

Health Service Executive



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Quality Assurance Reference Centre
North East, Yorkshire and The Humber

**Formal Baseline Clinical Audit of Current Practice in Medical Ionising Radiation Protection
as required under Statutory Instrument 478 (2002)**

A Report to the Health Service Executive's Taskforce on the Implementation of the SI 478.

Survey Period: December 2007 to April 2008

Survey 1 of 3: Radiology & Nuclear Medicine

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Executive Summary

Three separate surveys have been undertaken to ascertain compliance with the Statutory Instrument (SI) 478 (2002) and its amendment SI 303 (2007), which cover the arrangements for clinical audit, justification and optimisation of ionising radiation equipment in medicine and dentistry. The three surveys deal with the separate areas of Radiology & Nuclear Medicine, Radiotherapy and Dentistry. This is the report on the Radiology survey.

All holders of ionising radiation equipment were identified by the register held by the Radiation Protection Institute of Ireland.

The range of responses provided has been impressive, given that this was a large questionnaire. In general, it is clear that the organisations which hold and use ionising radiation equipment for medical purposes are committed to the principles of the SI 478, which is to minimise the radiation dose given to the patient population, whilst maximising the benefits of the diagnostic information and treatments it brings.

As far as the authors of this report are aware, this survey is at the forefront of work in this area compared to other European countries. No other country has published or is known to be undertaking such a comprehensive survey of adherence to this important public health legislation.

The survey findings indicate that there are a number of challenges to the institutions, which hold or oversee the use of ionising radiation equipment. Actions are recommended for The HSE, the HSE's National Radiation Safety Committee, Holders of ionising radiation equipment and the Radiation Protection Institute for Ireland.

Main Findings

One hundred and fourteen organisations out of 125 (91%) responded to the survey. These organisations collectively deliver over three million patient exposures each year. The average is approximately 31,200 per organisation, but the range is very wide from 50 to 263,000 exposures per organisation.

Clinical audit in radiology, which is a requirement of SI 478, is in its early stages in many organisations. There are several issues related to lack of resources to undertake this work, but primarily, it appears that there is uncertainty about exactly how clinical audit in the context of ionising radiation should be undertaken. To address these weaknesses, further resources and initiatives at both a national and a local level will be required to ensure that it is properly embedded in the practice of all organisations, which hold ionising radiation equipment.

Quality improvement initiatives and structures to support them are not well embedded in all organisations.

The structures to support the local Radiation Safety Committees are, in most cases, satisfactory. However, there are some organisations, which appear not to be fulfilling their legal obligations in this respect. This needs to be addressed.

The review of SI 478/303 through these surveys has highlighted an issue, which needs to be resolved in terms of clarifying accountabilities and delegated responsibilities in relation to the National and the local Radiation Safety Committees. The HSE, the National Radiation Safety Committee and the Radiation Protection Institute of Ireland should work together to clarify and resolve and provide guidance on any issues with these governance arrangements.

Most organisations have satisfactory arrangements for referral, prescription, justification and optimization of ionising radiation procedures. Some recommendations have been made where there are concerns about the complete adherence to the requirements of the SI 478 in some organisations.

It is important for the HSE to listen to the comments from the organisations which have responsibilities for implementing SI 478 and for the HSE to continue to provide the leadership, which it has started with the establishment of the National Radiation Safety Committee and the commissioning of this baseline survey.

Key Recommendations

Forty recommendations have been made, with seventeen of those of the highest importance indicated at the beginning of the list.

Where necessary, lists of the organisations in question have been passed to the HSE to begin to address the issues prior to this report being published.

List of Recommendations

Recommendation	Priority	For the Attention of
1. Given that the survey returns were not signed in every case by both the Chief Executive/General Manager and the Practitioner in Charge, 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.	High	HSE & National Radiation Safety Committee
2. Any organisation that does not have a Practitioner in Charge (18%) and/or Radiation Protection Advisor (4%) should make an appointment forthwith.	High	Holders of ionising radiation equipment and to be monitored by the Radiation Protection Institute of Ireland
3. Any Organisation, which has been given approval by the Department for Health and Children to appoint a Radiation Safety Officer and has not done so, should make an appointment forthwith.	High	Holders of ionising radiation equipment and to be monitored by the HSE
4. A list of those organisations, which apparently do not meet their legal requirements to have a Radiation Safety Committee or relate to a regional Radiation Safety committee (19%), has been passed to the HSE, so that this can be addressed by the Radiation Protection Institute of Ireland.	High	HSE and Radiation Protection Institute of Ireland
5. A list of organisations, which did not answer Yes to the question “Do the Terms of Reference of this Radiation Safety Committee cover the requirements of the RPII and SI 125?” (21%) has been passed to the HSE. The HSE should pass this list to the Radiation Protection Institute of Ireland so that this can be addressed in each case.	High	HSE and Radiation Protection Institute of Ireland
6. The HSE should contact each organisation which did not answer “Yes in all aspects” to questions D15 (20%) and D16 (24%), which are around the proper records for making prescriptions for medical procedures which use ionising radiation. There may be legal consequences for those organisations, where there is no recorded prescription.	High	HSE

Recommendation	Priority	For the Attention of
7. Those organisations which have equipment which, it appears, is not checked by a medical physicist after major (21%) should do so urgently, as this is a legal requirement.	High	Each relevant organisation (HSE should re-audit those organisations)
8. A replacement date should be set for every installation. All organisations should check their records for each item of equipment to confirm that a date has been set or to set a replacement date where none exists. This is a legal requirement.	High	All holders of ionising radiation equipment.
9. Any installation used beyond its replacement date should be certified for continued use, taking into account issues of justification and optimisation. All organisations should check their records for each installation which is being used beyond its replacement date and seek urgent certification in this respect. This is a legal requirement. The HSE should clarify the mechanism for certification in this respect.	High	HSE and ALL holders of ionising radiation equipment
10. It is recommended that the HSE follow up the organisations, which did not respond to the survey (9%). It is possible that the reason for non-response may indicate some issues of concern about compliance with SI 478. It also may indicate a problem with the accuracy of the Radiation Protection Institute of Irelands records.	High	HSE
11. The HSE should review those organisations which undertake less than 300 exposures per year (4%).	High	HSE
12. The HSE should review the organisation which stated that it undertakes 50,000 exposures per year in only two fluoroscopy rooms. This does not seem feasible.	High	HSE
13. Any organisation which answered “No” or provided no answer to questions D1 (9%), D2 (7%) or D11 (11%) on issues of written documentation or records should review this urgently and make the necessary improvements.	High	All holders of ionising radiation equipment
14. Any organisation indicating that it does undertake procedures for an occupational health surveillance scheme, but does not have clear indication from the Medical or Dental Councils and the National Authority for Occupational Safety and Health that it is safe to do so (20%) should desist from undertaking these procedures immediately and review its arrangements.	High	All holders of ionising radiation equipment

Recommendation	Priority	For the Attention of
15. Organisations conducting research projects/clinical trials that involve the use of ionising radiation exposures, but which could not answer “Yes” to questions 47.1 through to 47.7, should review their arrangements urgently.	High	All holders of ionising radiation equipment
16. All women who are of child bearing age should be asked if they may be pregnant or, in nuclear medicine, if they are breastfeeding. Any organisation which was not able to answer “Yes in all aspects” to questions D40 (17%) and D41 (13%) should review and improve their arrangements in this respect urgently.	High	All holders of ionising radiation equipment
17. It is assumed that the Porters, Administrators, Health Care Assistants, Biochemist and Dark Room Attendant are not given responsibilities for justifying or undertaking ionising radiation procedures, but have been listed for completeness by the respondents, due to a misunderstanding of the question asked. The HSE should investigate the responses given by those organisations with staff that may not be legally qualified to undertake ionising radiation procedures. This list has already been sent to the HSE.	High	HSE
18. All organisations which use comforters or carers, who may be exposed during the procedure, should provide written information on the risks and obtain written consent.		
19. The National Radiation Safety Committee should provide guidance which clarifies the distinction between the roles of the Radiation Protection Advisor and the Medical Physics Expert.		HSE & National Radiation Safety Committee
20. 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.		HSE & National Radiation Safety Committee
21. Given the quality of the information provided in this survey, it would be possible in future surveys to gather additional data which would enable the calculation of complete population dose from medical ionising radiation. The National Radiation Safety Committee should ensure that this occurs and that this important public health measure is ascertained.		National Radiation Safety Committee
22. Each organisation which is a holder of ionising radiation equipment for medicine		All holders of ionising radiation equipment

Recommendation	Priority	For the Attention of
should review its committee structure and plans for Clinical Audit.		
23. The HSE with the National Radiation Safety Committee should provide further guidance on Clinical audit structures. Guidance notes and training packages to support the implementation of the legislation should also be considered.		HSE and National Radiation Safety Committee
24. A minimum frequency of local Clinical Audit meetings should be recommended by the HSE and the National Radiation Safety Committee as six monthly for all organisations/locations. These should be formal minuted meetings with clear terms of reference, a forward plan of audits and a clear record of adherence to the audit cycle. Consideration might be given to making recommendations on the choice of clinical audit undertaken, for example high dose procedures, paediatrics and screening programmes.		HSE and National Radiation Safety Committee
25. The Chair role of the Clinical Audit Committee for radiology in each organisation/location should be given its due importance by being an appointment made by the Chief Executive / General Manager of the organisation/location, with a clear remit provided, which sets priorities in terms of a minimum range of audit subject areas to be addressed in the work programme. These subject areas should be chosen on the basis of a risk assessment, which takes into account high dose, high risk or high volume procedures. It is suggested that the National Radiation Safety Committee provide advice to the Chief Executive of the HSE in respect of clarifying the lines of delegated accountabilities for these Clinical Audit and Radiation Safety Committees.		All holders of ionising radiation equipment
26. The HSE via the National Radiation Safety Committee should work with the Medical Council and the Faculty of Radiologists to develop audit criteria further and to build on tools and work undertaken already in this area in other European countries, for example the “100 Recipes for Audit” produced by the Royal College of Radiologists, U.K.		HSE and National Radiation Safety Committee
27. All organisations using ionising radiation equipment should be involved in most of the areas of “quality improvement” which were specified in the Section C of the questionnaire, and should be able to demonstrate this if requested by the HSE.		All holders of ionising radiation equipment

Recommendation	Priority	For the Attention of
<p>28. The authors of the report have wondered whether there is any conflict of interest in a Radiologist being the Chair of the Radiation Safety Committee in a radiology department. The potential conflict lies in the responsibility of the Radiologist to deliver a service, whilst also being responsible for monitoring the safety of that service. It is suggested that this is debated between the National Radiation Safety Committee and the Radiation Protection Institute of Ireland.</p>		
<p>29. The Chief Executive of the HSE should clarify the lines of accountability and allocation of delegated responsibilities for the public hospital Radiation Safety Committees. (The principle behind this issue will apply to the Clinical Audit Committees also)</p>		HSE
<p>30. The National Radiation Safety Committee should work with the Radiation Protection Institute of Ireland to recommend a minimum frequency of meeting of the local or regional Radiation Safety Committees.</p>		National Radiation Safety Committee and Radiation Protection Institute of Ireland
<p>31. The National Radiation Safety Committee should develop some guidance on Risk Management and Incident Handling, which includes guidance on feedback on incidents to professionals both internal to and external to the organisation and to patients or other affected people such as carers. Incident reporting for ionising radiation incidents would benefit from national reporting mechanisms which enabled dissemination of the nature of incidents to a wide range of professionals and organisations.</p>		The National Radiation Safety Committee
<p>32. All organisations should have written protocols to prevent accidental exposures for each installation.</p>		All holders of ionising radiation equipment
<p>33. A medical physicist must be consulted by the practitioner for issues of optimisation, quality control, dose, and the evaluation of patient administered activity for every installation and there should be evidence available to demonstrate this.</p>		All holders of ionising radiation equipment
<p>34. All organisations should review their approach to accepting referrals for ionising radiation procedures. Without a transparent and documented rationale for accepting referrals it is difficult to account for the justification process used.</p>		All holders of ionising radiation equipment

Recommendation	Priority	For the Attention of
35. The National Radiation Safety Committee should issue a clear statement to all holders of ionising radiation equipment about the need to record dose for each procedure and to summarise and audit these records regularly.		The National Radiation Safety Committee
36. Those organisations which could not answer “Yes in all aspects” to question D27 (34%) on the issue of providing written instructions to the patients and carers/guardians who have been subject to radio-nuclides should review their arrangements and make use of existing information and resources on this subject.		All holders of ionising radiation equipment
37. The National Radiation Safety Committee should debate and make a recommendation on what would be considered to be acceptable in Ireland respect of the “availability” of a medical physicist when nuclear medicine procedures are undertaken.		The National Radiation Safety Committee
38. The National Radiation Safety Committee should consider whether the following items of equipment should still be in use and notify each organisation of its conclusions: Cardiac Angio, Cardiac Ultrasound, Computer Tomography (CT), Mammography and Fluoroscopy equipment that are over eight years old.		The National Radiation Safety Committee
39. The National Radiation Safety Committee should consider whether the general X-ray equipment over twelve years old should still be in use and notify each organisation of its conclusions.		The National Radiation Safety Committee
40. The wording of the staff table has misled some respondents. Several respondents have recorded physicians, such as general surgeons as “other staff”, when these should have been recorded in the “Other Physician” column of the questionnaire. Future questionnaires should review the wording in this respect.		National Radiation Safety Committee

Introduction

The Medical Exposure Directive (MED) (97/43/Euratom) deals with the health protection of individuals against the dangers of ionising radiation in relation to medical exposure. The Directive is the main legal instrument dealing with the protection of patients undergoing procedures, which utilise ionising radiation and the protection of comforters or carers of those patients. The MED aims to eliminate the practice of unnecessary medical exposures and thereby reduce dose levels to the population. The MED was transposed into the legislation through Statutory Instrument SI 478 in October 2002 and was updated in 2007 by SI 303.

SI 478 looks at justification, optimisation, clinical responsibility, clinical standards and audit, protocols for procedures and equipment, training and special practices. Justification that the medical benefits outweigh the risks of a procedure and optimisation of radiation dose and the effectiveness of a procedure, are key elements in implementing radiation protection in medicine. There is also a requirement that all installations using ionising radiation perform clinical audit on an ongoing basis. The definition of clinical audit under SI 478 is:

“a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary”.

In essence, a clinical audit should look at the work of all healthcare professionals involved with ionising radiation and all elements of their work that affect justification and optimisation. Currently the Medical and Dental Councils are responsible for providing written protocols on radiology practice. Further information on these standards is available from www.medicalcouncil.ie/medical_ionising_radiation. The Health Service Executive (HSE) is required to monitor the implementation of clinical audit. It has commissioned the Quality Assurance Reference Centre, based in the North East of England, to carry out a questionnaire as an initial stage of this monitoring process.

Method

It was decided to use a questionnaire-based approach to establish a baseline of current compliance and awareness of the regulation for clinical audit. The aim of the questionnaire was to obtain an insight in to the way in which clinical audit and the responsibilities, set out in SI 478, are structured and carried out at local level. The results of this questionnaire will be analysed and used to inform the further development of standards and clinical audit of medical ionising radiation in Ireland.

It is the intention of the HSE, the Medical Council, the Dental Council, the Health Information and the Quality Authority (HIQA) and the National Radiation Safety Committee (NRSC) that this information will contribute to continuous quality improvement for the benefit of the patient. It is

intended that further advice and assistance will be given to organisations to enable them to comply with SI 478 and SI 303.

In the spring of 2007 a taskforce was formed by the HSE to make recommendations on the implementation of SI 478 (and SI 303). The HSE's taskforce on the implementation of SI 478 has commissioned this questionnaire. The membership of the taskforce included representatives from national organisations and from Radiology, Dentistry, Radiography and Medical Physics. The taskforce was dissolved in December 2007 and the new NRSC established by HSE will receive this report of the survey.

The consultancy organisation, the Quality Assurance Reference Centre, was appointed in the summer of 2007. The questionnaires were circulated to all holders of radiological ionising radiation equipment from December 2007 up until the final deadline of April 2008. Results were then collated and analysed in May 2008.

Confidentiality

The questionnaire submissions are treated as confidential. The questionnaires were seen and considered only by the support staff to the NRSC and the Quality Assurance Reference Centre, who analysed the submissions and produced this report for the NRSC and the Chief Executive Officer of HSE. The Chief Executive Officer of the HSE owns the data provided.

Consultancy organisation

Consultancy advice, administration and analysis of this baseline audit were provided by the Quality Assurance Reference Centre for the North East, Yorkshire and The Humber NHS regions of England. This organisation has a long history of providing comprehensive quality assurance services and has a high level of expertise in research and audit in radiation protection.

Commentary on Study Design

In the summer of 2007, the HSE taskforce on ionising radiation and the application of SI 478 requested tenders for an organisation to provide a survey of compliance with SI 478. Its requirement was to set a basic picture of the scope of the use of ionising radiation equipment, adherence to the requirements of SI 478 and in particular to concentrate on the implementation of clinical audit and other governance structures which ensure the appropriate use of ionising radiation equipment in medicine. This survey was designed to do this and at the same time provide some guidance and indication of best practice in this area.

The statutory nature of the survey, which required 100% response rate, should be commented upon. Out of 125 questionnaires sent out, 114 were returned. This is a very high response rate for a survey (91%). It is considered that responses received in such circumstances are less likely to be full and open. However, we were pleased to note that in most cases a good level of response was given, with open and candid comments.

In addition to this, the scope of the requirement for the survey was to assess compliance with SI 478 in context of the provider organisations, and not some of the wider, national organisational

issues which were in the SI 478 to support the implementation. Despite these issues, the survey should be considered to be very successful as it has drawn out a range of areas where further work and need for improvement have been identified. It provides a very strong base for the HSE to work with the provider organisations and opens up a range of issues to be addressed. This work would be considered to be at the forefront in Europe in this respect. Few, if any other EU countries have comprehensive data available on clinical audit and compliance with the Medical Exposures Directive.

Acknowledgements

Many thanks to all the Chief Executives, General Managers, Practitioners, Radiologists, Radiographers, Radiation Protection Advisors, Medical Physics Experts, Radiation Safety Officers, Radiographic Services Managers and all others who contributed to this survey, your participation has been greatly appreciated.

Results

SECTION A: RESPONSE RATE

Commentary

A very high response rate of 114 out of 125 was achieved (91%). This was achieved by a combination of:

- the statutory nature of the requirement to complete the questionnaire
- the request being made to Chief Executives/General Managers
- non-responders were individually followed up by the QARC and by the HSE
- deadline extensions were given up to 3 months after the originally closing date

Despite the extended deadlines, eleven organisations did not respond. These organisations were as follows:

- **Greenlea Clinic, Terenure**
- **Frawley's Pharmacy, Roscrea**
- **T/A Wexford Radiology**
- **Welply Stanley Trust, Millbrook Hospital, Bandon**
- **St Ita's Hospital, Portrane**
- **Brookfield Clinic, Rialto**
- **St Mary's Orthopaedic Hospital, Gurranabraher**
- **Cardinal InHealth Limited, Dublin**
- **St Bricin's Military Hospital, Dublin**
- **St Camillus' Hospital, Limerick**
- **St John of God's Hospital, Wexford**

Recommendation

It is recommended that the HSE contact the organisations, which did not respond to the survey (9%). It is possible that the reason for non-response may indicate some issues of concern about compliance with SI 478. It also may indicate a problem with the accuracy of the Radiation Protection Institute of Ireland's records.

SECTION A: RESPONSIBILITY AND ACCOUNTABILITY FOR IONISING RADIATION IN MEDICINE WITHIN THE ORGANISATIONS

Table 1: Number of questionnaires that were signed off by the CEO/General Manager and/or the Practitioner in Charge.

Responsible Person	Sign-off provided		Sign-off not provided	
	Number	%	Number	%
CEO/General Manager	69/114	61	45/114	39
Practitioner in Charge	65/114	57	49/114	43

Commentary

Thirty six out of 114 organisations did not provide a signature for both the CEO/General Manager and Practitioner in Charge.

It is disappointing that, in a high proportion of cases, the questionnaires were not signed off by those responsible for the application of the SI 478. Application of the SI 478 is an important public health and safety issue with legal requirements and should be taken seriously by holders of ionising radiation equipment.

Recommendation

Given that the survey returns were not signed in every case by both the Chief Executive/General Manager and the Practitioner in Charge, 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.

Table 2: Responsible persons identified

Responsible Person	Yes		No	
	Number	%	Number	%
Practitioner in Charge	94	82	20	18
Radiation Protection Advisor	110	96	4	4
Medical Physics Expert	100	88	14	12
Radiation Safety Officer	98	86	16	14
Radiographic Services Manager	86	75	28	24

Commentary

In total, 114 replies were received. Of these, a large fraction of organisations report they have an appointed Practitioner in Charge, a Radiation Protection Advisor, a Medical Physics Expert, a Radiation Safety Officer and a Radiographic Services Manager. However it is of concern that 20 centres do not have a Practitioner in Charge and four centres didn't have a Radiation Protection: Advisor given that these are legal requirements.

We note that 14 organisations do not have a Medical Physics Expert; we would speculate that the reason for this is that the Radiation Protection Advisor is performing both roles, which is acceptable. Some clarification is needed in these organisations of the distinction between the Radiation Protection Advisor and the Medical Physics Expert roles.

Recommendations

Any organisation that does not have a Practitioner in Charge (18%) and/or Radiation Protection Advisor (4%) should make an appointment forthwith.

Any Organisation, which has been given approval by the Department for Health and Children to appoint a Radiation Safety Officer and has not done so, should make an appointment forthwith.

The National Radiation Safety Committee should provide guidance which clarifies the distinction between the roles of the Radiation Protection Advisor and the Medical Physics Expert.

SECTION B: STAFFING AND WORKLOAD

Staff responsible for justifying or undertaking ionising radiation procedures in your organisation

	Total WTE	Average per organisation	Median per organisation	Maximum per organisation	Minimum per organisation
Radiologists	239.11	2.78	2.00	13.00	0.00
Trainee Radiologists	65.10	1.07	0.00	11.00	0.00
Radiographers	1085.96	11.31	5.30	63.00	0.00
Trainee Radiographers	46.50	0.82	0.00	24.00	0.00
Medical Physicist	85.77	1.23	1.00	10.00	0.00
Interventional Cardiologists	71.80	1.20	0.00	12.00	0.00
Dentist	32.05	0.54	0.00	6.00	0.00
Clinical Engineer	54.35	0.89	0.00	7.00	0.00
Other Physician	194.20	3.18	0.30	30.00	0.00
Other Staff	183.02	3.16	1.00	25.82	0.00

Commentary

This should provide useful workforce planning information for radiology and Medical Physics for the HSE.

One organisation was unable to provide an answer on whole time equivalents of staffing or numbers of exposures in any discipline.

The "Other Staff" were identified. Some of these are of concern as to whether they can be properly qualified to justify or undertake ionising radiation procedures. These have been brought to the attention of the HSE for further enquiry (see list below).

The wording of the staff table has misled some respondents. Several respondents have recorded physicians, such as general surgeons as "Other Staff", when these should have been recorded in the "Other Physician" column of the questionnaire. Future questionnaires should review the wording in this respect.

It is assumed that the Porters, Administrators, Health Care Assistants, Biochemist and Dark Room Attendant are not given responsibilities for justifying or undertaking ionising radiation procedures, but have been listed for completeness by the respondents, due to a misunderstanding of the question asked.

Recommendations

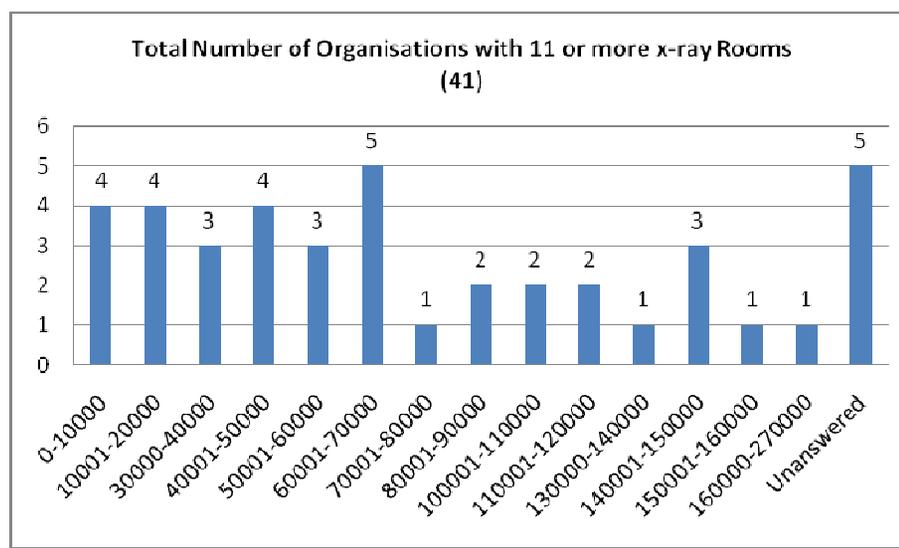
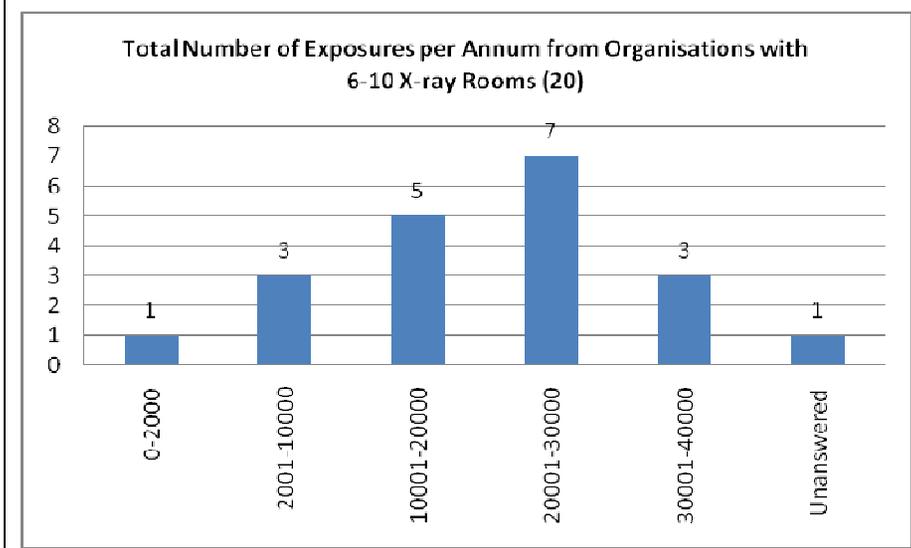
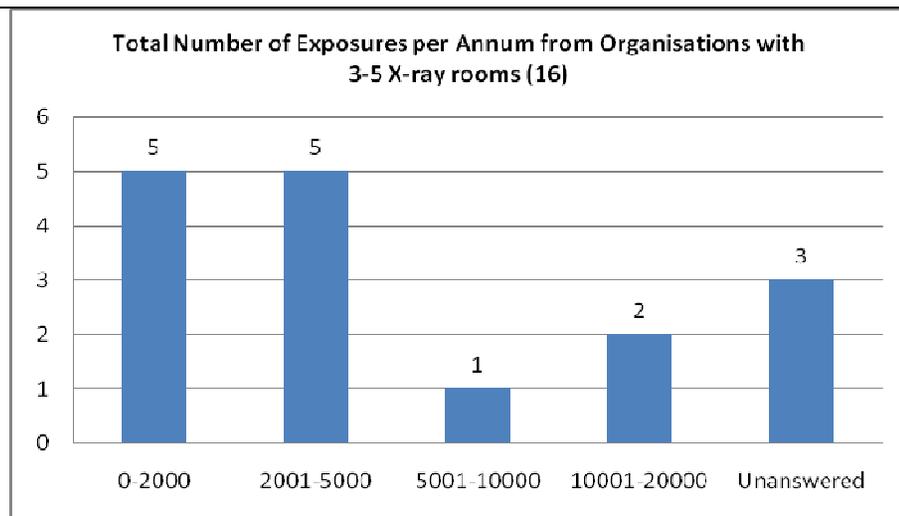
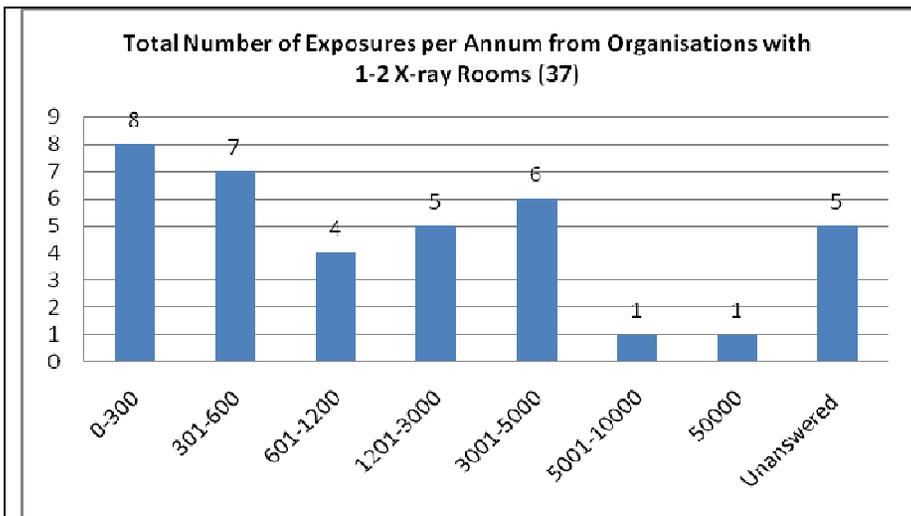
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It is assumed that the Porters, Administrators, Health Care Assistants, Biochemist and Dark Room Attendant are not given responsibilities for justifying or undertaking ionising radiation procedures, but have been listed for completeness by the respondents, due to a misunderstanding of the question asked. The HSE should investigate the responses given by those organisations with staff that may not be legally qualified to undertake Ionising radiation procedures. This list has already been sent to the HSE.

List of “Other” Staff

- **(Needs to be investigated by HSE) “O H N”**
- **(Needs to be investigated by HSE) Administrative staff**
- **(Needs to be investigated by HSE) Biochemist**
- **(Needs to be investigated by HSE) Care Assistant**
- **(Needs to be investigated by HSE) Dark Room Attendant**
- **(Needs to be investigated by HSE) Porter**
- Anaesthetist
- Chest Physicians
- Colorectal surgeon
- DXA Operator/Technician/Nurse
- Endocrinologist
- Gastroenterology
- General Surgeon
- GP
- Haematologist
- Nephrology
- Neuro surgeon
- Nuclear Medicine technologist
- Orthopaedic surgeon
- Radiography Assistants
- Respiratory
- Urologists
- Vascular surgeon

SECTION B (CONTINUED): NUMBERS OF ORGANISATIONS AND NUMBERS OF EXPOSURES TO BE UNDERTAKEN IN A ONE YEAR PERIOD



Summary of number of patient exposures

	WTE	Average	Median	Maximum	Minimum
Patient Exposures	3,121,362	31,213.62	10,995.5	263,600	50

Commentary

The numbers of exposures per X-ray room were basically as would be expected with a range of organisations, using the full range of current ionising radiation procedures.

Given the quality of the information provided in this survey, it would be possible in future surveys to gather additional data which would enable the calculation of complete population dose from medical ionising radiation.

One might be concerned by organisations that only undertake a very small number of procedures. These should be reviewed by the HSE.

Similarly, one might be concerned about an organisation which undertakes an excessively large volume of procedures. One organisation stated that it undertakes 50,000 exposures per year in only two rooms. This does not seem feasible.

Recommendations

Given the quality of the information provided in this survey, it would be possible in future surveys to gather additional data which would enable the calculation of complete population dose from medical ionising radiation. The National Radiation Safety Committee should ensure that this occurs and that this important public health measure is ascertained.

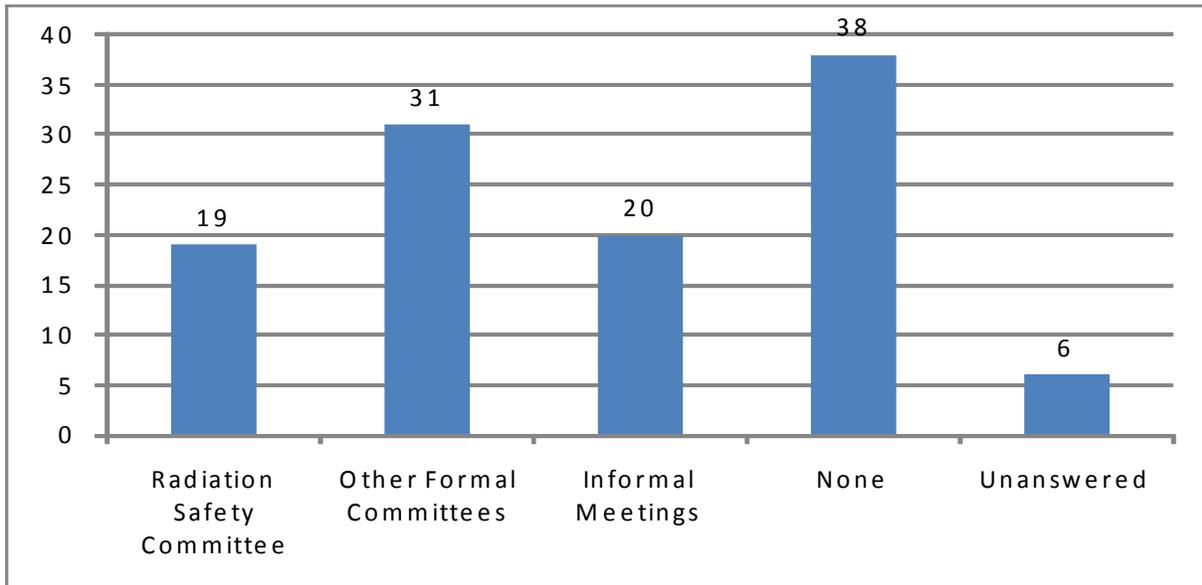
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The HSE should review the organisation which stated that it undertakes 50,000 exposures per year in only two fluoroscopy rooms. This does not seem feasible.

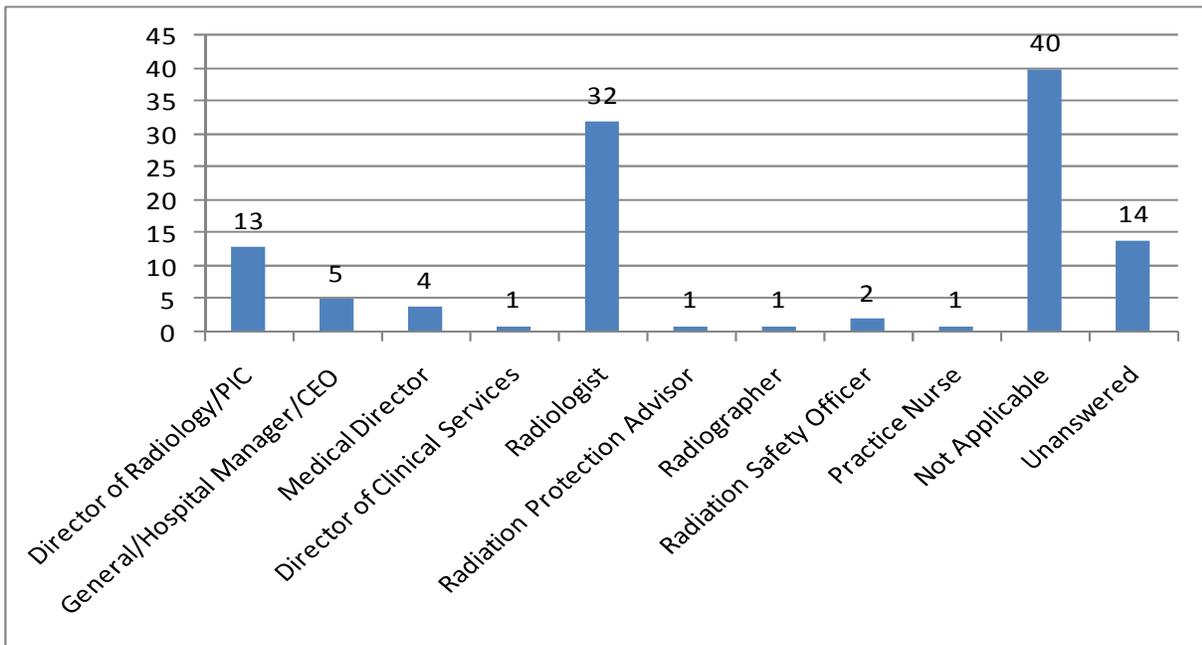
SECTION C: STRUCTURES AND MANAGEMENT ARRANGEMENTS FOR RADIOLOGICAL CLINICAL AUDIT, INCIDENT HANDLING AND RADIATION PROTECTION

Clinical Audit

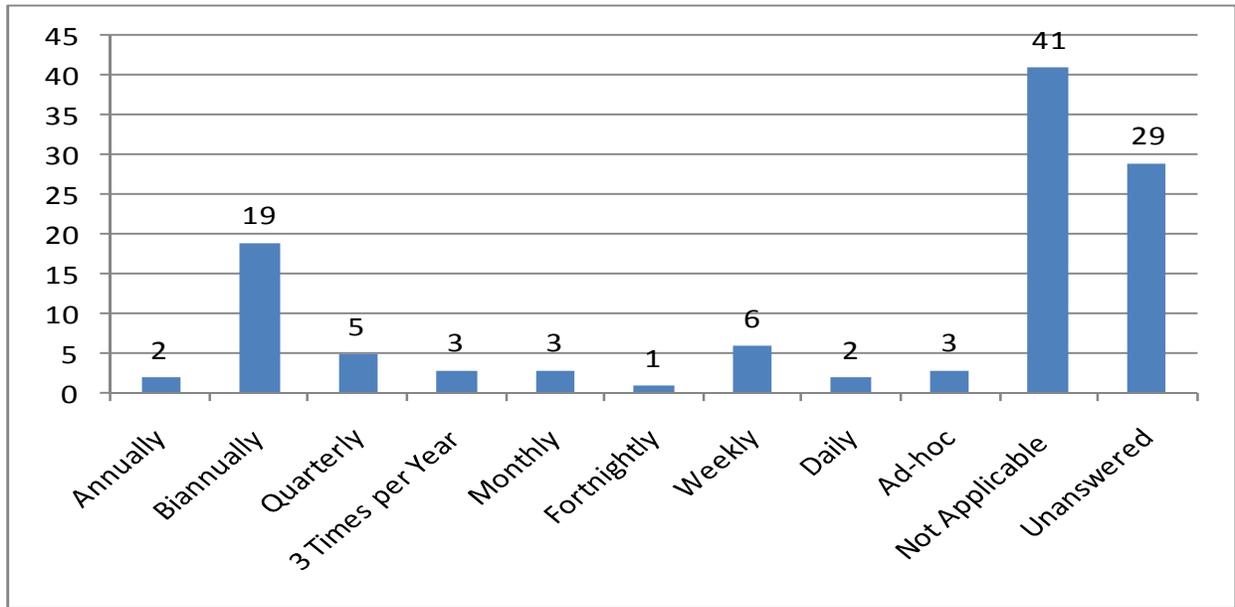
C1. What formal/ informal structures are in place for Radiological clinical audit? (e.g. committees, peer reviews, team meetings etc)



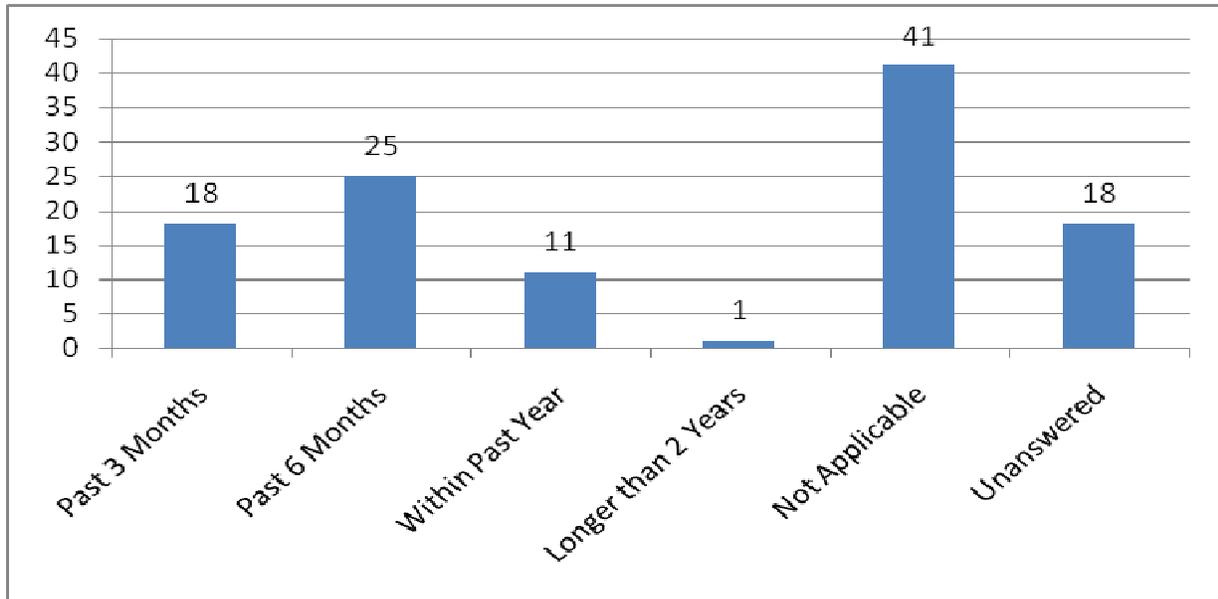
C2. Who has lead responsibility as the Chair of the committee/peer review/team meeting etc?



C4. What is the frequency of meeting?



C5. What was the date of the last meeting?



Commentary

The legal requirement for clinical audit in radiology was a new function introduced in SI 478. Alongside this, a more detailed guidance on the supporting structures and resources needed within organisations has yet to be rolled out. This is reflected in the comments received.

Clinical audit is an important issue which requires due time and interest and it is not appropriate to add this to the agenda of the Radiation Safety Committee, which already has a full range of responsibilities. Clinical audit should be conducted in formal meeting structure.

An optimal **minimum** frequency of local clinical audit meetings would be six monthly in any organisation/location.

The Chair role in the group is important with a need for that person to be assigned the role by the Chief Executive / General Manager of the organisation, with clear remit provided.

Recommendations

Each organisation which is a holder of ionising radiation equipment for medicine should review its committee structure and plans for Clinical Audit.

The HSE with the National Radiation Safety Committee should provide further guidance on Clinical audit structures. Guidance notes and training packages to support the implementation of the legislation should also be considered.

A minimum frequency of local Clinical Audit meetings should be recommended by the HSE and the National Radiation Safety Committee as six monthly for all organisations/locations. These should be formal minuted meetings with clear terms of reference, a forward plan of audits and a clear record of adherence to the audit cycle. Consideration might be given to making recommendations on the choice of clinical audit undertaken, for example high dose procedures, paediatrics and screening programmes.

The Chair role of the Clinical Audit Committee for radiology in each organisation/location should be given its due importance by being an appointment made by the Chief Executive / General Manager of the organisation/location, with a clear remit provided, which sets priorities in terms of a minimum range of audit subject areas to be addressed in the work programme. These subject areas should be chosen on the basis of a risk assessment, which takes into account high dose, high risk or high volume procedures. It is suggested that the National Radiation Safety Committee provide advice to the Chief Executive of the HSE in respect of clarifying the lines of delegated accountabilities for these Clinical Audit and Radiation Safety Committees.

Commentary

It is important that clinical audit is systematic and that this is overseen within a suitable committee structure with clear lines of accountability.

Recommendations

Each organisation which is a holder of ionising radiation equipment for medicine should review its committee structure and plans for Clinical Audit.

The HSE with the National Radiation Safety Committee should provide further guidance on Clinical audit structures. Guidance notes and training packages to support the implementation of the legislation should also be considered.

A minimum frequency of local Clinical Audit meetings should be recommended by the HSE and the National Radiation Safety Committee as six monthly for all organisations/locations. These should be formal minuted meetings with clear terms of reference, a forward plan of audits and a clear record of adherence to the audit cycle. Consideration might be given to making recommendations on the choice of clinical audit undertaken, for example high dose procedures, paediatrics and screening programmes.

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C7. SECTION C (CONTINUED): ASSESSMENT OF RADIOLOGICAL CLINICAL AUDIT ACTIVITY

The organisations were asked to list and describe their clinical audit activities in respect of radiology under the following headings:

Practice/Procedure	Has it been audited in the past year?		Were actions taken on the basis of the results found?		Are repeat audits planned for this issue?	
	Yes	%	Yes	% of those audited	Yes	% of those audited
Clinical Image Quality	49	43	33	77	41	84
Reject Analysis	42	37	26	62	41	98
Justification	44	39	28	64	31	70
Image Interpretation	24	21	18	75	23	96
Safety	56	49	42	75	42	75
Assessment of non-ionising alternatives	24	21	16	67	19	79
Other	8	7	9	113	5	63

Commentary

It is apparent from the responses to this question that, despite the lack of clarity noted earlier about the necessary supporting structures for clinical audit, many departments are undertaking clinical audit in one form or another. Audit of safety, Clinical Image Quality and justification appear to be the most common. However over 75% of the respondents took action based on the audit findings and over 80% planned further audits.

Those respondents who undertook audit activity found it to be a rewarding experience and plan to repeat the exercise, which is entirely in accordance with good practice regarding clinical audit. Perhaps those units that have found it to be a rewarding experience could be engaged to assist with the rollout and development of clinical audit in radiology across the country.

It is however of concern that 20 out of the 114 (18%) organisations have not undertaken any clinical audit activity around the subject of ionising radiation in the past year.

There appears to have been some confusion amongst respondents about what is meant by the “other” audits as eight respondents stated that they undertook an audit but nine stated that they had acted upon the results, which has resulted in some response rates of over 100%.

C8. What criteria are used to prioritise radiological clinical audits for the future?

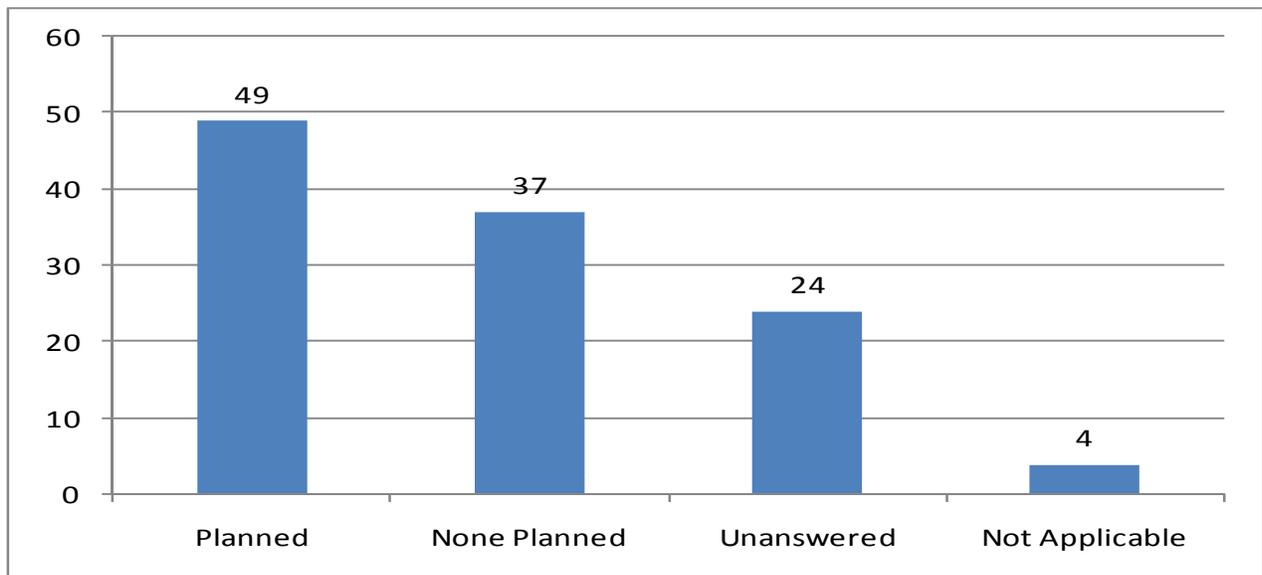
Commentary

Many enthusiastic individual responses were received. However there was no consistent clinical audit theme and the responses appeared to lack strategic focus.

Recommendations

The HSE via the National Radiation Safety Committee should work with the Medical Council and the Faculty of Radiologists to develop audit criteria further and to build on tools and work undertaken already in this area in other European countries, for example the “100 Recipes for Audit” produced by the Royal College of Radiologists, U.K.

C9. Please list any radiological clinical audits that you have planned for the forthcoming year



Commentary

It is unacceptable that only 49 out of 114 organisations have planned audits for the forthcoming year. This indicates the lack of structure to support clinical audit mentioned earlier.

SECTION C (CONTINUED): QUALITY IMPROVEMENT INITIATIVES

C10. Quality Improvement Initiatives

Do you have any of the following quality improvement activities in place:	Yes		No		Unanswered	
	Number	%	Number	%	Number	%
Quality improvement team	47	41	53	46	14	12
Quality improvement projects	55	48	41	36	18	16
Risk management structure	74	65	30	26	10	9
Complaints review programme	69	61	30	26	15	13
Guidelines, policies and procedures being developed	83	73	20	18	11	10
Protocols being developed	70	61	29	25	15	13
Patient pathways being developed	43	38	57	50	14	12
Accreditation standards being implemented	60	53	37	32	17	15
Patient involvement projects	25	22	77	68	12	11
Research/ Clinical trials	24	21	76	67	14	12

Commentary

This is one of the more revealing sets of replies in the audit. For example, between 61% and 73% of respondents undertook risk management activities, complaints review programme, development of protocols and policies/procedures, leaving 27% - 39% not involved in these key activities at all. Between 43% and 60% of respondents have a quality improvement team, quality improvement projects, developing accreditation standards and patient pathways. About a fifth of respondents were involved in research/clinical trials or projects involving patients.

Five out of the 114 (5%) organisations have none of the quality improvements above in place.

All organisations using ionising radiation equipment should be involved in most of these areas of quality improvement.

Recommendation

All organisations using ionising radiation equipment should be involved in most of the areas of “quality improvement” which were specified in the Section C of the questionnaire, and should be able to demonstrate this if requested by the HSE.

SECTION C (CONTINUED): RADIATION PROTECTION

C11. Does your organisation have its own local Radiation Safety Committee or does it relate to a regional Radiation Safety Committee?	Yes		No		Unanswered	
	Number	%	Number	%	Number	%
	95	83	17	15	2	2

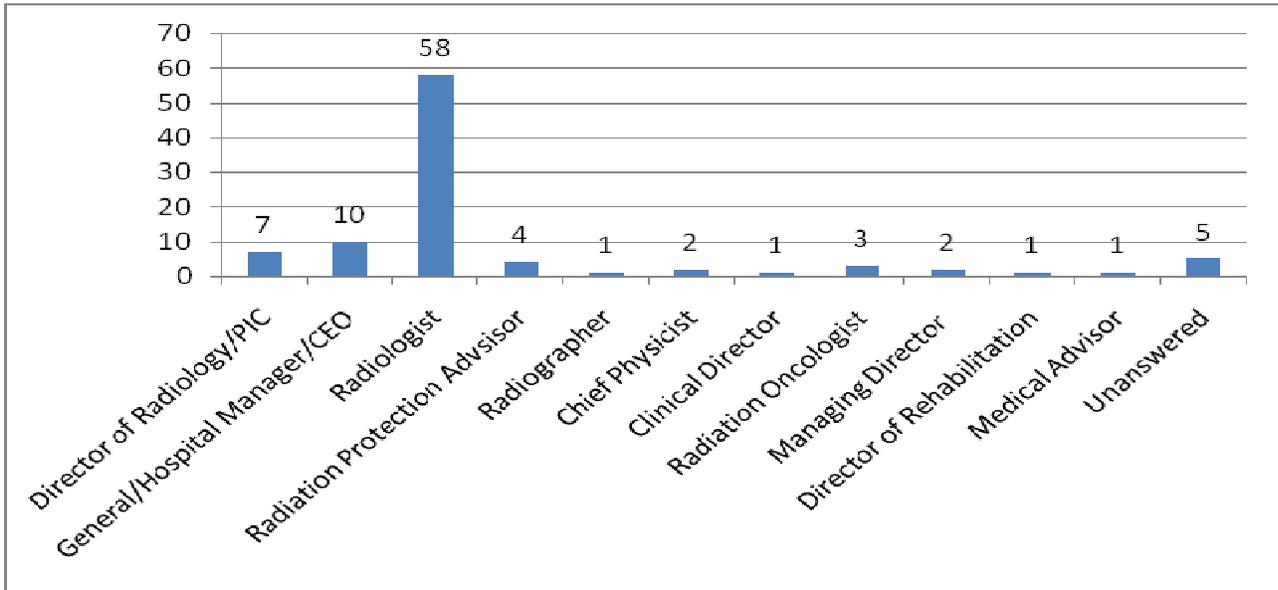
Commentary

It is surprising to discover that while 83% of respondents have a Radiation Safety Committee the remainder does not, given that this is a legal requirement.

Recommendation

A list of those organisations, which apparently do not meet their legal requirements to have a Radiation Safety Committee or relate to a regional Radiation Safety committee (19%), has been passed to the HSE, so that this can be addressed by the Radiation Protection Institute of Ireland.

C12. Who has lead responsibility as the Chair of the committee?



Commentary

We note with interest that 58 of the 95 respondents (51%) a Radiologist acted as Chair of the Radiation Safety Committee. Whilst acceptable in current practice, we would ask whether this could result in a potential conflict of interest.

Recommendation

The authors of the report have wondered whether there is any conflict of interest in a Radiologist being the Chair of the Radiation Safety Committee in a radiology department. The potential conflict lies in the responsibility of the Radiologist to deliver a service, whilst also being responsible for monitoring the safety of that service. It is suggested that this is debated between the National Radiation Safety Committee and the Radiation Protection Institute of Ireland.

C13. What are the lines of reporting and accountability for the activities of this committee?

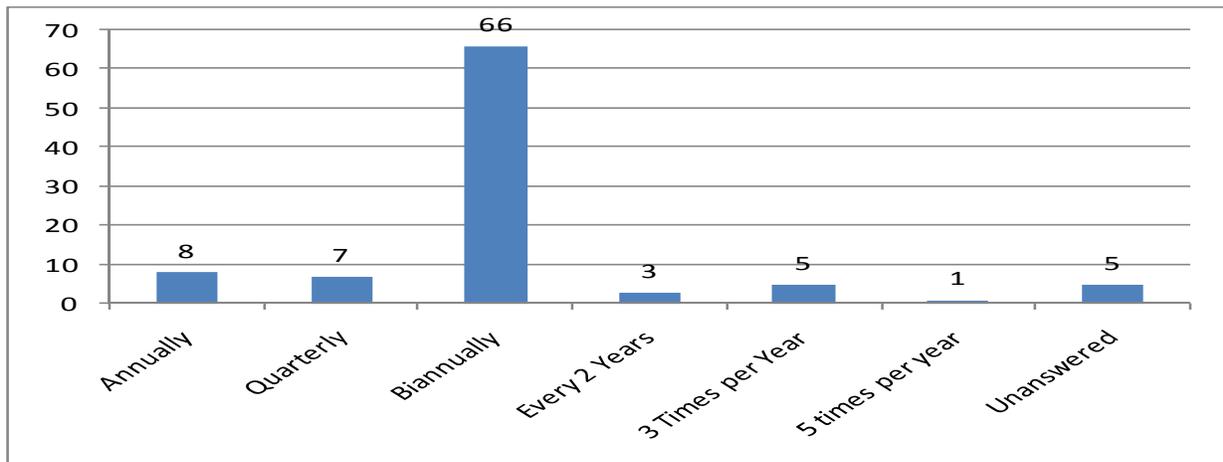
Commentary

Most of the answers provided relate to the composition of the committee and in a number of cases identified the local hospital manager for public hospitals as the accountable officer. This leaves the question of the accountability relationships to be clarified in the majority of cases. The legal status of the Chief Executive in the voluntary hospitals and private organisations is clear. However, in public hospitals the Chief Executive of the HSE is the legally accountable officer and so is legally responsible for delegating responsibility to the chair of the Radiation Safety Committee.

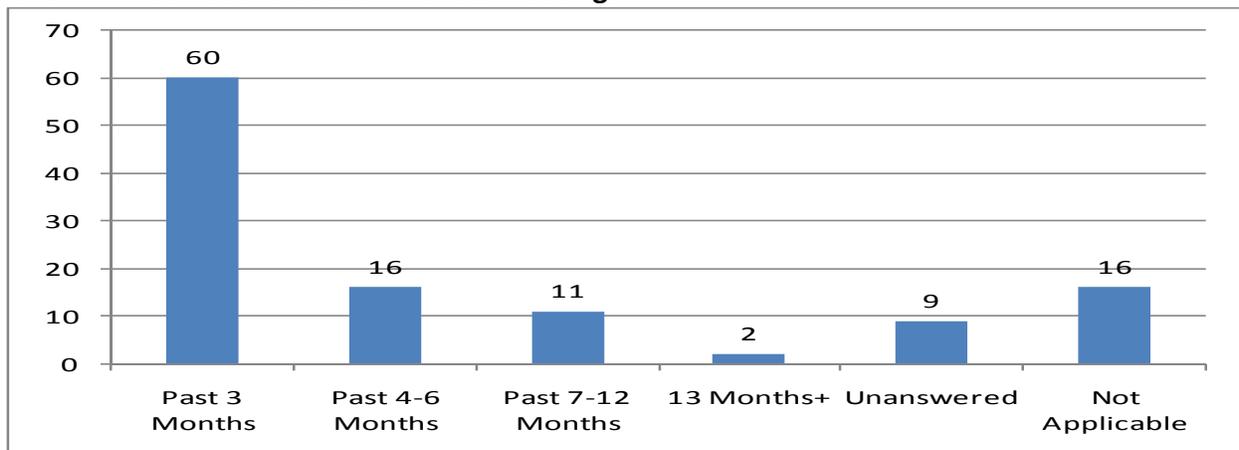
Recommendation

The Chief Executive of the HSE should clarify the lines of accountability and allocation of delegated responsibilities for the public hospital Radiation Safety Committees. (The principle behind this issue will apply to the Clinical Audit Committees also)

C14. What is the frequency of the meeting?



C15. What was the date of the last meeting?



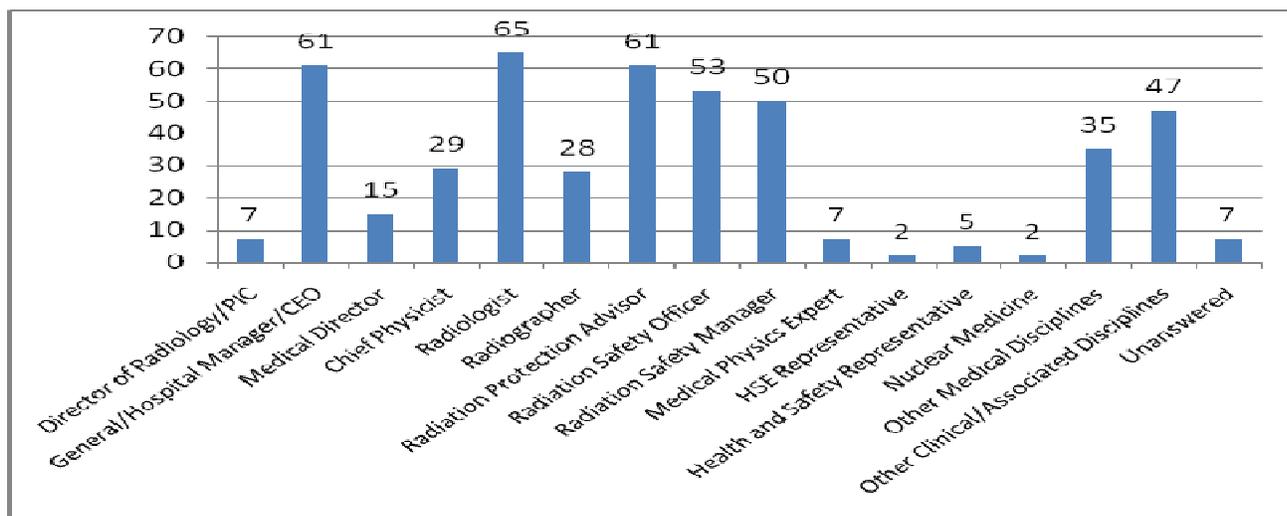
Commentary

The frequency of meeting will depend on the size and range of the radiological workload. However, we would comment that the frequency of once every two years is too long. An optimal minimum frequency should be every six months.

Recommendation

The National Radiation Safety Committee should work with the Radiation Protection Institute of Ireland to recommend a minimum frequency of meeting of the local or regional Radiation Safety Committees.

C16. What is the membership and multi-disciplinary involvement in the committee?



C17. Do the Terms of Reference of this Radiation Safety Committee cover the requirements of the RPII and SI 125?	Yes		No		N/A		Unanswered	
	Number	%	Number	%	Number	%	Number	%
	91	80	2	2	12	11	9	8

Commentary

It is of interest that only 80% of the committees cover the requirements of the RPII and SI 125. It is important to note that an integrated approach to the implementation on the ground of the provisions of SI 125 / RPII and SI 478 is desirable and will be rendered difficult if the Radiation Safety Committee can not or does not deal with both sets of provisions.

Recommendation

A list of organisations, which did not answer Yes to the question “Do the Terms of Reference of this Radiation Safety Committee cover the requirements of the RPII and SI 125?” (21%) has been passed to the HSE. The HSE should pass this list to the Radiation Protection Institute of Ireland so that this can be addressed in each case.

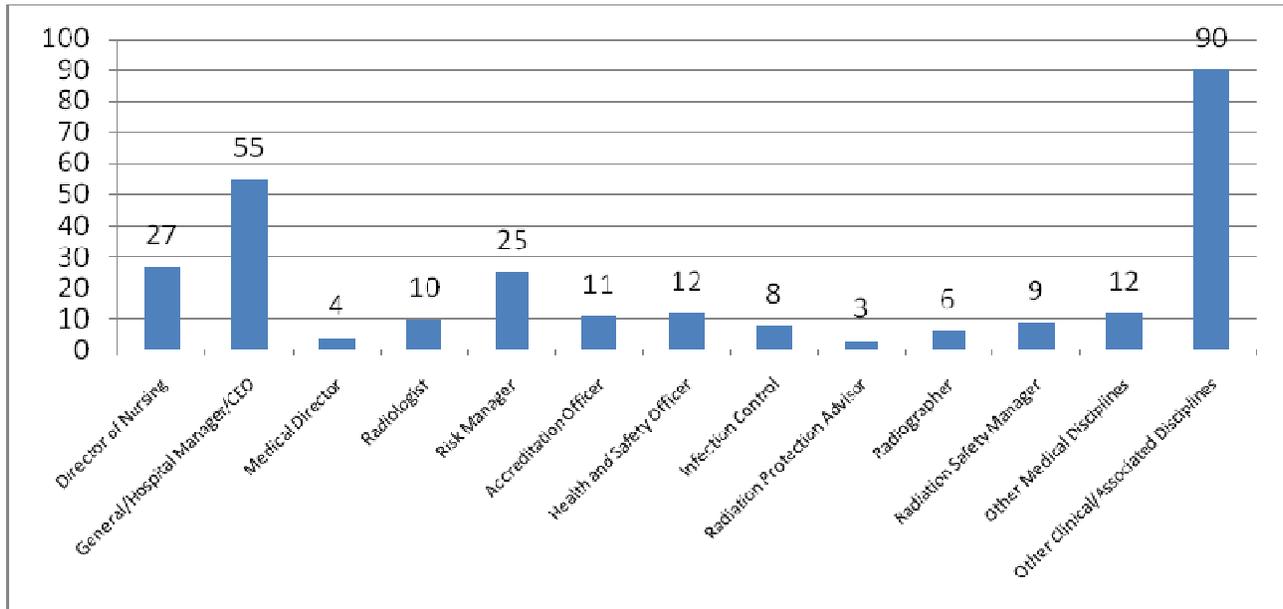
SECTION C (CONTINUED): RISK MANAGEMENT AND INCIDENT REPORTING

Risk Management/ Incident Reporting	Yes		No		Unanswered	
	Number	%	Number	%	Number	%
C19. Do you have procedures/guidelines for incident reporting?	110	96	2	2	2	2
C20. Do you have procedures/guidelines for incident review?	97	85	14	12	3	3
C21. Do you have an incident reporting form?	98	86	14	12	2	2
C22. Do you have an incident risk management committee?	60	53	50	44	4	4

Commentary

Most of the respondents appear to have a good risk management and incident reporting arrangements. Whilst only 53% of respondents have an incident risk management committee, this probably reflects the lack of need for a separate committee in smaller organisations or that these are dealt with in a Radiation Safety Committee.

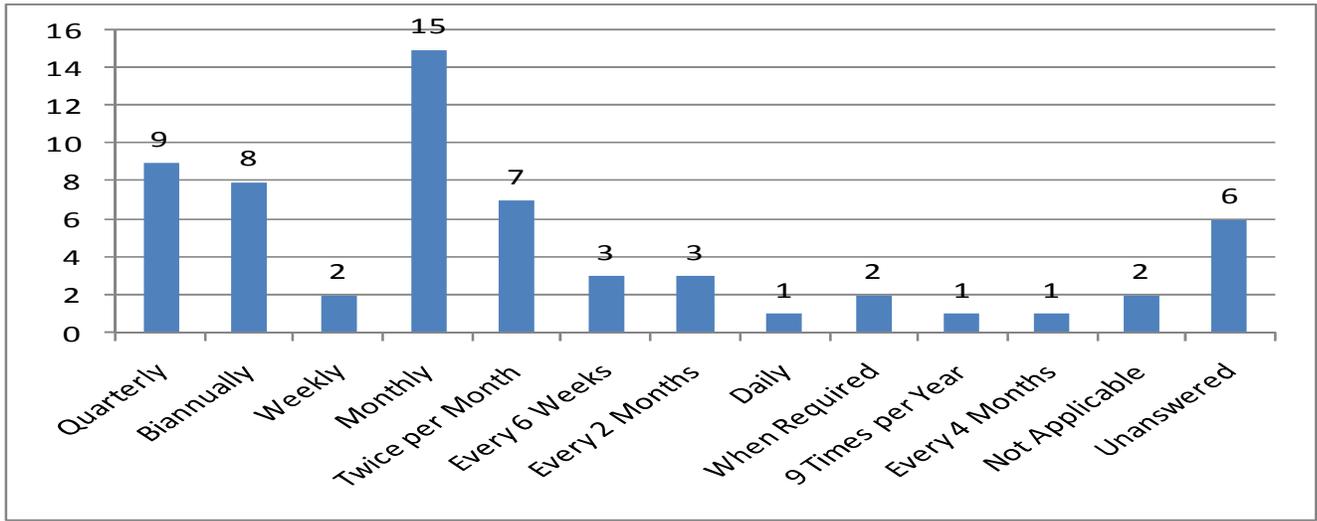
C23. If Yes to C22, please give the membership of the incident committee



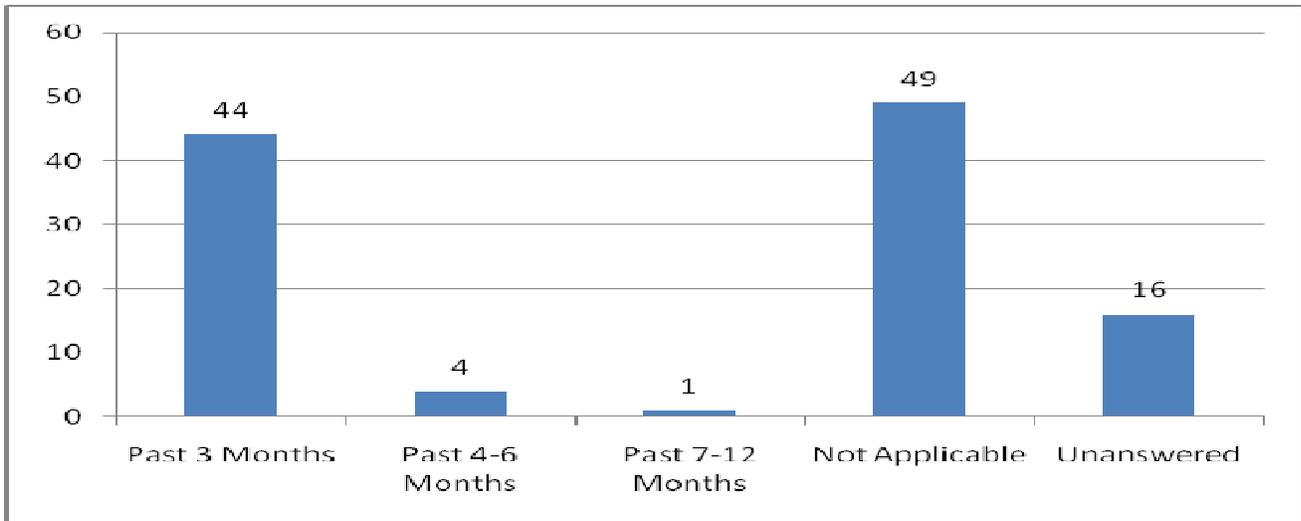
Commentary

There is a good broad composition and it has a reasonable spread of interest.

C24. How frequently does the committee meet?



C25. What was the date of the last meeting?



Commentary

The frequency probably reflects risks other than those central to this audit. We would suggest that six monthly or more frequently would be more appropriate.

C26. What feedback mechanisms are in place?

C27. What is the procedure for informing patients of incidents?

Commentary

The range of responses on the feedback mechanisms used shows thought and consideration of the issues around feedback on incidents both to the professionals in the clinical setting and to the patient or affected person.

Recommendation

The National Radiation Safety Committee should develop some guidance on Risk Management and Incident Handling, which includes guidance on feedback on incidents to professionals both internal to and external to the organisation and to patients or other affected people such as carers. Incident reporting for ionising radiation incidents would benefit from national reporting mechanisms which enabled dissemination of the nature of incidents to a wide range of professionals and organisations.

SECTION D: SAFETY, JUSTIFICATION AND OPTIMISATION, ADHERENCE TO THE REGULATIONS IN SI 478 (2002) AND SI 303 (2007)

DOCUMENTATION: The following questions have been grouped to identify issues related to documentation.

In many areas the SI 478 has requirements for documentation and records and this has been tested by the following questions.

Documentation is necessary for transparency and retrospective audit or review.

	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D1. There is written documentation, which clearly sets out the tests to be undertaken by the medical physicist, frequency of these and reporting and accountability arrangements for occasions when remedial action is required.	77	68	27	24	3	3	1	1	1	1	5	4
D2. The medical physicist maintains systematic records of the assessments made.	101	89	6	5	1	1	0	0	2	2	4	4
D11. Quality Assurance Programmes, written protocols or working instructions are established for every ionising radiation installation to prevent accidental exposures.	79	69	22	19	6	5	3	3	1	1	3	3
D14. Evidence can be provided for each installation that there has been consultation with the medical physicist by the practitioner for issues of optimisation, quality control, dose, and the evaluation of patient administered activity.	50	44	34	30	14	12	6	5	4	4	6	5
D15. All prescriptions for medical exposure are received electronically or in writing and signed by a named prescriber.	90	79	13	11	2	2	0	0	3	3	6	5

	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D16. The prescription states: Patient name and ID, the procedure requested, clinical details, pregnancy status, if appropriate, name of prescriber and date of request.	87	76	16	14	2	2	0	0	2	2	7	6

D18. What written information on protocols and guidance does your organisation provide to *prescribers*?

	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D21. Records are kept of the dose applied for each ionising radiation procedure conducted by your organisation.	45	39	30	26	25	22	4	4	5	4	5	4
D22. These records of dose are summarised and audited regularly.	16	14	15	13	31	27	36	32	8	7	8	7
D27. In the case of procedures involving radio-nuclides, written instructions are provided to the patient or legal guardian on the risks to which they are subject and for the purpose of restricting dose to others with whom they may come in contact.	18	66	4	15	5	19	0	0	0	0	0	0

Commentary on questions which related to Documentation

D1, D2, D11. It is pleasing to note that around 90% of centres have good practice in relation to written documentation and systematic records viz a viz quality assurance and acceptance testing. It is worrying that even with this level of compliance of good practice that small but significant proportions of centres do not have such records and documentation or have chosen not answer.

Recommendation

Any organisation which answered “No” or provided no answer to questions D1 (9%), D2 (7%) or D11 (11%) on issues of written documentation or records should review this urgently and make the necessary improvements.

D11. Just below 90% of respondents reported that they have written protocols or work instructions to prevent accidental exposures. The remainder should have these in place.

Recommendation

All organisations should have written protocols or Work Instructions to prevent accidental exposures for each installation.

D14. It is surprising that only three quarters of respondents could provide evidence for consultation with a Medical Physicist on issues of optimisation, given the level of response to D1, D2 and D11. Nearly 15% of respondents clearly did not feel that this consultation was worthy of recording.

Recommendation

A medical physicist must be consulted by the practitioner for issues of optimisation, quality control, dose, and the evaluation of patient administered activity for every installation and there should be evidence available to demonstrate this.

D15, D16. 91% of prescriptions are handled correctly in most respects. There may be medical legal consequences for the remaining 9%, if their answer implies that there are no recorded prescriptions or when this is not the case in all aspects. The HSE may wish to enquire why this is the case.

Recommendation

The HSE should contact each organisation which did not answer “Yes in all aspects” to questions D15 (20%) and D16 (24%), which are around the proper records for making prescriptions for medical procedures which use ionising radiation. There may be legal consequences for those organisations, where there is no recorded prescription.

D18. Just over half of respondents used the RCR, EU or local guidelines on referring criteria all of which would be regarded as acceptable. However there were a significant number of centres with no documented approach to accepting referrals which lacks transparency and makes it difficult to account for the justification process used.

Recommendation

All organisations should review their approach to accepting referrals for ionising radiation procedures. Without a transparent and documented rationale for accepting referrals it is difficult to account for the justification process used.

D21, D22. 65% of respondents keep records of dose applied for each procedure. It is of interest that 34% don't keep records of the dose applied. Only 27% summarise, review or audit these dose records. Just under half the information collected is never reviewed or audited.

Recommendation

The National Radiation Safety Committee should issue a clear statement to all holders of ionising radiation equipment about the need to record dose for each procedure and to summarise and audit these records regularly.

D27. It is surprising that in only 81% of procedures involving radio-nuclides does the patient receive written instructions given the easy availability of this information.

Recommendation

Those organisations which could not answer "Yes in all aspects" to question D27 (34%) on the issue of providing written instructions to the patients and carers/guardians who have been subject to radio-nuclides should review their arrangements and make use of existing information and resources on this subject.

EQUIPMENT: The following questions have been grouped to identify issues related to equipment.

	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D3. A written Acceptance Test has been performed and a report received from the medical physicist before each item of equipment has been used for medical exposures.	102	89	4	4	1	1	0	0	1	1	6	5
D4. All recommendations identified by the medical physicists for remedial action have either been complied with, and these actions have been systematically documented or written justification for continued use has been made	64	56	40	35	3	3	0	0	1	1	6	5
D8. Each item of equipment has a written regime of quality control measures, related to dose and administered activity, which has specified timescales and circumstances in which the measurements should be made and the records kept.	53	46	46	40	8	7	1	1	2	2	4	4
D9. These QC measures are recorded systematically in accordance with the timescales specified in the specified regime.	72	63	23	20	10	9	4	4	1	1	4	4
D10. All of these QC measurements are summarised and audited regularly, in accordance with the specified regime.	46	40	38	33	11	10	13	11	1	1	5	4

	Yes		No		Unanswered	
	Number	%	Number	%	Number	%
D29. Is there a preventative maintenance contract with manufacturers in place?	105	92	6	5	3	3

D30. If the answer to D29 is “No”, who maintains the equipment?

Out of the six organisations which answered “No” for question D29, all six provided details on who maintained their equipment as follows: “RSL Medical Officer distributor”, “Incidental due to very low workload”, “Maintenance carried out by agent”, “RPA carries out checks very 2 years”, “Siemens, when called in” and “Bio-Engineer”. Also the three “unanswered” left no comments.

	Yes		No		N/A		Unanswered	
	Number	%	Number	%	Number	%	Number	%
D31. Is equipment performance tested after major maintenance by a medical physicist?	90	79	17	15	2	2	5	4
D32. Has a replacement date been set for each item of equipment?	46	40	65	57	0	0	3	3
D33. Does your organisation have any items of X-ray equipment, which are being used beyond the replacement date?	31	27	62	54	5	4	16	14
D34. If “Yes” to D33, is there a written explanation of the decision to continue to use the item of equipment, which includes a report and certification for continued use from the medical physics expert?	19	17	7	6	66	58	22	18
D35. If “Yes” to D33, has the image quality specifically been assessed and certified as being within acceptable limits by the medical physics expert and the Practitioner in charge?	24	21	8	7	66	58	16	14
D36. Has the clinical image quality been assessed and certified as being within acceptable limits?	52	46	5	4	11	10	46	40

	Yes		No		N/A		Unanswered	
	Number	%	Number	%	Number	%	Number	%
D37. If "Yes" to D33, has a new replacement date been established?	17	15	14	12	66	58	17	15

D38. If "Yes", please provide details

	Yes		No		N/A		Unanswered	
	Number	%	Number	%	Number	%	Number	%
D39. Does your organisation have any ionising radiation equipment, which does not have a device that informs of the quantity of dose produced? (If yes please give details.)	70	61	39	34	0	0	5	4

The following Table was generated to demonstrate the ages of equipment, as this will indicate the relationship between equipment installed before 2002, when the SI 478 came into force, and the equipment which should have a device to record dose. All equipment installed from 2002 should have a device which records dose.

Equipment installed before the Introduction of Statutory Instrument 478 in 2002.

	1980	1982	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	Unanswered	Total	Overall Percentage
Cardiac Angio Rooms															1				1	1	2	1	6	27
Cardiac Ultrasound Rooms															1	4	1	2	3	4	1	8	24	46
CT Rooms																	2	2	3	3	3	3	16	28
CR Rooms																	1		6	9	16	17	49	31
Dental					1			1			1			1		6	2	3	2	1	3	6	27	44
DXA Rooms																		1	1	1	4	9	16	23
Fluoroscopy Rooms		1								1	1			1	1	4	9		3	6	6	4	37	54
General X-ray Rooms	1		1		3		2	1	3	1	2	2	3	3	3	8	28	8	8	9	15	18	119	56
Gynaecology Ultrasound Rooms															1	3	2	1	5	2	6		20	48
MRI Rooms																		1	2	3	1	2	9	26
Mammography Rooms																	4	1	3	2	4	1	15	22
Mobile C-arm X-ray Systems									1		1	1	3	1	1		3	2	8	3	7	7	38	46
Mobile X-ray Systems			3	2		2	2	1	3	5	1	4	3	7	4	5	6	18	10	9	23	22	130	69
Nuclear Medicine / PET Rooms										1			1		2			3	5	4		5	21	62
Radiology Ultrasound Rooms												2			3	3	1	6	14	8	9	23	69	40
Urodynamics																			1				1	50
Vascular Angio Rooms																	4		5	1		1	11	69
Vascular Ultrasound Rooms												1		1					10	1	2		15	94
Other X-ray Rooms						1									1		1		3		5	1	12	41
Total	1	1	4	2	4	3	4	3	7	8	6	10	10	14	18	33	64	48	93	67	10	128	636	46

Equipment: The following questions have been grouped to identify issues related to Equipment.

D3, D4. 93% of acceptance tests are generally documented and respondents report that a similar percentage act upon the written report supplied by the Medical Physicist.

D8, D9, D10. Documentation of QC measures is good in over 80% of centres, though the level of auditing is less.

D29, D30, D31. A surprisingly high 92% of centres report having a preventative maintenance contract which is impressive. Out of the six organisations that answered “No” for question D29, four detailed who maintained their equipment as follows: “the Radiation Protection Advisor every two years”, “Maintenance carried out by the engineer”, “Carried out by the Bio-Medical engineer”, the remaining three. Also the three “unanswered” left no comments. In 79% of organisations the equipment performance is tested after major maintenance by a Medical Physicist. There is a legal requirement on the remaining 21% which, it appears, is not being met.

Recommendation

Those organisations which have equipment which, it appears, is not checked by a medical physicist (21%) should do so urgently, as this is a legal requirement.

D32. Only 40% of respondents indicated compliance with the requirement to set a replacement date for equipment this means that nearly 60% are non compliant in this regard.

Recommendation

A replacement date should be set for every installation. All organisations should check their records for each item of equipment to confirm that a date has been set or to set a replacement date where none exists. This is a legal requirement.

D33, D34, D35, D37. It would appear that of the 46 respondents who have set a replacement date 31 are using the equipment beyond that date. In only 19 centres is there a report and certification for continued use, although image quality has been assessed to be within acceptable limits in 24 centres. In 17 centres a new replacement date has been set.

D36. On the basis of the answers to this question, it appears that the wording of this question was ambiguous and confusing. The results from this will be ignored.

D38. Most of the free commentary replies in this area did not justify why the equipment was in continued use beyond the replacement date.

Recommendation

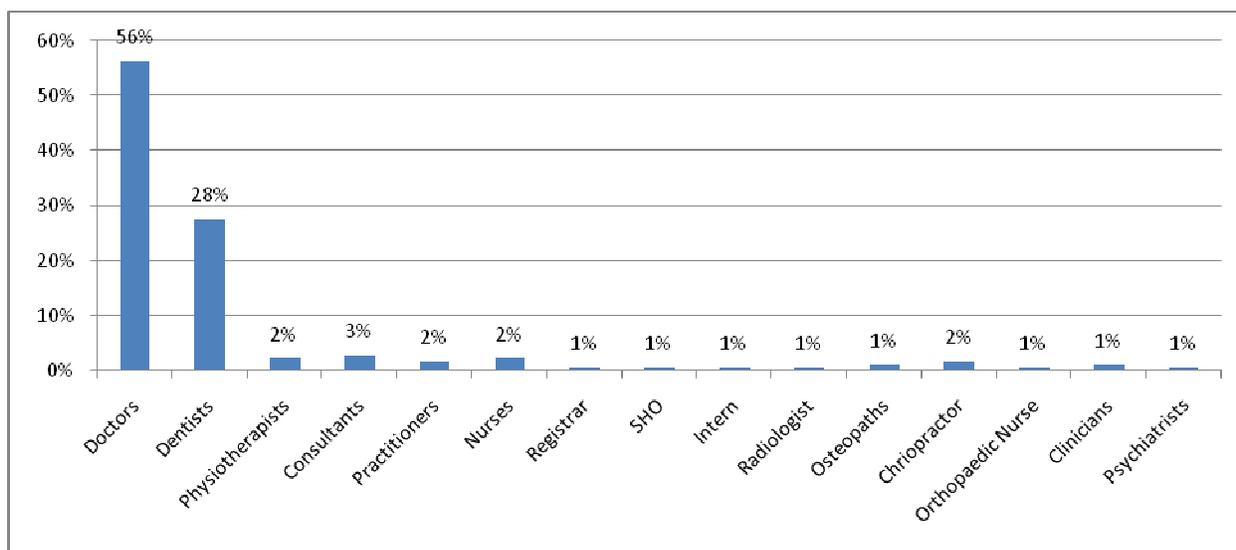
Any installation used beyond its replacement date should be certified for continued use, taking into account issues of justification and optimisation. All organisations should check their records for each installation which is being used beyond its replacement date and seek urgent certification in this respect. This is a legal requirement. The HSE should clarify the mechanism for certification in this respect.

D39. Over 61% of equipment is equipped to inform of the quantity of dose produced. Whilst 34% of equipment does not have a device to inform the user of the quantity of dose produced. This correlates with the 29% of the installed base of relevant equipment that was in place before 2002, the date of the SI 478 which established this requirement.

Justification: The following questions have been grouped to identify issues related to Justification.

	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D5. Local protocols, based on national guidance, are held, which provide referral criteria for all of the standard types of medical exposure that your organisation undertakes.	72	63	21	18	5	4	4	4	6	5	6	5
D6. These local protocols include referral criteria, an assessment of the benefits and risks to the individual, the operators and wider society.	55	48	19	17	17	15	5	4	7	6	11	10
D7. Written protocols are in place to ensure the ALARA principle is applied.	87	76	8	7	4	4	1	1	4	4	10	9
D12. The practitioner in charge has recommended the referral criteria for procedures undertaken.	73	64	11	10	10	9	5	4	7	6	8	7
D13. Prescribers are provided with these written criteria by your organisation for use, when considering the appropriateness of their request.	36	32	31	27	22	19	7	6	8	7	10	9

D17. Please list the categories of professional, from which your organisation accepts prescriptions (e.g. doctors, dentists, nurses, osteopaths).	Total In Ireland
Doctors	102
Dentists	53
Physiotherapists	4
Consultants	9
Nurses	1
Registrar	2
SHO	1
Medical v Clinical	1
Radiologist	1
Osteopaths	2
Chiropractor	3
Orthopaedic Nurse	2
Clinicians	1
Psychiatrists	1
Medical Officer	1
Occupational Self Referral	1
Nurse Practitioner	11
Cardiologist	1
ED	1
Medical Practitioner	1
N/A	1
Unanswered	6



	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D19. Medical exposures undertaken are Justified and authorised by a named practitioner.	88	77	12	11	0	0	8	7	1	1	5	4
D20. The practitioner and prescriber seek, where practicable, to obtain previous diagnostic information and records relevant to the planned exposure.	76	67	29	25	2	2	1	1	0	0	6	5
D23. All individuals to whom responsibility to deliver a medical exposure has been delegated by a practitioner have also undertaken a formal course(s) in radiation safety, which has been approved by the medical and dental councils. Additional training has been undertaken where usually high dose procedures are involved	72	63	7	6	8	7	2	2	18	16	7	6
D24. When responsibility has been delegated by a practitioner, a radiographer is present at all times when a medical ionising radiation procedure is undertaken (except in specific circumstances)	73	64	1	1	2	2	2	2	29	25	7	6

D25. Please list all the specialities of the persons who have been delegated this responsibility E.g. Cardiologists, Orthopaedic Surgeons etc	Total In Ireland
Cardiologists	29
Orthopaedic Surgeons	33
Urologists	11
Pain Control Anesthesia	6
Radiologists	4
Radiographer	6
Gastroenterologists	12
Hepatologists	1
Vascular Surgeons	10
Anaesthetists	7
Neuro Surgeons	5
Dentists	4
General Surgeons	12
Oncologists	1
Endocrinologists	2
Plastic Surgeons	1
Endoscopy Surgeon	1
Gynaecologists	1
Lithotripsy Practitioners	1
Medical Physicists	1
Nurses	5
Physicians	1
Rheumatologists	2
Respiratory	2
GI/Biliary Physician	1
Pain Specialist	2
Pathology	1
N/A	42
Unanswered	9
Nephrologist	1
GP	1
SpR	1
None	6
Senior Member of Medical Team	1
Physicians	1
Back Pain Surgeons	1
GI Surgeon	1

D26. Please list those specialities where DXA scanning is involved	Total In Ireland
Radiographers	10
Radiologist	3
Rheumatologists	10
Orthopaedic Surgeons	7
Gynaecology	2
Endocrinology	3
Cystic Fibrosis	1
Diabetes	2
Respiratory	1
Gastrology	2
Oncology	2
Paediatric	2
Clinical Age Assessment Unit	1
Doctors	1
Nurse	8
Technicians	1
Geriatrics	3
Medical Physicians	1
Neurology	1
General Practitioner	7
N/A	58
Unanswered	7
SpR	1
None	3
UCC	2
See Attached Certificate (no certificate attached)	1
GP Referral	1
Medical Rehab Patients	1

	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D28. A medical physicist is available when nuclear medicine procedures are undertaken. (In the comments box, please state what is determined by your organisation to be meant by “available” in these circumstances)	15	13	8	7	2	2	1	1	83	73	5	4

Commentary

There was a varied range of responses to the issue of what “available means in these circumstances. The range was from present in the room to available by phone if needed.

Recommendation

The National Radiation Safety Committee should debate and make a recommendation on what would be considered to be acceptable in Ireland respect of the “availability” of a medical physicist when nuclear medicine procedures are undertaken.

	Yes		No		N/A		Unanswered	
	Number	%	Number	%	Number	%	Number	%
D42. Does your organisation conduct exposures on Medical-Legal grounds?	22	19	86	75	0	0	6	5
D43. Are the exposures authorised in writing by a court and are they considered to be justified by the practitioner?	9	8	45	39	50	44	10	9
D44. Does your organisation conduct exposures as part of an occupational health surveillance scheme?	19	17	84	74	3	3	8	7

	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D45. Medical exposures as part of occupational health surveillance are only undertaken where there has been clear guidance given by the Medical and Dental Councils and the National Authority for Occupational Safety and Health to indicate that it is safe	15	80	1	5	1	5	0	0	1	5	1	5

Comment

It is concerning that the 19 organisations which answered “Yes” to D44, did not all answer “Yes in all aspects” to D45.

Recommendation

Any organisation indicating that it does undertake procedures for an occupational health surveillance scheme, but does not have clear indication from the Medical or Dental Councils and the National Authority for Occupational Safety and Health that it is safe to do so (20%) should desist from undertaking these procedures immediately and review its arrangements.

	Yes		No		N/A		Unanswered	
	Number	%	Number	%	Number	%	Number	%
D46. Does your organisation conduct research projects/clinical trials that involve the use of ionising radiation exposures?	19	17	88	77	3	3	4	4
D47. Does the following apply in all of these research projects/ clinical trials?	13	11	5	4	88	77	5	7
D47.1 The ethics committee approval has been given.	18	16	0	0	91	80	5	4

	Yes		No		N/A		Unanswered	
	Number	%	Number	%	Number	%	Number	%
D47.2 Are in accordance with criteria as may be directed by Medical, Dental Councils.	15	13	1	1	91	80	7	6
D47.3 Local Radiation Safety Committee approval has been given	12	11	6	5	91	80	6	5
D47.4 Written information has been given to the individual to explain the risks.	16	14	1	1	91	80	6	5
D47.5 Written consent is obtained from each individual.	16	14	2	2	91	80	5	4
D47.6 Dose constraints are established	13	11	3	3	91	80	7	6
D47.7 Doses are individually planned	11	10	5	6	91	80	7	6

Commentary

Organisations conducting research projects/clinical trials that involve the use of ionising radiation exposures should also be able to answer “Yes” to questions 47.1 through to 47.7.

Recommendation

Organisations conducting research projects/clinical trials that involve the use of ionising radiation exposures, but which could not answer “Yes” to questions 47.1 through to 47.7, should review their arrangements urgently.

	Yes		No		N/A		Unanswered	
	Number	%	Number	%	Number	%	Number	%
D48. Do you use comforters or carers who may be exposed to radiation during procedures? (If Yes, please describe the dose constraints which are applied)	60	53	36	33	3	3	15	13
D49. If Yes, is written information on radiation risk provided to and written consent obtained from these comforters or carers?	13	11	53	46	32	28	15	13

Commentary

It is surprising that all organisations which use comforters or carers, who may be exposed during the procedure, do not provide written information on the risks and obtain written consent.

Recommendation

All organisations which use comforters or carers, who may be exposed during the procedure, should provide written information on the risks and obtain written consent.

Pregnancy: The following questions have been grouped to identify issues related to Pregnancy.

	Yes in all aspects		Yes in most aspects		Not really but in a few aspects		No not at all		Not Applicable		Unanswered	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
D40. Before a procedure is undertaken, all women of child bearing age are asked if they are pregnant or breastfeeding and this is documented	95	83	10	9	3	3	0	0	1	1	5	4
D41. If pregnancy cannot be excluded, the special justification for undertaking a medical ionising radiation exposure is made and documented, or the procedure is postponed if possible, in accordance with procedures approved by the Medical and Dental Council	99	87	2	2	0	0	0	0	5	4	8	7

Recommendation

All women who are of child bearing age should be asked if they may be pregnant or, in nuclear medicine, if they are breastfeeding. Any organisation that was not able to answer “Yes in all aspects” to questions D40 (17%) and D41 (13%) should review and improve their arrangements in this respect urgently.

SECTION E: INVENTORY OF DIAGNOSTIC AND INTERVENTIONAL EQUIPMENT

The following tables, which describe the number and types of equipment is a valuable information resource for planning purposes to the HSE.

	Number of Organisations that have this type of equipment	Mean	Mode	Maximum	Minimum
Cardiac Angio Rooms	20	1.3	1	2	1
Cardiac Ultrasound Rooms	20	2.6	2-3	8	1
Computed Tomography (CT) Rooms	49	1.2	1	3	1
Computer Radiography (CR)	47	3.4	3	12	1
Dental	36	1.7	3	4	1
DXA (also called DEXA) Rooms	60	1.2	1	3	1
Fluoroscopy Rooms	52	1.3	1	3	1
General X-Ray Rooms	85	2.5	1	9	1
Gynaecology Ultrasound Rooms	12	3.5	1	16	1
Magnetic Resonance (MRI) Rooms	32	1.1	1	2	1
Mammography Rooms	34	2.0	1	33	1
Mobile C-Arm X-Ray Systems	41	2.0	1	6	1
Mobile X-Ray System	61	3.1	1	16	1
Nuclear Medicine / PET Rooms	22	1.5	1	3	1
Radiology Ultrasound Rooms	63	2.7	1	10	1
Urodynamics	1	2.0	2	2	2
Vascular Angio Rooms	11	1.5	1	2	1
Vascular Ultrasound Rooms	7	2.4	1	9	1
Other X-Ray Rooms	9	3.2	1	8	1

Table Showing Year Machines Were Installed. (Note that this survey included Ultrasound deliberately to provide information to the HSE on see capacity for alternative non Ionising Radiation equipment.)

	1980	1982	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008 (Incomplete Year)	Unanswered	Total
Cardiac Angio Rooms															1				1	1	2	1	2	3	6	1	3	1	22
Cardiac Ultrasound Rooms															1	4	1	2	3	4	1	7	4	3	9	5		8	52
CT Rooms																	2	2	3	3	3	4	5	4	16	12		3	57
CR Rooms																	1		6	9	16	1	15	23	27	43		17	158
Dental					1			1			1			1		6	2	3	2	1	3	6	5	7	4	12	1	6	62
DXA Rooms																		1	1	1	4	10	10	11	13	9	1	9	70
Fluoroscopy Rooms		1								1	1			1	1	4	9		3	6	6	4	7	4	12	5		4	69
General X-ray Rooms	1		1		3		2	1	3	1	2	2	3	3	3	8	28	8	8	9	15	11	16	19	29	16	1	18	211
Gynaecology Ultrasound Rooms															1	3	2	1	5	2	6	3	4	2	4	8	1		42
MRI Rooms																		1	2	3	1	7	4	2	8	4		2	34
Mammography Rooms																	4	1	3	2	4	5	5	7	6	17	12	1	67
Mobile C-arm X-ray Systems									1		1	1	3	1	1		3	2	8	3	7	8	4	6	16	11		7	83
Mobile X-ray Systems			3	2		2	2	1	3	5	1	4	3	7	4	5	6	18	10	9	23	13	8	12	14	11		22	188
Nuclear Medicine / PET Rooms										1			1		2			3	5	4			1	3	8	1		5	34
Radiology Ultrasound Rooms												2			3	3	1	6	14	8	9	8	12	16	23	40	4	23	172
Urodynamics																			1							1			2
Vascular Angio Rooms																	4		5	1		2			1	2		1	16
Vascular Ultrasound Rooms												1		1					10	1	2					1			16
Other X-ray Rooms						1									1		1		3		5		8		4	5		1	29
Total	1	1	4	2	4	3	4	3	7	8	6	10	10	14	18	33	64	48	93	67	107	90	110	122	200	204	22	128	1384

Table Showing Items of Equipment that are over ten years old.

	1980	1982	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	Total	Overall %
Cardiac Angio Rooms															1				1	5
Cardiac Ultrasound Rooms															1	4	1	2	8	15
CT Rooms																	2	2	4	7
CR Rooms																	1		1	1
Dental					1			1			1			1		6	2	3	15	24
DXA Rooms																		1	1	1
Fluoroscopy Rooms		1								1	1			1	1	4	9		18	26
General X-ray Rooms	1		1		3		2	1	3	1	2	2	3	3	3	8	28	8	69	33
Gynaecology Ultrasound Rooms															1	3	2	1	7	17
MRI Rooms																		1	1	3
Mammography Rooms																	4	1	5	7
Mobile C-arm X-ray Systems									1		1	1	3	1	1		3	2	13	16
Mobile X-ray Systems			3	2		2	2	1	3	5	1	4	3	7	4	5	6	18	66	35
Nuclear Medicine / PET Rooms										1			1		2			3	7	21
Radiology Ultrasound Rooms												2			3	3	1	6	15	9
Urodynamics																			0	0
Vascular Angio Rooms																	4		4	25
Vascular Ultrasound Rooms												1		1					2	13
Other X-ray Rooms						1									1		1		3	10
Total	1	1	4	2	4	3	4	3	7	8	6	10	10	14	18	33	64	48	241	17

Table Showing Cardiac Angio, Cardiac Ultrasound, Computer Tomography (CT), Mammography and Fluoroscopy Equipment that are over eight years old.

	1982	1991	1992	1995	1996	1997	1998	1999	Total	Overall Percentage
Cardiac Angio Rooms					1				1	5
Cardiac Ultrasound Rooms					1	4	1	2	8	16
Computed Tomography (CT) Rooms							2	2	4	7
Fluoroscopy Rooms	1	1	1	1	1	4	9		18	26
Mammography Rooms							4	1	5	15

Recommendation

The National Radiation Safety Committee should consider whether the following items of equipment should still be in use and notify each organisation of its conclusions: Cardiac Angio, Cardiac Ultrasound, Computer Tomography (CT), Mammography and Fluoroscopy equipment that are over eight years old.

Table Showing General X-Ray Equipment over Twelve Years Old.

	1980	1984	1986	1988	1989	1990	1991	1992	1993	1994	Total	Overall Percentage
General X-Ray Rooms	1	1	3	2	1	3	1	2	2	3	19	9

Recommendation

The National Radiation Safety Committee should consider whether the general X-ray equipment over twelve years old should still be in use and notify each organisation of its conclusions.

Table Showing Equipment that has been installed within the last three years.

	2005	2006	2007	Total	Overall Percentage
Cardiac Angio Rooms	3	6	1	10	45
Cardiac Ultrasound Rooms	3	9	5	17	33
CT Rooms	4	16	12	32	56
CR Rooms	23	27	43	93	59
Dental	7	4	12	23	37
DXA Rooms	11	13	9	33	47
Fluoroscopy Rooms	4	12	5	21	30
General X-ray Rooms	19	29	16	64	30
Gynaecology Ultrasound Rooms	2	4	8	14	33
MRI Rooms	2	8	4	14	41
Mammography Rooms	7	6	17	30	45
Mobile C-arm X-ray Systems	6	16	11	33	40
Mobile X-ray Systems	12	14	11	37	20
Nuclear Medicine / PET Rooms	3	8	1	12	35
Radiology Ultrasound Rooms	16	23	40	79	46
Urodynamics			1	1	50
Vascular Angio Rooms		1	2	3	19
Vascular Ultrasound Rooms			1	1	6
Other X-ray Rooms		4	5	9	31
Total	122	200	204	526	38

Table Showing established replacement dates for machines

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2021	None	Overdue	Un - answered	Total
Cardiac Angio Rooms		1			1	1		1	2	3		1				10	20
Cardiac Ultrasound Rooms		1		2	4		7	2	2	5	3			3		23	52
CT Rooms		2	3	1	2	2	1	1	4	6	2			1		32	57
CR Rooms		10	4	9		11	8	6	2	12	14			1		72	149
Dental		4	1	2	1	1	1		2	3	9				1	37	62
DXA Rooms			1	2		3	2	1	5	7	1	1				44	67
Fluoroscopy Rooms	1	6	1	4	2	4		5		6	1			2		37	69
General X-ray Rooms	3	23	8	6	4	9	4	11	6	7	3			4	1	121	210
Gynaecology Ultrasound Rooms		8	1	5		3	1	2	1	1	1					19	42
MRI Rooms		1	1	1	1	2	3	1	2	2	1					19	34
Mammography Rooms		6	4	2		4	4	16	12	3						16	67
Mobile C-arm X-ray Systems		5	2	3		6	4	5	2	10	3			2		40	82
Mobile X-ray Systems	1	13	3	5	2	6	11	5	7	7	2		1	4		121	188
Nuclear Medicine / PET Rooms		3	2	4				1	2	6	1			1		13	33
Radiology Ultrasound Rooms				3		3		2	1	1	1					22	33
Urodynamics	2	6	6	8	2	6	2	12	12	10	8	1		5		87	167
Vascular Angio Rooms																2	2
Vascular Ultrasound Rooms		3		2			1									10	16
Other X-ray Rooms				3							1					15	19
Total	7	92	37	62	19	61	49	71	62	89	51	3	1	23	2	740	1369

Table Showing Which Machines are Computed Radiography or Direct Digital Radiography

	CR		DR		DR/CR		Unanswered		Total
	No.	%	No.	%	No.	%	No.	%	
Cardiac Angio Rooms	1	5	6	30			13	65	20
Cardiac Ultrasound Rooms			1	2			51	98	52
Computed Tomography (CT) Rooms	3	5	8	14			46	81	57
Computer Radiography (CR)	51	32					107	68	158
Dental	12	19	23	37			27	44	62
DXA (also called DEXA) Rooms	1	1	5	7			64	91	70
Fluoroscopy Rooms	14	20	19	28	3	4	33	48	69
General X-Ray Rooms	101	48	50	24	4	2	56	27	211
Gynaecology Ultrasound Rooms			1	2			41	98	42
Magnetic Resonance (MRI) Rooms			5	15			29	85	34
Mammography Rooms	2	3	36	54			29	43	67
Mobile C-Arm X-Ray Systems	12	14	18	22			53	64	83
Mobile X-Ray System	101	54					87	46	188
Nuclear Medicine / PET Rooms			4	12			30	88	34
Other X-Ray Rooms	8	28					21	72	29
Radiology Ultrasound Rooms	3	2	18	10			151	88	172
Urodynamics							2	100	2
Vascular Angio Rooms	1	6	4	25			11	69	16
Vascular Ultrasound Rooms							17	100	17

SECTION F: OVERALL COMMENTS FROM RESPONDENTS

Summary of comments

Only 35 out of 100 respondents gave a final overall comment.

The following issues were highlighted to be of concern to those who commented:

- Lack of training course availability for DXA practitioners, Nurse Prescribers
- Clinical Audit criteria, structures and methods for radiology need to be developed further at a national level to support local radiology departments and their organisations.
- The requirement to undertake Clinical Audit set out in the SI 478 needs to be resourced at a local level since it is labour intensive.
- There are a number of legal issues around in the SI 478, which are not well understood by prescribers and practitioners and these need to be drawn out, clarified and publicised by the HSE.
- One Unit highlighted local concerns for radiation safety. Details of this Unit have been passed to the HSE to enquire further about the nature of these concerns.
- The full application of the SI 478 is difficult in small or single handed departments.
- The Medical Council has defined a practitioner as a radiologist, radiation oncologist or dentist. This means that the other specialities fall into the category of Medical Specialist and carry out practical aspects of medical exposure as delegated by the practitioner. The role of the practitioner in procedures that are carried out by Medical Specialists has not been fully explored either at national level or in this questionnaire. In particular how the responsibilities divide in the case of an interventional procedure carried out by a cardiologist or an interventional surgeon is not clear. According to the legislation, the practitioner has clinical responsibility with all that the role entails. This is clearly a situation that is fraught with potential difficulties.
- The SI 478 does not make adequate provision for health professionals other than practitioners and radiographers to carry out medical exposures.
- There is uncertainty and concern about the training provided or undertaken by nurses and chiropractors, who were enabled under the SI 478 revision, SI 303 to request X-ray examinations.
- Training and information about the requirements of SI 478/SI 303 could have been better at its introduction, and training/better information would be valued now. It is felt that this is a “national” responsibility.
- Clearer guidance is needed in the field of occupational health exposures
- Lack of funding restricts the ability of organisations to meet their equipment replacement obligations, their clinical audit requirements and the documentary requirements of SI 478.

.....END OF REPORT.....