decide (method, criteria) which risk reduction actions should be implemented and,
- to use feedback from reporting and analysis of events as appropriate.

Successful risk management in radiotherapy entails developing a culture of safety through appropriate leadership, training, resourcing and selection of appropriate methodologies with guidance from an experienced risk manager. A dedicated multidisciplinary risk management group for radiotherapy is recommended, along with a quality management system that encompasses the entire patient journey.

Regarding the reactive or retrospective component, this section of the Framework goes into detail on the taxonomy and reporting of radiation incidents in Ireland, as there are multiple (though similar) definitions, requirements, pathways and frameworks. It touches on Learning Systems to complete the retrospective aspect of risk management, but does not go into detail, as it is well covered by the HSE and European Commission documents that are referenced.

Similarly, the prospective component of risk management is mentioned, but not detailed. Again the relevant HSE and EC documents are referenced, and centres are advised to consult with these.

The EC publication is specific to radiotherapy. Two of the methods it describes are derived from the ASN work on FMECA (Failure Mode, Effect and Criticality Analysis) and IAEA-FORO work on Dedicated Risk Matrix. The HSE Integrate Risk Management Policy is based on ISO 31000 Principles, and provides a general approach to proactive risk management aligned with current HSE principles and structures. Its importance rests, inter alia, with its risk matrix and clear definitions of responsibilities. This allows HSE radiotherapy departments to interact with the wider HSE milieu.

In order to better understand Risk Management, readers are directed to two publications by the European Commission:

- European Commission: Radiation Protection N^{o} 181 – General guidelines on risk management in external beam radiotherapy (European Commission (EC), 2015a)
- European Commission: Technical supplement to Radiation Protection N^{o} 181 – General guidelines on risk management in external beam radiotherapy (European Commission (EC), 2015b)

Nationally, the HSE Quality Assurance and Verification Division (QAVD) have published a detailed framework on the analysis of incidents (Health Service Executive - Quality Assurance and Verification Division, 2018). It references the Yorkshire Contributory Factors Framework, which is a useful learning tool for all clinical incidents. The framework recommends that lessons learned be formulated into recommendations that are prospectively integrated into the existing service plan or policies, with prospective monitoring on their effects.

HSE QAVD has also issued a detailed policy on risk management (Health Service Executive - Quality Assurance and Verification Division, 2017), based on ISO 31000 Risk Management Principles (2018).

The EC document RP N^{o} 181 (mentioned above) provides excellent recommendations on the setting up of proactive and reactive risk management systems (pp 52 – 59), in terms of requirements both locally and nationally (European Commission (EC), 2015a).

Finally, bear in mind that the management of risk is one dimension of overall quality of care.

Part i) Retrospective analysis of events

i) Taxonomy and implications for reporting of radiation incidents in Ireland

Several international classification systems define patient safety incidents (World Health Organization (WHO), 2009, European Commission (EC), 2015a, Civil Liability (Amendment) Act, 2017, Council Directive 2013/59/Euratom, 2013). While the definitions are broadly similar, some confusion can arise due to subtle variations in the use of certain terminologies.

World Health Organization

The World Health Organization (WHO) has developed a common taxonomy in its report Conceptual Framework for International Classification of Patient Safety (2009). The foundation definitions are of 'event' and 'circumstance', as follows:

Event:	Is something that happens to or involves a patient.
Circumstance:	Is a situation or factor that may influence an event, agent or person(s).
Harm:	Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death. [WHO classifies harm into degrees: None, Mild, Moderate, Severe, Death] [Page 18 2009 Publication]

From these definitions, the WHO defines a patient safety incident as follows (it also shortens the term patient safety incident to 'incident'):

Patient Safety Incident:	Is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient.

The WHO then refines this definition into 4 subtypes of patient safety incidents (or 'incidents'):

Reportable circumstance:	Is a situation in which there was significant potential for harm, but no incident occurred (e.g. a defibrillator unused in an arrest then found to be not working subsequently).
Near miss:	Is an incident which did not reach the patient.
No harm incident:	Is one in which an event reached a patient but no discernable harm resulted.
Harmful incident (adverse event):	Is an incident that results in harm to a patient.

The European Commission

The European Commission (referred to as EC from here on) produced the document Radiation Protection N^{o} 181 – General guidelines on risk management in external beam radiotherapy (2015a). It has near-identical definitions to the WHO, but does not use the term 'incident'. Instead it uses 'event' throughout.

Event:	Something that happens to or involves a patient (WHO, 2009a,b). A circumstance that could have resulted, or did result, in unnecessary harm to a patient
Significant event (Notifiable event):	An event that should be notified to authorities according to national criteria defined by regulation
Near miss event (Near miss):"	An event which could have resulted in unintended harm to the patient but which did not reach the patient (i.e. without consequence for the patient).
Minor or no harm event	An event that reaches the patient but does not harm the patient"

The key difference with the WHO lies in the EC definition of 'event' in that it initially adopts the WHO definition of 'event', but then adds the WHO definition of 'patient safety incident' and amalgamates the two. Hence the EC definition of 'event' encompasses the WHO definitions of 'event' *and* 'incident'.

This is not a major issue, as long as readers understand the principle distinctions involved.

The Irish Law

The Civil Liability (Amendment) Act (2017) was published in November 2017. Part 4 of it legislates for Open Disclosure, and Part 4, Section 8 defines 'patient safety incident' as follows:

Patient Safety Incident	a) an incident which has caused an unintended or unanticipated injury, or harm, to the patient and which occurred in the course of the provision of a health service to that patient, (b) an incident— (i) which has occurred in the course of the provision of a health service to the patient and did not result in actual injury or harm, and (ii) in respect of which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm, (c) the prevention, whether by timely intervention or by chance, of an unintended or unanticipated injury, or harm, to the patient in the course of the provision, to him or her, of a health service, and in respect of which the health services provider has reasonable grounds for believing that, in the absence of such prevention, could have resulted in such injury, or harm, to the patient.

It can be seen that (a) is equivalent to a 'Harmful incident/Adverse event' by WHO definitions, or to an 'Event' by EC definition.

Similarly, (b) is equivalent to a 'no harm incident' under WHO, and a 'minor or no harm event', under EC.

Finally (c) is equivalent to a 'near miss' under WHO, and a 'near miss event (near miss)' under EC.

Irish Radiation Regulations (NRSC and MERU)

COUNCIL DIRECTIVE 2013/59/EURATOM (Council Directive 2013/59/Euratom, 2013) of 5 December 2013 lays down basic safety standards (EC BSS) for radiation protection. It came into effect on 6th February 2018, and the transposition into the appropriate Irish statutory instrument will be completed. This will replace SI 478 (2002), under which the National Radiation Safety Committee was established to advise the CEO of the HSE on Radiation Safety Issues for Patients. The National Radiation Safety Committee has produced guidelines as an aid to classifying radiation incidents to patients.

The Medical Exposure Radiation Unit (MERU) currently resides in the HSE Quality Assurance Verification Division, though it will transfer to HIQA under the new statutory instrument. The role of the Medical Exposure Radiation Unit, HSE is to regulate patient radiation protection practices in radiological facilities, both private and public, and receive advice from the National Radiation Safety Committee. It has published a comprehensive Radiation Protection Manual (MERU, 2013, MERU, 2017), Section 3 of which covers incident reporting and learning. It defines incidents as follows:

A patient radiation incident:	Occurs where the delivery of radiation during an imaging procedure or treatment is different to that intended or where there is none intended for the patient, resulting in unnecessary variation in exposure, unless due to patient factors (Medical Exposure Radiation Unit (MERU), 2013)[1,2].
Near miss patient radiation safety incident	Is a potential patient radiation incident that is detected before an imaging procedure or treatment (radiology/radiotherapy/nuclear medicine) takes place. There is no adverse outcome; the potential risk was identified and prevented (Medical Exposure Radiation Unit (MERU), 2013) [3].
Patient radiation incidents reportable to MERU (2017) Notifiable Incidents[4]:	• Radiotherapy dose or volume variation from total prescribed > 10% • Radiotherapy dose or volume variation from the fraction prescribed >20%. • Radiotherapy dose given to comforters and carers without consent greater than Medical Council guidelines of 3mSv for adults under 60 years of age and 6mSv for those over 60 • Deterministic effects from radiotherapy • Any other radiation exposure incident considered to have serious patient safety implications • No dose intended / incorrect patient >1mSv • Dose to foetus >1mSv • Dose to breastfed child > 1mSv • Incorrect procedure / anatomy • Incorrect radiopharmaceutical • Therapeutic nuclear medicine - administered activity different by 20% than intended.

[1] This relates closely to the new EC BSS definition of unintended exposure as: "medical exposure that is significantly different from the medical exposure intended for a given purpose."
[2] It does not refer to harm or injury, potential or actual, unlike the WHO, EC and the Irish Law. This has implications for reporting lines, learning and actions – described subsequently in greater detail.
[3] This is similar to other definitions of near miss, although it more strongly implies an active identification of the risk before the treatment. WHO and EC allow for the risk being identified after the treatment. It simply did not result in an event reaching the patient under their terms.
[4] all other incidents and near misses must also be reported annually to MERU for trending purposes

	• Diagnostic overexposure of an adult of more than twice the exposure intended that leads to >10mSv or 20 times the dose intended. • Diagnostic over exposure of a child of more than twice the exposure intended that leads to >3mSv or 15 times the dose intended. • Deterministic effects as a result of interventional radiology. • Administration of a skin dose of 15Gy in a diagnostic environment. • Therapeutic dose given instead of diagnostic dose e.g. radioiodine.

MERU Classification of incidents in radiotherapy

The Patient Radiation Protection Manual (2017) contains a table which classifies radiation incidents in terms of severity for reporting purposes:

Incident severity	Examples	Individuals to be notified	Time scale
1 Minor Incident	Dose or volume variation from prescribed total dose <5% and fractional dose 10 – 20%. Near miss or unsafe condition which could potentially cause a treatment error.	Hospital Risk Manager, Clinical Specialist or Senior Radiation Therapist, Radiotherapy Services Manager (RTSM), Treating Consultant only if *actual* patient impact, RSC Chairperson.	Within 24 hours
2 Potential Serious Incident	A near miss that could have been a serious incident.	Hospital Risk Manager, Clinical Specialist or Senior Radiation Therapist,	Within 24 hours
3 Serious Incident	Dose or volume variation from prescribed total dose 5 - 10% and 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.	Hospital Risk Manager, RTSM, Head of Physics, Treating Radiation Oncologist. RSC Chairperson.	Within 24 hours
4 Potential major incident	A near miss that could have been a major incident.	Hospital Risk Manager, CEO / General Manager, RTSM, Head of Physics, Director of Nursing, Treating Radiation Oncologist	Within 24 hours
5 Major Incident	Dose or volume variation from prescribed total dose of 10 - 20%. Radiation dose or medication error causing side effects requiring major treatment and intervention or hospitalisation. Set up variation that will/could impact on normal tissue e.g. heart, lung, eyes, kidney.	Hospital Risk Manager, CEO / General Manager, RTSM, Head of Physics, Director of Nursing, Treating Radiation Oncologist, RSC Chairperson.	Immediate
6 Critical Incident	Radiation dose or medication error causing death or disability. Dose or volume variation from prescribed total dose > 20%. Incorrect volume.	Hospital Risk Manager, CEO / General Manager, Clinical Director, RTSM, Head of Physics, Director of Nursing, Treating Radiation Oncologist, RSC Chairperson.	Immediate

The MERU Radiation Protection Manual has a comprehensive Radiotherapy Patient Incident Form, which must be filled for every incident and near miss. It distinguishes which incidents are immediately notifiable to MERU, and the appropriate parties to notify for each class of incident severity. Additional steps are given for Major and Critical Incidents. The manual also provides a template for annual returns for all patient radiation incidents.

HSE Quality Assurance and Verification Division (QAVD)

The HSE QAVD published its HSE Incident Management Framework in 2018. When an incident occurs, it is categorised, according to the HSE Risk Impact Table, in order to help determine the level of review required, as well as inform immediate steps required to eliminate further harm or risk. Definitions contained in the HSE Incident Management Framework (2018) include:

Patient Safety Incident:	Taken directly from the Irish legislation
No Harm Incident:	An incident reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances.
Near Miss:	An incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user.
Serious Incident:	An incident that results in a rating of major or extreme as per the HSE's Risk Impact Table.
Serious Reportable Event:	Serious reportable events are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers. Serious reportable events are mandatorily reportable by services to the Senior Accountable Officer [actually not all that precise]
Serious Harm:	Harm that result in a rating of major or extreme as per the HSE's Risk Impact Table
Adverse Event:	An incident which results in harm that may or may not be the result of an error.
Dangerous Occurrences	Dangerous occurrences may result from a sequence of events and circumstances involving a combination of unsafe acts, unsafe conditions, system failures, human factors and/or omissions. It most directly relates to the term 'reportable circumstance' as defined by the WHO (2009)
Error	The failure of a planned action to be completed as intended or use of a wrong inappropriate or incorrect plan to achieve an aim.
Harm:	Similar to the WHO classification (2009), but classified into negligible, minor, moderate, major and extreme (HSE Integrated Risk Management Policy – Part 2 – Impact Table).
Hazard	A circumstance, agent or action with the potential to cause harm
Incident:	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm. Incidents can be clinical or non-clinical

Management of Incidents (HSE QAVD Framework)

The Framework encompasses all potential sources including: Incidents, Complaints, Audit, Regulatory feedback, Protected Disclosure, Health and Safety / Dangerous occurrences, Confidential Recipient (Health Service Executive - Quality Assurance and Verification Division, 2018). Any of these may apply to a situation in a radiotherapy facility.

A number of initial steps are recommended in the management of incidents, including:

- The provision of appropriate medical treatment or other care to manage the harm that has occurred, relieve suffering and minimise the potential for further harm to occur.
- Consideration of open disclosure (as per the HSE QID algorithm below)
- Assignment of a liaison person
- Initiate appropriate support systems for involved staff
- Mitigate risk to others

Next, steps to ensure appropriate initial reporting and notification are taken, including:

- Informing the Risk Manager
- An appropriate National Incident Report Form is filled and submitted for input to the National Incident Management System, to fulfil the service's obligation to inform the State Claims Agency
- The Senior Accountable Officer is informed of Serious Incident (those rated Major or Extreme by the HSE's Risk Impact Table – see below)

Next categorisation and initial assessment takes place:

- Categorisation is done using the HSE's Risk Impact Table

Table 1 Risk Matrix (Health Service Executive - Quality Assurance and Verification Division, 2017)

	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme(5)
Almost certain (5)	**5**	**10**	**15**	**20**	**25**
Likely (4)	**4**	**8**	**12**	**16**	**20**
Possible (3)	**3**	**6**	**9**	**12**	**15**
Unlikely (2)	**2**	**4**	**6**	**8**	**10**
Rare/Remote (1)	**1**	**2**	**3**	**4**	**5**

- Definitions of Harm (Horizontal top) and Probability (Vertical left) are given in the Appendix
- Category 1 is in green, category 2 is orange, and category 3 is in red. The level of review is:
    - Category 1: Level 1 Comprehensive Review
    - Category 2: Level 2 Concise Review (some Category 1)
    - Category 3: Level 3 Aggregate Review

HSE Quality Improvement Division (HSE QID)

National Policy for Open Disclosure 2015 (HSE, 2015), on foot of HIQA and Commission on Patient Safety.

Definitions

Adverse event	An incident which results in harm to a person that may or may not be the result of an error.
Error	The failure of a planned action to be completed as intended or use of a wrong inappropriate or incorrect plan to achieve an aim.
Harm	Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury.
Incident	An event or circumstance which could have or did lead to unintended and/or unnecessary harm and/or a complaint, loss or damage.
No harm event	An incident occurs which reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances.
Patient safety incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

This policy has an algorithm for when open disclosure should be performed:

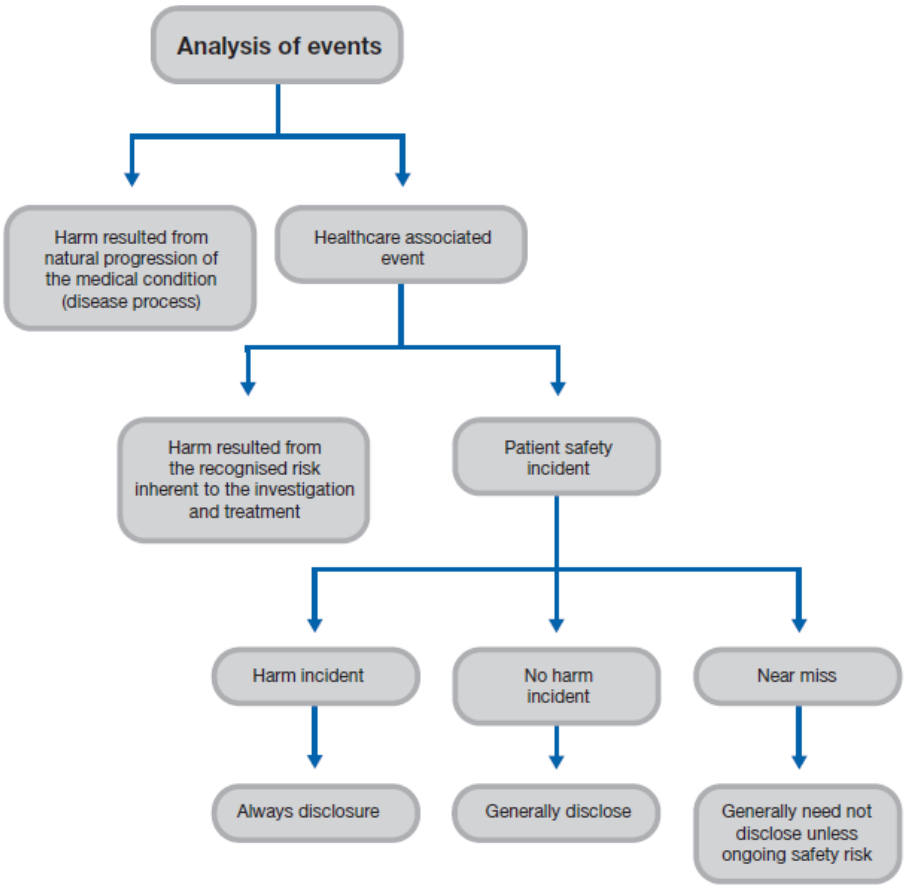


Figure 1 Circumstances when disclosure should take place, as demonstrated above (HSE, 2015)

Initial Management of Incidents: implications from discussion around taxonomy and frameworks
From the above discussion, a number of key aspects emerge regarding the management of incidents in radiotherapy

1. Staff must be clear on the definitions of and pertaining to patient and radiation safety incidents.
    a. The definitions in Irish law are clear and concordant with the WHO and the HSE. Application of them gives clear guidance on when open disclosure is indicated
    b. The definitions in MERU are specific to radiotherapy. They must also be applied to ensure consistent classification and recording, and to give guidance on when to inform MERU and other relevant parties of an incident
    c. Categorisation of risk / harm from a particular incident is likely best derived by applying the HSE Risk Impact Table.

2. There is a clear national methodology for the classification of radiation safety incidents, as provided by MERU
    a. This classification systems facilitates the reporting and recording of such incidents
    b. This system also contains prompts for who should be informed of such incidents

3. The HSE Open Disclosure Policy provides clear guidance of when patients or relevant persons should be informed of a radiation safety incident
    a. In short, all incidents should be the subject of open disclosure – except for near misses, where HSE has advised they can be judged on a case-by-case basis
    b. The Civil Liability (Amendment) Act 2017 provides guidance on how an open disclosure, apology, clarification and further information are to be delivered

4. The HSE Incident Management Framework provides guidance on the steps to be taken in an incident, depending on the categorisation of the incident.
    a. Initial steps and informing NIMS (including the National Incident Reporting Form (NIRF)), as per the State Claims Agency
    b. The HSE Risk Impact Table provides a tool to categorise an incident

The category determines the level of the subsequent review, as well as who to inform.

Summary Risk Management a) (i) Taxonomy and reporting in Ireland
In the event of a radiation incident, immediate treatment must be instigated, ongoing harm abrogated, safety ensured and risk minimised. Other key strands include reporting requirements as per:

- MERU and the National Radiation Safety Council guidelines
- National Incident Management System for the State Claims Agency
- Risk Management as per local structures and the HSE Framework for Incident Management
- Consideration of Open Disclosure as per the HSE policy and the Civil Liability (Amendment) Act 2017

Part ii) Learning Systems for Radiation Incidents

After accurate classification, reporting and management of an incident, it is critical that the incident is analysed and learning obtained. The results are then fed into the proactive component of risk management within the unit, but also at national and international levels. Whatever methodology is used, the key questions to be answered are:

A) What happened?
B) Why did it happen?
C) What can we learn?
D) What needs to change?
E) How do avoid only good intentions? i.e. implementation methods include: RCA (Root Cause Analysis); ALARM; Causal Tree Analysis (CTA) and ORION.

RCA	The objective of root cause analysis (RCA) during event analysis is to identify the root causes (deeper causes, latent conditions, latent causes, latent factors, contributing factors) behind the immediate causes (direct causes, active failures) observed on the event. This includes the 5 'whys' mentioned above. In addition an Ishikawa fishbone diagram can be used to show different classes of causes: Environment; Manpower; Methods; Material; Equipment; Management and Money.
ALARM	The ALARM method does not attempt to identify only root causes (latent causes) as the Root Cause Analysis RCA). The objective of the analysis is precisely to understand the complexity of causes. The analysis identifies errors in health care and requires an accurate knowledge of standard processes and procedures related to each career in order to identify deviations during analysis. There are seven steps, including a) decision to investigate; b) choice of investigation team; c) collection of facts and data; d) description of event sequence; e) identification of healthcare errors; f) identification of contributing factors; g) recommendations and actions plans. The HSE Framework utilises similar paradigms for incident investigation and analysis.
CTA	Causal Tree Analysis (CTA) was developed by the Institut National de Recherche et de Sécurité (French national institute for occupational health and safety research, INRS) to investigate and research accident factors in the area of workplace accidents and professional risks. Specific training is necessary for the person preparing the causal tree to acquire the formal elements for presenting information and constructing the tree.
ORION	Integrates the ALARM and CTA methods, as well as a version of the ROSIS form.
HFACS	Human Factor Analysis and Classification System) (Portaluri et al., 2009) is a method of detailed event analysis for the identification of latent and active failures. It provides a practical framework for identifying failures, and is dedicated to external radiotherapy

Readers are also referred to the presence of existing international systems specific for radiotherapy, including:

ROSEIS	Radiation Oncology Safety Education and Information System (hosted by ESTRO – the European Society for Radiotherapy and Oncology) It is a voluntary web-based platform designed for use as an individual clinic reporting and learning tool and also as a platform to exchange or share information with the wider radiotherapy community. It represents an evolution of the original ROSIS project.
SAFRON	Safety in Radiation Oncology (hosted by the International Atomic Energy Agency) This is an integrated voluntary reporting and learning system of radiotherapy incidents and near misses

Part iii) **Proactive Risk Management**

EC RP N^{o} 181 (EC, 2015a) outlines key aspects of proactive risk management, noting it is generally more time consuming to learn and implement than reactive methods. At a minimum, a facility needs to develop systems that

a) Identify potential hazards and failures from published and local knowledge;

b) Identify the impact or consequences of such failures or hazards, using an approved system, such as FMECA (Failure Mode Effect and Criticality Analysis) or PRA (Preliminary Hazard and Risk Analysis); and

c) Utilize a criticality matrix to prioritise efforts according to likelihood and severity.

Once experience has been gained, a deeper assessment (defence in depth approach) is recommended using systems such as the Fault Tree (FTA) or Event Tree Analysis (ETA). A final step is the integration of the reactive learning and feedback from analysis of incidents and events.

This is summarised by the EC document below:

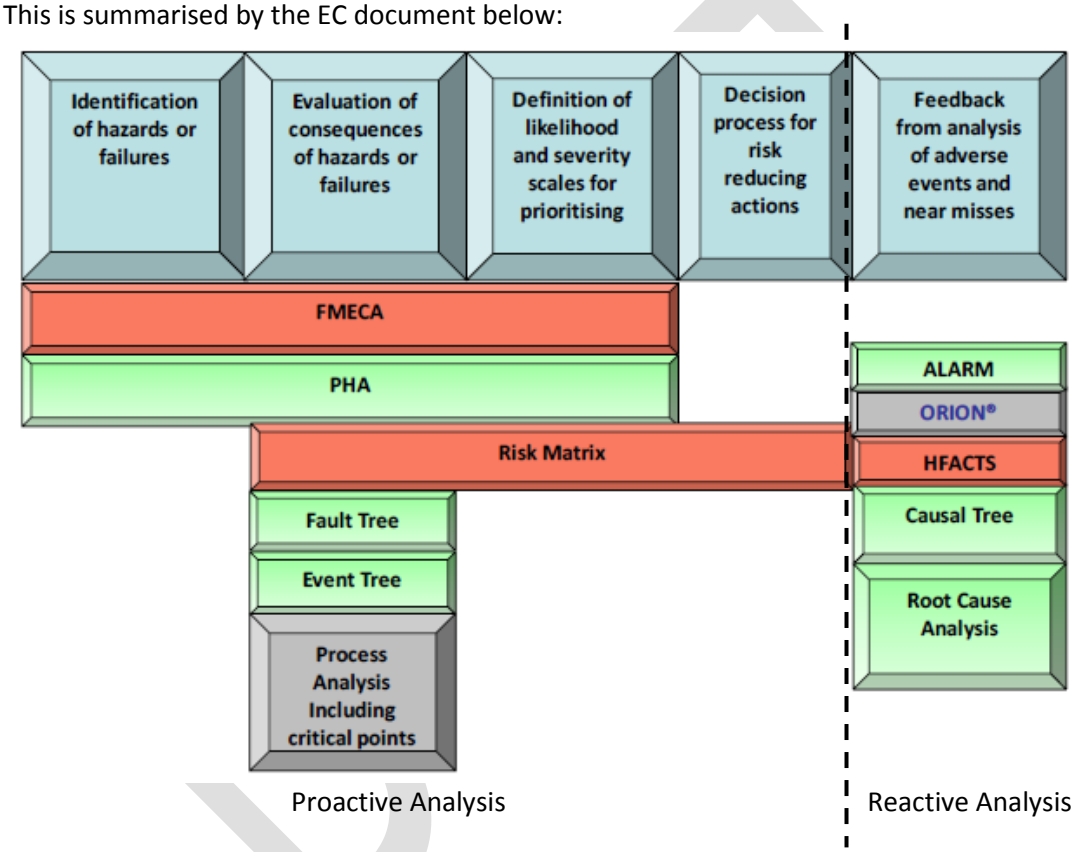


Figure 2 Risk management targets within proactive risk assessment and reactive analysis of events (the upmost blue boxes). The applicability of available assessment or analysis methods (the rectangles below the upmost boxes) is shown by the position and length of the rectangle (e.g., FMECA and PHA [PRA] can be applied for the first three targets). The green colour indicates a generic method, red indicates a generic method specifically adapted for external beam radiotherapy, and the gray colour indicates an approach rather than a method.

A brief description of the terms and proactive systems referred to includes:

FMECA The FMEA method permits identification of single failures (basic events), preventive, corrective and detective measures (barriers) and prioritization, if a criticality evaluation is included. For each component under study, one must identify a) possible failure modes and their causes; b) consequences of the failure mode on the system; c) existing preventive, corrective and detective measures. The ASN radiotherapy-specific adaptation of this applies these principles to the domains of (i) patient pathway (ii) equipment; (iii) human and organizational factors. It also modifies the scales and in dices for probability and severity, as described below.

FMEA (General)

FMEA (Specific – ASN - Radiotherapy)

Likelyhood index (frequency index)	Level	Criteria
L1	Very infrequent	Once every ten years
L2	Infrequent	Once every five years
L3	Not very frequent	Once a year
L4	Frequent	Once a month
L5	Very frequent	Once a day

Severity index	Level	Criteria: Consequences for the patient
S1	Minor	No obvious harm
S2	Significant	Temporary harm (less than a month)
S3	Critical	Harm that does not affect daily life
S4	Severe	Harm that affects daily life
S5	Catastrophic	Death of the patient

	SEVERITY SCALE				
LIKELIHOOD	S1	S2	S3	S4	S5
P5	C2	C2	C3	C3	C3
P4	C1	C2	C2	C3	C3
P3	C1	C1	C2	C2	C3
P2	C1	C1	C1	C2	C3
P1	C1	C1	C1	C1	C2

Determining the probability of an event		
Level	Criterion	Score
Very rare	Once every 5 years	1
Rare	Once a year	2
Frequent	Once a month	3
Very frequent	Once a session	4

Determining the severity of an event		
Level	Criterion	Score
Not very critical	Temporary discomfort, malaise, unpleasantness	1
Critical	Prolonged discomfort Reversible damage or impairment Medical treatment required Temporary handicap	2
Very critical	Delayed consequences, but marked for the patient Irreversible damage or impairment Permanent handicap Not life threatening	3
Serious	Short-term fatal outcome for the patient Life threatening	4

Figure 3 Examples of likelihood scale, severity scales (EC, 2015a, 2015b) and probability of an event (EC, 2015b)

PHA/PRA

PHA/PRA allows for the identification of the scenario which describes (i) how the system, from a process-based point of view, handles each hazard, (ii) what existing measures are in place to limit the likelihood (probability) of the scenario and/or (iii) the criticality of the consequences

Risk Matrix

Developed in Spain by FORO in conjunction with IAEA. This method estimates risk as R = f x P x C, where f is the frequency (or annual frequency of occurrence) of the hazard (initiating event) that challenges the process; P is the probability of failure of the barriers provided; C is the severity of the potential harm (consequences). It requires a progressive approach that involves a) identifying, by means of a proven methodology (e.g., FMEA or PRA), the hazards and the barriers provided to avoid an accidental exposure to the patient; b) applying an initial, simple conservative screening to sort events according to their risk by means of a previously constructed risk matrix; c) finally applying the second screening to those initiating events that resulted in high risk after the first screening and by focusing efforts on a deeper, more realistic safety assessment of those cases.

FTA and ETA

Two methods that provide more comprehensive risk assessment that takes into account combinations of failures and probabilistic assessment: FTA is a deductive method, that is, a top down approach for qualitative assessment to what extent a fault or a basic event can propagate in the sequence leading up to the ultimate event. ETA, in contrast, is an inductive method for identifying the propagation of an initiator (failure, incident, etc.) and its possible consequences on the system (potential undesirable event); ETA is also known as the "barrier assessment method

Appendix B Audit

Definition

Two definitions are useful for the purposes of this framework: the EU Basic Safety Standards (Council Directive 2013/59/Euratom, 2013) is specific for radiation exposure, whereas the HSE (Health Service Executive (HSE), 2013) is applicable to a broader clinical national perspective:

EU: "*[Audit] means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary*."

HSE: "*A quality improvement process that seeks to improve care and outcomes through systematic review of care against explicit criteria and the implementation of change*."

Distinctions

The European Commission document RP N^{o} 159 (EC, 2009), gives guidance on audit in radiotherapy.

Distinction is made between *Internal* and *External* Audit.

- For *internal audit* the department sets the scope and objectives, frequently enough to cover significant parts of the programme in a year, as part of its own quality assurance and improvement procedures.
- *External audits* involve outside experts assessing the entire patient pathway, after agreement with relevant national or other bodies regarding legal requirements or other priorities. External audits should occur at least once every five years. This can be performed by national bodies, e.g. MERU-HIQA or EPA, or a recognized international one e.g. IAEA.

Audits provide a cyclical approach to quality improvement, as described by the RCR below (European Commission (EC), 2009):

Audits need to abide by standards of good practice. The standard of good practice may be based on legal requirements, results of research, recommendations and/or consensus statements by learned societies, or even local agreement where other sources for standards are unavailable. Standards can subsequently be divided into three levels of specificity, which in turn set the depth of the audit(European Commission (EC), 2009):
Level 1: is generic such that it can be applied to any of diagnostic radiology, nuclear medicine or radiotherapy, e.g. a quality system is present.
Level 2: is generic to a specific field such as radiotherapy, and can be applied to any treatment site for example
Level 3: is specific to a specific treatment, e.g. a specific clinical protocol

The end of this chapter gives a summary of Level 2 standards of good practices as specific audit criteria.

Audits, particularly internal, are facilitated by the presence of quality indicators, which are measureable variables related to specified parts of standards of good practice. The indicators in this Framework provide a starting point, though they do not set out to be exhaustive.

Irish context
While not radiation-specific, the following help inform the reader of the relevant statutory and regulatory environment nationally.

The Commission on Patient Safety and Quality Assurance report (DoHC, 2008) stated that "Clinical audit arguably constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service that it provides". It outlined a model for clinical audit as a continuous process for quality improvement, based on the PDCA (Plan-Do-Check-Act) cycle, virtually identical to the RCR figure above. Emerging from this report, several important bodies emerged in relation to clinical audit:

- **HIQA:** provides clear standards for audit, summarized at the end of this chapter
- **NCEC:** resides with the National Patient Safety Office of the DOH, and has a remit to establish and implement processes for the prioritisation and quality assurance of clinical guidelines and clinical audit so as to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines and National Clinical Audit.
- **NOCA:** is the National Office of Clinical Audit, and works with the NCEC, RCSI and HSE to create sustainable clinical audit programmes at national level.
- **HSE QID:** The HSE Quality Improvement Division has developed "A Practical Guide to Clinical Audit". Though not radiotherapy-specific, it contains principles that can inform readers of the local milieu for clinical audit.
- **Health Information and Patient Safety Bill:** This will give statutory definition to clinical audit and related matters. Publication is expected shortly

Summary
Facilities are recommended to develop a culture of continuous internal audit, delivered against indicators that help measure compliance with accepted standards of care. They must adhere to current statutory and regulatory guidelines, and it is recommended that they also utilise the indicators contained in this framework. A dedicated multidisciplinary team, with appropriate training support and resources should carry out audit work and report it to the quality, management, and risk teams. This should also help prepare departments for external audits.

Table 2 EC recommendations of standards for a level 2 radiotherapy audit (European Commission (EC), 2009)

Structure	Mission and Vision		Aims clearly defined, along with the required infrastructure, resources and practice
	Organization and Management Structure		Organizational chart detailing management and reporting lines for all collaborators
	Personnel and Training		Staff numbers and expertise sufficient to deliver full spectrum of activities Documentation available on all staff primary qualifications, continuing education, and training for effective and safe use of all current and new equipment
	Premises, equipment and materials		Documented policy for maintenance, upgrading and replacement of all equipment to ensure optimum delivery of treatments, including during a machine breakdown New techniques introduced by defined protocol including justification, staff involvement and balancing of available resources
Process	Justification and referral process	Access to radiotherapy	Clear policies on referral criteria and processes, particularly for specialist procedures Patient access and waiting times are defined and measured in the context of workload, available resources and other factors
		Treatment decision	Made by a full multidisciplinary team (MDM) in accordance with evidence based guidelines and using the required minimum dataset for treatment decisions
	Treatment Practices and guidelines [Evidence based protocol driven] [Prescription has minimum dataset]	Patient immobilisation	Most appropriate for the treatment
		Imaging	Most appropriate for the treatment
		Treatment dose planning	Evidence based guidelines for contouring Target Volumes and Organs at Risk Optimized treatment plans evaluated and signed by the Treatment Planner and Radiation Oncologist Dose delivery times for each beam should be double-checked by independent personnel Protocol for data transfer from TPS
		Treatment charts	The permanent record of treatment delivered, from which and auditor may accurately check and recalculate the treatment delivered to the patient Chart must contain: patient ID; dose total, fractionation, overall time; technique (field definition, patient position, accessory devices), OAR definition and critical dose levels, monitoring of side effects; variations in overall treatment time from that prescribed originally Departmental policy for regular chart checks Clear signatures for those involved in all aspects of treatment including: daily deliver, routine review of patient, verification and approval of verification images
		Treatment verification	Protocols for daily verification of treatment parameters, signed, and with actions and responsibility of deviation clearly noted
		Brachytherapy	A programme is present for sources, which includes: a detailed inventory; replacement and disposal plans; protocols for storage, maintenance, preparation and use Treatment planning is performed according to an internationally accepted system, with clear protocols for combination with external beam treatments The treatment record includes: time of source insertion and removal; source distribution and activity; source position verification; and dose delivered to target volumes and OAR A specialized multidisciplinary team is involved; with special attention to protection of staff and public, and close monitoring of patients

Process	Quality Management	Dosimetry	Sufficient functioning dosimetry equipment, with valid calibration certificates to ensure: regular checks on all therapeutic equipment including beam output, and measurement of dose during treatment delivery, including conventional and technologically advanced techniques The department participates in external dosimetry audits
		Quality Assurance Programmes	For all treatment units, simulators, imaging modalities, accessory equipment, treatment planning systems and networking systems Policies and procedures for commissioning of new equipment, acceptance testing and routine quality control procedures Records available for maintenance procedures, findings and actions taken Clear and understandable instruction manuals Defined quality indicators relating to structure, process and outcome
		Reporting incidents/near incidents	There is a system for reporting incidents; protocols for actions to be taken; reporting and learning to avoid repetition and enhance quality and safety The information flow and documentation control is organized and assessed in clinical audits
	Information flow and document control		Procedures are in place to monitor side-effects, morbidity, tumour control and survival
Outcome			Protocols are in place for the management of side effects and actions for management of significant deviations from outcomes

HIQA standards pertaining to Audit

Features of a service meeting this standard are likely to include (HIQA, 2012):

2.8.1 Use of relevant national performance indicators and benchmarks, where they exist, to monitor and evaluate the quality and safety of the care and its outcomes.

2.8.2 Where national metrics do not exist, the development or adoption of performance indicators and benchmarks in accordance with best available evidence to monitor and evaluate the quality and safety of the care provided and outcomes.

2.8.3 Use of a variety of outcome measures to evaluate the effectiveness of healthcare including:

– Clinical outcomes
– Service users' perspectives on their outcomes
– Service users' experience of care
– Feedback from healthcare professionals.

2.8.4 Use of information from monitoring and evaluation to improve care and to disseminate learning.

2.8.5 Monitoring and evaluation of performance by developing and implementing clinical and non-clinical audits and implementing improvements based on the findings.

2.8.6 An agreed annual plan for audit, which incorporates participation in national audit programmes, and local, targeted audits conducted in line with service requirements and priorities.

2.8.7 An evidence-based methodology, in line with national guidelines where they exist, is used in the conduct of audit.

2.8.8 Clinical governance arrangements that ensure findings from clinical audits are reported and monitored effectively.

2.8.9 Dissemination and public reporting of information about the quality and safety of care delivered and quality improvement programmes.

2.8.10 Provision of requested information to relevant agencies, including national statutory bodies, in line with relevant legislation and good practice.

Appendix C Personnel and Organisation

The EU Basic Safety Standards state that "*a high level of competence and a clear definition of responsibilities and tasks among all professionals involved in medical exposure is fundamental to ensure adequate protection of patients undergoing medical radiodiagnostic and radiotherapeutic procedures. This applies to medical doctors, dentists and other health professionals entitled to take clinical responsibility for individual medical exposures, to medical physicists and to other professionals carrying out practical aspects of medical radiological procedures, such as radiographers and technicians in radiodiagnostic medicine, nuclear medicine and radiotherapy*"(Council Directive 2013/59/Euratom, 2013).

This puts a direct responsibility on a unit to ensure that all professionals are appropriately trained and are clear as to their functions within the unit. Indirectly, there is a requirement for a workforce profile conducive to optimisation of radiotherapy dose delivery.

Key personnel and groupings are defined in European and Irish legislation, and described by the NRSC and the MERU Patient Radiation Protection Manual. These include: Practitioner, Practitioner in charge, medical physics expert, radiation protection expert or advisor, radiographer, radiation safety officer and radiation safety committee. In addition, this framework recommends defined personnel to be organised into teams responsible for Radiation Safety, Risk Management, Audit and Quality.

Note: smaller departments will often have overlapping membership of these groups due to numbers of staff and time available. This is not a problem, and should be seen as an opportunity for good communications facilitated by the more horizontal organisation, provided the definitions, roles and responsibilities of the functional groupings are clear. MERU indicate, for example, that the Radiation Safety Committee can assume multiple tasks or that the tasks can be assigned to separate groups, provided governance, terms of reference etc are clear.

It is important that a unit has clear documented terms of reference and policies for each of its teams, including, membership, reporting structures, meeting frequencies and minutes.

Teams

Management: comprises the leads of all personnel groupings in the unit – medical, physics, radiographer, nursing, clerical, etc. This group is responsible for running the unit in line with all international and national statutory and regulatory requirements and with best practice standards. It is chaired by the Practitioner in Charge, who is appointed by the Holder to be the person in charge of the installation. Staff report to the practitioner in charge through the management group on all matters pertaining to the patient pathway through the unit. The management group receives reports from the teams for Radiation Safety, Risk Management, Audit and Quality, informs the relevant reporting bodies and acts appropriately based on the findings. The management group is responsible for interactions with bodies from the wider hospital group, e.g. risk management, clinical directorates, executive managment team, and nationally e.g. NCCP, MERU/HIQA, HSE etc.

Risk Management: this multidisciplinary group is responsible fo both the proactive and reactive aspects of risk management in the unit. It is resourced and trained to carry out its functions, and works with a experienced Risk Manager, who may work outside the radiotherapy department. The Risk Management team ensure risks are studied prospectively using validated methodology, in line with the requirements of Article 63 of the EU Basic Safety Standards (Council Directive 2013/59/Euratom, 2013). It is responsible for the reporting of incidents to MERU-HIQA, EPA, the hospital risk manager, NIMS-SCA, and the radiotherapy managment team. It is responsbile for ensuring that a learning system is in place that allows lessons to be assimilated from incidents and

incorporated into improved practicees and the proactive risk assessment process, as well as being disseminated nationally and internationally.

Audit and Quality: this group is repsonsible for developing a culture of continuous audit and improvement within the unit. It conducts internal audit along all parts of the patient pathway, measuring current practice and/or indicators against agreed standards, brings the findings to the managment, safety and risk teams, agrees changes in practices and re-measures. It derives standards from international and national legislation and regulations; from this framework and other sources as appropriate. It should assist in preparing units for comprehensive periodic external audit.

Radiation Safety Committee: As per SI 478 (soon to be revised), "A Holder may establish a local radiation safety committee in respect of a particular installation and that committee shall have regard to the advice of the National Radiation Safety Committee" (EC, 2002). Where a radiotherapy unit is part of a larger hospital, the RSC will span diagnostic radiology, nuclear medicine and radiotherapy. It is recommended however that each radiotherapy unit continually addresses the issues arising from the advice of the NRSC through either a smaller focused Radiation Safety Team, or via a combination of the other teams mentioned above. Again, the critical point is that units must be compliant with statutory and regulatory requirements of the NRSC and its executive arm. The MERU patient radiation protection manual gives further details on radiation safety committees.

Personnel

The following is not intended to represent an exhaustive list of personnel required to run a radiotherapy unit, but it lists key members whose roles are detailed in specific pieces of legislation. Where possible, the EC BSS have been used, but a new statutory instrument giving effect to it will soon be published, and this framework will be subsequently revised to reflect that. In some instances SI 478 is used (EC, 2002).

Practitioner: a person whose name is entered on the register established under Section 26 of the Medical Practitioners Act (1978) and who meets such other requirements as may be specified by the Medical Council from time to time to allow them to take responsibility for an individual medical exposure. Responsibilities include:

- Clinically responsible (along with his/her colleagues) for all ionising radiation exposures performed in their institution. "Clinical responsibility" means responsibility regarding individual medical exposures attributed to a Practitioner, notably: justification; optimisation; clinical evaluation of the outcome; co-operation with other specialists and staff, as appropriate, regarding practical aspects; obtaining information, if appropriate, of previous examinations; providing existing radiological information and/or records to other Practitioners and/or Referrers, as required; giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate.
- Authorise radiological procedures subject to the conditions in the regulations.
- May not authorise the use of a practice which has been considered by the Medical and Dental Councils and which has not been approved by them.
- Make arrangements to satisfy him/herself that the procedure prescribed is justified.
- Consult with the Medical Physics Expert assigned to the installation on optimisation, including the consistent production of adequate diagnostic information or therapeutic outcome, patient dosimetry, and quality assurance, including quality control and the assessment and evaluation of patient doses or administered activities, and on matters relating to radiation protection concerning medical exposures.

Radiation Therapists: means a person who has successfully completed an approved course of training for that category of persons and who is qualified to be employed as a radiographer by a health board
Responsibilities include:

- Ensure adherence to justification procedures.
- Advise on dose optimisation.
- A Radiographer appointed as Radiation Safety Officer in designated locations records and maintains records of regular Quality Control tests.
    - The Radiation Safety Officer should be considered for responsibility to maintain the Radiation Protection training records of all relevant staff at the facility
- In Clinical Audit, the Radiographic Services Manager ensures that agreed standards and protocols are in place and adhered to.
- In Adverse Incident reporting relating to ionising radiation for medical exposures, the Radiographic Services Manager ensures incidents are recorded and managed according to agreed protocols.

Radiation Protection Officer (Article 84, EC BSS):
Depending on the nature of the practice, the tasks of the radiation protection officer in assisting the undertaking, may include the following:
(a) Ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;
(b) Supervise implementation of the programme for workplace monitoring;
(c) Maintaining adequate records of all radiation sources;
(d) Carrying out periodic assessments of the condition of the relevant safety and warning systems;
(e) Supervise implementation of the personal monitoring programme;
(f) Supervise implementation of the health surveillance programme;
(g) Providing new workers with an appropriate introduction to local rules and procedures;
(h) Giving advice and comments on work plans;
(i) Establishing work plans;
(j) Providing reports to the local management;
(k) Participating in the arrangements for prevention, preparedness and response for emergency exposure situations;
(l) Information and training of exposed workers;
(m) Liaising with the radiation protection expert

Radiation Protection Expert (From EC BSS. Note = RPA in Ireland)
The radiation protection expert gives competent advice to the undertaking on matters relating to compliance with applicable legal requirements, in respect of occupational and public exposure. The radiation protection expert shall, where appropriate, liaise with the medical physics expert. The radiation protection expert may be assigned, if provided for in national legislation, the tasks of radiation protection of workers and members of the public. The advice of the radiation protection expert shall cover, where relevant, but not be limited to, the following:
(a) Optimisation and establishment of appropriate dose constraints;
(b) plans for new installations and the acceptance into service of new or modified radiation sources in relation to any engineering controls, design features, safety features and warning devices relevant to radiation protection;
(c) Categorisation of controlled and supervised areas;
(d) Classification of workers;
(e) Workplace and individual monitoring programmes and related personal dosimetry;
(f) Appropriate radiation monitoring instrumentation;
(g) Quality assurance;

(h) Environmental monitoring programme;
(i) Arrangements for radioactive waste management;
(j) Arrangements for prevention of accidents and incidents;
(k) Preparedness and response in emergency exposure situations;
(l) Training and retraining programmes for exposed workers;
(m) Investigation and analysis of accidents and incidents and appropriate remedial actions;
(n) Employment conditions for pregnant and breastfeeding workers;
(o) Preparation of appropriate documentation such as prior risk assessments and written procedures;

Medical Physics Expert (EC BSS, Article 83): the medical physics expert takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following:
(a) Optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;
(b) The definition and performance of quality assurance of the medical radiological equipment;
(c) Acceptance testing of medical radiological equipment;
(d) The preparation of technical specifications for medical radiological equipment and installation design;
(e) The surveillance of the medical radiological installations;
(f) The analysis of events involving, or potentially involving, accidental or unintended medical exposures;
(g) The selection of equipment required to perform radiation protection measurements;
(h) The training of practitioners and other staff in relevant aspects of radiation protection
The medical physics expert shall, where appropriate, liaise with the radiation protection expert

Workforce Profile: the unit is responsible for ensuring that it has the correct numbers of people with the correct skills to allow it do deliver its treatments in line with the principles of justification and optimisation, in line with Europrean directives. Each workforce member must have the appropriate recognised professional qualification, with evidence of it and ongoing approved continuous professional development.

International models are available to calculate appropriate staff numbers in terms of factors such as patient numbers, linear acclerator numbers and complexity of treatments delivered. These are referenced in the National Workforce Plan for Radiation Oncology (NCCP). The NCCP, HSE and DOH ensure that sufficient resources

Appendix D Glossary

Please find below a list of definition. Where possible, definitions are taken from national legislation. However many are awaiting formal statutory definition: in such cases definitions are taken from the relevant European Commission legislation and/or the relevant national regulatory authorities or governance structures, e.g. HSE QAVD, QID, MERU, HIQA etc.

All definitions below are referenced for clarity:
[1] Civil Liability (Amendment) Act (2017)
[2] European Commission Basic Safety Standards (Council Directive 2013/59/Euratom, 2013)
[3] World Health Organization's Conceptual Framework for the International Classification of Patient Safety, (2009)
[4] HSE Safety Incident Management Framework (2018)
[5] The Health Act (2004)
[6] National Standards for the Conduct of Reviews of Patient Safety Incidents (Health Information and Quality Authority (HIQA) and Mental Health Commission (MHC), 2017)
[7]European Commission Radiation Protection N^{o} 181 General guidelines on risk management in external beam radiotherapy (European Commission (EC), 2015a)
[8] Template for Developing a Patient Radiation Protection Manual – (MERU, 2013)
[9] International Commission for Radiation Protection publication 103 (International Commission on Radiological Protection (ICRP), 2007)
[10] Patient Radiation Protection Manual – (Medical Exposure Radiation Unit (MERU), 2017)

It must be kept in mind that such definitions may be superseded as new legislation and/or regulations are enacted. These definitions will be reviewed, and likely revised, on foot of publication of the Health Information and Patient Safety Bill and the statutory instrument that will give national effect to the new EC Basic Safety Standards legislation.

Accidental Exposure[2]	Means an exposure of individuals, other than emergency workers, as a result of an accident
Adverse Event[4]	An incident which results in harm, that may or may not be the result of an error
Adverse Error Event[2,7]	Event involving accidental or unintended medical exposures[2] An event that results in unintended harm—either minor or serious—to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient. All treatment-related side effects are excluded[7]
Agent[3]	Is a substance, object or system that acts to produce change
Apology[1]	In relation to an open disclosure of a patient safety incident, means an expression of sympathy or regret
Audit[4]	The assessment of performance against any standards and criteria (clinical and non-clinical) in a health, mental health or social care service
Audit, clinical[2]	Means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary.
Audit, Clinical[4]	A quality improvement process that seeks to improve care and outcomes through systematic review of care against explicit criteria and the implementation of change
Authorisation[2]	Means the registration or licensing of a practice;
Circumstance[3]	A situation or factor that may influence an event, agent or person(s).
Clinical responsibility[2]	Means responsibility of a practitioner for individual medical exposures, in particular, justification; optimisation; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing

	existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate
Complaint[5]	A complaint means a complaint made about any action of the Executive, or a Service Provider that, is claimed does not accord with fair or sound administration practice, adversely affects the person by whom, or on whose behalf, the complaint is made
Competent authority[2]	Means an authority or system of authorities designated by Member States as having legal authority for the purposes of this(EC Basic Safety Standards) Directive
Controlled area[2]	Means an area subject to special rules for the purpose of protection against ionising radiation or preventing the spread of radioactive contamination and to which access is controlled
Deterministic effect[9]	Injury in populations of cells, characterised by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Also termed tissue reaction. In some cases, deterministic effects are modifiable by post-irradiation procedures including biological response modifiers
Disease[3]	A physiological or psychological dysfunction
Dose limitation[2]	In planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures
Emergency[2]	Means a non-routine situation or event involving a radiation source that necessitates prompt action to mitigate serious adverse consequences for human health and safety, quality of life, property or the environment, or a hazard that could give rise to such serious adverse consequences
Emergency exposure situation[2]	Means a situation of exposure due to an emergency.
Error[3]	A failure to carry out a planned action as intended or application of an incorrect plan. Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase
Event[3]	Something that happens to or involves a patient
Exposure[2]	Means the act of exposing or condition of being exposed to ionising radiation emitted outside the body (external exposure) or within the body (internal exposure)
Governance, clinical[4]	A system through which service providers are accountable for continuously improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit
Harm[3]	Impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. The degree of harm relates to the severity and duration of harm and the treatment implications, that result from a patient safety incident
None	Service-user outcome is not symptomatic or no symptoms have been detected and no treatment is required
Mild	Service-user outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (for example, extra observation, investigation, review or minor treatment) is required.
Moderate	Service-user outcome is symptomatic, requiring intervention (for example, additional operative procedure or additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function.
Severe	Service-user outcome is symptomatic, requiring life-saving intervention or major surgical or medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function.
Death	On balance of probabilities, death was caused or brought forward in the short-term by the incident.

Hazard[3]	A circumstance, agent or action with the potential to cause harm.
Health[3]	The state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.
Healthcare[3]	Services received by individuals or communities to promote, maintain, monitor or restore health
Incident Review[4]	Incident review involves a structured analysis and is conducted using best practice methods, to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally
Injury[3]	Is damage to tissues caused by an agent or event
Inspection[2]	An investigation by or on behalf of any competent authority to verify compliance with national legal requirements;
Ionising radiation[2]	Energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3×10^{15} hertz or more) capable of producing ions directly or indirectly
Just Culture[4]	An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action
Justification[2]	Decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause. Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm
License[2]	Permission granted in a document by the competent authority to carry out a practice in accordance with specific conditions laid down in that document
Medical Exposure[2]	Exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research
Medical Physics Expert[2]	An individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognised by the competent authority
Medical Radiological[2]	Pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes
National Incident Management System[4]	The National Incident Management System, hosted by the Clinical Indemnity Scheme, is a highly secure web-based database which facilitates direct reporting of adverse events by State authorities and healthcare enterprises; it is the single designated system for reporting of all incidents in the public healthcare system i.e. for HSE and HSE funded services
Near Miss[6]	An incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user.
No Harm incident[4]	An incident occurs which reaches the service user but results in no injury to the service user. Harm is avoided by chance or because of mitigating circumstances
Normal exposure[2]	Exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including minor incidents that can be kept under control, i.e. during normal operation and anticipated operational occurrences;

Notification[2]	Submission of information to the competent authority to notify the intention to carry out a practice within the scope of this Directive
Open disclosure of a patient safety incident[1]	Where a health services provider discloses, at an open disclosure meeting, that a patient safety incident has occurred in the course of the provision of a health service that disclosure shall be treated as an open disclosure, and the information and/or apology shall not to invalidate insurance; constitute admission of liability or fault; or not to be admissible in proceedings. This applies when the disclosure is made to a patient, a relevant person or the patient and a relevant person; and applies to the information and/or an apology at the open disclosure meeting, the additional information meeting or in a subsequently provided clarification.
Optimisation[2]	Radiation protection of individuals subject to public or occupational exposure shall be optimised with the aim of keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors. The optimisation of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses and be consistent with the medical purpose of the exposure, as described in Article 56. This principle shall be applied not only in terms of effective dose but also, where appropriate, in terms of equivalent doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold for tissue reactions.
Patient[1] **Patient**[3]	means, in relation to a health services provider, a person to whom a health service is, or has been, provided is a person who is a recipient of healthcare
Patient outcome[3]	The impact upon a patient which is wholly or partially attributable to an incident [*Note: this Framework also includes a broader view of patient outcome, specifically in terms of cancer control and side effects*]
Patient Radiation Safety Incident[8]	Occurs where the delivery of radiation during an imaging procedure or treatment is different to that intended or where there is none intended for the patient, resulting in unnecessary variation in exposure, unless due to patient factors.
Near miss patient radiation safety incident[8]	Is a potential patient radiation incident that is detected before an imaging procedure or treatment (radiology/radiotherapy/nuclear medicine) takes place. There is no adverse outcome; the potential risk was identified and prevented.
Non-notifiable patient radiation incidents[10] **(documented on location. No report to MERU)**	• Radiotherapy dose or volume variation from total prescribed > 10% • Radiotherapy dose or volume variation from the fraction prescribed >20%. • Radiotherapy dose given to comforters and carers without consent greater than Medical Council guidelines of 3mSv for adults under 60 years of age and 6mSv for those over 60 • Deterministic effects from radiotherapy • Any other radiation exposure incident considered to have serious patient safety implications • No dose intended / incorrect patient >1mSv • Dose to foetus >1mSv • Dose to breastfed child > 1mSv • Incorrect procedure / anatomy • Incorrect radiopharmaceutical • Therapeutic nuclear medicine - administered activity different by 20% than intended. • Diagnostic overexposure of an adult of more than twice the exposure intended that leads to >10mSv or 20 times the dose intended. • Diagnostic over exposure of a child of more than twice the exposure intended that leads to >3mSv or 15 times the dose intended.

	• Deterministic effects as a result of interventional radiology. • Administration of a skin dose of 15Gy in a diagnostic environment. • Therapeutic dose given instead of diagnostic dose e.g. radioiodine.
Patient safety[3]	Is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.
Patient safety incident[1] ***Note:*** ***This is the statutory definition contained in Irish Law.*** ***It is analogous to the WHO taxonomy, which is given in parentheses in blue text, with superscript 3.*** ***It is also analogous to the European Commission terms given in blue text, with superscript 7. These are defined separately in this chapter.***	(a) an incident which has *caused* an unintended or unanticipated injury, or harm, to the patient and which occurred in the course of the provision of a health service to that patient. [Harmful incident[3]] (b) an incident which has occurred in the course of the provision of a health service to the patient and did not result in actual injury or harm, and in respect of which the health services provider has reasonable grounds to believe placed the patient *at risk* of unintended or unanticipated injury or harm [No Harm incident[3]; Minor or no harm Event[7]] (c) the *prevention*, whether by timely intervention or by chance, of an unintended or unanticipated injury, or harm, to the patient in the course of the provision, to him or her, of a health service, and in respect of which the health services provider has reasonable grounds for believing that, in the absence of such prevention, could have resulted in such injury, or harm, to the patient [Near Miss[3,4]; Near miss event[7]]
Practice[2]	A human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation
Practitioner[2]	A medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements
Protected disclosure[4,5]	Protected Disclosure describes a procedure where employees, in good faith and where they have reasonable grounds for believing that the health or welfare of patients/clients or the public may be put at risk, or where there is waste of public funds or legal obligations are not being met, can report these so that the matter can be investigated. The Protected Disclosures of Information as provided for in the Health Act 2004 (as amended by the Health Act 2007) legislation also provides statutory protection for health service employees from penalisation as a result of making a protected disclosure in good faith in accordance with this procedure.
Quality[3]	The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge
Quality assurance[2]	Means all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance.
Quality control[2]	Means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled

Practitioner[2]	A medical doctor, dentist or other health professional who is entitled to take clinical responsibility for an individual medical exposure in accordance with national requirements
Radiation protection expert[2]	An individual or, if provided for in the national legislation, a group of individuals having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose competence in this respect is recognised by the competent authority
Radiation Protection Officer[2]	An individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements
Radiotherapeutic[2]	Pertaining to radiotherapy, including nuclear medicine for therapeutic purposes
Radiation Source[2]	An entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material
Registration[2]	Authority, or granted by national legislation, through a simplified procedure, to carry out a practice in accordance with conditions laid down in national legislation or specified by a competent authority for this type or class of practice
Regulatory control[2]	Any form of control or regulation applied to human activities for the enforcement of radiation protection requirements
Relevant Person[1]	A person who is a parent, guardian, son or daughter, a spouse, or a civil partner of the patient; or a person who is cohabiting with the patient; or a person whom the patient has nominated in writing to the health services provider as a person to whom clinical information in relation to the patient may be disclosed.
Reportable circumstance[3]	Situation in which there was significant potential for harm, but no incident occurred
Risk[3]	Is the probability than an incident will occur
Risk Management[4]	One of a number of organisational systems or processes aimed at improving the quality of health care, but one that is primarily concerned with creating and maintaining safe systems of care
Risk management, for patient safety in external beam radiotherapy[7]	Identifying, assessing, analysing, understanding, and acting on risk issues in order to reach an optimal balance of risk, benefits and costs. Only risks related to the use of radiation are considered. Risk management thus comprises all the aspects of the organization to improve safety including, as specific tools, proactive risk assessment (study of risk) and reactive analysis of adverse error events and near misses.
Safety[3]	is the reduction of risk of unnecessary harm to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment
Safety[9]	The achievement of proper operating conditions, prevention of accidents, or mitigation of accident consequences
Serious Incident[4]	An incident that results in a rating of major or extreme as per the HSE's Risk Impact Table
Serious Reportable Event[4]	Serious Reportable Events are a defined subset of incidents which are either serious or that should not occur if the available preventative measures have been effectively implemented by healthcare providers. Serious Reportable Events are mandatorily reportable by services to the Senior Accountable Officer [Significant or Notifiable Event[7]]
State Claims Agency[4]	The National Treasury Management Agency is a State body which operates with a commercial remit to provide asset and liability management services to Government and is designated as the State Claims Agency when performing the claims and risk management functions delegated to it under the National Treasury Management Agency (Amendment) Act 2000
Stochastic effects[9]	Malignant disease and heritable effects for which the probability of an effect occurring, but not its severity, is regarded as a function of dose without threshold
Threshold Dose for tissue reactions[9]	Dose estimated to result in only 1% incidence of tissue reactions

Undertaking[2]	means a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities
Unintended exposure[2]	means medical exposure that is significantly different from the medical exposure intended for a given purpose

Appendix E Local Facility Self-assessment tool

Patient Outcomes and the Quality Improvement Cycle		Implemented	Commenced	Not started	Not applicable
1	Tumour-control outcomes are recorded in patients receiving radical courses of radiotherapy.				
2	Toxicities, acute and late, are recorded using validated instruments.				
3	Patient reported outcomes, satisfaction, complaints, concerns and feedback are recorded.				
4	The Radiation Treatment Programme has a Quality Improvement Cycle, which audits the above data and other KPI's for deficits in comparison to accepted benchmarks, addresses the deficit and re-measures the outcomes.				
5	The Radiation Treatment Programme provides written, visual or online educational materials about radiation treatment planning, delivery, side-effects and follow-up to patients and their families.				
6	The programme has documented informed-consent policies, in line with national standards and legislation, including specific guidelines for women and men of child-bearing age.				
7	The programme offers patients information and participation on available national and international clinical trials that have been examined by the competent ethics body. The programme monitors the percentage of patients enrolled on clinical trials.				

Guidelines and Key Performance Indicators		Implemented	Commenced	Not started	Not applicable
8	As part of justification, the radiation treatment programme utilizes national radiation planning and treatment guidelines and protocols. The rationale for non-adherence to guidelines is documented in individual cases.				
9	The Radiation Treatment Programme has a system that monitors and effects compliance with the national KPI's for Radiation Oncology defined by the NCCP.				

Guidelines and Key Performance Indicators		Implemented	Commenced	Not started	Not applicable
10	Patients have their case discussed at an appropriate multi-disciplinary meeting as part of the justification process for a radiation treatment.				

Governance Structures		Implemented	Commenced	Not started	Not applicable
11	The Radiation Treatment Programme has clearly defined its reporting structure, and the responsibilities of all personnel (including suitable delegate) and committees, to ensure accountability for the quality and safety of care it provides, and the resources used to achieve this. The links with local, group and national health bodies are clearly defined.				
12	There is an identified head of the Radiation Treatment Programme, a radiation oncologist, to whom all staff report regarding all aspects of the programme with suitable managerial and financial support.				
13	There is a strategic plan, with facility-agreed timeframe (not greater than 5 years), that identifies on-going development and resource needs of the facility in order to maintain or improve the service provided, and that is consistent with group and national policies and requirements. Resource needs include infrastructure, equipment, workforce and models of service.				
14	Documented management decisions, policies and procedures incorporate and support care delivered in accordance with the guidelines and requirements of the relevant national and international healthcare and statutory bodies including the NCCP, HIQA, HSE, DOH, MERU, and Irish Medical Council, and European Union.				

Workforce		Implemented	Commenced	Not started	Not applicable
15	Core personnel, including Medical Physics Expert(s), Radiation Protection Experts (Advisors), Radiation Safety Officer, Practitioner(s), Lead Practitioner, have their roles and responsibilities clearly defined in line with national and European legislation – particularly with regard to radiation safety, justification and optimisation.				
16	There is a workforce plan to ensure sufficient numbers, mix and skills of staff to ensure patients are treated within national laws, guidelines and standards of care.				
17	The programme ensures that all staff have the necessary qualifications, credentials, certifications and licenses; and successfully complete appropriate, accredited continuous professional development programmes; and are fully trained in radiation protection, optimisation and new techniques				
18	Evidence of time and funding during working hours allocated to education, research and development, administration and quality assurance and improvement activities.				

Radiation Treatment Quality Assurance		Implemented	Commenced	Not started	Not applicable
19	Compliance with technical quality control, policies and procedures is monitored and audited by a Radiation Treatment Quality Committee (RTQC).				
20	The RTQC is responsible for the program's Quality Improvement Cycle, which conducts audits, assesses deficits in outcomes against benchmarks, and addresses the deficits and reassesses/ audits again.				
21	The RTQC has documented terms of reference that meet all the requirements for composition, committee chair, meeting frequency, accountabilities and keeping of minutes.				
22	The RTQC has a blame-free process for personnel to access the committee and to report concerns about radiation treatment quality or safety.				

Safety, Incidents and Learning		Implemented	Commenced	Not started	Not applicable
23	There is a radiation safety programme that fulfils the national and EU legislative requirements, in terms of personnel, their roles and responsibilities, training, and equipment.				
24	There is a Radiation Safety Committee, whose membership and terms of reference meet NRSC guidelines. Minutes and records are kept of meetings, record of attendance, recommendations and actions taken.				
25	The programme, through a defined group, undertakes a proactive assessment of risk, preferably using an accepted methodology. It incorporates lessons learnt retrospectively into this proactive assessment process.				
26	The Radiation Treatment Programme has written policies and procedures that address the reporting, investigation, action, documentation, and monitoring of radiation treatment incidents. These are compliant with local, group and national requirements.				
27	Radiation incidents are integrated (using an appropriate system) into a feedback, learning and improvement cycle for staff, consistent with National, EU and HSE policies on clinical incidents and learning.				
28	The programme has a policy of open disclosure with regard to safety incidents, in line with national legislation and guidance.				
29	The facility has patient pregnancy protocols, compliant with MERU guidelines, which inter alia record a) pregnancy status throughout all procedures; b) decision and justification to treat while pregnant; c) incidents of inadvertent foetal exposure; d) waiver form and procedure.				

Data Management, Protection and Datasets		Implemented	Commenced	Not started	Not applicable
30	Each patient record contains the Minimum Dataset, as defined by the NCCP for radiation treatment.				
31	All treatment planning data is retained sufficient to recreate the original treatment plan for a given patient.				
32	All treatment verification data is retained for 25 years, in order for them to be reconstructed in a clinically meaningful way if required.				
33	All equipment, calibration, dosimetric and planning system data is recorded and traceable. This includes all equipment service records, Quality Assurance records and replacement due dates.				
34	All patient data is kept in accordance with the General Data Protection Regulation (GDPR), national statutes regarding Data Protection and HIQA National Standards for information governance.				
35	All paper and electronic records are managed in compliance with HSE Medical Records policy and HIQA National Standards for the management of healthcare records.				

Planning Peer Review and Quality Controls		Implemented	Commenced	Not started	Not applicable
36	Contouring of targets and organs-at-risk is guideline based, and reviewed at a departmental peer-review planning meeting along with the treatment plan technique, dosimetry and DVHs for radical or re-treatment case.				
37	Site specialization is encouraged amongst radiation oncologists, with appropriate mix to allow peer-review and cross cover.				
38	The radiation treatment prescription meets all criteria outlined in Irish recommendations, to deliver treatment addressing dose prescription, site and laterality, patient identification and authorisation.				
39	Radiotherapy treatment plans, dose calculations, and patient set-up data are independently reviewed prior to beginning treatment in all cases.				

Planning Peer Review and Quality Controls		Implemented	Commenced	Not started	Not applicable
40	There are identification procedures that: a) Verify patient identity and, b) Match the patient to their treatment prescription and plan prior to each treatment session.				
41	There are policies and procedures to monitor patients with pacemakers/defibrillators or implantable devices during radiation treatment.				

Radiation Treatment		Implemented	Commenced	Not started	Not applicable
42	There are identification procedures that **a**) Verify patient identity and, **b**) Match the patient to their treatment prescription and plan prior to each treatment fraction.				
43	A visual monitoring system is in place for the observation and monitoring of patients during treatment.				
44	Documented use of a verification system that incorporates equipment interlocks on out-of-tolerance treatment parameters and include clear instructions on the management of overrides.				
45	There is assessment of image based verification in accordance with facility treatment management guidelines				
46	Patients are reviewed during radiation treatment in accordance with facility patient management guidelines.				
47	When radiation treatment is being delivered, a Radiation Oncologist and a Medical Physicist are present at the radiation treatment facility or capable of responding within a time limit set by a programme				
48	There are policies and procedures guiding the planning and safe delivery of emergency radiation treatment				
49	New types of treatment are justified in advance, before being generally adopted: staff are fully trained in all aspects of new techniques				

Equipment and Dosimetry		Implemented	Commenced	Not started	Not applicable
50	Documented quality assurance programme for radiation therapy equipment and systems that includes all tests, their frequencies and tolerances; a protocol for managing test failures, non-compliances or equipment/system failures including action levels, reporting requirements and action taken				
51	Records of equipment uptime and downtime should be maintained. Delays of treatment and unscheduled breaks in treatment should be recorded				
52	Records of acceptance tests and commissioning data for all radiotherapy equipment, new treatment techniques and new methods of dose calculations. Commissioning is independently reviewed, and checked with measurements (as necessary) by a qualified individual (usually a medical physicist) who was not involved in the commissioning.				
53	For new equipment, all personnel involved with its calibration, operation, or maintenance are appropriately trained				
54	Documented audit of radiation treatment machine calibration or dosimetry at least annually, as well as documentation: 1) that the facility has successfully participated in an external dosimetric intercomparison conducted with a non-affiliated organisationally separate service within the last two years and which has been reviewed and actioned as appropriate, and 2) that the facility has successfully participated in a level III dosimetric intercomparison within the last five years and which has been reviewed and actioned as appropriate.				
55	Documented dosimetry that includes: • Derivation of all factors • Independent check of clinical dosimetric data by a medical physicist				
56	At least one check of all monitor units, exposure time or dwell time calculations for each treatment plan.				

Equipment and Dosimetry		Implemented	Commenced	Not started	Not applicable
57	Records of traceability of all radiation equipment calibrations including documentation of independent checking				
58	Equipment for monitoring radiation and for use in responding to emergency situations				
59	The programme has clear documented policies and procedures for the control of radionuclides and radioactive sources that comply with national and EU legislation.				
60	An up to date inventory of all equipment is maintained				
61	A copy of the facility RPII licence is on display				

Appendix F Minimum Dataset

Data Item	Data Item Number	Definition	Operation	Format
Demographics				
Name	RO – 101	Given name; family name	DDT[1] / Manual	TEXT
UHI	RO – 102	Unique Health Identifier – national identifier	DDT / Manual	NUMERIC
MRN	RO – 103	Medical Record Number – for the treating network	DDT / Manual	NUMERIC
DOB	RO – 104	As per PAS / Passport / Baptismal Certificate	DDT / Manual	DD/MM/YYYY
Gender	RO – 105	Male (1); Female (2); Other(3); Transgender (4); NS (9)	DDT / Manual	NUMERIC
Ethnicity	RO – 106	As per PAS / Passport / Baptismal Certificate	DDT / Manual	NUMERIC
Contact Address	RO – 107	Include Eircode	DDT / Manual	ALPHANUMERIC
Contact Numbers	RO – 108	Mobile / Landline / Designated Contact	DDT / Manual	NUMERIC
Dates and Timelines				
GP Referral Letter Date	RO – 201	Date GP referral received by Referring Team in Cancer unit	DDT / Manual	DD/MM/YYYY
1st OPD Referring Team	RO – 202	Date Referring Team in Cancer unit first saw patient	DDT / Manual	DD/MM/YYYY
Diagnostic Biopsy Date	RO – 203	Date of Biopsy confirming tissue diagnosis of cancer	DDT / Manual	DD/MM/YYYY
MDM Date	RO – 204	Date of MDM index- discussion of patient's case	DDT / Manual	DD/MM/YYYY
Referral to RT – Dictation date	RO – 205	Date Referral to Radiotherapy dictated	DDT / Manual	DD/MM/YYYY
Referral to RT – Date received	RO – 206	Date Referral to Radiotherapy received	Dropdown OIS[3]	DD/MM/YYYY
1st RT Review Date	RO – 207	Date of 1st Radiotherapy Consultation with patient	Dropdown OIS	DD/MM/YYYY
Alert for RT Date	RO – 208	Date RO Alerted Patient for Treatment on OIS	Dropdown OIS	DD/MM/YYYY
RTT Date	RO – 209	Date RO deems all pre-requisites fulfilled to commence radiotherapy	Dropdown OIS	DD/MM/YYYY
CT Simulation Date	RO – 210	Date of CT simulation	Dropdown OIS	DD/MM/YYYY
Contours Approval Date	RO – 211	Date RO approves contours	Dropdown OIS	DD/MM/YYYY
Plan Approval Date	RO – 212	Date RO approves radiotherapy treatment plan	Dropdown OIS	DD/MM/YYYY
Planning Meeting Date	RO – 213	Date patient's plan is discussed at Planning Meeting	Dropdown OIS	DD/MM/YYYY
Actual Start Date	RO – 214	Date radiotherapy actually commences	Dropdown OIS	DD/MM/YYYY
Planned Completion Date	RO – 215	Intended date of completion when 1st fraction delivered	Dropdown OIS	DD/MM/YYYY
Actual Completion Date	RO – 216	Actual date of delivery of final fraction of radiotherapy	Dropdown OIS	DD/MM/YYYY

Data Item	Data Item Number	Definition	Operation	Format
Cancer Diagnosis				
Anatomic Location	RO – 301	ICD - 10	Dropdown OIS	ALPHANUMERIC
Laterality	RO – 302	1 – Right ;2 - Left ; 3 – Bilateral ; 4 – Midline; 5 – N/A	Dropdown OIS	NUMERIC
Morphology	RO – 303	ICD - 10	Dropdown OIS	ALPHANUMERIC
TNM Stage – Clinical	RO – 304	AJCC	Dropdown OIS	ALPHANUMERIC
TNM Stage - Pathological	RO – 305	AJCC	Dropdown OIS	ALPHANUMERIC
Patient Performance Status	RO – 306	ECOG (0 – 5)	Dropdown OIS	NUMERIC
Documents [3]				
Referral Letter	RO – 401	Initial referral from cancer unit to radiotherapy	DDT / Manual	PDF / WORD
MDM Summary	RO – 402	Copy of Index Discussion at Cancer MDM	DDT / Manual	PDF / WORD
Diagnostic Biopsy Report	RO – 403	Report of Histology confirming cancer diagnosis	DDT / Manual	PDF / WORD
Post-operative Pathology Report	RO – 404	Report of post-operative histology of cancer surgery	DDT / Manual	PDF / WORD
Imaging Reports	RO – 405	Reports of all staging imaging investigations	DDT / Manual	PDF / WORD
SACT Plan	RO – 406	Copy of systemic anti-cancer treatment prescription	DDT / Manual	PDF / WORD
Signed Consent Form	RO – 407	Copy of signed consent form for radiotherapy treatment	DDT / Manual	PDF / WORD
Planning Meeting Minutes	RO – 408	Copy of Planning Meeting Discussion of radiotherapy plan	DDT / Manual	PDF / WORD
Planning Data				
Planning Dataset	RO – 501	Sufficient to recreate the radiotherapy plan on any network TPS	DDT	DICOM
Treatment Set up Data				
Treatment Set up Dataset	RO – 601	Sufficient to recreate treatment set up on any network	DDT	
Treatment Prescription				
Radiotherapy Centre	RO – 701	Dropdown menu – key code to all ROI Radiotherapy Centres	Dropdown OIS	NUMERIC
Radiation Oncologist	RO – 702	Dropdown menu – key code to all ROI HSE centre radiation oncologists	Dropdown OIS	NUMERIC
Clinical Trial Status	RO – 703	1 = On offered trial ; 2 = declined offered trial ; 3 = trial not offered / available	Dropdown OIS	NUMERIC
Trial Protocol Number	RO – 704	NIH Reference	DDT / Manual	NUMERIC
National Guideline	RO – 705	1 = On national treatment guideline ; 2 = Off national treatment guideline	Dropdown OIS	NUMERIC
RT Treatment Episode Number	RO – 706	1 = 1st ; 2 = 2nd ; 3 = 3rd ; 4 = 4th etc. in patient's lifeftime	Dropdown OIS	NUMERIC
Clinical Indication	RO – 707	1 = RT to loco-regional disease; 2 = RT to metastatic disease	Dropdown OIS	ALPHANUMERIC

Data Item	Data Item Number	Definition	Operation	Format
Treatment Intent	RO – 708	1 = Radical ; 2 = Palliative	Dropdown OIS	NUMERIC
Cancer Treatment Sequence	RO – 709	1 = Primary ; 2 = Adjuvant ; 3 = Neo-adjuvant	Dropdown OIS	NUMERIC
Anatomic Target	RO – 710	ICD – 10	Dropdown OIS	ALPHANUMERIC
Treatment Prescription (continued)				
External Beam Technique	RO – 711	E.g. V-Sim / 3D-Conformal / IMRT – see reference below[4]	Dropdown OIS	ALPHANUMERIC
Brachytherapy	RO – 712	See reference below[5]	Dropdown OIS	ALPHANUMERIC
Brachytherapy source / rate	RO – 713	See reference below[6]	Dropdown OIS	ALPHANUMERIC
Total Prescribed Dose	RO – 714	Gy / cGy	Dropdown OIS	NUMERIC
Total Received Dose	RO – 715	Gy / cGy	Dropdown OIS	NUMERIC
Number of Fractions	RO – 716	Total number of fractions delivered	Dropdown OIS	NUMERIC
Fraction Pattern	RO – 717	E.g. daily / twice daily / weekly etc.	Dropdown OIS	ALPHANUMERIC
On Treatment Review				
CTCAE – Acute Effects	RO – 801	Common Terminology Criteria for Adverse Events NCI-DCTD-CTEP[7]	Dropdown OIS	ALPHANUMERIC
Post Treatment				
Patient Reported Outcomes	RO – 901	Annual self-assessment questionnaire – standardized instrument	Postal / Online	ALPHANUMERIC
CTCAE - Evolving	RO – 902	Common Terminology Criteria for Adverse Events NCI-DCTD-CTEP	Dropdown OIS	ALPHANUMERIC
Recurrence – Date	RO – 903	Biopsy date or imaging date	NCRI	DD/MM/YYYY
Recurrence - Type	RO – 904	1 (Local) ; 2(Regional Nodal); 3 (Metastasis)	NCRI	ALPHANUMERIC
New malignancy - Date	RO – 905	Biopsy date	NCRI	DD/MM/YYYY
New malignancy - Location	RO – 906	Anatomic Site ICD - 10	NCRI	ALPHANUMERIC
New malignancy - Morphology	RO – 907	Histology – ICD-10	NCRI	ALPHANUMERIC
Date of Death	RO – 908	As recorded by the General Register Office	GRO	DD/MM/YYYY

[1]**D**igital **D**ata **T**ransfer from appropriate IT platform to OIS, versus **Manual** entry of data into OIS

[2]**Dropdown OIS** = data entered via drop-down menu on the OIS

[3]Retained on OIS – Subject to revision if National EPR obviates requirement

[4]External Beam Technique

1. Virtual Simulation
2. 3D – Conformal Plan (no intensity or arc modulation)
3. IMRT
4. VMAT
5. Stereotactic Radiotherapy

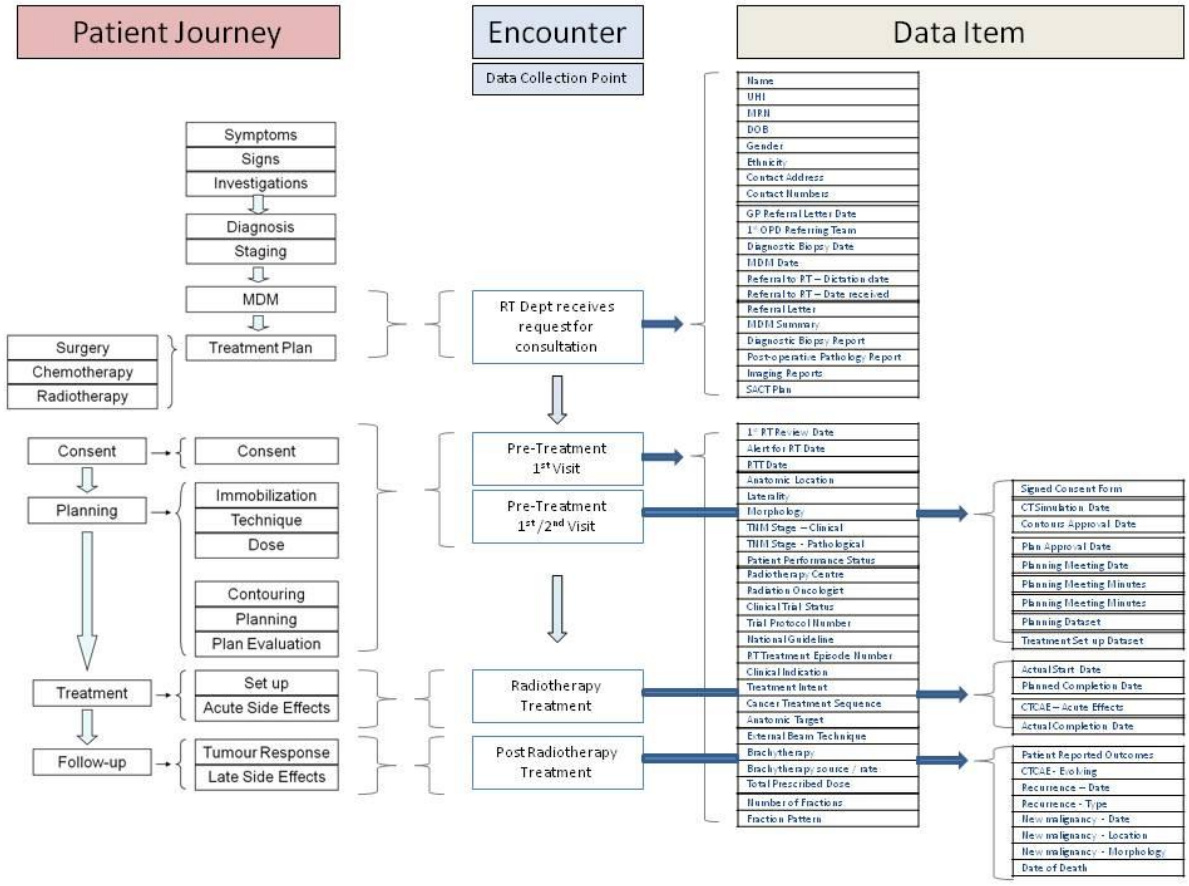
[5]Brachytherapy

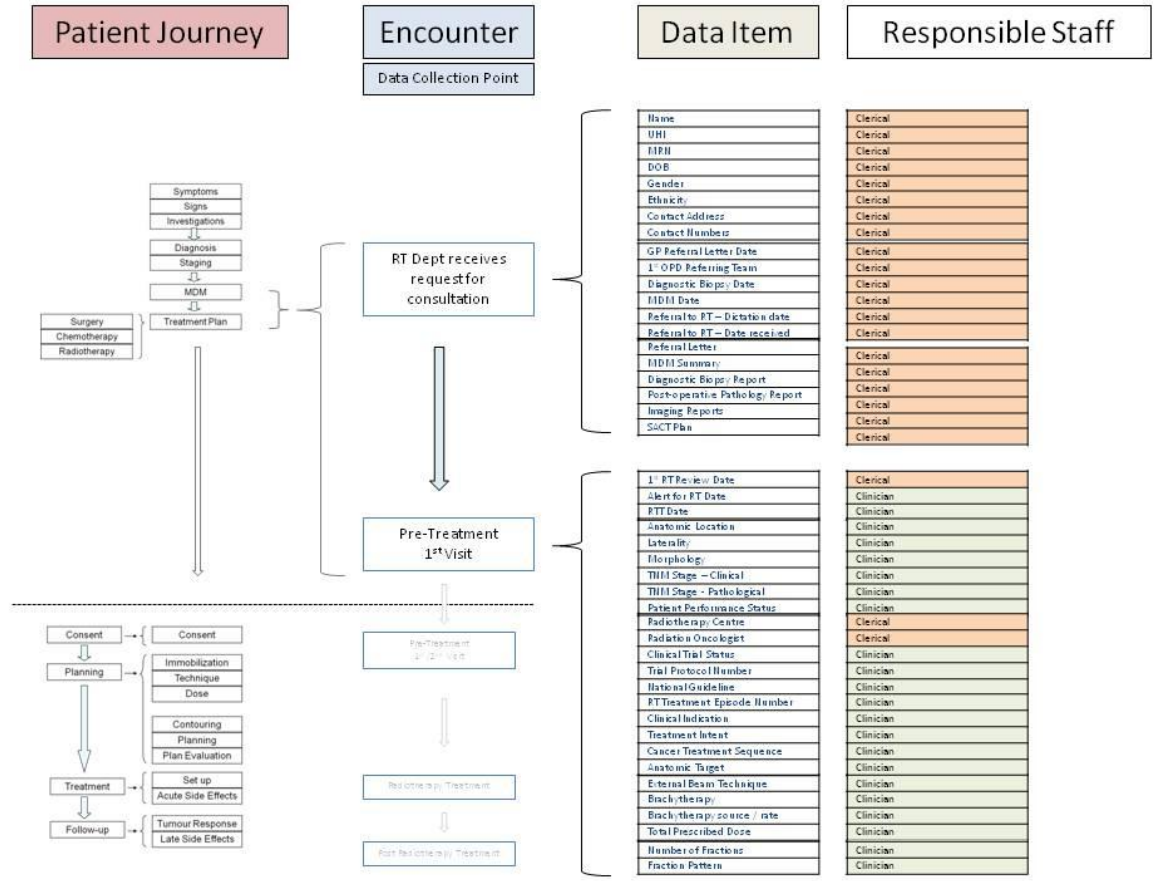
1. Interstitial Mono-therapy
2. Interstitial Boost
3. Intra-cavitary Mono-therapy
4. Intra-cavitary Boost

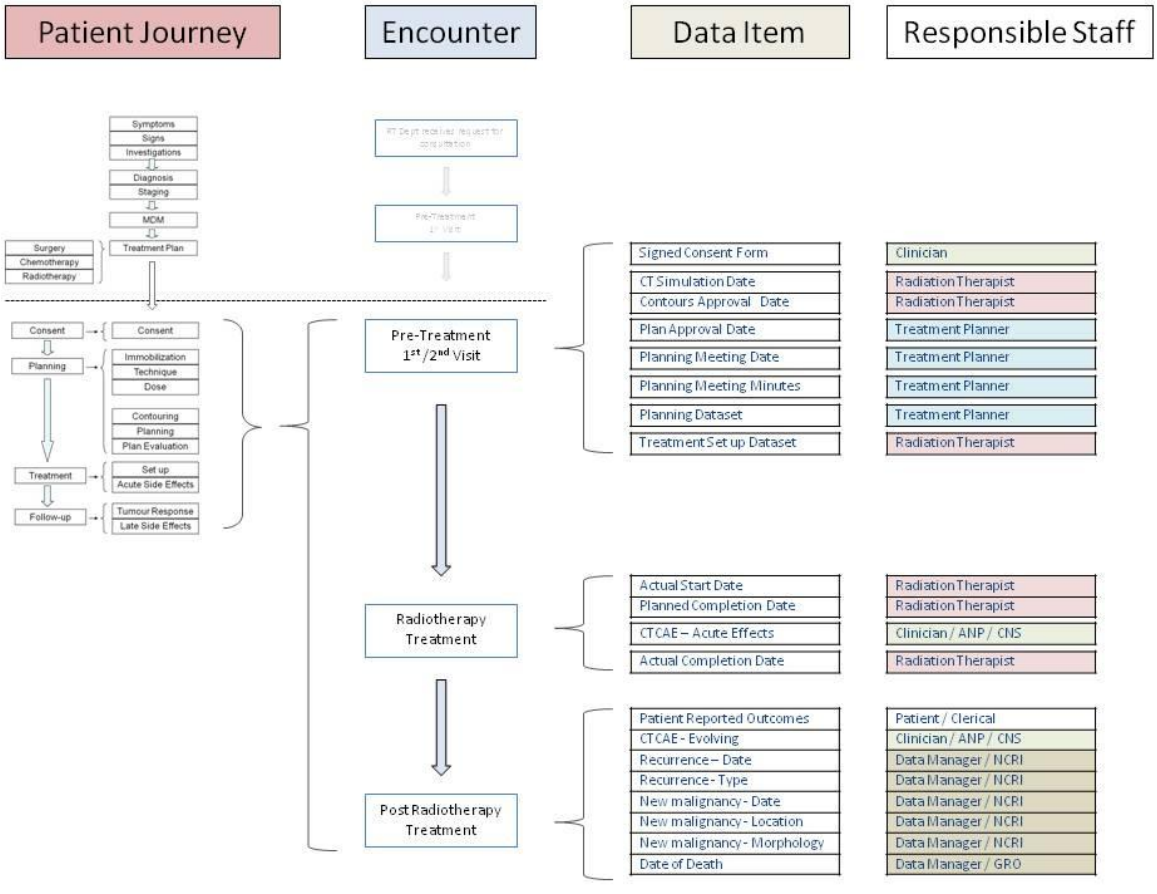
[6]Brachytherapy source / rate

1. HDR – ^{192}Ir
2. LDR – Au
3. LDR – Pd

[7] **NCI-DCTD-CTEP** = National Cancer Institute – Division of Cancer Treatment & Diagnosis – Cancer Therapy Evaluation Programme




Patient Journey
Encounter
Data Collection Point
Data Item
Responsible Staff
Symptoms
Signs
Investigations
Diagnosis
Staging
MDM
Treatment Plan
Surgery
Chemotherapy
Radiotherapy
RT Dept receives request for consultation
Pre-Treatment 1st Visit
Consent
Planning
Immobilization
Technique
Dose
Contouring
Planning
Plan Evaluation
Treatment
Set up
Acute Side Effects
Follow-up
Tumour Response
Late Side Effects
Name
UHI
MRN
DOB
Gender
Ethnicity
Contact Address
Contact Numbers
GP Referral Letter Date
1st OPD Referring Team
Diagnostic Biopsy Date
MDM Date
Referral to RT – Dictation date
Referral to RT – Date received
Referral Letter
MDM Summary
Diagnostic Biopsy Report
Post-operative Pathology Report
Imaging Reports
SACT Plan
1st RT Review Date
Alert for RT Date
RTT Date
Anatomic Location
Laterality
Morphology
TNM Stage – Clinical
TNM Stage - Pathological
Patient Performance Status
Radiotherapy Centre
Radiation Oncologist
Clinical Trial Status
Trial Protocol Number
National Guideline
RT Treatment Episode Number
Clinical Indication
Treatment Intent
Cancer Treatment Sequence
Anatomic Target
External Beam Technique
Brachytherapy
Brachytherapy source / rate
Total Prescribed Dose
Number of Fractions
Fraction Pattern
Clerical
Clinician


Patient Journey
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Radiotherapy
Consent
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Immobilization
Technique
Dose
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Planning
Plan Evaluation
Treatment
Set up
Acute Side Effects
Follow-up
Tumour Response
Late Side Effects
Pre-Treatment 1st /2nd Visit
Radiotherapy Treatment
Post Radiotherapy Treatment
Signed Consent Form
CT Simulation Date
Contours Approval Date
Plan Approval Date
Planning Meeting Date
Planning Meeting Minutes
Planning Dataset
Treatment Set up Dataset
Actual Start Date
Planned Completion Date
CTCAE – Acute Effects
Actual Completion Date
Patient Reported Outcomes
CTCAE - Evolving
Recurrence – Date
Recurrence - Type
New malignancy - Date
New malignancy - Location
New malignancy - Morphology
Date of Death
Clinician
Radiation Therapist
Treatment Planner
Clinician / ANP / CNS
Patient / Clerical
Data Manager / NCRI
Data Manager / GRO

Appendix G Published Peer Review Paper

Appendix H Search Methodology

Search Strategy

Research question
The following research question was developed:
What quality assurance guidelines/frameworks exist for radiation oncology services?

Search terms:
A combination of Medical Search Headings (MeSH) and free text were used as search terms. These were developed from key word searches of relevant papers. Embase was also searched for synonyms. Search terms used were: "radiation oncology" OR "radiation therapy" OR "radiotherapy" OR "radiation treatment*" OR "radiation therapies" AND "quality assurance" OR "quality control" OR "quality assessment" AND "framework*" OR "assurance" OR "standard*" OR "guideline*".
Boolean search terms were used. Language restrictions (English language) were applied along with publication restrictions to within the last five years.

Database searches
Relevant databases which included Cochrane, Pubmed, CINHAL and Embase were searched using the search terms and restrictions outlined above in January 2017. 2,732 titles were screened, 71 abstracts read and 26 articles were chosen for further full-text review. Search details are presented below (Tables 1 - 4).

Inclusion criteria:
- National quality assurance guidelines, recommendations or frameworks for radiation
- Published in the English language
- Published in the last five years

Exclusion criteria:
- Local level or regional guidance for quality assurance
- Guidance for specific tumour sites, equipment or treatment modalities.
- Guidance published more than five years previously

National Guidelines
A number of English-speaking developed countries with a clinical setting similar to Ireland's were identified for targeted searches. These included the United Kingdom, Australia, New Zealand, Canada and the United States.

A number of websites which serve as repositories for national clinical guidance were searched. These were:

1. United States National Guideline Clearing House
2. National Institute for Clinical Excellence
3. Scottish Intercollegiate Guideline Network
4. Canadian Medical Association Infobase
5. New Zealand Guideline Group
6. Australian National Health and Research Council

Societies and Training Bodies
Three national quality assurance guidelines had been identified by the working group. These were:

1. The Canadian Partnership for Quality Radiotherapy's[5] *Quality Assurance Guidelines for Canadian Radiation Treatment Programs*
2. Australian and New Zealand'[6]s *Radiation Oncology Practice Standards*
3. The American Society for Radiation Oncology[7]'s *Safety is no Accident – A Framework for Quality Radiation Oncology and Care*.

As these guidelines are recent and endorsed by their respective training bodies and societies a decision was made not to further search for US, Canadian, New Zealand or Australian guidance.
The UK (Royal College of Radiologists, Institute of Physics and Engineering in Medicine (IPEM) and The Society of Radiographers) and ESTRO websites were searched for any relevant frameworks or guidance.

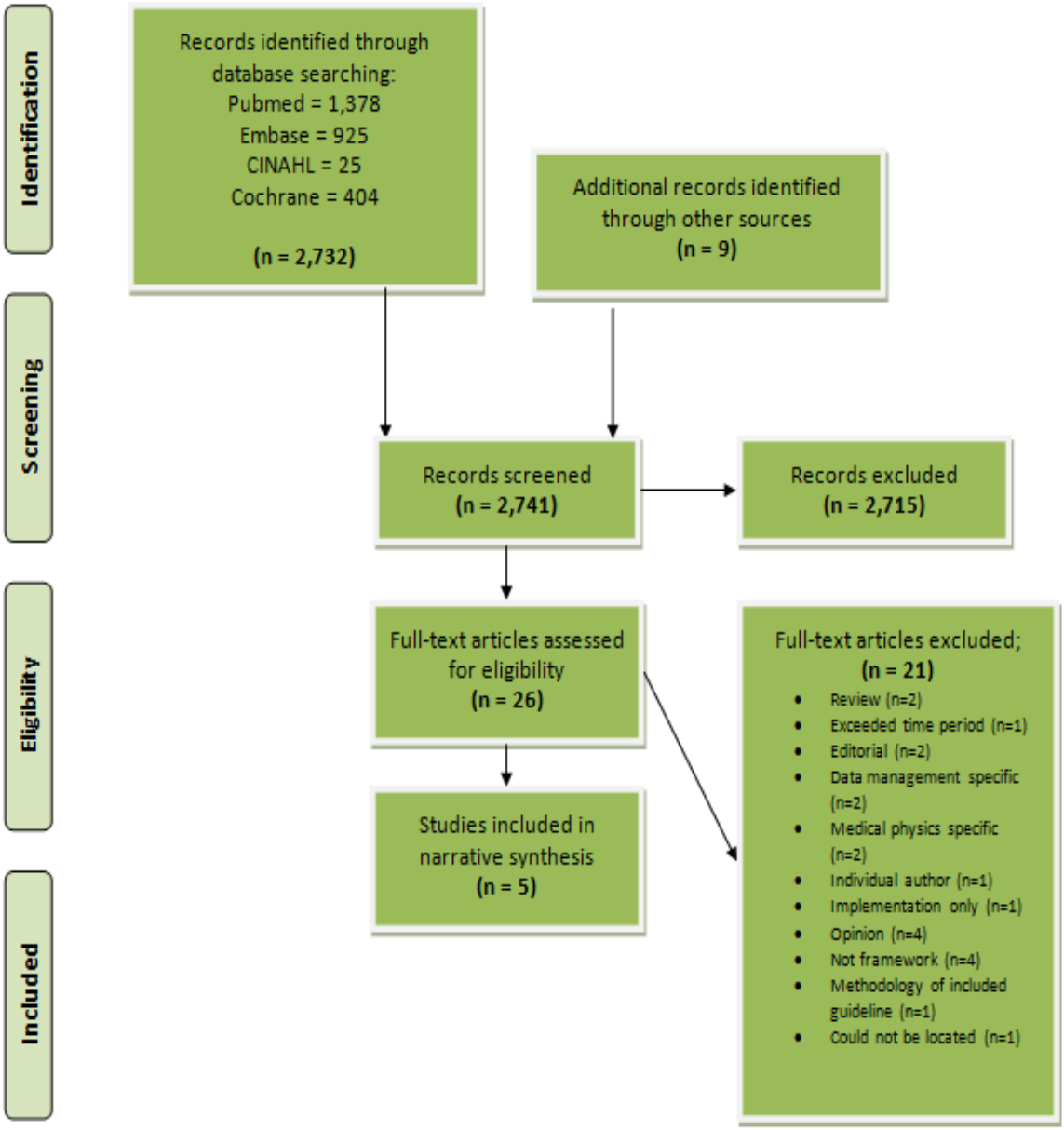
A flow diagram summarising the search strategy is shown below (Figure 1).

The search identified five international guidelines or frameworks for potential inclusion:

1. The Canadian Partnership for Quality Radiotherapy's *Quality Assurance Guidelines for Canadian Radiation Treatment Programs* (Canadian Partnership for Quality Radiotherapy, 2015)
2. Australian and New Zealand's *Radiation Oncology Practice Standards* (The Faculty of Radiation Oncology et al., 2011)
3. The American Society for Radiation Oncology's *Safety is no Accident – A Framework for Quality Radiation Oncology and Care* (American Society for Radiation Oncology, 2012).
4. Quality assurance and quality control for radiotherapy/medical oncology in Europe: Guideline development and implementation (Valentini et al., 2013)
5. Radiotherapy Risk Profile – Technical manual (World Health Organisation, 2008).

The latter document is strictly speaking outside the time frame specified and also not a framework for quality assurance. It does, however outline areas of risk in radiotherapy and mitigating measures which may prove useful as a cross-reference for the completed framework.

[5] Canadian Association of Radiation Oncology, Canadian Organisation of Medical Physicists, Canadian Association of Medical Radiation Technologists and the Canadian Partnership Against Cancer
[6] The Faculty of Radiation Oncology, The Royal Australian and New Zealand College of Radiologists, Australian Institute of Radiography, The Australasian College of Physical Scientists and Engineers in Medicine (ASPSEM)
[7] American Association of Medical Dosimetrists, American Association of Physicists in Medicine, American Board of Radiology, American Brachytherapy Society, American College of Radiology, American College of Radiation Oncology, American Radium Society, American Society for Radiation Oncology, American Society of Radiologic Technologists, Association of Freestanding Radiation Oncology Centers, Society of Chairmen of Academic Radiation Oncology Programs, Society for Radiation Oncology Administrators.


Identification
Screening
Eligibility
Included
Records identified through database searching:
Pubmed = 1,378
Embase = 925
CINAHL = 25
Cochrane = 404
(n = 2,732)
Additional records identified through other sources
(n = 9)
Records screened
(n = 2,741)
Records excluded
(n = 2,715)
Full-text articles assessed for eligibility
(n = 26)
Full-text articles excluded;
(n = 21)
Review (n=2)
Exceeded time period (n=1)
Editorial (n=2)
Data management specific (n=2)
Medical physics specific (n=2)
Individual author (n=1)
Implementation only (n=1)
Opinion (n=4)
Not framework (n=4)
Methodology of included guideline (n=1)
Could not be located (n=1)
Studies included in narrative synthesis
(n = 5)

Acronyms

AGREE	Appraisal of Guidelines Research and Evaluation
ASTRO	American Society for Radiation Oncology
CEO	Chief Executive Officer
CINAHL	Cumulative Index of Nursing and Allied Health Literature
EC	European Commission
ESTRO	European Society for Radiotherapy and Oncology
HTA	Health Technology Assessment
ICRU	International Commission on Radiation Units and Measurements
IPEM	Institute of Physics and Engineering in Medicine
KPI	Key Performance Indicators
MERU	Medical Exposure Radiation Unit
MeSH	Medical Search Headings
MP	Medical Physicist
MPE	Medical Physicist Expert
NCCP	National Cancer Control Programme
PPPG	Policies, Procedures, Protocols and Guidelines
RPE	Radiation Protection Expert
RPO	Radiation Protection Officer
RTQAC	Radiation Therapy Quality assurance Committee
TNM	Tumour, Node, Metastasis
WHO	World Health Organization

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