Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Final Report of the HSE Task Force on

Implementation of

Statutory Instrument 478 (2002) and

Statutory Instrument 303(2007)

April 2008

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INTRODUCTION

The HSE established a Task Force in April 2007 to consider and make recommendations in relation to implementation of Statutory Instrument 478, which deals with radiation protection of the patient. The Task Force has also incorporated the amendments to SI 478 which were introduced by SI 303 in June 2007 in to its discussion and recommendations throughout this report.

The Task Force submitted an Interim Report at the end of July 2007. That report contained an outline of the ongoing work of the Task Force, which included meeting with additional stakeholders, continuing discussions with the Radiation Protection Institute of Ireland and the Health and Information Quality Authority, developing a suitable questionnaire to be used as a baseline audit tool.

This is the final report of the Task Force. The Group is aware that already several of the recommendations contained in the Interim Report have been acted upon; for example, the baseline audit and establishment of the National Radiation Safety Committee (propose name is amended to Medical Exposures Radiation Committee). However, so as to avoid reference to two separate documents this final report consists of the content of the interim report with some small changes and also a number of additional observations and recommendations.

BACKGROUND:

In October 2002 Statutory Instrument, SI 478 European Communities (Medical Ionising Radiation Protection) Regulations (2002), on the protection of patients exposed to ionising radiation, was passed into law. This transposed earlier European Directives on the medical use of ionising radiation into Irish Law.

These regulations lay down measures for the protection of individuals in relation to medical ionising radiation exposure of patients, as part of their medical diagnosis or treatment, and regulate exposure in all circumstances. In addition total population dosage is to be monitored and reported on annually.

Over the past 25 years the increasing use of Ionising Radiation for medical purposes has resulted in an overall increase of radiation dose to the patient and to the population in general. This is especially true because of new technological advances and sophisticated techniques used in diagnosis and treatment. When indicated and correctly used these procedures have resulted in major benefits for the individuals involved and for the population as a whole, however effective regulation is required. The Medical and Dental Councils, as required by SI 478, have published the Criteria for Clinical Audit, Diagnostic Reference Levels, etc.
(see: - http://www.medicalcouncil.ie/medical_ionising_radiation/default.asp and www.dentalcouncil.ie)

The current regulations place considerable responsibilities on the CEO of the HSE, all Holders of radiological equipment both public and private, Prescribers and Practitioners administering ionising radiation, Medical Physicists and Radiographers.

The Regulations of October 2002 set out a timescale for full implementation, with the Medical and Dental Councils required to adopt criteria for clinical audit within two years, and the first audit, under the Regulations, not more than three years after the date of adoption of criteria for clinical audit. Recognising that the full implementation of the audit requires necessary co-operation between the agencies and stakeholders involved, the HSE established a Task Force in April 2007, which included representatives from the main interested parties to report on an Action Plan for full implementation of the Statutory Instrument.

In June 2007, the Minister signed the statutory instrument 303 (2007) in to law, which amends SI 478. The main amendment is a) the introduction of An Bord Altranais assigned to maintain a register of prescribers, allowing for certain nurses to prescribe under the regulation and b) making exceptions to the requirement to have a radiographer present in the cases of dental procedures and low dose dexa scanning in certain circumstances.

TASK FORCE TERMS OF REFERENCE:

The HSE appointed a Task Force in April 2007 to address the implications of SI 478. For membership of Task Force and subgroups, see appendix 1

The Terms of Reference of the Task Force are:

1. To consider the issues raised in legislation (SI478 of 2002 and subsequently, SI 303 of 2007), concerning medical ionising radiation protection.
2. To present proposals for adoption by the HSE and other stakeholders in relation to the implementation of the Regulations.
3. To report re the above by 31st July 2007.
4. To make proposals for, and oversee, the commencement of a national audit by October 2007.

Having regard to the tight timetable for producing a report and commencing a national audit the Task Force set up four subgroups to undertake specific work and to report back to the main Task Force. The subgroups were as follows:

Subgroup 1
To produce a framework for clinical audit for national use which will evolve over time.

Subgroup 2
To recommend organisational structures for the operation and support of the Radiation Safety Committee. Recommend normal links between the national, regional and local committees, where they exist, and make recommendations for the operation and support of the audit structures at local level.

Subgroup 3
To identify the resource issues, including equipment, facilities, training and manpower, make recommendations, both short and long term in relation to any deficiencies identified, including costings and training. To quickly provide interim recommendations to inform the Estimates Process (identifying resource needs for 2008).

Subgroup 4
To identify best practice, including dose levels and guidelines. To identify communication requirements in relation to all stakeholders and examine the training requirements and implications and make recommendations concerning same.

Additional subgroups were established after the interim report was submitted in July 2007, these being;

Baseline Audit Subgroup
To develop a baseline clinical audit tool with consultants engaged in its design, distribution and analysis.

Governance subgroup
To review legislation and its proposed amendments and report on clarification of HSE's obligations in respect of governance relating to medical ionising radiation.

Legislative review subgroup
To examine the current legislation and prepare draft amendments for consideration by the Department of Health and Children, based on recommendations of the Task Force.

MAIN RESPONSIBILITIES UNDER CURRENT LEGISLATION; STATUTORY INSTRUMENT NO. 478 (2002) AND STATUTORY INSTRUMENT NO. 303 (2007) (see * below):

Responsibility of Department of Health and Children

- Currently, the Minister for Health and Children is the Competent Authority for SI 478 and SI 303.

Responsibility of CEO, HSE

- Hold and maintain a register of all medical radiological installations in Ireland – October 2007.
- Appoint Clinical Auditor. Holders must ensure that clinical practice is audited and undertaken by October 2007.
- Establish and resource a national Radiation Safety Committee (RSC) to advise CEO on matters pertaining to the safety of radiological installations and general practices and may issue guidance notes to comply with regulations – October 2007.
- CEO can introduce measures, on advice of RSC, to protect health and safety of patients, public or employees.

Responsibility of Holders

- Ensure that practice is audited at least once every five years, the first to be undertaken no longer than three years from the date of adoption of the criteria and to bear the cost of the audit.
- Designate one individual as Practitioner in Charge who will recommend referral criteria for use of the facility.
- Designate a named medical physics expert with responsibility for the facility.
- Ensure that appropriate quality assurance programmes are implemented for the installation.
- Ensure that a written inventory of all radiological equipment is maintained.
- Ensure equipment complies with criteria of acceptability and take appropriate action if it fails to meet the criteria.
- Ensure that referral criteria are advised to prescribers.

Responsibility of Irish Medical and Dental Councils

- Adopt criteria for clinical audit within two years of the making of the regulations.
- Establish written protocols for every type of standard radiological practice.
- Promote the use and establishment of standard diagnostic reference levels.
- Establish the dose constraint for those knowingly and willingly helping in the support and comfort of patients undergoing medical diagnosis or treatment.
- Establish approved procedures for medical exposures to be conducted on pregnant and breast-feeding females.
- Make decisions on medical exposure for biomedical and medical research.
- Make decisions on medical exposure for occupational health surveillance.
- Consider the use of new practices for approval.
- Approve training.

Responsibility of the Practitioner in Charge

- Recommend referral criteria.
- Clinically responsible (along with his/her colleagues) for all ionising radiation exposures performed in their institution.
- Determine the manner in which services involving ionising radiation will be delivered.

Responsibility of Practitioner

- 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 or herself that the procedure prescribed is justified.
- Liaison with prescribers to guide best practice in use of ionising radiation.

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.
- Shall provide any additional information considered necessary by the practitioner in charge to optimise service delivery and reduce risk to the patient.

- 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 Physicist

- Conduct 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.
- The medical physicist is involved in planning therapeutic doses.
- The medical physicist is involved in dose optimisation particularly in pregnancy and breast feeding.
- The medical physicist must express their views on continued suitability of use of equipment beyond its anticipated lifetime.
- The medical physicist must check equipment after major maintenance.

Responsibility of Faculty of Radiologists

- The Faculty of Radiologists is the Training Body responsible to the Medical Council for the educational standards of 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. In relation to the current legislation, the Faculty of Radiologists is a body that both the Medical and Dental Councils are required to consult in relation to the adoption of criteria for clinical audit.

Responsibility of An Bord Altranais

- Establish and maintain a register for nurse prescribers and set educational standards and requirements for nurse prescribers, working closely with The Faculty of Radiologists in this regard.

Responsibility of the *Radiographer*

- The Radiographer is responsible for dose optimisation and ensuring adherence to justification. The role of the Radiographic Services Manager in clinical audit is to ensure that agreed standards and protocols are in place and adhered to. The Radiation Safety Officer is responsible for recording and maintaining records of QA tests and patient dose information.

Responsibility of National Radiation Safety Committee/ Medical Exposure Radiation Committee with the support of the Medical Exposures Radiation Unit, HSE

- Advise the CEO, HSE on any matter pertaining to the safety of radiological installations and general practices in such installations and may issue guidance notes to holders, practitioners, practitioners in charge and prescribers to assist them to comply with the relevant provisions of the regulations.
- Monitor the population dosage and include their findings in the annual report.
- Receive reports on incidents as required and advise where appropriate.

- Gather lifetime data on equipment and an assurance that each piece is recorded as being suitable for use and maintained. This would ensure that there is a written inventory locally and a record of maintenance.
- Produce annual report.
- Any other appropriate matters that may arise.

** The responsibilities listed above are principally those outlined in legislation. In a small number of instances, additional responsibilities are included where considered relevant*

IMPACT OF LEGISLATION ON CLINICAL PRACTICE AND FUTURE DEVELOPMENTS:

European Council Directive 97/43/Euratom looks at justification, optimisation, clinical responsibility, protocols for procedures and equipment, training and special practices. It is also concerned with protection of pregnant and breast-feeding females undergoing radiological exposures and with population doses. Likewise, in its transposition into Irish legislation, *Statutory Instrument No. 478 (2002)* has at its core, the purpose of protecting patients and the comforters or carers of those patients.

Like *European Council Directive 97/43/Euratom,* these regulations determine the 'clinical responsibility' of practitioners with regard to justification of exposures, evaluation of outcomes, obtaining information from previous radiological examinations, and informing patients of the risks associated with exposure as compared against the net benefit of such exposure. The emphasis of *Statutory Instrument No. 478 (2002)* is on quality assurance and quality control at all levels of the structure, process and outcome for the patient. It emphasises that staff performing radiological procedures must undergo specific training to ensure safety for both for patients and staff.

Regulations under *Statutory Instrument No. 478 (2002)* emphasise that where it is deemed necessary to undergo a diagnostic radiology procedure, all doses should be kept as 'low as reasonably achievable' which allows quantifiable and measurable recording of data relevant to the exposure. New diagnostic radiology procedures must undergo increased scrutiny under *Statutory Instrument No. 478 (2002)* to ensure that the exposure and outcome for the patient is in line with international best practice.

In effect, these regulations determine the 'clinical responsibility' of practitioners with regard to justification of exposures, evaluation of outcomes, obtaining information of previous radiological examinations, and with regard to informing patients of the risks associated with exposure as compared against the net benefit of such exposure, as appropriate.

The regulations require that population dosage be monitored and the results included in an annual report relating to radiation safety.

The medical exposure directive, 97/43/Euratom which is transposed in Irish law by SI 478 stipulates that member states shall ensure that practitioners and other staff involved in a radiological procedure have *adequate and practical training for the purpose of radiological practice* as well as *relevant competence in Radiation Protection*. Ireland is required to ensure appropriate curricula and recognition of corresponding diplomas, certificates, or formal qualifications and to encourage the introduction of a radiation protection course in the basic curriculum of medical and dental schools.

ACTIVITIES OF THE TASK FORCE

Background

The Task Force first considered a number of previous reports relating to this matter including the report produced by the Health Boards' Executive (HeBE) working group on medical ionising radiation in July 2005. Since its establishment in April 2007, the Task Force has undertaken a number of activities, the main ones being listed below:

1. Meetings of Task Force and subgroups
2. Information gathering exercise
    a. Presentations from international experts.
    b. Lecture on the 2007 from International Commission on Radiological Protection on radiological protection in medicine – organised by RPII and Association of Physical Scientists in Medicine.
3. Legal advice
4. Procurement process relating to audit
5. Consultation with various stakeholders

1. Meeting of Task Force and subgroups

The Task Force met on eight occasions. Much valuable work was done by the subgroups. The Chair and Secretary of the Task Force met with the chairs of the subgroups regularly. Proposals and suggestions arising from same played an important part in directing Task Force discussion.

2. Information gathering exercise

A significant amount of documents, including the HeBE report form 2005, were sourced and reviewed as part of the work of the Task Force. These will shortly be available as a website link at www.hse.ie/en/radiation. These documents include regulations, guidelines and experiences of EU countries and various presentations, reports and legislation from Ireland.

a. Lecture, RPII

The lecture organised by the RPII and Association of Physical Scientists in Medicine covered the 2007 ICRP Recommendations and Radiological Protection in Medicine.

b. Presentations from International Experts

Steve Ebdon-Jackson, Health Protection Agency, UK and Hannu Jarvinen, Radiation and Nuclear Safety Authority (STUK), Finland, presented their country's solution to addressing the requirement of clinical audit in the European legislation. No framework exists in EU and countries are at different stages. STUK have been engaged to develop an EU framework but it is envisaged that this will take a number of years. Both countries have emphasised self-audit which is monitored locally. In Finland, they have employed outside agencies to set up criteria and monitor audits; in UK, the focus is on local audit and national inspection.

3. Legal advice
The Task Force sought legal advice; this indicated that a delay in receiving clinical criteria for audit from one of the statutory bodies charged with doing this could not be relied on as a reason for not keeping to the timetable to carry out the first audit within the timeframe specified in the regulations.

4. Procurement process
The Task Force also established a procurement group to oversee the appointment of a consultancy to conduct an initial baseline clinical audit. The Quality Assurance Reference Centre, UK was subsequently selected for this purpose.

5. General Statutory Bodies and Stakeholder Consultation

Discussions took place during the lifetime of the Task Force with all the named statutory bodies with responsibilities under SI 478 and its amendments. In addition, meetings took place with Health Information and Quality Authority who it is proposed will be named in the amendments proposed by the Task Force. Other interested stakeholders were invited to meet Task Force for the purpose of exchange of views and information (see appendix 2).

Statutory Bodies with named statutory responsibility in the regulations:

a. Meeting with RPII
b. Meeting with Health Information and Quality Authority
c. Meeting with John O'Brien, National Director, National Hospitals Office, HSE
d. Meeting with Irish Medical Council
e. Meeting with Irish Dental Council
f. Meeting with An Bord Altranais
g. Meeting with Department of Health and Children

The Task Force met with the following stakeholders:

- Orthodontic Society of Ireland
- Faculty of Radiologists
- Irish Hospital Consultants Association
- Superintendent Radiographers Association, including radiotherapy managers.
- Association of Physical Scientists in Medicine
- Independent Hospitals Association of Ireland and IBEC
- Biomedical Division of Engineering Ireland and the Clinical Engineering Voluntary Registration Board / Biomedical/Clinical Engineering Association of Ireland
- Irish Institute of Radiographers
- SIPTU representing radiographers
- Irish Dental Association
- Dublin Risk Management Forum, radiology subgroup
- Irish Radiotherapy Physics Group

In addition, the Task Force invited the Irish Medical Organisation, the State Claims Agency, the Irish College for General Practitioners, IMPACT, Association of Physical Scientists in Medicine and the Irish Nurses Organisation for consultation.

The following is not a comprehensive report in relation to all the stakeholder meetings but does draw attention to some of the more important points arising from the consultation process, which influenced the findings of the Task Force.

Statutory Bodies with responsibility under legislation:

a. Meeting with RPII

Meeting discussed transfer of some data held by RPII. Radiological Protection Institute of Ireland and HSE agreed content of data to be transferred and RPII were in a position to have this available to HSE by November 2007. This will form the basis of the register of installations that is required to be held by HSE under current legislation and will need to be added to.

b. Meeting with HIQA

At the meeting, the Task Force put the case that, although it was still in the middle of deliberations and had not taken firm decisions, a picture was beginning to emerge whereby it was identified that the audit could be divided into two separate areas:

1. Clinical Audit:

Perhaps this could be carried out locally to a large extent, with some external input.

2. Regulatory Audit/Inspection:
    a. As the legislation stood at the present time there was a requirement on the HSE to register all holders of medical ionising equipment.
    b. Appoint a Radiation Safety Committee to advise the HSE.
    c. Audit

The Task Force was beginning to recognise that there might be issues in relation to HSE and the audit, as the HSE were the owners with regard to the public sector.

HIQA have agreed to assume responsibility for the co-ordination of the development of the standards for Ionising Radiation Safety, although this will require legislative change and they could not meet deadline of October 2007. They will need someone to project manage the development of standards with a view to commencing audit in 18 months.

c. Meeting with John O'Brien, National Director, National Hospitals Office, HSE

The National Hospitals Office is responsible for the majority of medical radiological services in the HSE. The Task Force met with John O'Brien for his views on the proposal to establish the Task Force and its terms of reference. Staff from the NHO directorate were appointed to the Task Force and sub groups.

d. Meeting with Irish Medical Council

The Irish Medical Council advised that on completion of its responsibility under SI 478, it provided copies of all relevant documentation to the CEO,

HSE and to the General Managers/CEO's of all the major hospitals. The Medical Council outlined its support for the Task Force and suggested a revision of the legislation, in particular with regard to the setting of standards; this was addressed by the Task Force.

e. Meeting with Irish Dental Council

The Irish Dental Council has recently produced its criteria for clinical audit. They are supportive of Task Force and will support a communications programme to raise awareness amongst dentists.

f. Meeting with An Bord Altranais

An Bord Altranais has recently been given responsibility in the amendment to SI 478 – SI 303(2007), to establish a register of suitably qualified nurses to prescribe in certain conditions. The Bord has established a committee to review its requirements and is working with the Medical Council and the Faculty of Radiologists to ensure optimum standards and practice.

g. Meeting with Department of Health and Children

Following the interim report of the Task Force, there was a meeting with the department to brief them on the proposals of the Task Force in relation to proposed change of competent authority from Department of Health and Children to Health Information and Quality Authority. The Task Force recommended that proposed changes to legislation be expedited. The Department of Health and Children have agreed to examine legislation following production of the final report of the Task Force.

Consultation - Emerging Themes

Responsibilities under SI 478

Statutory Instrument SI 478 (2002) predated the establishment of HIQA which is a standards setting authority. The fact that HIQA has now been established raises issues in relation to the role of the Medical and Dental Councils, the Minister as competent authority and the role of HSE as a consequence.

Conflict of Interest

The current legislation raises questions with many stakeholders concerning the independence of the HSE in carrying out audits and setting standards for not only itself but also all holders of radiological installations, including private facilities. Recent amendments in SI 303 (2007) were welcome but there would need to be additional amendments to address issues of conflict of interest, covering areas such as regulatory inspection, incident reporting and transfer of functions to an independent body.

Communication:

A national awareness exercise for all involved is required to inform them of their requirements in SI478/SI303 and how they can meet them, what structures are in place, etc. A series of seminars is suggested to raise awareness of requirements under regulations and guidance on how to satisfy requirements. Consultation is essential to secure buy in from stakeholders and also to inform decision-making.

CEO's/managers of both public and private facilities need to appreciate their obligation with regard to SI 478. It was acknowledged that the provision of clear information outlining holders' responsibilities in relation to compliance with SI 478 and amendments would facilitate compliance.

Training and Education
Appropriate and certified training is seen as key to achieving implementation of SI 478. This should be available to and availed of by all relevant professionals, preferably as part of their Continuing Professional Development/Continuing Medical Education and revised at appropriate intervals and supported by Irish Medical Council, Irish Dental Council, An Bord Altranais and the Statutory Board for Health and Social Care Professionals and a register maintained. It was suggested that, as part of the appointment of specialists with a role in radiation, the person needs to provide evidence of appropriate training in radiation protection and practice.

Clinical Audit
Clinical audit is welcomed by all but some pointed out it should be set in the context of having standards available and applied. It can also be a significant resource issue, particularly for Radiologist sessions and expanding the workload of the medical physicist and radiographer.

Prescribers
The introduction of a new category of prescribers in SI 303 was raised by a number of stakeholders. The Task Force was satisfied, however, that An Bord Altranais have put in place mechanisms to ensure appropriate standards and registration requirements, limiting the selection of prescribers for their register and proposing a training course of approximately 30 hours' duration. The Bord will work closely with The Faculty of Radiologists to ensure optimum standards in training and practice.

Those representing radiographers urged that radiographers be recognised as prescribers. The Task Force had reservations about this as it would give rise to a conflict of interest because of the important regulatory role of radiographers. There was some discussion by the Task Force on this issue.

Use of DXA scanning and training
This was raised as an issue which requires further clarification and will require amendment to current legislation.

Resources
Many highlighted the lack of resources, both in time available for audit and the availability of staff to meet requirements of compliance under SI 478.

Statutory registration of medical physicists and clinical engineers
Both medical physicists and clinical engineers suggested that their profession be included as a profession to be registered by the Statutory Board for Health and Social Care Professionals

Structures
Without formal arrangements locally that allow for the regular conduct of audit, its review and the implementation of subsequent changes, it will be difficult for staff to

engage in clinical audit. The question arose regarding who would be involved in clinical audit and what structures would need to be in place, such as local radiation safety committees and their link to the national committee.

DISCUSSION

Current legislation SI478 – European Communities (Medical Ionising Radiation Protection) Regulations 2002, as amended in 2007, puts considerable responsibilities on the Chief Executive Officer of the Health Services Executive (HSE) and on the holders of medical ionising radiation equipment. The Regulations also make requirements of the Medical and Dental Councils, including the adoption of criteria for clinical audit and promoting the establishment and the use of standard diagnostic reference levels for radio-diagnostic examinations.

The 2002 Regulations set a timeframe for full implementation with the Medical and Dental Councils required to produce the protocols and the criteria for clinical audit within two years (by October 2004). The first audit of holders of ionising radiation equipment was to be undertaken within three years thereafter.

The Medical Council produced the necessary documentation including standards, clinical audit criteria and dose reference levels within the required timeframe - Autumn 2004.
(http://www.medicalcouncil.ie/medical_ionising_radiation/default.asp)

The Dental Council encountered some delays as regards expert advice and thus documents only came to hand in 2007.

Having regard to the fact that there has been some delay in relation to the Dental Council in producing the protocols and criteria for clinical audit, the question arose as to whether that pushed forward the time that others had to comply with the legislation. The Task Force sought legal guidance on this issue and the advice was to the effect that a failure by one party to meet the time requirements could not be relied on as a reason for not undertaking the first audit within the time envisaged in the Regulations and would not be in keeping with the spirit of the Regulations.

The Regulations place significant responsibilities on the holder of medical ionising radiation equipment, be they institutions or individuals, public or private and the HSE has a function in relation to all holders.

The duties of the HSE in this regard include:

- To maintain a register of all medical ionising radiation equipment in the functional area of the HSE.
- The appointment of an Audit Team.
- The appointment of a National Radiation Safety Committee

It will be of importance that all holders regardless of category are supportive regarding the implementation of the Regulations. Consequently the system must be seen as being fair and transparent and holders must have confidence in the system.

The Task Force has identified a possible conflict of interest in relation to the HSE functions covering all holders on the one hand and the fact that the HSE itself is the

"owner" (holder) of radiological equipment in the public sector. In addition this issue was also raised by some of the stakeholders in discussion.

The Task Force is of the view that these issues could be dealt with, if many of the functions of the Medical and Dental Councils outlined in the Regulations and the responsibility of the Chief Executive Officer of the HSE in relation to audit transferred to the Health Information and Quality Authority (HIQA). In this regard it is of note that HIQA was not in existence when the legislation was introduced. It is recognised that the foregoing would require an amendment to the Regulations.

It is envisaged that the Medical and Dental Councils will remain responsible for the educational requirements of medical and dental practitioners, prescribing and performing medical ionising procedures and maintenance of standards. It is also envisaged that the Medical and Dental Councils, together with the Faculty of Radiologists, will have a role in relation to ongoing review and sanctioning of current and new practices.

Representatives of the Task Force had a meeting with HIQA in June 2007. Arising from this meeting it appears that HIQA would be willing to assume responsibility of the co-ordination of the development of standards for ionising radiation safety, subject to appropriate amendment to the Statutory Instrument. Obviously this could not be done within a timeframe that would allow for Health Information and Quality Authority to oversee an audit in 2007. HIQA indicated that they would see a 10-month development process and consequently might not be in a position to complete the standards until the latter half of 2008. They indicated that they could only see things moving forward if the HSE resourced a suitably qualified and experienced person to work with HIQA to manage the project in the short term. They indicated that in the interim they would be happy to work with the Task Force.

It is recommended that the medical ionising regulations be amended to designate HIQA as the competent authority in relation to the setting of standards, ensuring that the regulations are complied with and ensuring that a local clinical audit is carried out at regular intervals in a sufficiently rigorous manner and meets required standards.

It is recommended that the amending legislation in relation to the designating HIQA as the competent authority be expedited.

HIQA clarified that they will set their own standards and will involve appropriate expertise. As a consequence they request the HSE to provide a person to project manage the process with them.

It is recommended that in the short term HSE second a suitably experienced person member to HIQA to project manage the necessary developments.

If the proposals as outlined above are accepted and moved on with reasonable speed it would probably be late 2008 before standards development would be completed and well into 2009 before HIQA would be fully functional in relation to monitoring standards in relation to clinical audit and compliance with regulations.

Current legislation requires an initial audit to be undertaken by Autumn 2007, and the Task Force in its interim report **recommended that the HSE conduct an initial base line audit by questionnaire.** Consequently, a small sub-group with appropriate expertise was established to draw up the necessary questionnaire. A firm of consultants was engaged for a limited number of daily sessions to aid the sub-group and analyse and report on the results of the questionnaire. The questionnaire for radiology and radiotherapy was issued in December 2007. A dental questionnaire will issue in early 2008.

Having regard to the report of the Task Force sub-group that looked at a clinical audit framework and the presentations and information that the experts from Finland and the UK presented to the Task Force, it is the view that, in the first instance, clinical audit should be carried out at local level (a self audit process with institutions) with some independent external input.

Over and above that, it is recommended that HIQA should set and regularly review standards, ensure that regulations are complied with and ensure that the local clinical audit is sufficiently rigorous and meets the required standards. Stakeholders identified a significant issue in relation to releasing people for audit work and a significant time commitment for individual practitioners, particularly private clinicians such as dentists etc. In addition capital costs may be significant.

It is recommended that the audit process should be conducted at local level (primarily self audit) with some independent, external input.

It is recommended that radiological departments carry out regular, routine self-audit.

The Task Force is strongly of the view that audit in relation to the use of medical ionising radiation should be a multidisciplinary process. Ideally, for this purpose, a multidisciplinary team should be established which should include as appropriate radiologists/radiation oncologists/dentist, radiographer/dental nurse, medical physicist, non-radiological consultants using radiological equipment as appropriate and senior management.

It is recommended that an appropriate multi-disciplinary audit process for medical ionising radiation protection should be established in all relevant institutions.

It is recommended that smaller institutions with limited facilities should have formal links with the audit process to which the practitioner in charge is associated.

It is recognised that an adequate audit system needs to be ongoing and thus can be time consuming. This should be recognised and allowed for in contracts of employment.

It is recommended that relevant staff should have senior management support and necessary resources, together with specific, protected time to carry out their

responsibilities and functions in relation to clinical audit and to allow the holder meet statutory requirements.

Apart from the audit, current legislation requires the HSE to establish and maintain a register of holders of medical ionising equipment. In addition the HSE is required to establish a national radiological safety committee.

In relation to the register, the Radiological Protection Institute of Ireland (RPII) is the body that licenses holders of ionising equipment to have custody and charge of medical ionising radiation equipment. As part of this exercise they gather information, some of which would be of value to the HSE in fulfilling its role. In regard to this matter with both the HSE and the RPII having some similar requirements including holding a register, this could lead to much duplication and unnecessary waste of effort. Representatives of the Task Force had discussions with the RPII following which a process was put in place to allow for the ongoing transfer of appropriate relevant data between HSE and Radiation Protection Institute of Ireland. The HSE now holds a register of installations with ionising equipment.

Under the legislation, the CEO of the HSE is required to establish a National Radiological Safety Committee, which will advise the CEO on relevant matters relating to medical ionising radiation and will monitor the population dosage. Again this is an area where there is potential for conflicts of interest. However, the Task Force is of the view that, initially at least, the HSE should establish and resource this committee. In forming the view that this committee should be established by HSE, the Task Force were strongly influenced by the fact that HSE is responsible for public health and that an important function of the committee will be monitoring the overall population dose of medical ionising radiation.

It is recommended that the National Radiation Safety Committee (NRSC) should be titled, "Medical Exposure Radiation Committee" (MERC) and that legislation be amended accordingly. *

(*Medical Exposures Radiation Committee (MERC) is the term that will be used for the remainder of this report.)

It is recommended that the functions of MERC should include:

Monitor the population radiation dose arising from medical uses of radiation.
To receive reports in relation to radiation incidents
To define what are major and minor incidents
To promote education in relation to the use of medical ionising radiation, including education of the public
To advise on, facilitate and monitor appropriate training
MERC should be advised where equipment is in use that is past its due date of replacement.
To advise the CEO on appropriate matters relating to radiation protection.
To produce an annual report for the CEO, HSE.

It is recommended that the membership of MERC should not exceed 12 in number.

It is recommended that the membership of MERC should consist of a chairperson and includes the following:

Consultant Radiologist
Superintendent Radiographer
Consultant Radiation Oncologist
Medical Physicist
Dental Practitioner
Consultant in Public Health Medicine
Health Service Management, Public Sector
Health Service Manager, Private Sector
Prescriber
Representative from Radiation Protection Institute of Ireland

As the committee will be coming in to possession of sensitive information from both public and private sector, it is important that it operates to the highest standards of practice and consequently **it is recommended that the committee have an ethical code of practice which should be published. It is further recommended that the membership and working of the committee be covered by a confidentiality clause.**

It is recommended that the one of the first tasks of the MERC be to consider the analysis/report arising from the baseline, questionnaire-based, initial audit.

It appears that there is no explicit arrangement in the legislation for dealing with Major and Minor Incidents involving ionising radiation. It should be mandatory for holders of equipment and employers to report, on a no blame basis, all ionising radiation incidents, major and minor.

It is recommended that all medical ionising radiation *major incidents* should be reported to HIQA and copied to the CEO of the HSE and copied to the Medical Exposure Radiation Committee

It is recommended that all medical ionising radiation *minor incidents* should be reported to the CEO of the HSE and copied to the Medical Exposure Radiation Committee. In turn either should report the matter to HIQA, if thought appropriate.

The Task Force understands that when HIQA carries out inspections it is normal practice to give a report to the institution concerned together with a work-plan to rectify any deficiency within an agreed timeframe.

It is recommended that HIQA reports relating to medical ionising radiation protection should be copied to the Medical Exposure Radiation Committee.

The Medical Exposure Radiation Committee has an important role as set out in legislation, including advisory and monitoring population dosage. If it is to function adequately, it will require appropriate support, both professional and administrative. The HSE should establish a specific office or unit to support its functions relating to

medical ionising radiation protection including the development and maintenance of a register of medical radiological installations and support of the Medical Exposure Radiation Committee.

It is recommended the HSE establish a dedicated office to support it in respect of its functions in relation to medical ionising protection legislation. Such an office should have available to it the services of a medical physicist, a radiographer and other appropriate professional and administrative staff.

Legislation assigns important functions to Medical Physicists. It requires that a Medical Physicist be assigned whole time or part time by the holder. The definition of a Medical Physicist being, an expert in radiation physics or radiation technology applied to exposure, whose training and competence to act is recognised by a competent authority.

The Task Force had been made aware that there is an inadequate number of trained Medical Physicists available in the country. For the purposes of meeting obligations under the new legislation there is a significant shortfall in relation to Medical Physicists requirements. Training in this area is post-graduate and for a duration of 2 years. There is urgency in getting more Medical Physicists into the system.

It is recommended that, in the short term, the HSE support a 2 year training scheme for Medical Physicists with at least 6 posts per annum until such time as adequate numbers are available to the service.

It is recommended that Medical Physicists should be state registered with the Statutory Board for Health and Social Care Professionals and this is a matter that should be expedited.

It is recommended that the HSE and Department of Health and Children consider the requirements for the number of medical physicists for the future in its workforce planning framework.

Resulting from meetings with various stakeholders it is apparent that there are some important players who have a limited understanding of their obligations in relation to this legislation. There is a need for an information/communication exercise involving stakeholders and professionals and other involved in relevant service delivery.

It had been the intention of the Task Force to hold a series of information/communication meetings around the country prior to completing the final report. However, difficulties arose in undertaking such an exercise in late 2007. The Task Force consider the undertaking of an information/communication exercise to be essential.

It is recommended that an information/communications exercise in relation to obligations and responsibilities relating to the legislation be undertaken at a number of locations throughout the country during 2008.

<u>Other recommendations:</u>

The Task Force see it as essential that all those using medical ionising radiation equipment should have appropriate training and keep up to date in relation to same.

It is recommended that all non-radiological specialists using ionising radiation equipment should have appropriate training and certification and be required to keep up to date. This should be a requirement of their contract and also should be part of the audit requirement.

As the availability of other diagnostic imaging equipment can influence the use of ionising radiation equipment, it is recommended that an inventory of non-ionising radiation imaging equipment be included in an assessment of best practice for diagnostic imaging.

It is recommended that legislation be updated to support enforcement in relation to those not legally entitled to provide radiology services.

Clinical engineers are often involved in work involving medical ionising in state registration under the Statutory Board for Health and Social Care Professionals.

It is recommended that Clinical Engineers should be state registered with the Statutory Board for Health and Social Care Professionals.

Legislation should require that servicing of medical ionising radiation equipment be only carried out by appropriately trained staff.

It is recommended that the Dental Council make it mandatory for dental practitioners to attend appropriate training courses on an ongoing basis in relation to dental radiology.

It is recognised that it will take time to give effect to some of the recommendations contained in this report and their implementation is dependent upon legislative change and the cooperation of stakeholders involved. A transition committee should be established on a temporary basis to oversee changes in stakeholder responsibility in moving from the existing legislation to the proposed amended legislations taking in to account the recommendations of the Task Force.

It is recommended that a transition committee be established to include representatives of HSE, HIQA, IMC, DOHC, and IDC.

During the course of discussion with a number of stakeholders, concern was expressed about the involvement of nurses as prescribers. One of the stakeholders that met with representatives of the Task Force was An Bord Altranais. The Task Force members who met with this group were impressed at the proposed level of training that nurses would have to undertake before they could act as prescribers in this regard.

It is recommended that nurses who prescribe radiological procedures should have completed a recognised training course which is approved by An Bord Altranais and has the support of the Faculty of Radiologists.

The Task Force were advised that, where non-radiological specialists carry out radiological procedures and the radiographers are required to be in attendance, their role can be unclear. The Task Force is of the view that where such procedures are carried out radiographers have an important role in ensuring that radiation protection measures are in accordance with agreed protocols.

It is recommended that, for radiological procedures carried out by non-radiological specialists, the attending radiographer and clinically responsible practitioner should ensure that radiation protection measures are in accordance with agreed protocols during the procedure.

Representatives of the radiographers who met with the Task Force expressed the view that radiographers should be approved as prescribers. This was considered by the Task Force and the Task Force is aware of the facility of section 14.4 (SI 478 (2002)) which allows for a practitioner to accept an x-ray referral from a non prescriber. This would allow for local arrangements to be put in place within institutions which would facilitate radiographers in relation to ordering x-ray examination or additional exposures where they consider this appropriate.

It is recommended that radiologists should consider making use of the section 14.4 facility within specific institutions where they consider this appropriate to allow radiographers use their professional judgment in relation to the taking of alternative or additional images.

The Task Force is aware that the Department of Health is awaiting the final report before considering amending Regulations to involve HIQA in the process, as per recommendations. As a consequence there was a desire to submit the report in a timely fashion. However, it is recognised that there are still several issues that require attention.

In the past, Radiation Safety Committees operated at local Health Board level. In addition to the structures as set out in this report, the Task Force recognises that there could be advantages in having a number of such committees at regional level. Some thought needs to be given to the precise numbers of such committees and their function.

It is recognised that the application of the Regulations is going to cause some difficulties, particularly for single handed dental practitioners. This is a matter that may need further consideration. The baseline questionnaire being issued to dental practices in early 2008 should provide information that will be of value in this regard for the future.

It is suggested that these several matters be considered, either by the Task Force being asked for an additional report, a new group formed for the purpose, or by the Medical Exposures Radiation Committee

HSE TASK FORCE - LIST OF RECOMMENDATIONS

It is recommended that the medical ionising regulations be amended to designate HIQA as the competent authority in relation to the setting of standards, ensuring that the regulations are complied with and ensuring that a local clinical audit is carried out at regular intervals in a sufficiently rigorous manner and meets required standards.

It is recommended that the amending legislation in relation to the designating HIQA as the competent authority be expedited.

It is recommended that in the short term HSE second a suitably experienced person member to HIQA to project manage the necessary developments.

The Task Force in its interim report **recommended that the HSE conduct an initial base line audit by questionnaire.**

It is recommended that the audit process should be conducted at local level (primarily self audit) with some independent, external input.

It is recommended that radiological departments carry out regular, routine self-audit.

It is recommended that an appropriate multi-disciplinary audit process for medical ionising radiation protection should be established in all relevant institutions.

It is recommended that smaller institutions with limited facilities should have formal links with the audit process to which the practitioner in charge is associated.

It is recommended that relevant staff should have senior management support and necessary resources, together with specific, protected time to carry out their responsibilities and functions in relation to clinical audit and to allow the holder meet statutory requirements.

It is recommended that the National Radiation Safety Committee (NRSC) should be titled, "Medical Exposure Radiation Committee" (MERC) and that legislation be amended accordingly. *

(*Medical Exposures Radiation Committee (MERC) is the term that will be used for the remainder of this report.)

It is recommended that the functions of MERC should include:

Monitor the population radiation dose arising from medical uses of radiation.
To receive reports in relation to radiation incidents
To define what are major and minor incidents

To promote education in relation to the use of medical ionising radiation, including education of the public
To advise on, facilitate and monitor appropriate training
MERC should be advised where equipment is in use that is past its due date of replacement.
To advise the CEO on appropriate matters relating to radiation protection.
To produce an annual report for the CEO, HSE.

It is recommended that the membership of MERC should not exceed 12 in number.

It is recommended that the membership of MERC should consist of a chairperson and includes the following:

Consultant Radiologist
Superintendent Radiographer
Consultant Radiation Oncologist
Medical Physicist
Dental Practitioner
Consultant in Public Health Medicine
Health Service Management, Public Sector
Health Service Manager, Private Sector
Prescriber
Representative from Radiation Protection Institute of Ireland

It is recommended that the committee have an ethical code of practice which should be published. It is further recommended that the membership and working of the committee be covered by a confidentiality clause.

It is recommended that the one of the first tasks of the MERC be to consider the analysis/report arising from the baseline, questionnaire-based, initial audit.

It is recommended that all medical ionising radiation *major incidents* should be reported to HIQA and copied to the CEO of the HSE and copied to the Medical Exposure Radiation Committee

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It is recommended that HIQA reports relating to medical ionising radiation protection should be copied to the Medical Exposure Radiation Committee.

It is recommended the HSE establish a dedicated office to support it in respect of its functions in relation to medical ionising protection legislation. Such an office should have available to it the services of a medical physicist, a radiographer and other appropriate professional and administrative staff.

It is recommended that, in the short term, the HSE support a 2 year training scheme for Medical Physicists with at least 6 posts per annum until such time as adequate numbers are available to the service.

It is recommended that Medical Physicists should be state registered with the Statutory Board for Health and Social Care Professionals and this is a matter that should be expedited.

It is recommended that the HSE and Department of Health and Children consider the requirements for the number of medical physicists for the future in its workforce planning framework.

It is recommended that an information/communications exercise in relation to obligations and responsibilities relating to the legislation be undertaken at a number of locations throughout the country during 2008.

It is recommended that all non-radiological specialists using ionising radiation equipment should have appropriate training and certification and be required to keep up to date. This should be a requirement of their contract and also should be part of the audit requirement.

As the availability of other diagnostic imaging equipment can influence the use of ionising radiation equipment, it is recommended that an inventory of non-ionising radiation imaging equipment be included in an assessment of best practice for diagnostic imaging.

It is recommended that legislation be updated to support enforcement in relation to those not legally entitled to provide radiology services.

It is recommended that Clinical Engineers should be state registered with the Statutory Board for Health and Social Care Professionals.

Legislation should require that servicing of medical ionising radiation equipment be only carried out by appropriately trained staff.

It is recommended that the Dental Council make it mandatory for dental practitioners to attend appropriate training courses on an ongoing basis in relation to dental radiology.

It is recommended that a transition committee be established to include representatives of HSE, HIQA, IMC, DOHC, and IDC.

It is recommended that nurses that prescribe radiological procedures should have completed a prescribed training course which is approved by An Bord Altranais and has the support of the Faculty of Radiologists.

It is recommended that, for radiological procedures carried out by non-radiological specialists, the attending radiographer and clinically responsible practitioner should ensure that radiation protection measures are in accordance with agreed protocols during the procedure.

It is recommended that radiologists should consider making use of the section 14.4 facility within specific institutions where they consider this appropriate to allow radiographers use their professional judgment in relation to the taking of alternative or additional images.

Appendix 1, TASK FORCE MEMBERSHIP

Dr. Brian P. O'Herlihy	Director of Public Health, HSE; ***Chair of Task Force***
Michael Lyons	CEO, The Adelaide and Meath Hospital Dublin, Incorporating The National Children's Hospital, Tallaght, Dublin 24
Dr. Sheelah Ryan	Chair, National Cancer Screening Service
Dr Michael Hurley	Radiologist & Clinical Lecturer, Cork University Hospital and University College Cork, Board Member ,Medical Council & Chairman - Medical Ionising Radiation Committee, Medical Council, Board Member - Radiological Protection Institute Ireland
Wilfrid Higgins	Principal Engineer, Estates Management, HSE, formerly Department of Health and Children
Prof. Wil van der Putten	Chief Physicist and Registered Radiation Protection Advisor, Health Service Executive West, Hon. Professor in Medical Physics, NUI Galway, member of the Medical Devices Advisory Group of the Irish Medicines Board (stepped down from Task Force June 2007)
Dr Stephen Fennell	Manager of Medical, Dental & Veterinary Section of RPII's Regulatory Services Division, Medical Radiation Advisory Committee, RPII, Member - Medical Ionising Radiation Committee, Medical Council, Member European ALARA Network Steering Group, Chairman of European Radiation Protection Authorities Network
Dr. Stephanie Ryan	Radiologist, Children's University Hospital, Temple St. Faculty of Radiologists and Member - Medical Ionising Radiation Committee, Medical Council.
Bernadette Moran	Radiography Services Manager, St James's Hospital, Dublin 8
Dr. David Clarke	Principal Dental Surgeon, HSE
Dr. Michael Moriarty	Radiation Oncologist, Saint Vincent's Private Hospital, Department of Radiotherapy; formerly St. Luke's Hospital, Dublin 6
Paddy Gilligan	Medical Physicist, Mater Private Hospital, Board RPII and Member - Medical Ionising Radiation Committee, Medical Council
Dr. Donal McDonnell	Consultant in Oral Radiology University Dental School & Hospital Cork
Derek Greene	CEO, National Rehabilitation Hospital and Chair, Dublin Risk Management Forum Radiation Forum Standing Committee
Triona Fortune	Health Care Quality Manager, Health Information and Quality Authority
John Lamont	Registrar, Irish Medical Council
Karen Willis	SEO, Irish Medical Council, Secretary to Medical Ionising Radiation Committee - Medical Council
Cathleen O'Neill	Medical Physicist, University College Hospital, Galway
Prof. Neil O'Hare	Project Lead – National PACS Project, HSE
Dr Ronan Ryan	Consultant Radiologist Mayo General Hospital Castlebar, Board Member & Chairman of Radiation Protection Committee, Faculty of Radiologists, R.C.S.I
Erik Koornneef	Project Manager, Health Information and Quality Authority, (appointed Task Force December 2007)
Maire Ni Aonghusa	Radiography Services Manager, Waterford Regional Hospital (appointed to Task Force December 2007.)
Ciara Norton	Senior Manager, Environmental Health, Population Health; ***Secretary to Task Force***
Vera Furness	Senior Administrative Assistant, Environmental Health, Population Health

Appendix 2

Additional members co-opted to sub groups and procurement group:

Yvonne Davidson	National Programme for Radiation Oncology, Cork
Niall Phelan	Medical Physicist, National Breast Screening Programme
Suzanne Dennan	A/Radiography Services Manager, St James's Hospital Dublin
Dr Eamon Croke	Dental Practitioner Dublin.
Angela McGovern	Radiography Services Manager Cork University Hospital, Irish Institute of Radiographers, St Mary's Orthopaedic Hospital, St Finbarr's Hospital
Michael Casey	Medical Physicist, St Vincent's University Hospital, Dublin
Gerry O'Dwyer	Network Manager, HSE South
Anne McMenamin	Beaumont Hospital, Chair of Radiography Services Managers Association, Member NIMIS Project Board
Dr Geraldine O'Reilly	Medical Physicist, St James's Hospital Dublin
Maurice Fitzgerald	Private Dentist, Sligo
Nick Armstrong	A/Principal Dental Surgeon, HSE
Dr Jane Renehan	Principal Dental Surgeon Dublin, Lead Responsibility for Quality & Audit, Health & Safety, Radiation Safety & Continuing Professional Development Dublin North East, Member National Radiation Safety Committee.
Brendan White	Assistant Head of Portfolio & Category Management, HSE Procurement, Kilkenny
Ann Marie Murphy	Procurement, HSE
Prof. Peter McCarthy	Dean Faculty of Radiologists/Prof of Radiology NUI Galway, Member of NACMET, NIMIS
Michael Flynn	Internal Audit, HSE
Mairin Ryan	Health Information and Quality Authority
Maureen Windle	Former CEO, Northern Area Health Board
Fergus Neilson	Quality Assurance Reference Centre, UK
Gemma Lewis	Quality Assurance Reference Centre, UK

Appendix 3

List of stakeholders invited to meet Task Force – July – November 2007*

Fintan Bradley	Irish Radiotherapy Physics Group (IRPG)
Finbar Fitzpatrick	General Secretary, Irish Hospital Consultants Association
Prof Peter McCarthy	Dean, Faculty of Radiologists/Prof of Radiology NUI Galway, Member of NACMET and NIMIS.
Dr. Barry McMahon	Chairperson, Association of Physical Scientists in Medicine
Dr. Geraldine O'Reilly	Representative, Assocation of Physical Scientists in Medicine
Dr. dara Murphy	Convenor Radiation Protection Special Interest Group, Association of Physical Scientists in Medicine
Dr Mark McEntee	President, Irish Institute of Radiography and Radiation Therapy
Ciara Murphy	CEO, Irish Dental Association
Dr Anthony Coughlan	President, Orthodontic Society of Ireland
Dr Ailish Quinlan	Clinical Indemnity Scheme
Fionan O'Cuinneagain	Chief Executive, Irish College of General Practitioners
Dr Paula Gilvarry	President, Irish Medical Organisation
Ann McMenamin	Radiography Services Managers
Anna Rochford	Radiotherapy Services Managers
Dr. Danny O'Hare	Chairman, Independent Hospitals Association of Ireland
Dr. Ann McGarry	CEO, Radiological Protection Institute of Ireland (RPII)
John Mahady	Biomedical Engineering Division of Engineers Ireland
Meabh Smith	Clinical Engineering Voluntary Registration Board
Patrick Pentony	Clinical Engineering Voluntary Registration Board
Bernard Murphy	Biomedical Engineering Division, Engineers Ireland
Kevin Figgis	SIPTU
Liam Doran	General Secretary, Irish Nurses' Organisation
Kevin Callinan	National Secretary, IMPACT
Eugene Donoghue	CEO, An Bord Altranais

****A number of the above were unable to attend and were invited to make written submissions.***