Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

TO: **Holders of Medical Ionising Radiation Equipment**

FROM: **National Radiation Safety Committee, HSE**

DATE: **04 March 2010.**

RE: Guidance on Responsibilities in European Communities (Medical Ionising Radiation Protection) Regulations (Statutory Instrument (SI) 478 of 2002), as amended by the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations (SI 303 of 2007).

These regulations are intended to protect the patient from harmful effects of exposure to ionising medical/dental radiation.

The National Baseline Audits conducted in 2008 in Radiology, Nuclear Medicine, Dentistry and Radiotherapy in 2008 recommended that *"The HSE and the National Radiation Safety Committee should clarify and promote the requirements of SI 478 and ensure that all Holders of ionising radiation equipment are aware of these".*

This document is an initial guidance from the National Radiation Safety Committee to Holders of Medical/Dental Ionising Radiation Equipment in Ireland. It addresses some of the key responsibilities of Holders to assist them to comply with the relative provisions of the regulations. It also provides some advice on implementation issues, such as governance structures.

Disclaimer
This document is intended to act as a guideline to the regulations. It must be read in conjunction with the regulations referred to above and other laws, regulations or other responsibilities attaching to these roles. It does not purport to be comprehensive or to be a legal interpretation or to constitute legal or professional advice. Further guidance documents and changes in the regulations can be expected in the future that will necessitate the update of this guidance in due course. The advice given is wide-ranging and does not undermine an employer's legal responsibilities for implementing compliant local procedures.

This regulation concerns important issues of quality and patient safety. Currently, a national review is being undertaken to implement the

recommendations from the Report of the Commission on Patient Safety and Quality Assurance, 2008. This, and other national developments will have consequences for the implementation of SI 478 (2002) in the future. The National Radiation Safety Committee may issue further guidance in this regard.

Holders' Responsibilities - Guidelines

Significant responsibility for the protection of patients from the harmful effects of ionising radiation rests with the Holder who must ensure that appropriate provisions are put in place to meet the requirements of the regulations. The Holder means "any natural or legal person who has the legal responsibility under national law for a radiological installation". In almost all cases the Holder will also be the undertaking [licensee with the Radiological Protection Institute of Ireland] as defined under SI 125 (2000) and will have additional responsibilities set out in that statutory instrument. Practitioners in Charge, Practitioners, Radiographers, Medical Physics Experts and Prescribers and each person involved in the use of ionising radiation for the purpose of medical/dental exposures to patients also have the duty to comply with the provisions of the regulations.

1. Governance and Structures

The regulations state that a holder may establish a local radiation safety committee in respect of a particular installation and that committee shall have regard to the advice of the National Radiation Safety Committee. A number of other responsibilities are required of Holders. The National Radiation Safety Committee has reviewed these and recommended the following to assist Holders in fulfilling their legal requirements.

National Radiation Safety Committee Recommendation

The National Radiation Safety Committee has made the following recommendations to assist Holders in fulfilling their legal requirements and has provided advice on a local governance framework.

(a) Radiation Safety Committees.

Radiation Safety Committees are recommended to be in place in organisations that have a large volume of procedures and/or higher risk practices. This does not generally apply to smaller practices, for example a dental practice or dexa scanning practice.

Many Holders have established Radiation Safety Committees to meet the licence requirements of the Radiological Protection Institute of Ireland, under SI 125 (2000). Where these committees exist, it is recommended that their terms of reference are expanded to additionally advise the Holder on the following:

- Ensure and monitor compliance with SI 478/303
- Monitor risks and incidents
- Monitor quality assurance programmes

- Review and prioritise clinical audit
- Monitor equipment, maintenance and replacement criteria
- Monitor staff education and training
- Monitor patient dose levels
- Other responsibilities as may be delegated by the National Radiation Safety Committee or the Competent Authority

Note
(Arrangements similar or additional to above, such as risk or clinical audit committees, particularly in radiotherapy, that achieve the same aims within the quality, safety and risk framework of the facility may also be considered to be appropriate. These would need to demonstrate good governance and have an integrated approach to ensure the above agenda is delivered on.)

It is recommended that committees meet at minimum twice per year (4 times per year in radiotherapy) and be integrated in to the governance, risk and safety framework of the organisation.

It is recommended that membership includes, at a minimum:

- The CEO/Manager**(*see below)**, or their representative, should ideally chair the Committee
- Risk Manager
- Practitioner in Charge at a minimum and the possibility for an additional Consultant Radiologist and/or Consultant Radiation Oncologist as appropriate
- Radiography Services Manager and/or Radiation Therapy Services Manager as appropriate
- Radiation Protection Adviser**(**see note below)** / Medical Physics Expert
- A representative from each department using ionising radiation for patients
- Nurse, where nurses are prescribers/operators
- Representation from satellite hospitals/clinics, as appropriate
- Consultant in Public Health Medicine
- Dental Practitioner, where applicable

Note
(*)The CEO/hospital manager has the corporate responsibility and should ideally chair the committee but may nominate a suitable person to chair.
(**) The responsibilities of the Radiation Protection Adviser are set out in SI 125 (2000) and in the conditions that the Radiological Protection Institute of Ireland attaches to its licences.

Dental Radiation Safety Committees
Where these exist, it is recommended that their terms of reference are similarly extended. Their membership will differ to the above but should be reviewed and modified, where appropriate.

There may be some cases where the National Radiation Safety Committee will advise a Holder to establish a Radiation Safety Committee and the National Radiation Safety Committee will make contact directly with that Holder.

(b) Radiation Protection File

It is recommended that all Holders keep a Radiation Protection File on site. An example of the suggested contents of this file, particularly for dentistry, is listed in **appendix 1**. The Medical Exposure Radiation Unit will distribute guidelines on the contents and upkeep of this file to all Holders in 2010. This file will be expected to be made available, if requested, to the Medical Exposure Radiation Unit, HSE which has a responsibility to audit clinical practice.

2. Personnel

Engagement and training of persons involved in the use of ionising radiation.

It is recommended that the Holder ensures that all persons involved in the use of ionising radiation have the appropriate qualifications, authorisation, registration and training required to carry out their functions in compliance with the regulations and are aware of their responsibilities. It is recommended that the holder ensures that appropriate ongoing induction and training is provided, particularly when new or updated practices are introduced and when there is a change of personnel.

The Holder is required to:

- Designate one individual as Practitioner in Charge (a Practitioner has a specific definition in SI 478(2002)) who will recommend referral criteria for use of the facility.
- Designate a named Medical Physics Expert for the facility.

3. Equipment

Equipment Suitability

In addition to the requirements placed on the Holder by the Radiological Protection Institute of Ireland, SI 478 (2002) requires that the Holder has and maintains a written inventory of all radiological equipment and the National Radiation Safety Committee recommends that it is available if requested.

The Holder must ensure that their equipment complies with criteria of acceptability and take appropriate action if it fails to meet the criteria, based on the advice or action of the Medical Physics Expert.

National Radiation Safety Committee Recommendation

The National Radiation Safety Committee is considering the use of the draft version of the European Commission Radiation Criteria for Acceptability of Radiological, Nuclear Medicine and Radiotherapy Installations (RP91). This is available to download at http://ec.europa.eu/energy. The recommendation of the National Radiation Safety Committee will be notified to Holders in a separate guidance document.

The regulations currently require that the National Radiation Safety Committee authorises the extended use of all equipment beyond its anticipated lifetime. The National Radiation Safety Committee will issue guidance to Holders on how to inform the committee on the extended use of equipment.

4. Systems

Adverse Incident Reporting

It is recommended that Holders ensure they have systems in place to prevent and report adverse incidents. Notwithstanding the incident reporting requirements of the Radiological Protection Institute of Ireland, the National Radiation Safety Committee will issue recommendations and guidance to all Holders in 2010 on an external reporting mechanism for the reporting of adverse incidents.

Clinical audit

The Holder should ensure that the clinical practice is externally audited in accordance with the criteria adopted by the Irish Medical / Dental Councils at least once every five years.

The National Radiation Safety Committee plans to issue guidance on external and internal clinical audit in agreement with the Irish Medical / Dental Councils. All guidance will be developed within the context of national developments resulting from the Report of the Commission on Patient Safety and Quality Assurance, 2008 and the Adverse Event, Clinical Audit and Patient Safety Protocols being developed.

Quality Assurance

Quality Assurance means “all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and comply with agreed standards.” Holders must ensure that appropriate quality assurance programmes are implemented.

5. Protocols and Standards

Referral criteria

The Holder must ensure that referral criteria are advised to prescribers, based on the recommendation of the Practitioner in Charge.

Diagnostic Reference Levels

Diagnostic Reference Levels means “dose levels in medical radio diagnostic practices or, in the case of radio-pharmaceuticals, levels of activity for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment. These levels are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.” Those that have been established nationally are available at
http://www.hse.ie/eng/about/Who/Publications_and_Annual_Report.html

Other Responsibilities

In addition to Holders' responsibilities, personnel involved in the use of medical and dental ionising radiation have been assigned particular responsibilities in SI 478/303. The following is a summary and must be read in conjunction with the regulations and other laws, regulations or other responsibilities attaching to these roles.

Responsibility of the Practitioner in Charge (in addition to responsibilities of the Practitioner).

- Recommend referral criteria. It is expected that most departments already have criteria in place for many procedures. For example, the Faculty of Radiologists has recommended the use of the RCR (UK) referral criteria recommendations for diagnostic practice and these would be an acceptable foundation on which to base local criteria.
- Approve adjustments to be made to the equipment that are considered necessary by the Medical Physics Expert.

Responsibility of the Practitioner.

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

Responsibility of the Prescriber.

- Shall state in writing reason for requesting the particular procedure.
- Shall enquire as to and provide the Practitioner with the pregnancy status of relevant females for all ionising radiation exposures.
- With the Practitioner, shall seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure.

Responsibility of the Medical Physics Expert

Medical Physics Expert conducts the following activities or gives advice on the following:

- Patient dosimetry.
- The development and use of complex techniques and equipment.
- Optimisation, particularly in therapeutic and high dose procedures, paediatric, pregnancy and breast feeding.
- Quality assurance, including quality control.
- Periodic examinations of equipment and records, agree such adjustments to be made to the equipment subject to the approval of the Practitioner in charge, maintain a record of each examination and adjustment of equipment.
- Acceptance testing of new equipment and checking of equipment after major maintenance.
- The Medical Physics Expert must express their views on continued suitability of use of equipment beyond its anticipated lifetime, based on equipment criteria.
- Other matters relating to radiation protection.

Responsibility of the Radiographer

- Ensure adherence to justification procedures.
- Advise on dose optimisation.
- A Radiographer appointed as Radiation Safety Officer in designated locations records and maintains records of regular Quality Control tests.
- The Radiation Safety Officer, records and audits patient dose information for compliance with DRLs.
- In Clinical Audit, the Radiographic Services Manager ensures that agreed standards and protocols are in place and adhered to.
- In Adverse Incident reporting relating to medical ionising radiation, the Radiographic Services Manager ensures incidents are recorded and managed according to agreed protocols.

APPENDIX 1

Radiation Protection in Dental Practices

Dental radiography differs from medical radiography in that, in the majority of cases, the dentist acting in a single handed capacity is *defacto* the prescriber, the radiographer and the radiologist when a radiographic examination is required.

The dentist may also, by way of being a single handed practitioner, automatically become the "Practitioner in Charge" for the purposes of the legislation.

Outside of large organisations such as the HSE dental and orthodontic services and the Dental Schools, the majority of dental practitioners operate in a general dental practice setting with some practitioners in specialist / limited practice.

As private dental practices will often be staffed by the dental practitioner, occasionally an associate and his / her support staff, it would be impractical to have a Radiation Safety Committee. Instead, dentists who are RPII x-ray licence holders are required to hold a file of compliance on site.

The practice Dental Radiation or "Compliance File" should contain the following:

- ❑ A copy of the current x-ray licence including schedules 1, 2 and 3
- ❑ Personnel Dosimetry reports to be held for 7 years
- ❑ Commissioning reports - to be held for the life time of the equipment
- ❑ Annual service reports – to be held for the life time of the machine
- ❑ Maintenance reports – to be held for the life time of the machine
- ❑ Reports from the Radiation Protection Advisor
- ❑ Reports from the Medical Physics Expert, including a record of the annual number of exposure per machine type, where possible
- ❑ Copy of the safety operating procedures (local rules)
- ❑ Clinical Audit reports and associated data
- ❑ Details of radiation Incidents and reports, guidelines to follow
- ❑ Quality assurance program data to be held for the lifetime of the machine and a record of the replacement review date for each machine
- ❑ Staff training and induction reports
- ❑ Evidence of safe disposal of developer chemistry and lead foil
- ❑ Any correspondence relating to the radiographic practice at that location

Note: this is not an exhaustive list and additional documents may be considered necessary for inclusion.