

National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline

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Changing practice to support service delivery



National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline
Office of the Nursing and Midwifery Services Director (ONMSD), Health Service Executive (HSE)

This document is a National Guideline

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PART A

Introduction

This national guideline replaces the *Guiding Framework for the Implementation of Nurse Prescribing of Medical Ionising Radiation (X-Ray) in Ireland* (Office of the Nursing and Midwifery Services Director, Health Service Executive, 2009) to reflect new legislative, regulatory and professional regulation changes.

The aim of this national guideline is to provide guidance and a clinical governance framework for health service providers, within the Health Services Executive (HSE) and HSE Funded Agencies (Section 38), outlining lines of responsibility and accountability to support nurse and midwife authority to refer adults and children for radiological procedures that are underpinned by legislation and regulation. Health service providers can adopt this national guideline or develop their own local policies, procedures, protocols and guidelines (PPPGs) incorporating the regulatory requirements and the relevant legislation outlined in this document.

Nurse and midwife authority to refer for radiological procedures is an expanded role that nurses and midwives undertake following successful completion of a Nursing and Midwifery Board of Ireland (NMBI) approved education programme and having regard to legislation, associated regulations, professional regulation, national and local health service providers PPPGs.

European Council Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to medical ionising radiation, which relates to the medical exposures to ionising radiation, was transposed into Irish law in 2018, by Statutory Instruments S.I. No. 256 of 2018, (with amendments S.I. No. 332 and S.I. No. 413 of 2019). It replaces S.I. No. 478 and all its amendments including S.I. No. 303. In S.I. No. 256 the term Prescriber has changed to Referrer.

The Nursing and Midwifery Board of Ireland (NMBI) revised the *Requirements and Standards for Nurse Education Programmes for Authority to Prescribe Ionising Radiation (X-Ray)* (First

Edition) (An Bord Altranais, 2008) to address and reflect the legislative changes stipulated in S.I. No. 256 of 2018. They have been replaced with the *Nurse Authority to Refer for Radiological Procedures Standards and Requirements for Education Programmes*, (NMBI, 2020).

Each nurse/midwife referrer must refer for radiological procedures within their scope of practice and is individually accountable to keep up-to-date with advances in radiological procedures and clinical practice and must acknowledge any limitations in their competence. Referring in an accountable manner requires a sound knowledge base, upon which to make decisions in conjunction with their professional judgement. The nurse/midwife referrer must be able to justify and provide a rationale for taking a particular course of action.

Nurse Authority to Refer for Radiological Procedures Standards and Requirements for Education Programmes (NMBI, 2020), along with the relevant legislation and associated regulations, national and local health service providers PPPGs must inform the referral practices of the nurse/midwife. The scope and context of practice should be determined by the competencies for referral authority and the practice standards that a nurse/midwife referrer should adhere to as part of their professional responsibilities (NMBI, 2020), with reference to the *Scope of Nursing and Midwifery Practice Framework* (NMBI, 2015) and the *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives* (NMBI, 2021).

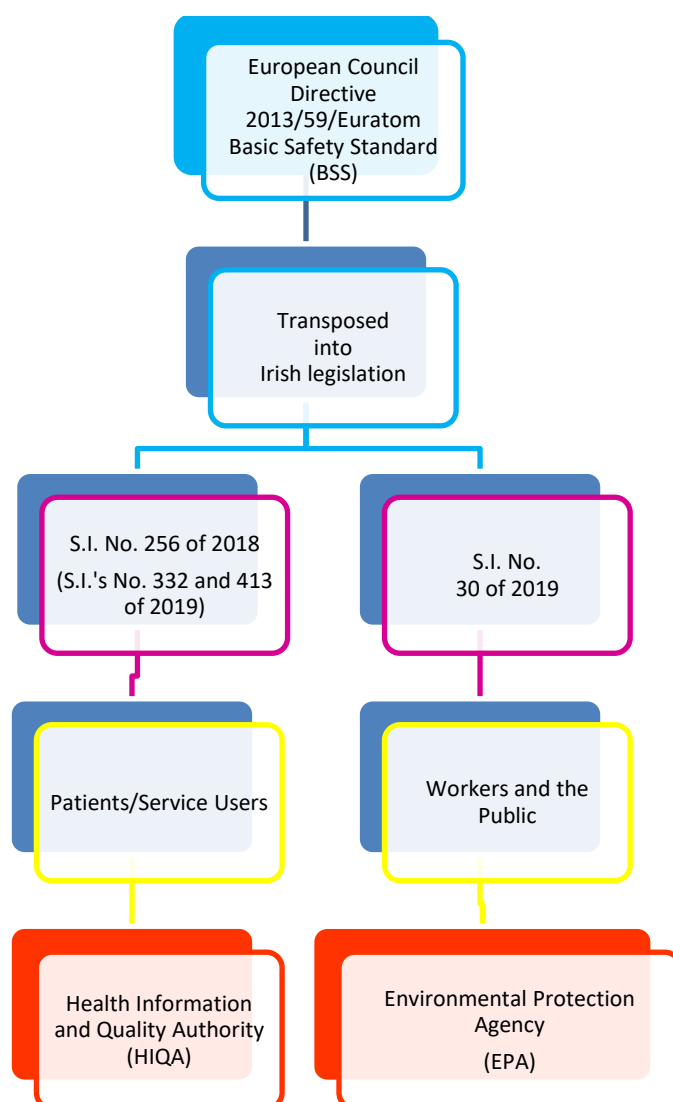
The clinical governance for referral practice is determined by the local health service providers PPPGs. It is recognised that referral practice requires a multidisciplinary approach to the provision of safe patient/service user care and should be planned in a collaborative manner. The sharing of information and advice by multidisciplinary team members is important in promoting evidence-based high quality and safe referrals which is a key objective of all referrers.

Legislation

The policy for the introduction of nurse/midwife referral of medical ionising radiation originated in the Department of Health and Children (DOHC) in 2007, to improve patient/service user care. In practice the current legislation S.I. No. 256 of 2018, authorises a nurse/midwife to refer a patient/service user to a practitioner for a radiological procedure provided that the nurse/midwife is registered with the NMBI and has successfully completed an approved NMBI education programme.

European Council Directive 2013/59/EURATOM, laying down basic safety standards for protection against the dangers arising from exposure to medical ionising radiation, was introduced in Europe and subsequently transposed into Irish law by separate S.I.'s in 2018 and 2019 (see Figure 1).

Figure 1: Legislative Framework for Radiation Protection (NMBI 2020 Amended).



Under S.I. No. 256 of 2018, the Health Information and Quality Authority (HIQA) is the competent and regulatory authority for medical ionising radiation procedures with responsibility for inspecting, monitoring and enforcing these regulations. The Environmental Protection Agency (EPA), under Statutory Instruments No. 30 of 2019 is responsible for the authorisation of medical facilities and enforcement (monitors compliance with regulations and licence conditions), including the protection of workers and members of the public against the dangers arising from exposure to ionising radiation.

The S.I. No. 256 of 2018 revoked:

- (a) the European Communities (Medical Ionising Radiation Protection) Regulations 2002 (S.I. No. 478 of 2002),
- (b) the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations 2007 (S.I. No. 303 of 2007),
- (c) the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations 2010 (S.I. No. 459 of 2010).

Statutory instruments No. 256 of 2018 defines a “referrer” as a person, being a member of one of the classes of persons referred to in Regulation 4(1), who is entitled to refer an individual for radiological procedures to a practitioner.

Regulation 4(1) of Part 2 of the requirements in relation to medical exposures stipulates who can be a referrer:

“Referrers

4. (1) A person shall not refer an individual for medical radiological procedures to a practitioner unless the person referring (“the referrer”) is—

- (a) a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives,
- (b) a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),
- (c) a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007),

- (d) a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or
- (e) a health care professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland, who is entitled in accordance with his or her employer's procedures to refer individuals for exposure to a practitioner."

In relation to the practical aspects of a radiological procedure, the legislative amendment S.I. No. 413 of 2019 to S.I. No. 256 of 2018 states:

"(4) Practical aspects of a medical radiological procedure may be delegated by—

- (a) the undertaking, or
- (b) the practitioner,

as appropriate, to one or more individuals—

- (i) registered by the Dental Council,
- (ii) registered by the Medical Council,
- (iii) registered by the Nursing and Midwifery Board of Ireland,
- (iv) whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005, or
- (v) recognised by the Minister under Regulation 19,

as appropriate, provided that such person has completed training in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body."

Regarding Education, Information and Training S.I. No. 256 of 2018 states in Part 4

"(3) The persons referred to in paragraph (1) must have successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection, as prescribed by—

- (a) the Dental Council,
- (b) the Irish College of Physicists in Medicine,
- (c) the Nursing and Midwifery Board of Ireland,

(d) the Radiographers Registration Board, or
(e) a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course, as appropriate, having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (Radiation Protection No. 175)".

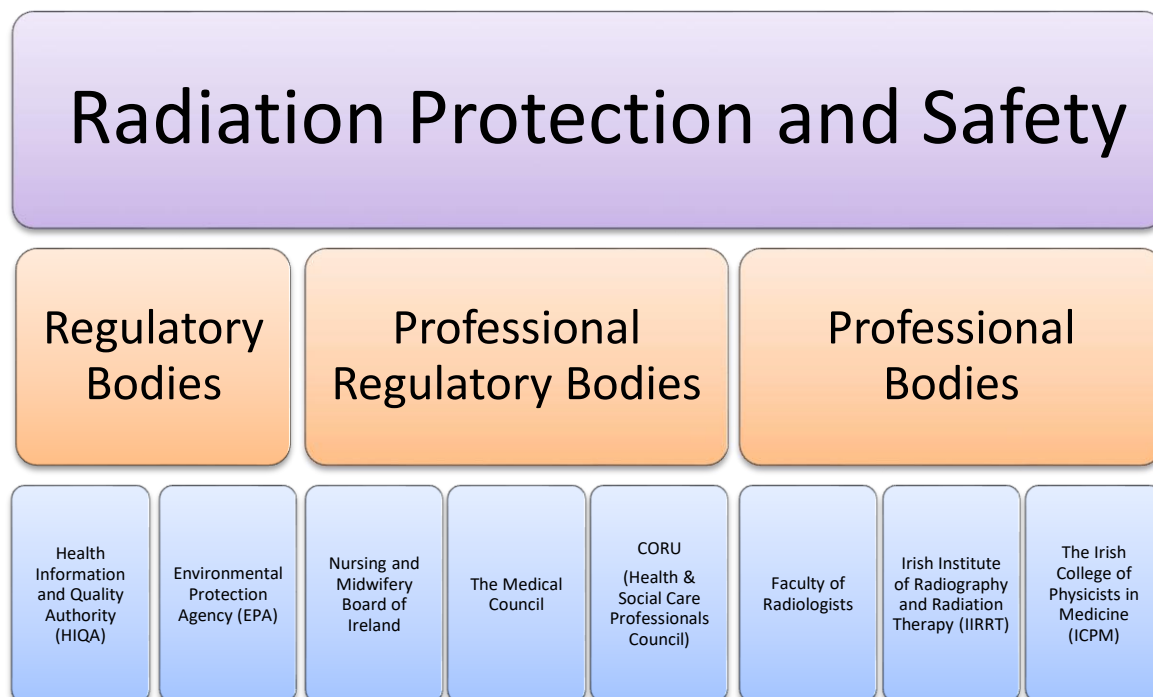
Other legislation and regulations that support nurse/midwife referrals are:

- *Nurses Rules (2010)* (S.I No. 689 of 2010),
- *Nurses and Midwives Act 2011* (S.I. No. 41 of 2011),
- *Nurses and Midwives Rules 2013* ((S.I. No. 435 of 2013) (Supplemental to 2010 Nurses Rules)),
- *Nurses and Midwives Register of Nurses and Midwives Rules 2018* (S.I. No. 219 of 2018).

Framework for Radiation Protection

In order to place medical ionising radiation in an appropriate context, it is useful to describe the other key regulatory and professional bodies involved in Radiation Safety and Protection as shown in Figure 2.

Figure 2: Framework for Radiation Protection



The Regulatory Bodies

The Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public. HIQA is the competent and regulatory authority for patient/service user radiation safety in public and private locations in Ireland. HIQA is responsible for ensuring compliance by inspecting, monitoring and enforcing the regulations that apply to medical ionising radiation.

The Environment Protection Agency (EPA)

The EPA has responsibility for both authorisation of medical facilities and enforcement (monitors compliance with regulations and licence conditions) and for the regulation of radiation protection of workers and the general public.

Professional Regulatory Bodies

The Nursing and Midwifery Board of Ireland

The Nursing and Midwifery Board of Ireland (NMBI), formerly An Bord Altranais, is the independent, statutory organisation which regulates the nursing and midwifery professions in Ireland. They work with nurses and midwives, the public and key stakeholders to enhance patient/service user safety and care. Protecting patients/service users and other members of the public is at the heart of what they do and they are committed to fulfilling this objective by supporting registered nurses and midwives to provide patient/service user care to the highest standards. The core functions of NMBI include, maintaining the Register of Nurses and Midwives, evaluating applications from Irish and overseas applicants who want to practise as nurses and midwives in Ireland, supporting nurses and midwives to provide care by developing standards and guidance that they can use in their day-to-day practice, setting requirements for nursing and midwifery education programmes in Higher Education Institutions (HEIs) and investigating complaints made from patients/service users, their families, health care professionals, employers and holding Fitness to Practise inquiries.

CORU

CORU (Health & Social Care Professionals Council) is the body responsible for regulating health and social care professions established under the Health and Social Care Professionals Act, 2005. CORU was established to protect the public by promoting high standards of professional conduct, education, training and competence through statutory registration of health and social care professionals. CORU maintains the Registration Board for Radiographers and Radiation Therapists.

The Medical Council

The Medical Council regulates medical doctors in the Republic of Ireland. The Council's purpose is to protect the public by promoting and better ensuring high standards of professional conduct and professional education, training and competence among doctors. The Medical Council's key responsibilities include, maintaining the Register of Medical Practitioners, ensuring the highest standards of medical training and education, promoting good medical practice, overseeing doctors' continuing professional development and investigating complaints against medical doctors.

Professional Bodies

Faculty of Radiologists

The Faculty of Radiologists of the Royal College of Surgeons in Ireland is the professional and academic body for clinical radiologists in Ireland. The Faculty's objectives are to advance the science, art and practice of radiology and its allied sciences and to promote education, study and research. It is the training body responsible to the Medical Council for the education standards for radiologists and for sanctioning with the Medical Council, radiation protection courses for non-radiologist medical practitioners undertaking medical ionising exposures under the control of the Practitioner in Charge.

The Irish College of Physicists in Medicine

The Irish College of Physicists in Medicine (ICPM) is the voluntary registration body for Medical Physicists in Ireland. Membership is open to those deemed to be competent to perform work which demands scientific knowledge and expertise in the application of physics and applied physics to problems of healthcare delivery and development. Registration with the ICPM enables standards of safety and quality and is intended to guard against unsafe, incompetent or unethical practice in medical physics. Employers and patients/service users can be assured that medical physicists meet international standards of education, training and competence, and abide by professional and ethical standards.

The Irish Institute of Radiography and Radiation Therapy

The Irish Institute of Radiography and Radiation Therapy (IIRRT) is the professional body responsible for the development of professional standards in radiography and radiation therapy, which are essential in maintaining and improving standards of care and management of patients/service users. The IIRRT is the professional body representing Radiographers and Radiation Therapists in Ireland. The remit of state registration is that of the Radiographers Board of CORU.

Professional Regulation for Nursing and Midwifery

In February 2008, An Bord Altranais published the first edition of the *Requirements and Standards for Nurse Education Programmes for Authority to Prescribe Ionising Radiation (X-Ray)*. These were replaced by the NMBI in March 2020 to reflect S.I. No. 256 of 2018 in the *Nurse Authority to Refer for Radiological Procedures Standards and Requirements for Education Programmes*. These professional standards guide health service and education providers in relation to the development, delivery and evaluation of nurse/midwife education programmes for authority to refer for radiological procedures. The education programme standards and requirements are specific in relation to:

- learning outcomes,
- competencies for authority to refer for radiological procedures,
- syllabus/indicative content,
- theoretical and clinical instruction,
- scope of practice guidance for nurse/midwife referrers of radiological procedures.

The purpose of these standards is to provide guidance for developing a flexible, innovative and practice-oriented nurse/midwife education programme for nurse/midwife authority to refer patients/service users, both adults and children for radiological procedures. On successful completion of the nurse/midwife referral education programme, it is expected that the nurse/midwife will independently and autonomously refer patients/service users, following appropriate clinical assessment exercising clinical judgement and decision-making specific for the patient/service user.

The NMBI supports and recognises that the delivery of nurse/midwife referral education programmes for nurse/midwife authority to refer patients/service users for radiological procedures requires interprofessional input and collaboration. The interests of no single professional group should dominate interprofessional education initiatives, and such initiatives should be planned in a collaborative manner. Interprofessional education, as part of the educational approach to deliver nurse/midwife referral education programmes should occur in a way that supports the personal identity, development and unique perspective of the nurse/midwife in their scope of practice (NMBI, 2015).

Nurse/midwife referrers must have successfully completed the education programme including the theoretical knowledge and clinical experience, in radiological procedures and radiation protection as directed by the NMBI, having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (EU) (Radiation Protection (RP) No. 175).

Regulation 4 in S.I. No. 256 of 2018 assures patients/service users that only appropriately trained and recognised healthcare professionals with appropriate knowledge and expertise have the authority to refer a patient/service user for a radiological procedure. The practitioner and those carrying out the practical aspects of radiological procedures must ensure that patients/service users have only been referred for radiological procedures by an appropriate individual.

Nurse/midwife referrers must undertake continuing education and training (S.I. No. 256 of 2018) including the relevant radiation protection requirements. Documented evidence of continuing professional development must be maintained for a rolling period of five years by the nurse/midwife referrer and the health service provider and be available at inspection by HIQA, the regulator.

This national guideline adheres to the regulatory framework for referral authority and has been developed in conjunction with the guidance issued by the NMBI including:

- *Recording Clinical Practice Guidance to Nurses and Midwives* (ABA, 2002),
- *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives* (NMBI, 2021),
- *Scope of Nursing and Midwifery Practice Framework* (NMBI, 2015),
- *Practice Standards for Midwives* (NMBI, 2015),
- *Nurse Authority to Refer for Radiological Procedures Standards and Requirements for Education Programmes 2nd edn* (NMBI, 2020).

Scope of Practice

The scope of nursing and midwifery practice is the range of roles, functions, responsibilities and activities which a registered nurse/midwife is educated, competent and has authority to perform (NMBI, 2015). The scope and context of practice should be determined with reference to the *Scope of Nursing and Midwifery Practice Framework* (NMBI, 2015). The standards and requirements for referral authority should be adhered to as part of their professional responsibilities. It is important that the nurse/midwife referrer must adhere to their scope of practice, the speciality within which they practice and the person's care pathway, relevant to their role. A referral for radiological procedures is determined by European and national legislation, professional regulations, education information and training, and the individual referrers' levels of competence.

The standards and requirements for education programmes (NMBI 2020) for nurse authority to refer patients/service users for radiological procedures recognise that a registered nurse who has successfully completed an approved education programme and the necessary training in radiation protection can refer for radiological procedures. The nurse/midwife with referral authority scope of practice can be expanded to include all radiological procedures. They can refer a person for radiological procedures, once local health service provider clinical governance arrangements are in place. These should include PPPGs for referrals for radiological procedures.

The nurse/midwife with authority to refer a person for radiological procedures makes an independent decision and is professionally accountable for the decision to refer and the follow up of the result of the radiological procedure. It is acknowledged that the named consultant holds ultimate responsibility for a person referred for a radiological procedure and their care, where the nurse/midwife functions as part of the multidisciplinary team. The referred person's named consultant assumes responsibility for treatment actions that may be necessary as a result of findings on a radiology procedure that the nurse/midwife may have requested (HSE, 2009).

Referral Practice Standards

The professional responsibilities of the nurse/midwife are addressed in the Nurse Authority to Refer for Radiological Procedures Standards and Requirements for Education Programmes

(NMBI, 2020) and should be viewed as the overarching mechanism under which a nurse/midwife is required to practice. The standards augment the clinical governance arrangements that are supported by this National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline (HSE, 2021) and the local health service providers PPPGs that support safe and professional practices for the implementation of nurse/midwife referral for radiological procedures.

Competencies

Competence is a complex multidimensional phenomenon, defined as the ability of the nurse/midwife referrer to practice safely and effectively, fulfilling their professional responsibility within their scope of practice (NMBI, 2015). It is also the attainment of knowledge, intellectual capacities, practice skills, integrity and professional and ethical values required for safe, accountable and effective practice as a registered nurse or registered midwife (NMBI, 2020). This is reflected in the competencies developed in the approved nursing/midwife education programme. These represent a framework to facilitate the assessment of the nurse/midwife referral Nurse Authority to Refer for Radiological Procedures Standards and Requirements for Education Programmes practice (NMBI, 2020).

The referral competencies for nurses/midwives as outlined in the *Nurse Authority to Refer for Radiological Procedures Standards and Requirements for Education Programmes* (NMBI, 2020) underpin their professional responsibility for referring. Upon successful completion of the education programme for Nurse/Midwife Authority to Refer for Radiological Procedures, it is acknowledged that the referrer has attained the competencies for referral authority. They have been deemed competent to refer a person for radiological procedures, as per the HEI/education providers' marks and standards for the theoretical and clinical elements of the programme. Nurse/midwife referrers are professionally and personally responsible to maintain their individual competency for referral practice.

Continuing Professional Development

Continuing education is a lifelong learning process which takes place after the completion of an education programme and training, and is a vital component of continuing professional development (CPD). It is essential for each nurse and midwife to engage in CPD, in order to acquire new knowledge and competence to practise effectively in an ever-changing

healthcare environment. Continuing professional and personal developments are required in order to maintain and enhance professional standards and to provide quality, competent and safe patient/service user care (NMBI, 2015).

The individual nurse/midwife referrer is responsible for undertaking relevant CPD activities in order to develop and maintain their professional referral practice. Under S.I. 256, nurse/midwife referrers must undertake CPD relevant to their referral practice.

The legislation states:

“(4) An undertaking shall ensure that the persons referred to in paragraph (1) undertake continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements.

(5) An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the exposure, and shall provide such records to the Authority on request”.

Inter-professional relationships, team working, peer support, clinical supervision facilitate CPD. These factors are in place in Ireland through the interdisciplinary approach, and through the provision of regular CPD days for nurse/midwife referrers. Other mechanisms for CPD can include reflection, journal clubs, multidisciplinary team meetings with case reviews and webinars. Changes to CPD requirements by NMBI must be adhered to by all nurse/midwife referrers.

Clinical Governance

Governance for quality and safety involves having the necessary structures, processes, standards and oversight in place to ensure that safe, person centred and effective services are delivered. Governance ensures the establishment of learning systems so that all experiences within a service are shared and used to improve services (HSE, 2016). It is a system through which health service providers are accountable for continually improving the quality and safety of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish (HIQA, 2019).

Health service providers, where nurse/midwife referral for radiological procedures is being undertaken should be cognisant of the Principles for Clinical Governance Development (HSE, 2012) (Appendix I). This framework supports health care teams who are accountable for the quality and safety of the care that they deliver. It is built on the model of the Chief Executive Officer / General Manager or equivalent working in partnership with the Clinical Director, Director of Nursing/Midwifery and service/professional leads. Health service providers must have formalised governance structures with clear accountability and responsibility arrangements (HIQA, 2019).

In September 2008, a national advisory committee for the implementation of nurse/midwife prescribing of medical ionising radiation was established by the Office of the Nursing and Midwifery Services Director (ONMSD) and advised on the governance arrangements that were to be in place at the time for the introduction of the initiative. The group continues to advise on the governance arrangement at a national level for nurse /midwife referrers.

Individual health service providers can develop local PPPGs which identify specific requirements and responsibilities for nurse /midwife referrer to meet their patients/service users and service needs to include clinical audit and risk management systems. Supporting staff education, training, learning and development is essential to the on-going safe delivery of medical exposures and enhancement of patient/service user care.

The *Undertaking*, as defined in the legislation, is the person or body who carries out, or engages others to carry out a radiological procedure or the practical aspects of a radiological procedure, is legally responsible for all medical exposures carried out and for providing safe,

effective care to patients/service users and other service users undergoing medical exposures to ionising radiation within its service. It must assure itself as to the quality and safety of any medical exposures carried out. It is important to ensure robust and effective corporate governance, operational and risk management arrangements are in place to ensure compliance with the regulations and communication across the organisation to ensure patient/service user safety. This should include a Radiation Safety Committee which is integrated with other organisational safe delivery of medical exposures structures, such as clinical audit and risk management committees (HIQA, 2019). There should be a clear allocation of responsibility for radiation protection for each person working within the service in relation to compliance with the regulations and they should be familiar of his or her individual and collective responsibilities (HIQA, 2019). It is important that individual professionals/groups should work in partnership and collaborate in the development of interprofessional service and educational requirements.

Policies, Procedures, Protocols and Guidelines (PPPGs)

Health service providers should continuously review PPPGs to ensure that they are comprehensive, appropriate, robust, up-to date and in line with evidence based practice, legislation and regulation, and that they continue to meet patient/service user's needs and expectations. Policies and procedures should be continuously evaluated and reviewed objectively by the service to ensure that nurse/midwife referral practice is continuously improved (HIQA, 2015). Health service providers will need to update their nurse/midwife referrers PPPGs to reflect this national guideline.

The health service provider is responsible for ensuring that staff and anyone engaged by them, understand local systems and processes and are supported in carrying out their individual roles through the provision of documented procedures. The documentation should reflect corporate and internal governance structures such as local health service provider PPPGs that should be in place, for optimisation and justification for radiological procedures to be performed (HIQA, 2019).

Audit

The Commission on Patient Safety and Quality Assurance (2008) identified clinical audit as a key and essential component of clinical governance, stating that it 'constitutes the single most

important method which any healthcare organisation can use to understand and assure the quality and safety of the service that it provides' (DOHC, 2008, p. 12). The nurse/midwife referrer must undertake audit of their referral practices to ensure that their practice is safe, appropriate, consistent and effectively monitored (HIQA, 2015) as determined by their local audit process for referral. Referrers must ensure their referral practice complies with the requirements/PPPGs of the health service provider for:

- audit of referral patterns/practices,
- reporting referral errors/incidents and near misses.

The health service provider must, monitor and evaluate the effectiveness of written PPPGs and adherence by staff through periodic audit and take appropriate action when PPPGs are not being adhered to. The local health service provider should conduct regular audits and implement recommendations from audit to evaluate the systems in place to support safe referral practice. Evaluation provides assurance to the health service provider that all medical exposures carried out are justified and optimised in line with relevant legislation and evidence-based best practices such as:

- monitoring assignment of clinical responsibilities of referrers,
- monitoring compliance with local optimisation procedures,
- monitoring compliance with local justification - framework (HIQA, 2019).

Toolkits have been developed to support audit of nurse/midwife referral practice which have details of recommended frequency and the audit process are available at:

<https://healthservice.hse.ie/filelibrary/onmsd/clinical-audit-guidance-and-audit-tool-for-nurse-midwife-referrers-for-radiological-procedures-july-2020.pdf>

The health service should conduct audits that encompass:

- quality and safety of referrals,
- rejection rates of non-justified referrals,
- provision of information to patients/service users or their representatives and carers and comforters.

The clinical audit results and reports must be documented and reported to the relevant person with overall responsibility and authority for the governance of medical exposures

(NMBI, 2020; HSE, 2020) as per the local governance arrangements for review and implementation of improvement plans and subsequent re auditing.

Risk Management

Governance for quality and safety involves having the necessary structures, processes, standards and oversight in place to ensure that safe, person centred and effective services are delivered (HSE, 2016). The health service provider is required under the regulations to implement an appropriate system for the record keeping and analyses of events involving, or potentially involving, accidental and unintended medical exposures to patients/service users, commensurate to the radiological risk posed by a type of practice.

The Incident Management Framework (IMF) (HSE, 2020) which is consistent with legislative and regulatory requirements states all incidents should be, identified, reported and reviewed so that learning from events can be shared to improve the quality and safety of services. In addition to the requirements set out in the framework, patient/service user safety incidents require disclosure in accordance with the requirements of the HSE Open Disclosure Policy (HSE, 2019).

Reported accidental and unintended radiation exposures remain low in Ireland. Reporting incidents and near misses highlight the need for vigilance and structures that ensure patient/service user safety when they are exposed to medical ionising radiation. Radiation incidents should be used as learning opportunities to improve radiation protection practices by preventing the reoccurrence of similar incidents (HIQA, 2019).

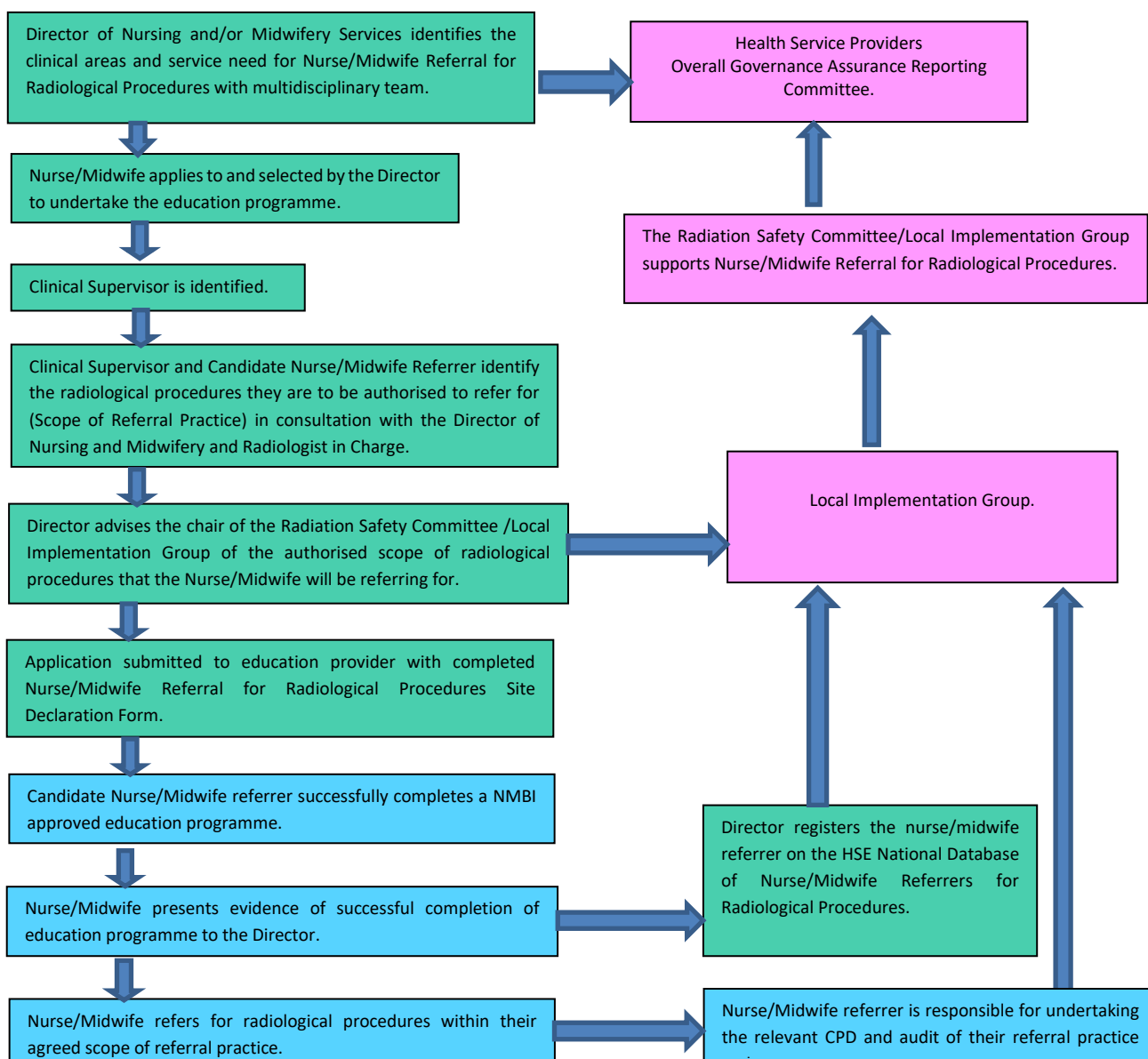
The health service provider with responsibility for personnel carrying out radiological procedures must ensure that the appropriate arrangements are in place to report the incident on the National Incident Management System (NIMS), as well as to HIQA (see section 6.0) and the EPA as appropriate, the occurrence of a significant event as outlined in the regulations. The regulations identify the specific roles and responsibilities of a health service provider regarding mandatory notifications (HIQA, 2019). The local HSE health service providers' radiology department also has responsibility to report incidents to the HSE National Radiation Protection Office.

Guideline Steps

1.0 Outline of Guideline Steps

The health service provider must clearly outline the functions of clinical governance and line management for nurse/midwife referral practice and indeed all referral practice within the facility. The nurse/midwife referrer should link with their professional nursing or midwifery line manager for support and guidance. The following sections and Figure 3 outline the essential criteria that need to be in place by the health service provider in order to support nurse/midwife referrers. The nurse/midwife authority to refer for radiological procedures initiative must have overarching support and oversight from senior executive managers for each health service provider.

Figure 3: Health Service Providers Governance Framework for Nurse and Midwife Referral for Radiological Procedures



1.1 Chief Executive Officer/General Manager or Other Senior Manager within the Health Service Provider

The Chief Executive Officer/General Manager or other senior manager within the health service provider is responsible for:

- governance and management arrangements, which must be in place to provide a quality safe service that is in compliance with the legislation S.I. No. 256 of 2018 including Regulation 4 in respect of all Referrers including nurse/midwife referrers,
- ensuring recognised healthcare professionals with appropriate knowledge, training and expertise, as defined in Regulation 4, can refer a patient/service for radiological procedures,
- practitioners accepting the referral and personnel carrying out the practical aspects of the medical exposures who must ensure that the referrals for radiological procedures are from an appropriate individual,
- identifying, in partnership with the Clinical Director or relevant Clinical Lead, Director of Nursing/Midwifery or relevant Nurse/Midwife Manager, the strategic direction of nurse/midwife authority to refer for radiological procedures and provide the structures and processes required for safe and appropriate referrals,
- the vesting of referral authority for nurses/midwives to the Director of Nursing/Midwifery within the overall clinical governance structure,
- a Local Implementation Group (LIG) reporting to the Radiation Safety Committee is in place, with representation from nurse/midwife referrers on both committees, to implement and support nurse/midwife referrers to refer for radiological procedures.

1.2 The Director of Nursing/Midwifery/or Relevant Nurse/Midwife Manager

(Referred to hereafter as the Director)

The Director is responsible for:

- ensuring governance arrangements are in place to oversee nurse/midwife referrals for radiology procedures,
- planning the strategic direction for nurse/midwife referrals for radiology procedures and in line with legislation, regulation, professional regulation and the *HSE National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline 2021*,
- securing necessary resources for safe and effective nurse/midwife referral for radiological procedures,

- ensuring local PPPGs to be in place,
- ensuring that nurses/midwives applying to undertake the education programme are selected according to identified clinical areas and service need,
- delegating responsibilities as deemed appropriate to a Nurse/Midwife Referral Site Coordinator, who is responsible for this initiative locally and for liaising with the applicant/candidate referrer, clinical supervisor, education provider and HSE National Lead for Nurse and Midwife Authority to Refer for Radiological Procedures in the ONMSD,
- signing the Site Declaration Form on behalf of the respective health service provider
- a sponsorship agreement, setting out the arrangements for study leave and financial support for the candidate referrer,
- adherence to risk management systems and processes in place by nurse/midwife referrers for the reporting and monitoring of adverse event, incidents, near misses and referral errors,
- evaluation of audit of referral practice for radiological procedures and reporting of audit results,
- liaising with the nurse/midwife referrer and the clinical supervisor regarding radiological procedures that have the nurse/midwife referrer will be referring for,
- arranging for the nurse/midwife referrer to be registered on the HSE National Database of Nurse and Midwife Referrers for Radiological Procedures,
- approving and authorising the nurse/midwife referrer in writing including a commencement date for referrals, within one month of confirmation of successfully completing the education programme,
- providing a list of nurse/midwife referrers to the Radiology Service Manager,
- liaising with the chair of the RSC/LIG regarding the approved radiological procedures that the nurse/midwife will be referring for,
- ensuring that arrangements are in place to provide access to CPD for all nurse/midwife referrers,
- addressing identified issues or breaches of the nurse/midwife referral practices,
- where necessary, the suspension of the nurse/midwife referral authority and informing the relevant stakeholders,
- delegating any of their responsibilities as appropriate.

1.3 Nurse/Midwife Referral Site Coordinator

The Nurse/Midwife Referral Site Coordinator support person is responsible for supporting nurse/midwife referral for radiological procedures delegated by the Director. This may involve:

- co-ordinating and supporting nurse/midwife referral practice at the local health service provider level,
- ensuring compliance with the legislative, regulatory and NMBI professional requirements and the HSE National Nurse and Midwife Referral for Radiological Procedures Guideline (HSE, 2021) and local PPPGs,
- acting as a central point of contact for the candidate referrer and key stakeholders, in relation to nurse/midwife referral practice where necessary with the applicant/candidate referrer, clinical supervisor, radiological department, education providers and HSE National Lead for Nurse and Midwife Authority to Refer for Radiological Procedures in the ONMSD,
- supporting audit and responding appropriately to audit reports undertaken on the nurse/midwife referral practices.

1.4 Line Manager of Candidate or Registered Nurse /Midwife Referrer

The Line Manager is responsible for:

- consulting with the multidisciplinary team and the Director, in identifying the service need for nurse/midwife referral for radiology procedures,
- consulting with the Director and Nurse/Midwife Referral Site Coordinator, in identifying appropriate candidate(s) to undertake the education programme and support the candidate during the education process,
- supporting the continuing professional development of the nurse/midwife referrer,
- informing the Director of any issues associated with the nurse/midwife referral practices and taking appropriate action,
- supporting audit and responding appropriately to audit reports undertaken on the nurse/midwife referral practices.

1.5 Candidate Nurse/Midwife Referrer

The candidate nurse/midwife referrer must:

- ensure they are registered on the register of nurses and midwives maintained by the NMBI,
- seek the approval and support of the Director to apply for the NMBI approved education programme,
- identify a clinical supervisor who will support them during the education programme,
- comply with the application process for the education programme.
- comply with sponsorship arrangements at local level, setting out study leave and financial agreement,
- liaise with the Nurse/Midwife Referral Site Coordinator on their progress as required,
- work with the clinical supervisor during the education programme to acquire the relevant clinical referral experience to be deemed a competent referrer,
- determine in consultation with the clinical consultant for the specialty the radiological procedures that will be utilised for patients/service users attending that specialty,
- liaise with the Radiologist in Charge regarding the radiological procedures that will be utilised,
- inform the Director of the agreed radiological procedures that will be utilised for patients/service users attending that specialty,
- undertake a variety of referrals within the scope of radiological procedures that the candidate referrer will refer for,
- successfully complete an approved education programme,
- within one month of successfully completing the education programme submit evidence to the Director to have their name entered onto the HSE National Database of Nurse and Midwife Referrers for Radiological Procedure.

1.6 The Clinical Supervisor

A clinical supervisor is a consultant medical practitioner who has committed to providing clinical instruction and supervision within the specific clinical practicum for the duration of the education programme. The clinical supervisor is responsible for:

- confirming their commitment to be a clinical supervisor through the inclusion of their signature on the Site Declaration Form,

- exploring with the candidate referrer their clinical learning needs and agreeing a programme/contract of learning at the start of the education programme. This is specific for each candidate referrer, reflecting their differing clinical skills and experience,
- determining the radiological procedures with the candidate referrer, in consultation with the Director and the Radiologist in Charge, that will be utilised with and by the nurse/midwife referrer for the cohort of patients/service users attending that specialty,
- providing the candidate referrer with supervision, support, teaching and learning opportunities over the duration of the programme. Aspects of this learning may be delegated to other experienced members of the team or experts in the specialty/area,
- providing the candidate referrer with supervision of a variety of referrals including the scope of radiological procedures that the candidate will refer for,
- providing learning opportunities and information updates necessary for evidence-based referral practices,
- meeting formally with the candidate referrer at regular intervals during the programme to review progress,
- formally assessing the candidate referrer's progress in the clinical setting using the assessment tool provided and at the end of the education programme, completing and 'signing off' the candidate's Competency Booklet/Clinical Supervisor Declaration.

1.7 The Radiation Safety Committee and Local Implementation Group

1.7.1 The Radiation Safety Committee

The Radiation Safety Committee (RSC) has overall responsibility for the use of ionising radiation in the health service provider. The RSC is responsible for radiation safety including radiation safety of patients/service users/public and works in compliance with S.I. 256 of 2018, its amendments and S.I 30 of 2019, it ensures and monitors compliance with EPA licence conditions and relevant guidance. The RSC should include at a minimum the following personnel as outlined in the Department of Health Circular B423/1 of 1983 which has been updated by guidelines from the National Radiation Safety Committee (HSE, 2010):

- CEO/General Manager/or delegated nominee,
- Risk Quality and Safety Manager,

- Consultant Radiologist/Consultant Radiation Oncologist,
- Radiography Services Manager/Radiation Services Therapy Manager,
- Radiation Protection Officer,
- Radiation Protection Advisor (RPA)/Medical Physics Expert (MPE),
- Representation from all departments using medical ionising radiation in the health service provider,
- Nurse/Midwife Referrer,
- Clinician Referrer that places high demand on radiology,
- Representation from satellite facilities that avail of the health service providers radiology services,
- Occupational health physician /specialist in public health medicine or other medical practitioner will be required to be co-opted onto the committee where any person require on-going medical surveillance as a result of radiation exposure.

Other medical/clinical or dental practitioners may also be co-opted onto the RSC where relevant including the Director or nominee. The CEO/General Manger has the corporate responsibility and should ideally chair the committee but may nominate a suitable person to chair for example the Radiologist.

The RSC will:

- ensure and monitor compliance with S.I 256 of 2018 including its amendments and S.I. 30 of 2019,
- ensure compliance in the undertaking providing medical exposure to ionising radiation as per the HIQA regulations,
- monitor risks and incidents,
- monitor quality and safety assurance programmes,
- review and prioritise clinical audit including audit reports of the nurse/midwife referral practices,
- monitor equipment, maintenance and replacement criteria,
- monitor staff education and training,
- monitor patient/service user dose levels,
- establish local Diagnostic Reference Levels (DRLs).

Other responsibilities as may be delegated by, the competent regulatory authorities HIQA and/or the EPA, the HSE National Radiation Protection Committee (NRPC) and the local health service provider.

1.7.2 Local Implementation Group

It is recommended that each health service provider has a Local Implementation Group (LIG) in place with specific terms of reference, reporting to the health service providers RSC and ultimately the health service provider overall governance assurance committee.

The purpose of the LIG is to support the implementation of nurse/midwife referral for radiological procedures in the service within a collaborative multidisciplinary context. The functions of the LIG may be subsumed into the overall radiology services' governance arrangements i.e. the RSC. The professional groups should work collaboratively and in partnership in the development of interprofessional service and education initiatives. Representatives from all the relevant professional stakeholders in local health service provider should be included in the membership of the LIG. Terms of reference should be agreed by the local health service providers RSC/LIG in respect of nurse/midwife referral for radiological procedures.

The Terms of Reference for the LIG can include the following:

- agree the governance structure for nurse/midwife referrers of radiology procedures,
- implement PPPGs to support nurse/midwife referrers,
- ensure robust clinical competency assessment systems are in place,
- ensure risk management structures that are in place are adhered to including review of all incidents,
- acknowledgement of the authorisation and the scope of radiological procedures that the nurse/midwife will be referring for, as informed by the Director,
- ensure audit systems and feedback mechanisms are in place including feedback\learning mechanisms,
- oversee evaluation process of referral practice,
- distribute minutes of meetings to all members and nurse/midwife referrers,

- support actions in a timely manner relating to nurse/midwife referrers, agree where appropriate to communicate electronically in the absence/deferral of face to face meetings,
- report to the health service providers RSC.

2.0 Eligibility to Refer for Radiological Procedures

The nurse/midwife referrer must:

- inform and present the Director with confirmation of successful completion of the approved education programme,
- receive in writing from the Director, of the commencement date on which they are authorised to commence referrals for radiological procedures (Appendix II),
- ensure a copy of this letter to commence referrals is maintained in the nurse /midwife's referrer's personnel file,
- ensure their name is registered on the HSE National Database of Nurse and Midwife Referrers for Radiological Procedures within one month of confirmation of successfully completing the education programme,
- inform the Director when they have received confirmation of registration on the HSE National Database of Nurse and Midwife Referrers for Radiological Procedures.

2.1 Nurse/Midwife Referrer

The nurse/midwife referrer must:

- be accountable and professionally responsible for all aspects of their referral authority,
- practice within a framework of professional accountability and legal boundaries,
- refer within their scope of practice and competencies,
- effectively and efficiently communicate with the patient/service user and complete an accurate and comprehensive medical and medication history,
- consider pre-existing medical conditions and previous diagnostic tests including imaging investigations which may affect the choice of radiological procedure to be referred for,
- have a valid clinical relationship with the patient/service user and only refer if they have appropriately assessed the patient/service user and received their consent,

- communicate clearly with the patient/service user in a language that they understand, including
 - the benefit/risk relative to the ionising radiation exposure,
 - the rationale for the referral,
 - the type and name of the procedure,
 - the purpose of the referral,
- utilise the health service providers radiology information systems/ Picture Archiving and Communication System (PACs) to support data collection of referrals as per the local PPPGs,
- maintain on-going communication and collaboration with members of the multidisciplinary team in order to enhance outcomes for patients/service users,
- participate in audit and other quality and safety assurance processes as per the local health service provider,
- the nurse/midwife referrer can access the HSE National Database of Nurse and Midwife Referrers of Radiology Procedures for reports to support their audits,
- commit to, and undertake, CPD to maintain their competence for referral authority,
- act as an informed advisor for other nurses/midwives undertaking the nurse authority to refer for radiological procedures education programme,
- inform the Director, their line manager and the Nurse/Midwife Referral Site Coordinator of any concerns pertaining to their competence regarding their referral authority,
- discuss with the Director and the Nurse/Midwife Referral Site Coordinator any situations where these responsibilities cannot, or are not being fulfilled.

3.0 Writing a Referral

The nurse/midwife referrer should adhere to the specific standards for writing referrals as required by legislation, regulation and the local health service providers PPPGs. It is mandatory that referral records:

- are in writing and legible/electronic,
- include the full name, address and date of birth of the patient/service user on the referral,
- include the healthcare record number if available,
- include pregnancy status where appropriate to the examination,

- include the clinical details for requesting the particular procedure,
- include details of previous radiological procedures if appropriate,
- contain adequate clinical/medical information to enable the practitioner to carry out the justification process,
- consent,
- instructions regarding the radiological procedure are understood and agreed by the patient/service-user,
- use accepted international and national recognised abbreviations,
- include the full name of the referrer including the NMBI Personal Identification Number (PIN),
- include the date and printed name in addition to the usual signature of the referrer,
- corrections must only be made by re-writing the referral.

3.1 Documentation

The nurse/midwife referrer should document in the patient/service user healthcare record, the following:

- the patient/service user assessment as appropriate,
- the justification for the referral,
- pregnancy status, if appropriate to the examination,
- previous diagnostic information/procedures,
- consent,
- evidence of benefits and risks of the radiological procedure including estimated radiation dose information provided to patients/service users and carers or comforters,
- when a practitioner has sought further medical data where necessary prior to the exposure taking place.

4.0 Justification and Optimisation

4.1 Justification

The system of radiation protection is based on the International Commission for Radiological Protection (ICRP) recommendations. The three key principles of radiation protection as

outlined by the ICRP are justification, optimisation and dose limitation. The two main principles for radiation procedures are justification and optimisation.

The justification of a medical exposure is the decision whether or not to carry out the medical exposure on the basis that the exposure should do more good than harm. The practice of justification of a particular medical exposure should take place to determine if the net benefits outweigh the possible risks of the radiation exposure. There must be written PPPGs relating to justification of referrals for all referrers in the health service provider which may include, but are not limited to:

- the framework for justification of individual exposures,
- education and training for those delegated responsibility,
- the use of clinical decision support tools: referral guidelines, i.e. the *iRefer Guidelines*, where applicable.

There must be documented evidence in the healthcare record that justification has taken place for the medical exposure/s and that all parts of the justification process have taken place, including but not limited to:

- review and appraisal of the referral,
- review of medical information and evidence that further medical information is sought where relevant ,
- evidence that individual patient/service user characteristics have been considered,
- evidence that justification is carried out by the referrer and the practitioner and that this designation is in line with the regulations and local policy,

The health service provider must ensure that for all individual medical exposures, both the practitioner and the referrer are involved in the justification process. The involvement of both the referrer and practitioner in justifying the medical exposure is essential in protecting the patient/service user by ensuring that only a medical exposure that is beneficial is carried out. This means that when a referrer refers a patient/service user for a radiological procedure to a practitioner, both the referrer and the practitioner must consider if the procedure is justified (HIQA, 2019).

4.2 Optimisation

Once a referral has been justified, each exposure is optimised. For a patient/service user, optimisation ensures that the radiation dose they receive is as low as reasonably achievable (ALARA), by systems, processes and personnel that each undertaking must have in place, while ensuring that the required clinical outcome is achieved. Optimisation should be evident right through the patient/service user's pathway, from referral to the practical aspects of the medical exposure.

5.0 Guidance for Referral Practice

The nurse/midwife referrers should be aware of best practice guidance and the health service providers PPPGs when referring for radiological procedures. As with all decisions, referring for radiological procedures must be within the registered nurse/midwife referrers' scope of practice. When a patient/service user is being referred for a radiological procedure, the process should incorporate the use of clinical decision support tools: referral guidelines, such as the *iRefer Guidelines*, to inform the referrer of the most appropriate examination for the patient/service user. This provides assurance to patients/service users that the examination they are having is the best option for them and that another referrer would have made the same decision. The nurse/midwife referrer should be knowledgeable of best practice for referring for radiological procedures. This includes determining:

- if there is an alternative radiological procedure that does not use ionising radiation that the patient/service user could be referred for,
- if the radiological procedure is appropriate to refer the patient/service users in the nurse/midwives referrers area of clinical practice.

All referrers must establish for relevant procedures whether a female of child-bearing age, subject to a medical exposure, is pregnant or breastfeeding and to record the answer in writing. All referrers (including new referrers) employed by the health service provider should be made aware of their responsibility at induction regarding enquiring as to the pregnancy status of a patient /service user they are referring and the referrers obligation to record the answer to such an inquiry in writing. The nurse/midwife referrer must be aware of the special protection responsibilities involved in referring children for medical ionising radiation procedures.

The health service providers PPPGs for nurse/midwife authority to refer for radiological procedures should outline the governance structures for the nurse/midwife to refer. This ensures the safety and quality and safety of care for patients/service users.

6.0 Adverse Incidents, Accidental or Unintended Exposure to Radiological Procedures

6.1 Adverse Incidents

The Incident Management Framework (HSE, 2020) defines an incident as 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 patient/service user complaints which are associated with harm (HSE, 2018, 2020). The health service provider is required to have appropriate mechanisms in place to report, assess and categorise, review and analyse incidents which can be clinical or non-clinical and include incidents associated with harm. Incidents, regardless of their impact, require management in line with the following steps:

- prevention through supporting a culture where safety is considered a priority,
- identification and immediate actions required (for patients/service users directly affected and to minimise risk of further harm to others),
- initial reporting and notification,
- assessment and categorisation,
- review and analysis,
- improvement planning and monitoring.

Though the process for managing incidents should be applied to all incidents, the level and depth of application will depend on a number of factors:

- the impact of the incident e.g. the level of harm caused,
- the number of patients/service users harmed,
- the potential for learning from the incident,
- the degree to which patient/service user or public confidence is an issue,
- the need to involve other services.

Therefore, whilst every incident requires a response, this should be proportionate to the impact, scale, complexity, and potential for improving the safety of the service and the following steps should be taken (HSE, 2018):

- nursing/midwifery staff should remain with the patient/service user and closely monitor for any adverse reaction,
- the patient/service user (and/or family/carer where appropriate) should be informed of what has happened by the nurse/midwife referrer or relevant nursing/midwifery and/or medical staff and/or radiology staff as per the National HSE Open Disclosure Policy (HSE, 2019),
- vital signs should be recorded in line with the local health service providers PPPGs,
- the relevant medical practitioner should be informed immediately and the patient/service user should be reviewed by a medical practitioner,
- the adverse event and all relevant nursing or midwifery and medical management and interventions must be recorded promptly,
- all information should be documented and retained in accordance with local PPPGs,
- the nurse/midwife referrer or relevant nursing or midwifery staff must report any suspected adverse event to relevant staff i.e. the line manager, radiology department, including the Radiation Protection Officer/Radiation Protection Advisor/Medical Physics Expert and the clinical risk manager in line with local PPPGs,
- on discharge the patient's/service user's General Practitioner (GP) should be informed as appropriate.

The nurse/midwife referrer should keep up to date with all referral information of the procedures they refer for including up-to-date safety information.

6.2 Accidental or Unintended Medical Exposures to Medical Ionising Radiation

Although the use of medical ionising radiation for diagnostic, interventional and therapeutic purposes is considered safe for the most part, unintended or accidental exposures to medical ionising radiation can and do occur. The majority of reported radiation incidents from medical exposures involve low radiation doses with minimal risk. However, some incidents of overexposure to medical ionising radiation have directly impacted on patient/service user safety and welfare.

A patient/service user radiation incident occurs where radiation delivered during a radiological procedure is different to that intended or where none is intended for the patient/service user. HIQA (2019) states that a

“Medical ionising radiation incident is an accidental, unintended or other incidents occurring or potentially occurring within an undertaking which could impact on the safety and welfare of patient/service users, carers and comforters or research volunteers”.

7.0 Reporting of Incidents, Radiation Incidents and Significant Events

7.1 Reporting of Incidents

All incidents involving patients/service users and all actions taken including details of the care provided must be factually and promptly documented in the patients/service user’s healthcare record and the relevant incident management form completed and submitted as per the health service providers PPPGs.

- the incident must be reported to the line manager as soon as possible,
- the incident and all actions taken must be promptly recorded and the relevant incident management form completed and submitted as per the health service providers PPPGs,
- the patient/service user (and family or carer where appropriate) must be informed of the incident as per National HSE Open Disclosure Policy (HSE, 2019).

It is also the responsibility of staff to complete the appropriate National Incident Report Form (NIRF 01 – V10) as per the Incident Management Framework (HSE, 2020) available at: <https://www.hse.ie/eng/about/qavd/incident-management/hse-2020-incident-management-framework-guidance.pdf> as soon as is practicable after the event occurs and within one working day. In completing a NIRF, staff must ensure that they provide all information and complete all mandatory fields required by the NIRF and ensure that any information provided is factual and not subjective. Services must clearly identify the route for submission of the NIRF for input onto the National Incident Management System (NIMS). The entering of an incident onto NIMS fulfills the health service provider’s statutory obligation to inform the State Claims Agency.

7.2 Reporting of Radiation Incidents

All health service providers are required under regulation 17 (1)(c) in S.I 256 of 2018, to implement an appropriate system for reporting and analysing events or near misses involving accidental or unintended radiation exposures to patient/service users. There is a statutory obligation under regulation 17 1 (e) to notify HIQA of significant events within 3 working days from the discovery of the incident.

The nurse/midwife referrer must be aware of the process for reporting and analysis of radiation incidents. When an incident occurs or is identified that involves a patient/service user that has been referred for a radiological procedure, the first response must be to the person directly affected. It is important to focus first and foremost on the affected person's physical needs through the provision of appropriate medical treatment or other care to manage the potential harm that may occur/has occurred, relieve suffering and minimise the potential for further harm to occur.

When any immediate action has been taken, the staff identifying the incident should, if they have not already done so, notify the incident to the manager on duty within the area where the incident occurred. They should undertake the steps as previously described (Section 6.1), as appropriate.

Health service providers with responsibility for medical exposures to ionising radiation must have appropriate systems for the record keeping and analyses of events involving, or potentially involving, accidental and unintended medical exposures to patients/service users. The system must be able to effectively manage report, review and analyse near-misses and actual accidental and unintended exposures to medical ionising radiation.

7.2.1 Lessons Learned from Notifications to HIQA of Accidental and Unintended Exposures

In general, significant events of accidental and unintended exposures submitted to HIQA in 2020 involved relatively low levels of radiation exposure. Health service providers must remain proactive with on-going vigilance in relation to the conduct of medical exposures due to the potential harmful effects from radiation. All stakeholders must have an active role in enhancing the radiation protection of persons undergoing medical exposures in Ireland (HIQA,

2021). HIQA is responsible, as the regulator to share lessons learned from the reporting and analysis of significant events.

In 2021 HIQA published a report relating to incidents reported from health service providers in 2020 outlining the different types of incidents and some lessons learned from how the incidents were dealt with.

The report identified that the total number of medical radiological procedures carried out in Ireland is estimated to be in excess of 3 million. In 2020 HIQA was notified of 76 events. This represented an 11% increase from notifications reported in 2019 (68).

In 2019 incidents were notified from the following modalities: computed tomography (CT), nuclear medicine, general radiography and radiotherapy services. In 2020 HIQA received notifications from imaging modalities that also included interventional cardiology, mammography and fluoroscopy for the first time. The incidents notified from diagnostic imaging in 2020 were as follows:

- CT = 48,
- PET/CT = 3,
- Nuclear medicine = 2,
- General x ray = 7,
- Interventional Cardiology = 2.
- Fluoroscopy = 1
- Mammography = 1.

No incidents were reported from dental or dual energy Xray absorptiometry (DXA). The most common error reported in diagnostic imaging failures were in patient identification, from the referral to initiating the exposure. Undertakings should have systems in place to ensure patients are identified at all stages of the imaging pathway. A varied approach to patient safety was also identified when reviewing the corrective measures. Some locations showed a comprehensive system based approach, however some focused on human error in isolation, without considering weaknesses in the systems. The findings in the report however do indicate that the use of radiation in medicine in Ireland is generally safe for patients.

7.3 Significant Events

Significant events are incidents involving medical exposure that are above or below an acceptable threshold and have the potential to cause harm (HIQA, 2019). Significant events can occur from diagnostic, interventional or therapeutic procedures. Significant events incidents are notifiable to HIQA when medical ionising radiation administered to the patient/service user was greater or different to what was intended. HIQA has defined notifiable incidents that must be reported to HIQA within **3 working days** from discovery.

A near miss is a potential patient/service user radiation incident that is detected before the radiological procedure takes place. The potential risk was identified and prevented. All non-notifiable incidents and near miss incidents must be recorded locally and can be made available to HIQA at an inspection.

Following the occurrence of a significant event, appropriate immediate actions and corrective measures must be implemented to ensure the safety and wellbeing of all patients/service users and to avoid the reoccurrence of such events. HIQA has defined a list of notifiable significant events reportable to them that meet criteria outlined by them see <https://www.hiqa.ie/sites/default/files/2019-10/Guidance-notification-of-significant-events.pdf>

Some incidents may be notifiable to more than one competent authority: HIQA and EPA. HIQA and the EPA (who are the competent authority for the protection of workers and members of the public), have a dual and collaborative role in the regulation of ionising radiation in Ireland under their respective legislation.

In some cases, local review, analysis and trending of all radiological safety incidents may lead to reclassification of incidents initially deemed non-notifiable to notifiable. Identification of multiple similar non-notifiable incidents may, on review, be identified as a potential safety concern, this means that such non-notifiable incidents are collectively reportable to HIQA. All significant events must also be reported onto the National Incident Management System (NIMS) to meet the health service provider's statutory obligation to inform the State Claims Agency.

8.0 The Clinical Indemnity Scheme: State Claims Agency

The Clinical Indemnity Scheme (CIS) was established in July 2002 and is managed by the State Claims Agency. Under the scheme, the state assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme. This includes the HSE and HSE funded agencies (Section 38) where:

- nurse and midwife referrers are individually and professionally accountable to the NMBI and their health service provider for all decisions pertaining to their referral practice.

The State Claims Agency has issued a statement in relation to clinical indemnity in respect of nurse and midwife referrers in the HSE and HSE funded agencies (Section 38). Details of cover provided for all clinical practitioners involved are outlined in Appendix III.

PART B

1.0 Initiation

Referral authority for nurses and midwives is founded on legislation, associated regulations and professional regulation. This national guideline has been developed in partnership with key stakeholders to comply with the HSE statutory obligations and to give practical effect to the governing legislation and the NMBI guidance documents.

1.1 Purpose

This national guideline was originally developed as a guiding framework and has been revised to provide information and guidance to support the health service provider with the introduction and implementation of nurse/midwife referral for radiological procedures in the HSE and HSE funded agencies (Section 38).

1.2 Scope

This national guideline applies to:

- nurses/midwives employed in the HSE and HSE funded agencies (Section 38), who have received a commencement date from the Director to commence referrals and whose name is entered on the HSE National Database of Nurse and Midwife Referrers of Radiological Procedures,
- nurses/midwives employed in the HSE and HSE funded agencies (Section 38) who are undertaking, or have undertaken an approved education programme in nurse and midwife referrers of radiological procedures and/or are in the process of registering as a nurse/midwife referrer on the HSE database,
- all key stakeholders supporting nurse/midwife referrers of radiological procedures in the HSE and HSE funded agencies (Section 38).

1.3 Aim and Objectives

1.3.1 Aim

The aim of this national guideline is to provide guidance and a clinical governance framework for the health service provider, within the Health Services Executive (HSE) and HSE Funded

Agencies (Section 38), outlining clear lines of responsibility and accountability to support nurse/midwife referrers of radiological procedures underpinned by legislation and regulation.

1.3.2 Objectives

- support best practice with regard to nurse/midwife referrals for radiological procedures,
- support the safety of patients/service users and staff,
- support the health service provider where nurse/midwife referrers of radiological procedures have been or are being implemented,
- link nurse/midwife referrers of radiological procedures to strategic service planning.

1.4 Outcomes

This national guideline will provide information and guidance to promote and enhance evidence based practice in nurse/midwife referrers of radiological procedures in Ireland.

1.5 Guideline Review Group

The National Lead for the Implementation and Audit of Nurse and Midwife Referrers of Radiological Procedures and the HSE National Advisory Committee for Nurse and Midwife Referrers of Radiological Procedures, ONMSD, (Appendix IV).

1.5.1 Conflict of Interest

Conflict of Interest Forms were completed by the Guideline Review Group and no conflicts of interest were noted (Appendix V).

1.5.2 Funding Body and Statement of Influence

This national guideline was commissioned by the HSE. The national guideline content was not influenced by the HSE or any other funding body. This process was fully independent of lobbying powers. The guideline content is based on current best research evidence, legislation, associated regulation, professional regulation and relevant expertise.

1.6 Guideline Governance Group

The Director of the Office of Nursing and Midwifery Services Director and the Chief Clinical Officer commissioned this national guideline. The National Lead for the Implementation and

Audit of Nurse and Midwife Referrers of Radiological Procedures (who reports to the Director of the ONMSD), managed, coordinated and administered the process.

1.6.1 Membership of the Approval Governance Group

Refer to Appendix VI for membership of the Approval Governance Group.

1.7 Supporting Evidence

References can be found in Section 8.0. Other supporting evidence can be found within the appendices.

1.7.1 Legislation, Regulation and Other Related Policies

Refer to Part A.

1.7.2 Policy Being Replaced by this Guideline

The HSE Guiding Framework for the Implementation of Nurse Prescribing of Medical Ionising Radiation (X-Ray) in Ireland (ONMSD, HSE, 2009) are being replaced by this guideline.

1.8 Glossary

Refer to Appendix VII for a full glossary.

2.0 Guideline Development

2.1 Guideline Methodology

The evidence relating to nurse/midwife referrers of radiological procedures was collected, critically appraised and used in this national guideline to update the existing HSE Guiding Framework for the Implementation of Nurse Prescribing of Medical Ionising Radiation (X-Ray) in Ireland (ONMSD, HSE, 2009).

2.2 Literature Search Strategy

A comprehensive literature search was undertaken originally which included a national and international literature review and peer review journals. The literature review focused on updated Irish legislation and associated regulations, professional regulation and relevant

publications to inform this national guideline. Articles from 2009 – 2021 were prioritised, the time frame since the publication of the previous framework.

2.3 Evidence Appraisal

Evidence appraisal was not applicable for this national guideline.

2.4 Grading of Recommendations

Grading of recommendations was not applicable for this national guideline.

2.5 Summary of the Evidence

In Ireland, nursing and midwifery policy direction supports the expanded role of the nurse/midwife as a national, measurable priority. The Department of Health (2020) *Statement of Strategy 2021-2023*, outlines five strategic priorities. Priority 3 is to “create a more responsive, integrated and person-centred health and social care service” (p.6).

A Policy on the Development of Graduate to Advanced Nursing and Midwifery Practice (DoH, 2019) outlines the future direction for role expansion in a structured way to address emerging and future service needs and drive integration between services. The HSE Service Plans have also identified increasing capacity of nurse/midwife referrers as a priority within the nursing and midwifery services (HSE, 2017, 2018). One of the key objectives of the HSE Service Plan (2020) is to strengthen the capacity and capability within nursing and midwifery to enhance frontline clinical leadership and practice. *Sláintecare Report (2017)* endorsed a number of health reforms to provide timely access to safe and high quality care, on the basis of medical need which is integrated with community care services, working together and practising outreach and in-reach, where appropriate. Nurse and midwife referral practice supports Goal 2 of the *Sláintecare Implementation Strategy (2019)* which is to “provide high quality, accessible and safe care that meets the needs of the population” (p.6).

Internationally and nationally the literature is notably sparse in relation to nurse/midwife referral of medical ionising radiation. The evidence suggests that as nurses/midwives take on new roles and responsibilities the authority and ability to refer for radiological procedures has improved both access and the timeliness of interventions for those seeking treatment.

Most studies have focused on nurse/midwife referral of radiological procedures in requesting and interpreting radiographic imaging triage in the Emergency Department(ED) (Free et al., 2008; Thompson et al., 2016). Al Abri et al. (2020) and Ho et al. (2018) found the application of the Ottawa Ankle Rules by the ED triage nurse and the nurses' utilisation of evidence-based clinical decision-making tools decreases the number of unnecessary radiographic tests, waiting time and length of stay in the ED. Similarly Considine et al. (2019) found, that when compared with physician-initiated referrals, nurse-initiated referrals uses no more resources, is safe and acceptable to patients/service users. Nurse-initiated referrals reduced emergency department length of stay and unplanned follow-up.

Job et al. (2019) evaluated the palliative advanced practice radiation therapy (APRT) role with respect to the impact on waiting times for patients/service users from referral to radiation treatment delivery. The ability of the APRT to define palliative radiation therapy fields and patient/service user satisfaction found reduced wait times from referral to treatment for palliative patients/service user and that the establishment of the APRT role is justified.

Some studies have focused on nursing knowledge regarding radiation safety (Dianati et al., 2014; Hyde, et al., 2016). An evaluation of a structured medical ionising radiation referral education programme in Australia, found that nurses on completion of this programme demonstrated increased accuracy and appropriateness in requesting radiographic procedures (Considine et al., 2013). Studies in Australia (Considine et al., 2013) and Canada (Health Professions Regulatory Advisory Council (HPRAC) (2008)) of the educational preparation for medical ionising radiation referral, found nurses referred for radiographic procedures within their scope of practice safely and appropriately. The outcomes assessed, in both studies, were compliant with scope of practice defined within the programme, accuracy and appropriateness of documenting patient/service user assessment data, and accuracy and appropriateness of radiographic procedure requests. Fry (2002) concurs that nurse referrals were appropriate and safe.

The respective regulatory authorities require that education programmes address professional and legislative frameworks for safe referral of medical ionising radiation within a nurses/midwives scope of practice, the development of clinical reasoning skills for evidence based decision making and clinical instruction through clinical supervision, which in Ireland

must be provided by a medical practitioner. In Ireland, the NMBI (2020) requires that nurses/midwives preparing to refer for medical ionising radiation identify and plan their continuing professional development needs to ensure continued competence beyond initial education. There is some reference in the literature that nurses/midwives educated to refer for medical ionising radiation procedures need to engage in continuing professional development following initial preparatory programmes. However, no details were provided on what this continuing education should involve.

Drennan et al. (2014) found that the Irish education programmes preparing nurses to refer for medical ionising radiation were evaluated positively in terms of the education programmes ensured that programme participants' were effectively and competently prepared to practice safely as nurse referrers of medical ionising radiation.

Hirvonen et al. (2019) conducted a study to explore nurses' knowledge of radiation use and radiation safety. Nurses worked across eight hospitals in operating theatres, first aid clinics and cardiology laboratories. Knowledge of radiation protection by nurses who had undergone a structured nurse-initiated X-ray education programme was compared to that of nurses with no such specialist training. Results were favourably disposed to nurses who had undergone the structured training and this study recommended that healthcare providers should provide structured education to all nurses working with, or exposed to, radiation.

In the UK, Thompson (2017) investigated the decision-making skills of nurse practitioners compared with those of medical doctors and found that nurse practitioners are key to the modernisation of the National Health Service. Studies have shown that compared with doctors, nurse practitioners can be efficient and cost-effective in consultations. This study suggests that nurse practitioner consultations are comparable to those of medical doctors in terms of correct diagnoses and therapeutic treatments. The information processing theory highlighted that both groups of professionals had similar models for decision-making processes.

An Irish review of nurse referral for medical ionising radiation (Drennan et al., 2014) demonstrated that the introduction of nurse referrals for medical ionising radiation procedures had a positive impact on patient/service user care and a significant effect on

facilitating patient/service user access to treatment and care in an equitable and timely manner.

The effectiveness of the practice of nurse referrers of medical ionising radiation, found that radiological investigations requested by nurse referrers were appropriate based on the patients/service users history and/or physical examination. Similarly the identification of the site for radiographic examination, provisional diagnosis and clinical information supplied to radiographers were identified as being of a high standard. Overall, nurse referrals for ionising radiation were appropriate and radiology referral forms were accurately completed (Drennan et al., 2014).

Patients/service users who came into contact with nurse referrers of medical ionising radiation were highly satisfied with the care they received. Patients/service users reported that they received comprehensive education and advice and that receiving a referral for a radiographic examination from a nurse had reduced the time they spent waiting for treatment. The majority were also of the opinion that the nurse referrer was comprehensive in their care, listened to their concerns and treated them as a person. They reported that they received care that was of a high quality and that nurse referrers facilitated their access to timely treatment and care (Drennan et al., 2014).

It also had a positive impact on the professional role of nurse referrers of medical ionising radiation. They felt confident in their ability to refer for medical ionising radiation. In particular, their ability to refer for medical ionising radiation had reduced delays in initiating treatment for as well as enabling patients/service users to access care quicker (Drennan et al., 2014).

Drennan et al. (2014) surveyed a variety of stakeholders were from the nursing, medical and radiography professions including stakeholders from education, regulation and policy. Overall there were good levels of support, with the majority of stakeholders reporting that the introduction of nurse referral for medical ionising radiation has had a positive impact on patient/service user care as well as meeting the clinical needs of patients/service user.

Additionally, there was support in terms of safety, with the majority of healthcare professionals and key stakeholders surveyed identifying that nurses had the knowledge to correctly refer for medical ionising radiation and that they had received adequate training for their role. The majority of clinical stakeholders also reported that the referral of medical ionising radiation should be extended beyond the remit of the medical profession (Drennan et al., 2014).

Though the Drennan et al. (2014) report found, attitudes towards, and perceptions of nurse referrers of medical ionising radiation were variable. Radiographers were overall supportive of nurse referrers of medical ionising radiation, however they tended to have more negative views on aspects of nurse referrers when compared to the nursing or medical professions. These perceptions generally related to the extent to which nurses had the necessary knowledge to safely refer for medical ionising radiation and the degree to which radiographers trusted nurses to refer for medical ionising radiation correctly. Although the majority of radiographer respondents agreed it had greatly improved the quality of care they could provide to patients/service users that nurse referrers of medical ionising radiation was successful, levels of agreement were significantly lower than other health care professionals.

These findings are supported in a number of studies on nurse referral for medical ionising radiation in other contexts, have found it to be broadly as safe as medical ionising radiation referral by physicians. Sociological literature on perceptions of safety indicates that these tend to be shaped by the ideological position of the professional rather than based on objective evidence. Hyde et al. (2016) examined perceptions of the safety of a nurse referral for medical ionising radiation initiative across three occupational groups: nursing, radiography and medicine. While the majority of respondents from all three groups perceived nurse referral for medical ionising radiation to be safe, the extent to which this view was held varied. The findings suggest that perceptions about safety and risk of nurse referral for medical ionising radiation are socially constructed according to the vantage point of the professional and may not reflect objective measures of safety. These findings need to be considered more broadly in the context of ideological barriers to expanding the role of nurses.

Drennan et al. (2014) found the majority of nurses referrers were actively referring, a number identified that there were limitations that were negatively impacting on their referral practice

due to limitations on the scope of referral practice including the inability to refer for medical ionising radiation for children and a restriction on the number of anatomical sites and procedures that nurse referrers were permitted to refer for. This has now changed in Ireland, in that children are being referred for medical ionising radiation procedures, with a limited scope of referral practice.

Although published evaluations of nurse/midwife referral of medical ionising radiation are limited, it is possible to make appraisals from existing literature relating to the education programmes, the effectiveness of the of nurse/midwife referrers of medical ionising radiation practice, the appropriateness of referral decisions and that nurses/midwives are competent to practice safely as nurse referrers of medical ionising radiation. In addition, some 'grey' literature (e.g. universities, professional and regulatory bodies websites and documentation) provide insights into preparation and continuing education for nurse/midwife referral for radiological procedures.

2.6 Resources

A budget impact analysis was not undertaken. This national guideline is a revision of the HSE Guiding Framework for the Implementation of Nurse Prescribing of Medical Ionising Radiation (X-Ray) in Ireland published in 2009. The guideline reflects current evidence based practice and should be budget neutral for its on-going implementation at health service provider level.

2.7 Outline of the Guideline Steps

Refer to Part A for the details of this national guideline.

3.0 Governance and Approval

3.1 Governance

The sponsors of this guideline development, the Director of the ONMSD and the Chief Clinical Officer have the authority and responsibility for managing and executing this national guideline. The Guideline Review Group worked with all resources to develop this national guideline.

3.2 Method for Assessing this Guideline as per the HSE National Framework for Developing Policies, Procedures, Protocols and Guidelines

This national guideline was reviewed to ensure compliance with the *Policies, Procedures, Protocols and Guidelines Checklist for Developing Clinical PPPGs* (HSE, 2016) (Appendix VIII).

3.2.1 National Stakeholder and Expert Review

Once this draft guideline received approval from the Guideline Review Group, consultation was undertaken with relevant stakeholders and experts to ensure consensus on this national guideline.

3.3 Copyright/Permission Sought

No copyright or permissions were required for this national guideline.

3.4 Approval and Sign Off

The final draft of the *HSE National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline* (2021) was submitted for approval, accompanied by the signed PPPG Checklist (Appendix VIII) confirming that all stages of this national guideline had been completed in accordance with the *HSE National Framework for Developing Policies, Procedures, Protocols and Guidelines* (PPPGs) (HSE, 2016). It was then signed off by the Director of the ONMSD and the Chief Clinical Officer HSE.

4.0 Communication and Dissemination

Once this national guideline is approved and signed off nationally it will be disseminated as soon as possible to all the local health service providers and relevant stakeholders. This approach will ensure that the guidance and information in this national guideline can be used to support nurse /midwife referrers and health service providers involved in nurse/midwife referral for radiological procedures.

The following activities will be undertaken:

- all relevant stakeholders to receive an electronic copy of the national guideline,
- the national guideline to be uploaded onto the relevant webpage,
<https://healthservice.hse.ie/about-us/onmsd/onmsd/specific-programmes/referral-medical-ionising-radiation-procedures.html>

- liaise with Nurse/Midwife Referral Site Coordinators in all health service providers for on-going dissemination,
- disseminate through the ONMSD HSE communication channels,
- circulate to the nurse/midwife referrers registered on the HSE database.

5.0 Implementation

5.1 Implementation of the Guideline

It is the responsibility of the local health service provider to adopt this national guideline and develop addenda in relation to local governance or develop their local PPPG to support the implementation of nurse/midwife referral for radiological procedures.

The ONMSD is responsible for leading the national implementation of nurse/midwife referral for radiological procedures in Ireland and have provided a suite of documents to support the initiative that are available at the following link: <https://healthservice.hse.ie/about-us/onmsd/onmsd/specific-programmes/referral-medical-ionising-radiation-procedures.html>

5.2 Barriers and Facilitators to Implementation

There are no known barriers that will impact the implementation of this national guideline.

5.3 Education

Education and information sessions will be provided on publication of this national guideline if required.

5.4 Responsibility for Implementation

All health service providers involved in nurse/midwife referral for radiological procedures have a responsibility for the implementation of this national guideline or their own local PPPG based on this guideline. Refer to Part A for detailed responsibilities for individual stakeholders.

5.5 The Health Service Providers Responsibility Relating to Nurse/Midwife Referrers

Each Chief Executive Officer, Chief Officer, General Manager, the Director of Nursing/Midwifery and the Clinical Director of the health service providers have corporate responsibility for the implementation of this national guideline or their own local PPPG.

5.6 Roles and Responsibilities

Senior Managers:

- support the implementation of this national guideline or their own local PPPG,
- assign personnel with responsibility, accountability and autonomy to implement this national guideline or develop their own local PPPG,
- provide managers with support to implement this national guideline and/or develop their own local PPPG, incorporating the legislative and regulatory requirements outlined in this document.
- ensure clinical and education staff are supported to implement this national guideline or their own local PPPG,
- monitor the implementation of this national guideline or their own local PPPG,
- ensure audit processes for referral practices are in place and conducted.

Heads of Department:

- ensure all relevant staff members are aware of this national guideline and local PPPGs,
- ensure staff are supported to undertake education programmes and related training, as appropriate.

Clinical Staff:

- clinical staff should comply with this national guideline or their own local PPPG. A copy of the signature sheet should be signed to show all relevant staff have read, understand and agree to adhere to this national guideline or local PPPG (Appendix IX).

6.0 Monitoring, Audit and Evaluation

6.1 The Plan

It is anticipated that this national guideline will provide national guidance and information on the introduction and implementation of nurse/midwife referral for radiological procedures. It is important that this national guideline or local PPPG is audited to support continuous quality improvement in relation to its implementation. The audit process should be undertaken from a multidisciplinary perspective.

6.1.1 Monitoring

The CEO, Chief Officer, General Manager, Clinical Director and Director of Nursing and/or Midwifery in each local health service provider have responsibility for supporting the implementation and monitoring of this national guideline or their local PPPG.

6.1.2 Audit

Audit of this national guideline or local PPPG should be undertaken to provide evidence to support continuous quality and safety improvement.

6.1.3 Evaluation

Evaluation of the effectiveness of this national guideline or local PPPG should be undertaken locally to support its implementation and sustainability.

7.0 Revision/Update

7.1 Procedure for Revising the Guideline

The Guideline Review Group has agreed that this national guideline will be reviewed on a 3-yearly basis and updated as appropriate. Therefore, this national guideline will be reviewed in 2024. An updated literature search will be undertaken at that time and the national guideline amended as appropriate.

7.2 New Evidence

As evidence emerges that require changes in practice a further review of the literature will be undertaken so that the national guideline will maintain its relevance and currency. Any updates/addenda to the national guideline in the interim period or as a result of the three year review will be subject to approval.

7.3 Version Control

The original HSE Guiding Framework for the Implementation of Nurse Prescribing of Medicinal Ionising Radiation (X-Ray) in Ireland was issued in 2009. This national guideline replaces the 2009 framework. This national guideline will be available on the HSE website. This is a controlled national guideline and will be available electronically at: <https://healthservice.hse.ie/about-us/onmsd/onmsd/specific-programmes/referral-medical-ionising-radiation-procedures.html>

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9.0 Appendices

Appendix I: Principles for Clinical Governance Development (HSE 2012)

Principle	Descriptor
Patient First	Based on a partnership of care between patients, families, carers and healthcare providers in achieving safe, easily accessible, timely and high quality service across the continuum of care.
Safety	Identification and control of risks to achieve effective efficient and positive outcomes for patients and staff.
Personal Responsibility	Where individuals as members of healthcare teams, patients and members of the population take personal responsibility for their own and others health needs. Where each employee has a current job-description setting out the purpose, responsibilities, accountabilities and standards required in their role.
Defined Authority	The scope given to staff at each level of the organisation to carry out their responsibilities. The individual's authority to act, the resources available and the boundaries of the role are confirmed by their direct line manager.
Clear Accountability	A system whereby individuals, functions or committees agree accountability to a single individual.
Leadership	Motivating people towards a common goal and driving sustainable change to ensure safe high quality delivery of clinical and social care.
Inter-Disciplinary Working	Work processes that respect and support the unique contribution of each individual member of a team in the provision of clinical and social care. Inter-disciplinary working focuses on the interdependence between individuals and groups in delivering services. This requires proactive collaboration between all members.
Supporting Performance	Managing performance in a supportive way, in a continuous process, taking account of clinical professionalism and autonomy in the organisational setting. Supporting a director/manager in managing the service and employees thereby contributing to the capability and the capacity of the individual and organisation. Measurement of the patients experience being central in performance measurement (as set out in the National Charter, 2010).
Open Culture	A culture of trust, openness, respect and caring where achievements are recognised. Open discussion of adverse events are embedded in everyday practice and communicated openly to patients. Staff willingly report adverse events and errors, so there can be a focus on learning, research and improvement, and appropriate action taken where there have been failings in the delivery of care.
Continuous Quality Improvement	A learning environment and system that seeks to improve the provision of services with an emphasis on maintaining quality in the future not just controlling processes. Once specific expectations and the means to measure them have been established, implementation aims at preventing future failures and involves the setting of goals, education, and the measurement of results so that the improvement is ongoing.

Appendix II: Sample Commencement Letter

Date *[insert details]*

Nurse/Midwife Referrers Name *[insert details]*

Clinical Grade *[insert details]*

Ward/Unit/Organisation *[insert details]*

Address 1

Address 2

Re: Commencement Date for Nurse/Midwife Authority to Refer for Radiological Procedures at *[insert name of the health service provider]*

Dear *[insert details]*

Congratulations on successful completion of the nurse/midwife authority to refer for radiological procedures education programme. This marks a milestone in the development of your professional practice. You are now authorised to commence referring for radiological procedures at *[insert name of the health service provider]* from *[insert date]*.

Please note that this authorisation gives you referral authority within your scope of practice and is in compliance with the relevant legislation, professional guidance and regulations in particular the following:

- HSE National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline 2021
- Nursing and Midwifery Board of Ireland (2020) Nurse Authority to Refer for Radiological Procedures Standards and Requirements for Education Programmes, 2nd edn

As a nurse/midwife referrer you are responsible for maintaining continued professional competence and auditing your referral practice in accordance with *[insert name of the health service provider]* and the NMBI requirements. The *HSE National Database of Nurse and Midwife Referrers for Radiology Procedures* is available which enables you to input your referral activity and run reports and assist you in auditing of your referral practice. This is available on the link: <https://www.hsedataportal.ie/npx/logon.html>

In order to support nurse and midwife referrers the ONMSD, has established the:

- Nurse and Midwife Referral for Radiological Procedures Website, click on link: <https://healthservice.hse.ie/about-us/onmsd/onmsd/specific-programmes/referral-medical-ionising-radiation-procedures.html>

It is important for you to keep up to date with referral information of radiological procedures including up-to-date safety information.

I would like to take this opportunity to wish you every success in using your new referral competencies within your clinical area of practice.

Yours sincerely,

Director of Nursing/Midwifery/ Relevant Nurse/Midwife Manager

Appendix III: State Claims Agency Statement regarding Clinical Indemnity for Nurse and Midwife Authority to Refer for Radiological Procedures February 2021



Gníomhaireacht Bainistíochta an Chisteáin Náisiúnta National Treasury Management Agency

An Ghníomhaireacht um Éilimh ar an Stát
State Claims Agency

February 2021

Nurse and Midwife Authority to Refer for Radiological Procedures.

The Clinical Indemnity Scheme (CIS) was established in July 2002 and is managed by the State Claims Agency (SCA). Under the scheme, the State assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme. This includes the voluntary and statutory services of the Health Service Executive. For more information on which enterprises are covered by the scheme, please go to www.stateclaims.ie

In relation to Nurse and Midwife Authority to Refer for Radiological Procedures, the CIS provides vicarious indemnity cover to nurse and midwife referrers and to all health practitioners providing professional medical services for and on behalf of the hospital/enterprise.

CIS indemnity is provided in respect of a suit for personal injuries brought by a person alleging negligence, statutory or at common law, in respect of the provision of, or failure to provide, professional medical services. Such a suit may be against any health practitioner, in their role regarding nurse and midwife referrals for radiological procedures, whether sued alone or together, arising from the referral for a medical radiological procedure or procedures by such a nurse and midwife referrer. The CIS does not provide cover in respect of criminal matters, i.e. where the Director of Public Prosecutions (DPP) directs criminal charges against a health practitioner.

The CIS does not provide representation for health practitioners in relation to fitness to practice issues. In that regard, the State Claims Agency advises health practitioners to purchase additional benefits cover, specifying cover in respect of criminal and fitness to practice matters, from their relevant defence organisations.

For the avoidance of any doubt, private practice settings and/or their indemnity/insurance providers are not required to extend indemnity to cover nurse midwife referrers for radiological procedures, employed by the voluntary and statutory services of the Health Service Executive, authorised to practice in their services on foot of a SLA between the HSE and the particular private practice setting. The HSE nurse and midwife referrer practicing in these settings is indemnified by the CIS in respect of the provision of his/her services.

For any queries regarding this please contact StateClaims@ntma.ie

 Duga an Stáichiste, Cé an Phoirt Thuaidh, Baile Átha Cliath 1, D01 A9T8,
Éire Treasury Dock, North Wall Quay, Dublin 1, D01 A9T8, Ireland

 +353 1 238 4900

 +353 1 238 4790

 DX: 21 Dublin

 www.stateclaims.ie

 stateclaims@ntma.ie

Appendix IV: Membership of the Guideline Review Group

1. Guideline Review Group Members

Name	Title	Location
Ms. Maureen Nolan	Director of Nursing, National Lead for the Implementation and Audit of Nurse and Midwife Referral for Radiological Procedures.	Office of the Nursing & Midwifery Services Director (ONMSD), Office of the Chief Clinical Officer (CCO), HSE.
Ms. Vivienne Browne	Director of the Regional Centre of Nursing & Midwifery Education	HSE, Dublin North, Academic Centre, Connolly Hospital, Blanchardstown
Ms. Maura Fitzgerald	Head of Nursing Integration and Development	University Hospital Limerick
Dr. Shane Foley	Radiographer	Irish Institute of Radiography and Radiation Therapy.
Ms. Michele Monahan	Radiography Services Manager	HSE Connolly Hospital
Ms. Bernadette Moran	Consultant Radiographer	Office of the Nursing & Midwifery Services Director (ONMSD), Health Services Executive.
Mr. Arnel Kidpalos	Education Officer	Nursing and Midwifery Board of Ireland(NMBI)

Appendix V: Conflict of Interest Declaration Form



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CONFLICT OF INTEREST DECLARATION

This must be completed by each member of the PPPG Development Group as applicable.

Title of PPPG being considered:

HSE National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline 2021

Please circle the statement that relates to you

- 1. I declare that I DO NOT have any conflicts of interest.**
- 2. I declare that I DO have a conflict of interest.**

Details of conflict (Please refer to specific PPPG)

(Append additional pages to this statement if required)

Signature

Printed name

Registration number (if applicable)

Date

This information provided will be processed in accordance with data protection principles as set out in the Data Protection Act. Data will be processed only to ensure that committee members act in the best interests of the committee. The information provided will not be used for any other purpose.

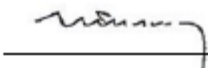

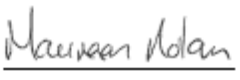
A person who is covered by this PPPG is required to furnish a statement, in writing, of:

(i) The interests of the person, and

(ii) The interests, of which the person has actual knowledge, of his or her spouse or civil partner or a child the person or of his or her spouse which could materially influence the person in, or in relation to, the performance of the person's official functions by reason of the fact that such performance could so affect those interests as to confer on, or withhold from, the person, or the spouse or civil partner or child, a substantial benefit.

Appendix VI: Membership of the Approval Governance Group

Please list all members of the relevant approval governance group (and title) who have final approval of the PPPG document.

<p>Dr Colm Henry</p> <p>Chief Clinical Officer, HSE</p>	<p>Signature </p> <p>Date: <u>October 22nd 2021</u></p>
<p>Dr Geraldine Shaw</p> <p>Nursing and Midwifery Services Director, Office of the Nursing & Midwifery Services Director (ONMSD), Office of the Chief Clinical Officer (CCO), HSE</p>	<p>Signature </p> <p>Date: <u>October 20th 2021</u></p>
<p>Chairperson:</p> <p>Maureen Nolan</p> <p>Director of Nursing, National Lead for the Implementation and Audit of Nurse and Midwife Referral for Radiological Procedures.</p>	<p>Signature </p> <p>Date: <u>October 20th 2021</u></p>

Appendix VII: Glossary of Terms

- **Accidental Exposure:** an exposure of individuals to ionising radiation, other than emergency worker, as a result of an accident.
- **Candidate Nurse/Midwife Referrer:** A nurse/midwife who is undertaking an approved programme of education and training leading to Authority to Refer for Radiological Procedures or a nurse/midwife who has successfully completed the approved education programme and is in the process of receiving Authority to Refer for Radiological Procedures from the Director of Nursing/Midwifery.
- **Carers and Comforters:** A carer and comforter is someone who incurs an exposure to ionising radiation, other than as part of their occupation, by helping in the support and comfort of a patient, or other service user having a medical exposure. For example, this may be a parent supporting a child having an X-ray at a dentist surgery.
- **Clinical Audit:** The Commission on Patient Safety and Quality Assurance (2008, page 152) defines clinical audit as 'a clinically led, quality improvement process that seeks to improve patient/service user care and outcomes through the systematic review of care against explicit criteria and to act to improve care when standards are not met'. In essence, clinical audit is the process of assessing clinical practice against standards (HSE, 2013).
- **Clinical Governance:** Clinical governance is a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients/service users in the care they deliver. It is built on the model of the chief executive officer (CEO)/ general manager (GM) or equivalent working in partnership with the Clinical Director, Director of Nursing/Midwifery and service manager. A key characteristic of clinical governance is a culture and commitment to agreed service levels and quality of care to be provided.
- **Clinical Indemnity Scheme (CIS):** The CIS was established in July 2002 and is managed by the State Claims Agency. Under the scheme the state assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme. CIS cover applies equally to the nurse and midwife referral for radiological procedures providing they have been authorised to so within the health service provider they are employed in.
- **Clinical Responsibility:** 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 radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing radiological information or records to other practitioners or the referrer, as required; and giving information on the risk of medical ionising radiation to patients/service users and other individual involved, as appropriate.
- **Clinical Supervisor:** A consultant medical practitioner who has committed to act as a mentor and provide clinical instruction and supervision within the specific clinical practicum for the duration of the education programme (An Bord Altranais, 2007).
- **Competence:** The ability of a nurse/midwife referrer to practice safely and effectively, fulfilling their professional responsibility within their scope of practice (NMBI, 2015).
- **Environmental Protection Agency:** an independent public body established under the Environmental Protection Agency Act 1992. It has a broad range of functions relating to environmental protection in Ireland, including environmental licensing; enforcement of environmental law; environmental planning, education and guidance;

monitoring, analysing and reporting on the environment; regulating Ireland's greenhouse gas emissions; environmental research development; strategic environmental assessment; waste management; and radiological protection.

- **Health Service Provider:** The Health Service Executive, a hospital, a nursing home, a clinic or other person whose sole or principal activity or business is, the provision of health services or a class of health services, to the public or a class of the public.
- **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 patient/service user complaints which are associated with harm. Incidents can be clinical or non-clinical and include incidents associated with harm to:
 - patients, service users, staff and visitors,
 - the attainment of HSE objectives,
 - ICT systems,
 - data security e.g. data protection breaches,
 - the environment (HSE, 2018),
- **Ionising Radiation:** radiation with enough energy so that during an interaction with an atom, it can remove tightly bound electrons from the orbit of an atom, causing the atom to become charged or ionised. Ionising radiation is not without risks, as the body can absorb some of the energy however, ionising radiation is a valuable medical tool for the diagnosis and treatment of diseases and injuries. Types of ionising radiation commonly used in radiological procedures are X-rays, beta and gamma radiation.
- **Justification:** The justification of a medical exposure is the decision whether or not to carry out the medical exposure on the basis that the exposure should do more good than harm.
- **Medical Exposure (Ionising Radiation):** an exposure of ionising radiation delivered to patients/service users or asymptomatic individuals as part of their own medical or dental diagnosis or treatment. Medical exposures are intended to benefit an individual's own health. Additionally, carers, comforters or and volunteers in medical or biomedical research may receive exposure to ionising radiation.
- **Medical Ionising Radiation Incident:** accidental, unintended or other incidents occurring or potentially occurring within an undertaking /health service provider involving the use of ionising radiation, which could impact on the safety and welfare of patients/service users, carers and comforters or research volunteers.
- **National Incident Management System (NIMS):** The NIMS is a confidential and highly secure web-based system. It is an end-to-end risk management tool that allows State authorities and health and social care enterprises to manage incidents throughout the incident lifecycle. It is the single designated system for reporting of all incidents in the public health and social care system i.e. for HSE and HSE funded services to fulfil their statutory requirements to report such incidents to the SCA.
- **National Incident Reporting Form (NIRF):** The NIRF was developed by the State Claims Agency in conjunction with all stakeholders including the HSE and HSE funded agencies (Section 38). Use of a NIRF assures the accuracy of data and clarity of information being reported. There are four forms in total;
 - Form 01 for Person,
 - Form 02 for a Crash/Collision,
 - Form 03 for Property, and
 - Form 04 for Dangerous Occurrences (Reportable Circumstances)/Complaints.

- **National Radiation Protection Committee (NRPC):** The HSE NRPC was established to maintain oversight of radiation protection practices across all HSE and HSE funded agencies (public hospitals and CHOs). The aim of this national committee is to provide advice and guidance to support local radiation safety committees in promoting best practice and demonstrating compliance with SI 256 (2018) and IRR19. The NRPC is supported by the National Radiation Protection Office.
- **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 in unintended or unanticipated injury or harm to a patient/service user during the provision of a health service.
- **No Harm Incident:** an incident where medical ionising radiation reaches the patient/service user but results in no injury to the patient/service user. Harm is avoided by chance or because of mitigating circumstances.
- **Non-Notifiable Incident:** an event relating to medical exposures to ionising radiation which is managed at a local level and does not need to be reported to HIQA as a significant event.
- **Non-Radiologist Medical Practitioners:** All medical practitioners who are not radiologists.
- **Notifiable Incident:** a significant event relating to medical exposures to ionising radiation which is reportable to HIQA. A list of reportable incidents is included in this document.
- **Nurse/Midwife Referrer for Radiological Procedures:** A nurse/midwife who has successfully completed the approved education programme and has Authority to Refer for Radiological Procedures.
- **Nurse/Midwife Referral Site Coordinator:** The person nominated by the Director of nursing/midwifery/public health nursing or relevant nurse/midwife manager on behalf of the health service provider to be the nurse/midwife referral liaison person. This person takes responsibility for the initiative locally, liaising with the education provider and the ONMSD (team with responsibility for implementing the initiative).
- **Open Disclosure** Open disclosure is defined as an open, consistent, compassionate and timely approach to communicating with patients/service users and, where appropriate, their relevant person following patient/service user safety incidents. It includes expressing regret for what has happened, keeping the patient/service users informed and providing reassurance in relation to on-going care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident. (HSE, 2019).
- **Optimisation:** The optimisation of a medical exposure is the process by which the most appropriate dose for each individual exposure is delivered. For a patient/service user, optimisation ensures that the dose they receive is as low as reasonably achievable (ALARA), while ensuring that the required clinical outcome is achieved.
- **Patient/Service User:** a person or a person who attends a health service provider for the purpose of undergoing a medical exposure. This includes a patient/service users, carers and comforters and volunteers participating in research.
- **Practical Aspects of Radiological Procedures:** the physical conduct of a medical exposure and any supporting aspects, including handling and use of radiological equipment, the assessment of technical and physical parameters (including radiation doses), calibration and maintenance of equipment, preparation and administration of radio-pharmaceuticals, and image processing.

- **Practitioner:** a person who is entitled to take clinical responsibility for a medical exposure under the regulations.
- **Radiographs:** often referred to as X-rays, these are two-dimensional images obtained to identify disease or injury.
- **Referrer:** a person who is entitled to refer patients/service users for radiological procedures to a practitioner in line with the regulations.
- **Regulatory Authority:** Health Information and Quality Authority.
- **Significant Event:** an event which should be notified to HIQA (and other competent authorities, if required) according to legislation.
- **Site Declaration Form:** A form completed by the Director of Nursing/Midwifery and signed by the clinical supervisor confirming the governance requirements for nurse/midwife referrers are in place in advance of each applicant undertaking the education programme. This form is part of the application process for all Higher Education Institutions (HEIs).
- **Undertaking (S.I 256 of 2018):** a person or body who has a legal responsibility for carrying out, or engaging others to carry out, a radiological procedure, or the practical aspects of a radiological procedure, as defined by the regulations. For the purpose of this guidance, this means the person or body legally responsible for medical exposures of ionising radiation.
- **Unintended Exposure:** medical exposure that is significantly different from the medical exposure intended for a given purpose.

Appendix VIII: Approved Policies, Procedures, Protocols and Guidelines Checklist

Standards for Developing Clinical PPPG	Checklist
Stage 1 Initiation	
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	<input checked="" type="checkbox"/>
Synergies/co-operations are maximised across departments/organisations (Hospitals/Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	<input checked="" type="checkbox"/>
<p>Title: HSE National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline 2021</p> <p>The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.</p>	<input checked="" type="checkbox"/>
The target users and the population/patient/service users group to whom the PPPG is meant to apply are specifically described.	<input checked="" type="checkbox"/>
The views and preferences of the target population have been sought and taken into consideration (as required).	<input checked="" type="checkbox"/>
The overall objective(s) of the PPPGs are specifically described.	<input checked="" type="checkbox"/>
The potential for improved health is described (e.g. clinical effectiveness, patient/service user safety, quality improvement, health outcomes, quality of life, quality and safety of care).	<input checked="" type="checkbox"/>
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	<input checked="" type="checkbox"/>
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	<input checked="" type="checkbox"/>

The PPPG is informed by the identified needs and priorities of patient/service users and stakeholders.	<input checked="" type="checkbox"/>
There is service user/lay representation on PPPG Development Group (as required).	<input checked="" type="checkbox"/>
Information and support is available for staff on the development of evidence-based clinical practice guidance.	<input checked="" type="checkbox"/>

Stage 2 Development	Checklist
The clinical question(s) covered by the PPPG are specifically described.	<input checked="" type="checkbox"/>
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/adopted from international guidance, their methodology is appraised and documented).	<input checked="" type="checkbox"/>
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	<input checked="" type="checkbox"/>
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	<input checked="" type="checkbox"/>
There is an explicit link between the PPPG and the supporting evidence.	<input checked="" type="checkbox"/>
PPPG guidance/recommendations are specific and unambiguous.	<input checked="" type="checkbox"/>
The potential resource implications of developing and implementing the PPPG are identified e.g. equipment, education/training, staff time and research.	<input checked="" type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient/service users flow and integrated care.	<input checked="" type="checkbox"/>
Budget impact is documented (resources required).	<input checked="" type="checkbox"/>

Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as appropriate).	<input checked="" type="checkbox"/>
Three additional standards are applicable for a small number of more complex PPPGs: Cost effectiveness analysis is documented. A systematic literature review has been undertaken. Health Technology Assessment (HTA) has been undertaken.	Not deemed necessary <input checked="" type="checkbox"/> Not undertaken
Stage 3 Governance and Approval	Checklist
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	<input checked="" type="checkbox"/>
The PPPG has been reviewed by the independent experts prior to publication (as required).	<input checked="" type="checkbox"/>
Copyright and permissions are sought and documented.	<input checked="" type="checkbox"/>

Stage 4 Communication and Dissemination	Checklist
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	<input checked="" type="checkbox"/>
Plan and procedure for dissemination of the PPPG is described.	<input checked="" type="checkbox"/>
The PPPG is easily accessible by all users e.g. PPPG repository.	<input checked="" type="checkbox"/>
Stage 5 Implementation	Checklist
Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.	<input checked="" type="checkbox"/>

Barriers and facilitators for implementation are identified, and aligned with implementation levers.	<input checked="" type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).	<input checked="" type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient/service users flow and integrated care	<input checked="" type="checkbox"/>
Stage 6 Monitoring, Audit, Evaluation	Checklist
Process for monitoring and continuous improvement is documented	<input checked="" type="checkbox"/>
Audit criteria and audit process/plan are specified	<input checked="" type="checkbox"/>
Process for evaluation of implementation and (clinical) effectiveness is specified.	<input checked="" type="checkbox"/>
Stage 7 Revision/Update	Checklist
Documented process for revisions/updating and review, including timeframe is provided.	<input checked="" type="checkbox"/>
Documented process for version control is provided.	<input checked="" type="checkbox"/>

I confirm that the above Standards have been met in developing the following:

Title of PPPG: HSE National Nurse and Midwife Authority to Refer for Radiological Procedures Guideline 2021

Name of person signing off on the PPPG Checklist: Maureen Nolan

Title of person signing off on the PPPG Checklist: Director of Nursing, National Lead for the Implementation and Audit of Nurse and Midwife Referral for Radiological Procedures

Signature of person signing off on the PPPG Checklist: Maureen Nolan

Date: October 20th 2021

This signed PPPG Checklist must accompany the final PPPG document in order for the PPPG to be approved.

Notes

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