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 March 2008

Survey 2 of 3: Radiotherapy

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Contents

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 Radiotherapy 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 radio therapeutic purposes are committed to the principles of the SI 478, which is to minimise the radiation dose given to the patient population, whilst maximizing 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

There are ten hospitals in which Radiotherapy is delivered Ireland. Each of these ten organisations were surveyed and all ten (100%) responded.

It was pleasing to note that there was a good general level of compliance in most aspects of the SI 478. Some specific shortcomings are identified in the recommendations.

Some Clinical Audit and quality improvement activity is ongoing in all organisations, although the breadth of this needs to be increased.

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.

Key Recommendations

Thirty four recommendations have been made; four of these of the highest importance are 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. The three organisations which stated that they do not obtain previous diagnostic and treatment information and records relevant to the definition of the treatment volume in every case should remedy this **urgently**.	High	Relevant Holder organisations
3. Any Organisation, which has been given approval by the Department for Health and Children to appoint a Radiation Safety Officer or Practitioner in Charge and has not done so, should make an appointment forthwith.	High	Holders of ionising radiation equipment and to be monitored by the HSE
4. The HSE should check with the organisations which listed nursing, admin and health care assistant staff as having responsibilities for justifying or undertaking ionising radiation procedures. It is assumed that the Nurses, Administrators and Health Care Assistants 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.	High	HSE
5. 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.		The HSE, National Radiation Safety Committee and the Radiation Protection Institute of Ireland
6. The HSE should follow up the two organisations that did not answer the question on the total number of patient exposures per annum and ascertain an answer. This should be provided as an addendum to this report to the National Radiation Safety Committee for information and comment.		HSE

Recommendation	Priority	For the Attention of
7. The organisation, which only currently holds informal clinical audit meetings, should formalise its clinical audit structures and work as it has described it would.		Relevant Holder organisation
8. The National Radiation Safety Committee should develop and issue guidance on what would be optimal structures to support clinical audit in radiotherapy.		National Radiation Safety Committee
9. The Chair role of the Clinical Audit Committee for radiology in each organisation should be given its due importance by being an appointment made by the Chief Executive / General Manager of the organisation, 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, for example on the basis of 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.		Relevant Holder organisations & HSE
10. The National Radiation Safety Committee should consider and recommended a minimum frequency of meetings for clinical audit.		National Radiation Safety Committee
11. The National Radiation Safety Committee should make recommendations on clinical audit structures, which include optimal membership of the Clinical Audit Committee.		National Radiation Safety Committee
12. In terms of subject areas to be covered by clinical audit, consideration might be given to areas requiring particular attention in the European Directive, for example high volume or high risk procedures. The National Radiation Safety Committee should debate and provide guidance on this.		National Radiation Safety Committee
13. The two organisations which either did not answer or stated that no clinical audits are planned should review their arrangements, since it is unacceptable that there is no forward programme of clinical audits. All organisations should have audits planned in their forward programme covering all of the areas specified within the report.		Relevant Holder organisations

Recommendation	Priority	For the Attention of
14. It is pleasing to note a high level of quality improvement activity taking place with radiotherapy departments. The situation would be further improved if all organisations were undertaking quality improvement initiatives in all the areas suggested in this report, including: patient pathways, accreditation standards being implemented and patient involvement.		Relevant Holder organisations
15. The authors of the report have wondered whether there is any conflict of interest in a Radiation Oncologist being the Chair of the Radiation Safety Committee in a radiotherapy department. The potential conflict lies in the responsibility of the Radiation Oncologist 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.		National Radiation Safety Committee & RPII
16. The National Radiation Safety Committee should make recommendations in conjunction with the RPII on local Radiation Safety Committee structures, which include optimal membership.		National Radiation Safety Committee & RPII
17. The National Radiation Safety Committee should work with the Radiation Protection Institute of Ireland to debate the relationship between the role of the local Radiation Safety Committees and SI 478.		National Radiation Safety Committee & RPII
18. The National Radiation Safety Committee should make recommendations on local Incident Committee structures, which include optimal membership.		National Radiation Safety Committee
19. The National Radiation Safety Committee should provide guidance on optimal feedback mechanisms for Incidents, which include procedures for feedback to patients where appropriate.		National Radiation Safety Committee

Recommendation	Priority	For the Attention of
20. The National Radiation Safety Committee should debate and develop recommendations on the frequency of meetings of Incident Committees in organisations, which hold radiotherapy equipment.		National Radiation Safety Committee
21. The organisation, which reported that a written acceptance test has not been performed and reported by a medical physicist in all cases should review the items of equipment in question and remedy this situation (The identity of this organisation has been made known to the HSE which will enquire on the circumstances described in that organisation's survey response).		Relevant Holder organisation
22. It is the case that there should be 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. This is not the case in all aspects in six out of 10 organisations. In one organisation, the medical physicist was reported to not keep systematic records in all aspects. These organisations should review their arrangements.		Relevant Holder organisations
23. The organisation which reported that either remedial action recommended by a medical physicist has not been acted upon, or written justification for its continued use has not been provided, should identify the item(s) of equipment in question and remedy this.		Relevant Holder organisation
24. Further work is needed in eight out of 10 organisations on local protocols for routine treatment of common cancer types.		Relevant Holder organisations
25. The three organisations which answered No to question D22, which was "Audit is carried out periodically to evaluate total doses delivered per patient", should review and change their practice to evaluate doses delivered to patients.		Relevant Holder organisations
26. The HSE should enquire with the organisation, which did not answer question D 19.1, which was "Medical exposures undertaken are justified and authorised by a named **practitioner**".		HSE
27. All patients should be reviewed at a multidisciplinary team meeting. Three out of 10 organisations should review their arrangements in this respect.		Relevant Holder organisations

Recommendation	Priority	For the Attention of
28. Further work is needed in two out of 10 organisations on development of QC measures and the overall Quality Assurance Programme.		Relevant Holder organisations
29. The HSE should enquire with the organisation which did not answer D23, which was "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."		The HSE
30. The Practitioner in Charge in three out of 10 organisations should ensure that there are referral criteria for all treatment procedures.		Relevant Holder organisations
31. Four organisations should check their arrangements so that verification films are checked and signed by the radiation oncologist in all cases		Relevant Holder organisation
32. Further work is needed by the one organisation out of 10, which stated that there is not a protocol for data checking data transfer in every case.		Relevant Holder organisation
33. The subject of equipment replacement dates and use of equipment beyond this date should be reviewed in four out of 10 organisations as they have not set such dates for all items of equipment. One out of 10 organisations should review its arrangements as one item is being used beyond its replacement date this continued use has not been certified.		Relevant Holder organisation
34. Those organisations which could not answer "Yes in all aspects" to the question on pregnancy, should review their arrangements urgently to ensure that this is done in all cases and properly documented.		Relevant Holder organisations

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 is 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 Quality Authority (HIQA) and 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 task force 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 organisations from December 2007 up until the final deadline of April 2008. Results were then collated and analysed early May 2008.

Confidentiality

The questionnaire submissions were 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.

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. The responses likely to be 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.

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. The authors of this report are not aware of any other European country auditing compliance with the European Medical Exposures Directive (EURATOM) in such a comprehensive way, in either published work or unpublished work in progress.

Acknowledgements

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

Results

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

Table 1: Completeness of sign-off

	Sign-off provided		Sign-off not provided	
	Number	**%**	**Number**	**%**
CEO/General Manager	7	70	3	30
Practitioner in Charge	6	60	4	40

Commentary

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

It is disappointing that the questionnaires were not signed off by those responsible for the application of the SI 478 in a high proportion of cases. 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

	Yes		Not defined		Unanswered	
Responsible Person	**Number**	**%**	**Number**	**%**	**Number**	**%**
Practitioner in Charge (Usually Medical/Clinical Director)	9	90	1	10	0	0
Radiation Protection Advisor	10	100	0	0	0	0
Medical Physics Expert	10	100	0	0	0	0
Radiation Safety Officer	9	90	0	0	1	10
Radiation Therapy Service Manager	10	100	0	0	0	0

Commentary

One organisation does not appear to have a Radiation Safety Officer. It is a legal requirement that they should do so. The details of this organisation have been passed to the HSE.

Recommendations

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

SECTION B: STAFFING AND WORKLOAD

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

	Total in Ireland WTE	Average per organisation WTE	Median per organisation WTE	Maximum per organis - ation WTE	Minimum per organisation WTE
Radiation Oncologist	27.3	2.73	1.8	11	0.1
Trainee Radiation Oncologists	12	1.2	0	12	0
Radiation Therapists	173.05	17.31	10.38	62	3.3
Student Radiation Therapists	13	1.3	0	12	0
Medical Physicists	47	4.7	2.5	12	2
Dosimetrists	18	1.8	1	8	0
Clinical Engineers	9	0.9	0	7	0

Commentary

The questionnaire offered the category of staff "other – please list" and some responses were completed. These included Nuclear Medicine Radiographers, Nurses, Administrators and Health Care Assistants. It is assumed that the Nurses, Administrators and Health Care Assistants 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.

However, the HSE should check this with the relevant organisations. A list of these organisations has been passed to the HSE for this purpose.

Recommendation

The HSE should check with the organisations which listed nursing, admin and health care assistant staff as having responsibilities for justifying or undertaking ionising radiation procedures. It is assumed that the Nurses, Administrators and Health Care Assistants 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.

SECTION B (CONTINUED): NUMBER OF PATIENT EXPOSURES PER YEAR

Total in Ireland	Average per organisation	Median per organisation	Maximum per organisation	Minimum per organisation
278,675	34,834	7,842.5	200,000	1,850

Commentary
Only eight out of ten organisations responded.

The great majority of patient exposures (200,000 out of 278,675) are undertaken by a single organisation.

Two organisations did not answer the question on the number of patient exposures.

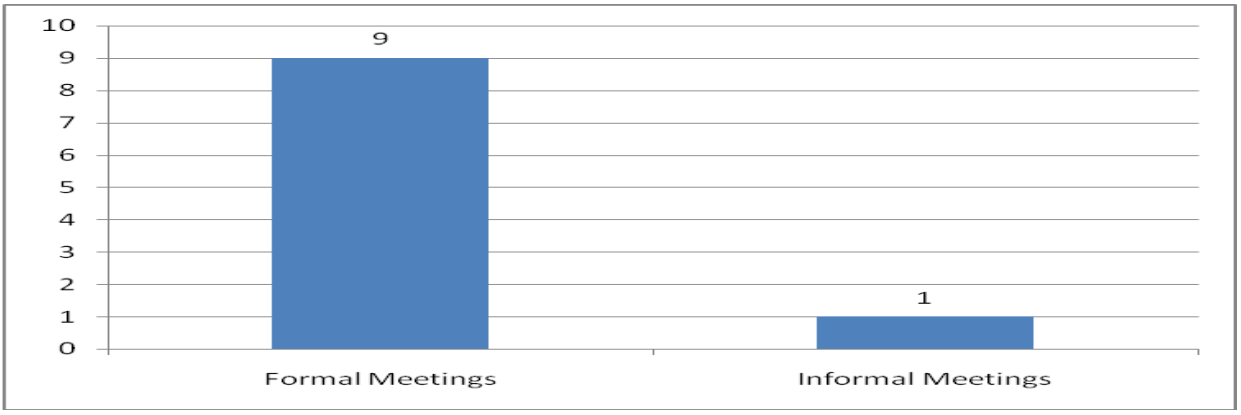
The minimum number of patient exposures out of the eight organisations which did answer was 1,850 per annum.

Recommendation
The HSE should follow up the two organisations that did not answer the question on the total number of patient exposures per annum and ascertain an answer. This should be provided as an addendum to this report to the National Radiation Safety Committee for information and comment.

SECTION C: STRUCTURES AND MANAGEMENT ARRANGEMENTS FOR RADIOTHERAPY CLINICAL AUDIT, RADIATION PROTECTION AND INCIDENT/NEAR INCIDENT HANDLING

Clinical Audit

C1. What formal/informal structures are in place for Clinical Audit in radiotherapy? (e.g. committees, peer reviews, team meetings etc)



Commentary

It is pleasing to note that nine out of ten organisations have formal clinical audit meetings. Informal meetings are not satisfactory. The organisation, where this is currently the case, stated that it was currently developing formal structures.

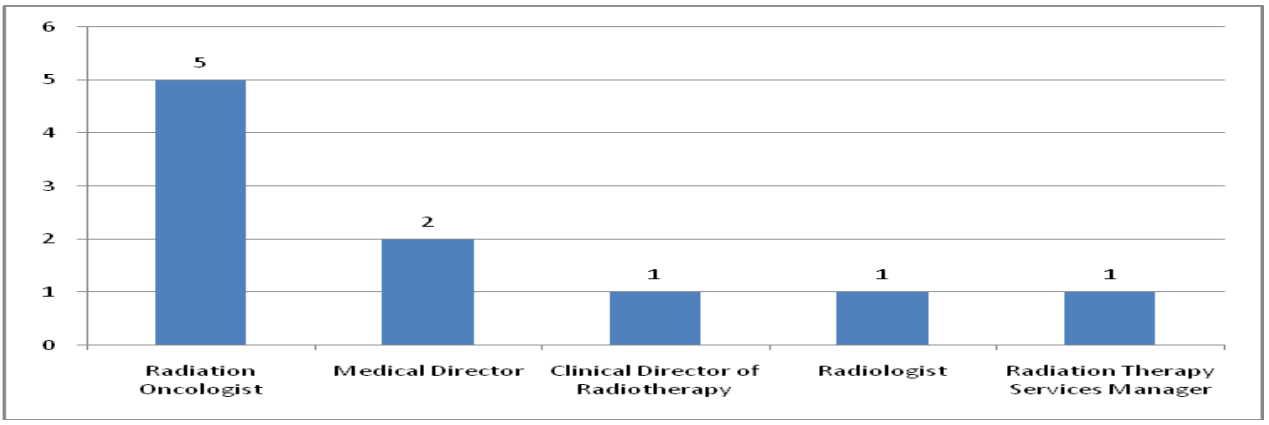
The range of formal structures for clinical audit meetings, described by the nine organisations, was quite varied. It was not clear from all of the answers that there was a single overarching Clinical Audit Committee in each organisation, which would set the policy and direction of clinical audit in the various sub-groups/committees. This would be an area which would benefit from advice/guidance from the National Radiation Safety Committee on optimal structures.

Recommendations

The organisation, which only currently holds informal clinical audit meetings, should formalise its clinical audit structures and work as it has described it would.

The National Radiation Safety Committee should develop and issue guidance on what would be optimal structures to support clinical audit in radiotherapy.

C2. Who has lead responsibility as the Chair of the committee/peer review/team meeting etc? (name and job title)



C3. What are the lines of reporting and accountability for the activities of this committee/peer review/team meeting etc?

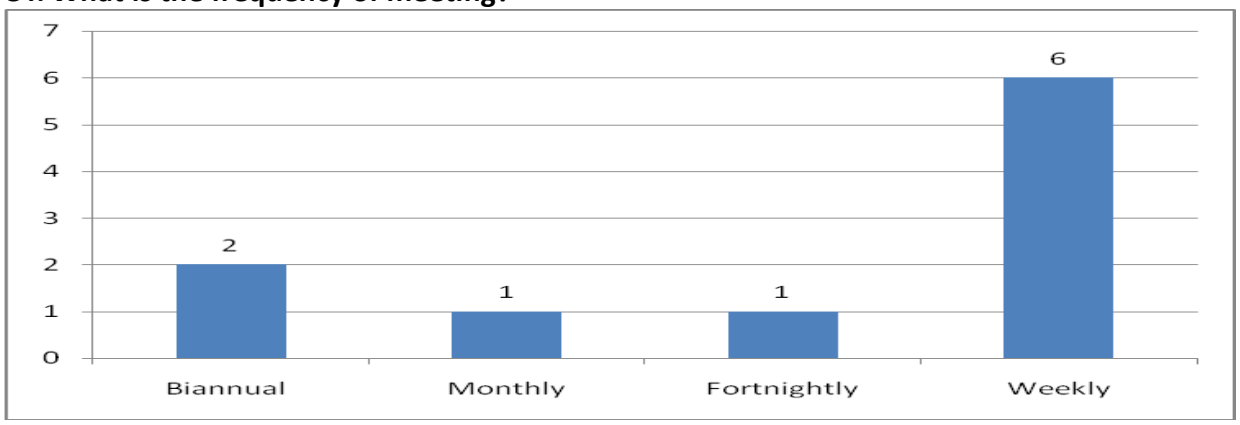
Commentary

The range of lines of reporting and accountability described appear to show a clear line to the Chief Executive of the organisation in most cases, which is most appropriate. However, some of the descriptions were not clear in this respect.

Recommendation

The Chair role of the Clinical Audit Committee for radiology in each organisation should be given its due importance by being an appointment made by the Chief Executive / General Manager of the organisation, 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, for example on the basis of 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.

C4. What is the frequency of meeting?



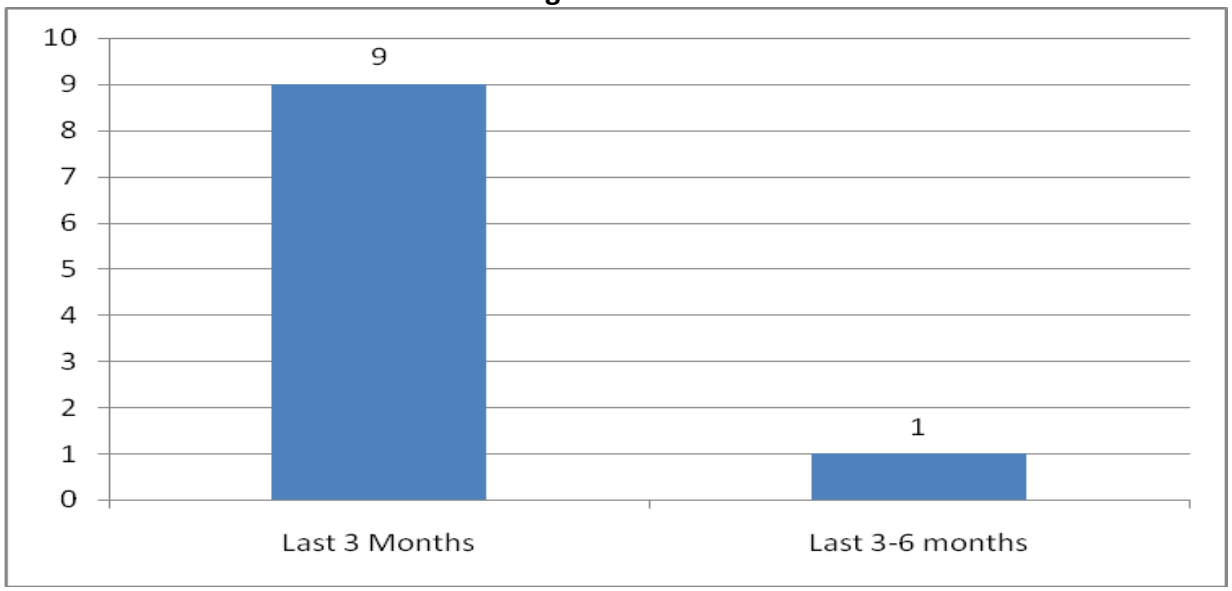
Commentary

It is pleasing to note the frequency of meetings for clinical audit. The National Radiation Safety Committee should consider this and recommended a minimum frequency.

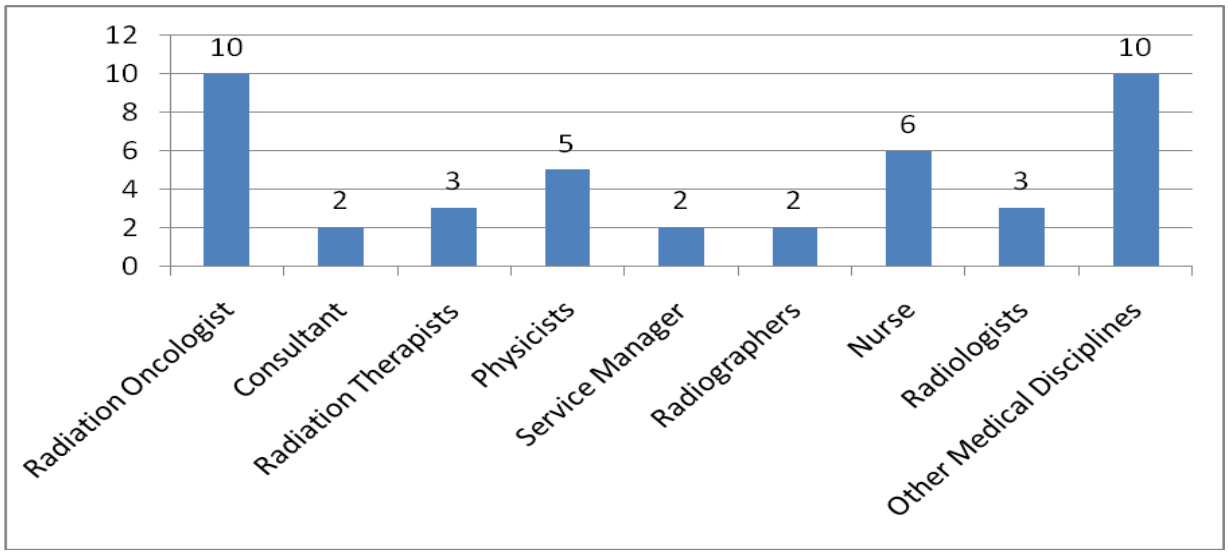
Recommendation

The National Radiation Safety Committee should consider and recommended a minimum frequency of meetings for clinical audit.

C5. What was the date of the last meeting?



C6. What is the membership and multi-disciplinary involvement in the committee/peer review/team meeting etc?



Commentary

The optimal membership of the Clinical Audit Committee would be representatives of all the main disciplines, which are involved / interested in the delivery and safety of ionising radiation in the organisation. None of the organisations were able to state that their committee included each of the following:

- **Radiation Protection Advisor**
- **Medical Physics Expert**
- **Radiation Oncologist**
- **Radiation Therapist**
- **Radiation Safety Officer**
- **Other interested / related disciplines**

None of the organisations has a Medical Physics expert on its Clinical Audit Committee.

Recommendations

The National Radiation Safety Committee should make recommendations on clinical audit structures, which include optimal membership of the Clinical Audit Committee.

C.7 ASSESSMENT OF CLINICAL AUDIT ACTIVITY

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

	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?	
Practice/Procedure	**Yes**	**%**	**Yes**	**%**	**Yes**	**%**
Referral criteria	2	20	2	20	4	40
Indications and decision to treat	2	20	1	10	4	40
Treatment preparation (e.g. Localisation, simulation, verification, immobilisation)	6	60	5	50	7	70
Treatment prescription	4	40	4	40	4	40
Planning procedures	6	60	4	40	5	50
Data accuracy	7	70	6	60	4	40
Treatment delivery	4	40	3	30	2	20
Follow up	2	20	2	20	1	10
Safety	6	60	5	50	3	30
Other	2	20	1	10	2	20

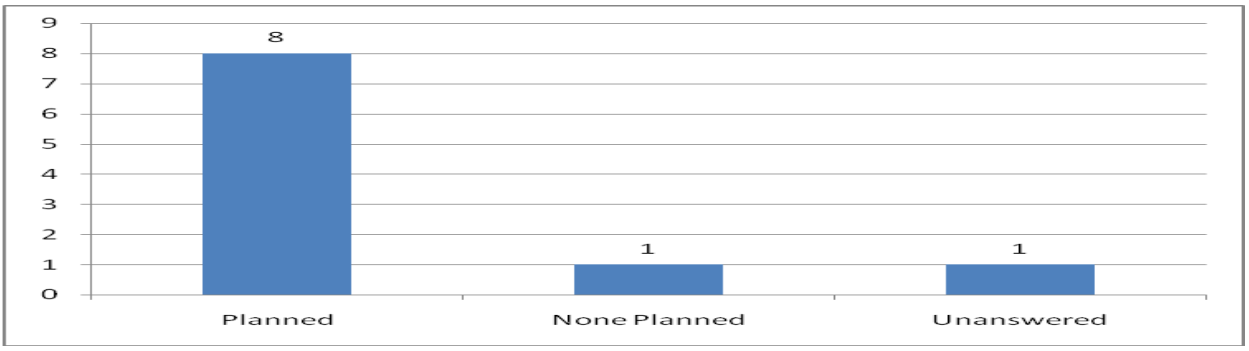
Commentary
Those organisations, which were able to describe audits undertaken in the past year, appear to be going around the audit cycle satisfactorily in most cases. If clinical audit was fully embedded in radiotherapy services, it would be expected that audits should be undertaken by all ten organisations in each of the categories listed.

C8. What criteria are used to prioritise clinical audits in radiotherapy 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
In terms of subject areas to be covered by clinical audit, consideration might be given to areas requiring particular attention in the European Directive, for example high volume or high risk procedures. The National Radiation Safety Committee should debate and provide guidance on this.

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



Commentary

It is unacceptable that two organisations did not respond or answered "None Planned" to this question.

Recommendations

The two organisations which either did not answer or stated that no clinical audits are planned should review their arrangements, since it is unacceptable that there is no forward programme of clinical audits. All organisations should have audits planned in their forward programme covering all of the areas specified within the report.

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	
	No.	%	No.	%	No.	%
Quality improvement team	10	100	0	0	0	0
Quality improvement projects	9	90	1	1	0	0
Risk management structure	10	100	0	0	0	0
Complaints review programme	9	90	0	0	1	10
Guidelines, policies and procedures being developed	10	100	0	0	0	0
Protocols being developed	10	100	0	0	0	0
Patient pathways being developed	7	70	1	10	2	20
Accreditation standards being implemented	7	70	1	10	2	20
Patient involvement projects	5	50	3	30	2	20
Research / Clinical Trials	5	50	3	30	2	20

Commentary

It is pleasing to note a high level of quality improvement activity taking place with radiotherapy departments. The situation would be further improved if all organisations were undertaking quality improvement initiative in all areas including patient pathways, accreditation standards being implemented and patient involvement.

Recommendations

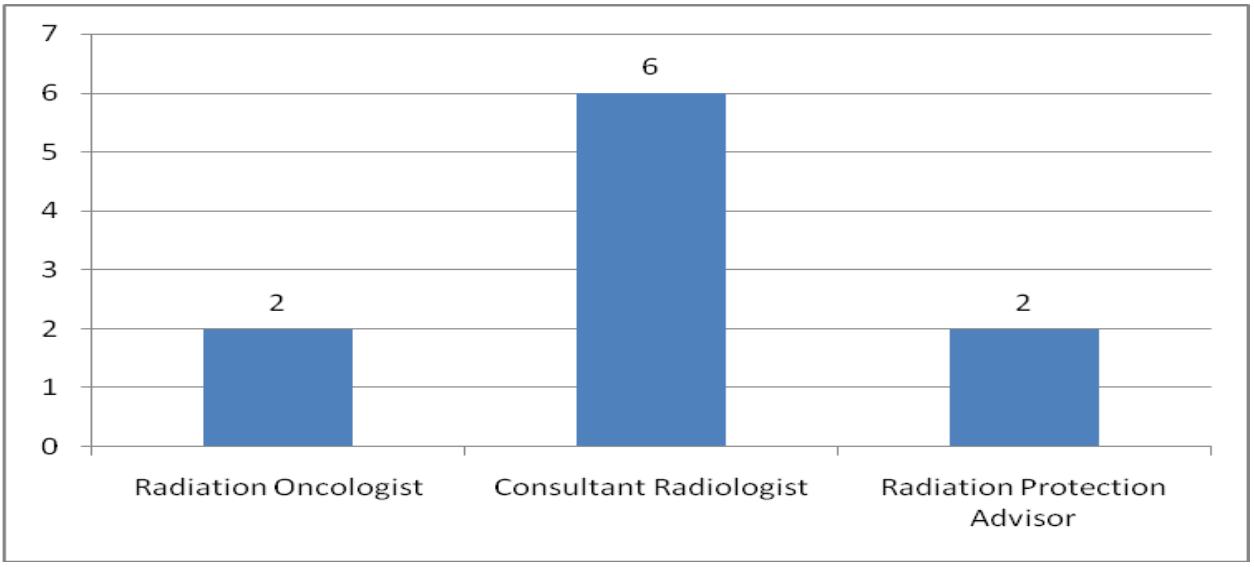
It is pleasing to note a high level of quality improvement activity taking place with radiotherapy departments. The situation would be further improved if all organisations were undertaking quality improvement initiatives in all the areas suggested in this report, including: patient pathways, accreditation standards being implemented and patient involvement.

SECTION C (CONTINUED): RADIATION PROTECTION COMMITTEE

	Yes		No	
	Number	**%**	**Number**	**%**
C11. Does your organisation have its own local Radiation Safety Committee or does it relate to a regional Radiation Safety Committee?	10	100	0	0

We asked the organisations to describe the following in respect of their Radiation Safety Committee:

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



Commentary

The legal obligation to have a Radiation Safety Committee has been met in all organisations which hold radiotherapy equipment.

Recommendation

The authors of the report have wondered whether there is any conflict of interest in a Radiation Oncologist being the Chair of the Radiation Safety Committee in a radiotherapy department. The potential conflict lies in the responsibility of the Radiation Oncologist 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?

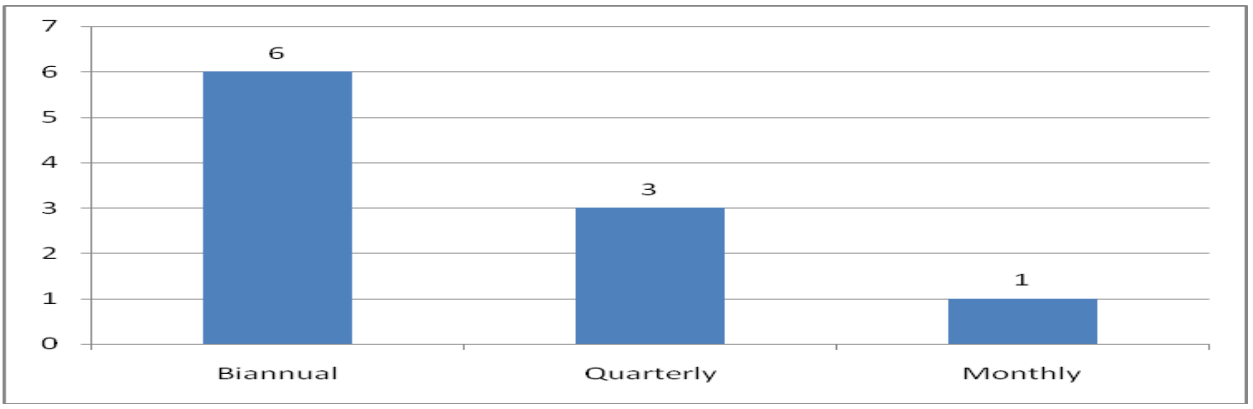
Commentary

The range of lines of reporting and accountability described appear to show a clear line to the Chief Executive of the organisation in most cases, which is most appropriate. However, some of the descriptions were not clear in this respect.

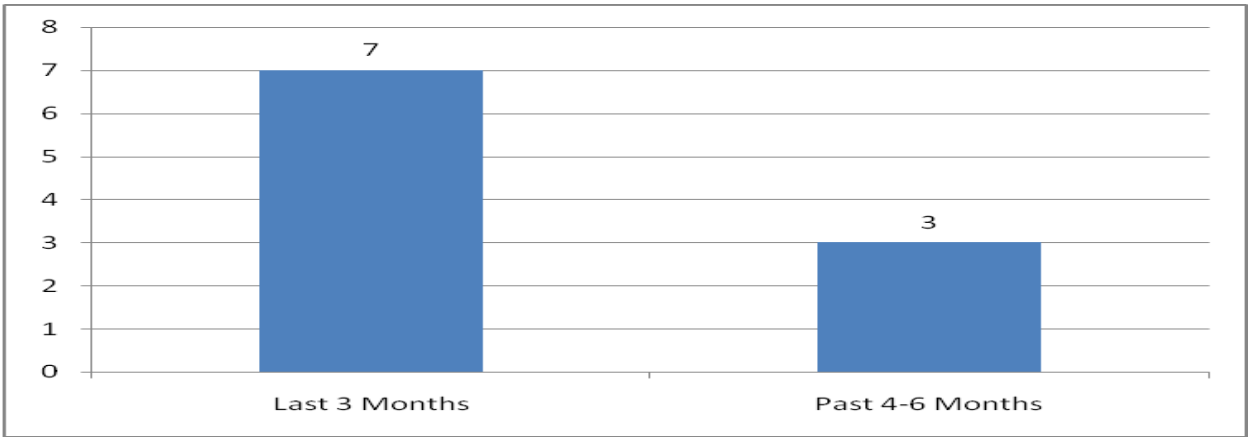
Recommendation

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.

C14. What is the frequency of meeting?



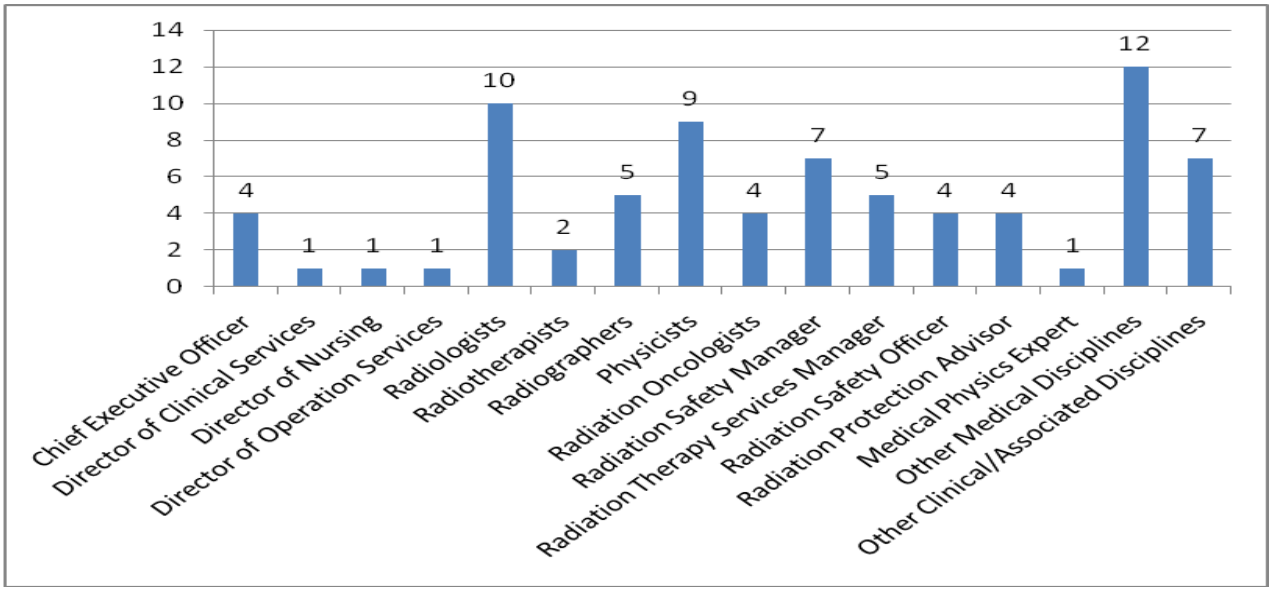
C15. What was the date of the last meeting?



Commentary

The stated frequency of meetings for the local Radiation Safety Committee is satisfactory and to be commended.

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



Commentary

The optimal membership of the local Radiation Safety Committee would be representatives of all the main disciplines, which are involved / interested in the delivery and safety of ionising radiation in the organisation. None of the organisations were able to state that their committee included each of the following:

- **Radiation Protection Advisor**
- **Medical Physics Expert**
- **Radiation Oncologist**
- **Radiation Therapist**
- **Radiation Safety Officer**
- **Other interested / related disciplines.**

Only one of the organisations has a Medical Physics Expert on its local Radiation Safety Committee.

Recommendations

The National Radiation Safety Committee should make recommendations in conjunction with the RPII on local Radiation Safety Committee structures, which include optimal membership.

	Yes		No	
	Number	**%**	**Number**	**%**
C17. Do the terms of reference of this Radiation Safety Committee cover the requirements of the RPII and SI 125?	10	100	0	0

Commentary

This is correct and to be commended.

	Yes		No	
	Number	**%**	**Number**	**%**
C18. Do the Terms of Reference of this Radiation Safety Committee cover some or all aspects of SI 478?	9	90	1	10

Commentary

The one organisation that answered "No" stated: "No, because SI 478 is about protecting the patient". This demonstrates a variation of opinion about the way that SI 478 relates to the role of the Radiation Safety Committee.

Recommendation

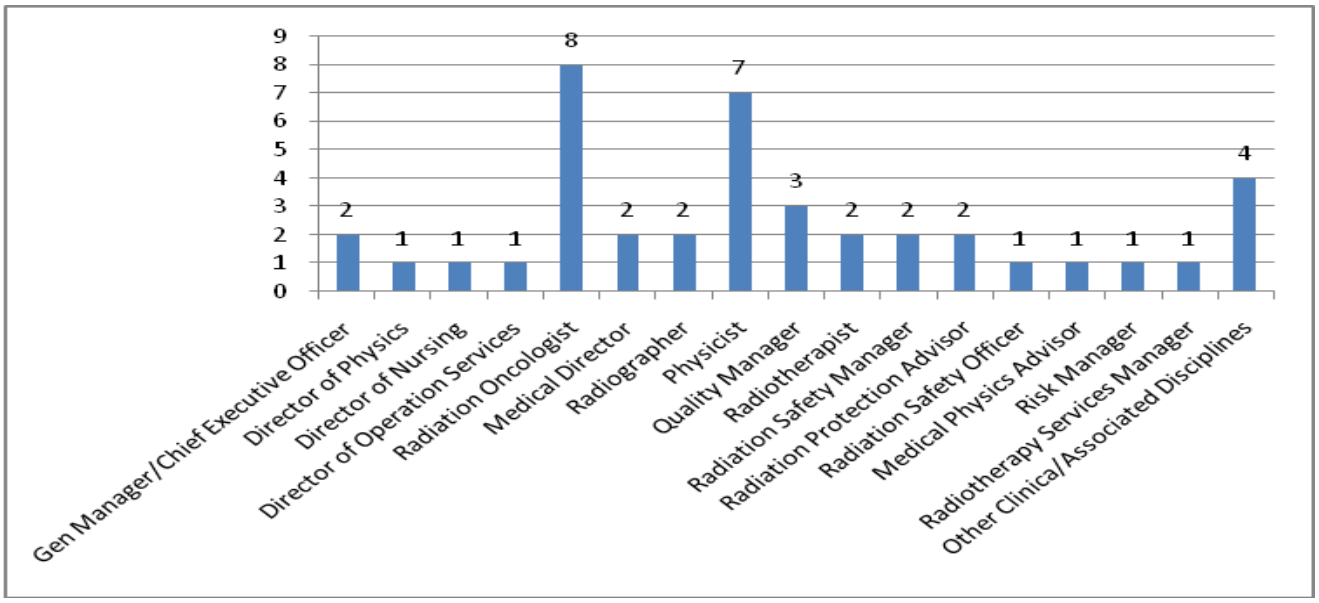
The National Radiation Safety Committee should work with the Radiation Protection Institute of Ireland to debate the relationship between the role of the local Radiation Safety Committees and SI 478.

SECTION C (CONTINUED): RISK MANAGEMENT/ INCIDENT REPORTING

Risk Management/ Incident Reporting	Yes		No	
	Number	%	Number	%
C19. Do you have procedures/guidelines for incident/near incident reporting?	10	100%	0	0%
C20. Do you have procedures/guidelines for incident/near incident review?	10	100%	0	0%
C21. Do you have an incident/near incident reporting form?	10	100%	0	0%
C22. Do you have an incident/near incident risk management committee?	10	100%	0	0%

Commentary
This is correct and to be commended.

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



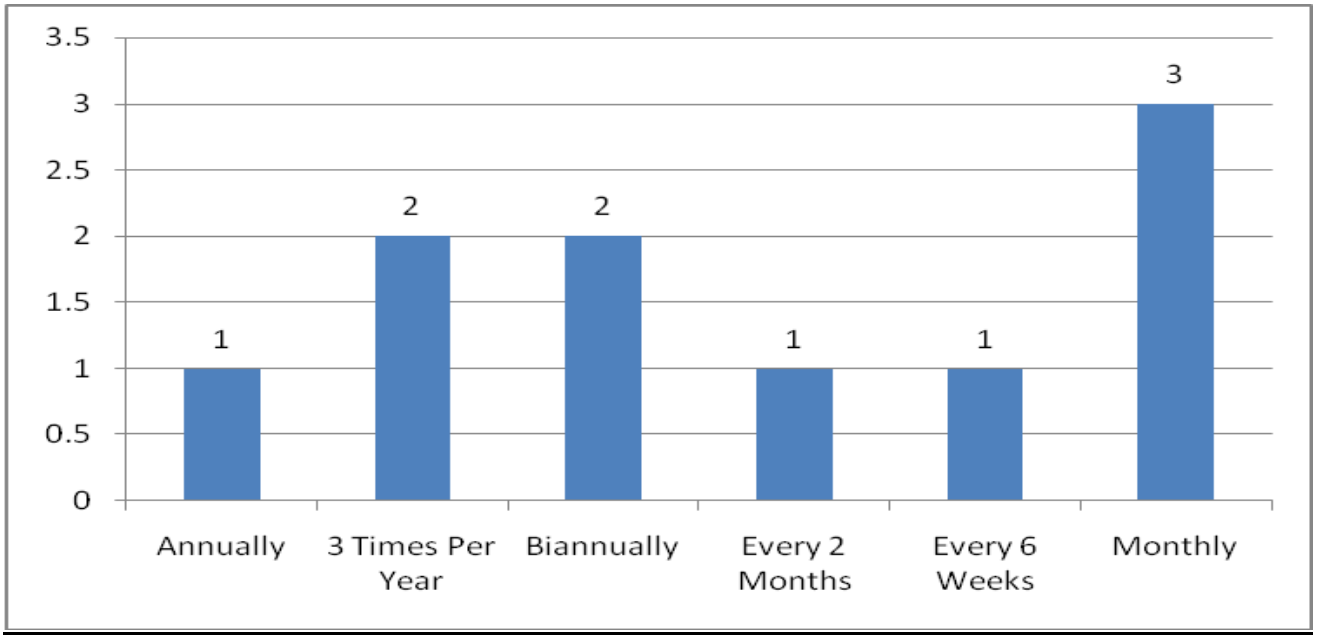
Commentary
The optimal membership of Incident Committee would be representatives of all the main disciplines, which are involved / interested in the delivery and safety of ionising radiation in the organisation. None of the organisations were able to state that their committee included each of the following:

- **Radiation Protection Advisor**
- **Medical Physics Expert**
- **Radiation Oncologist**
- **Radiation Therapist**
- **Radiation Safety Officer**
- **Other interested / related disciplines**

Only one of the organisations has a Medical Physics expert on its Incident Committee.

Recommendations
The National Radiation Safety Committee should make recommendations on local Incident Committee structures, which include optimal membership.

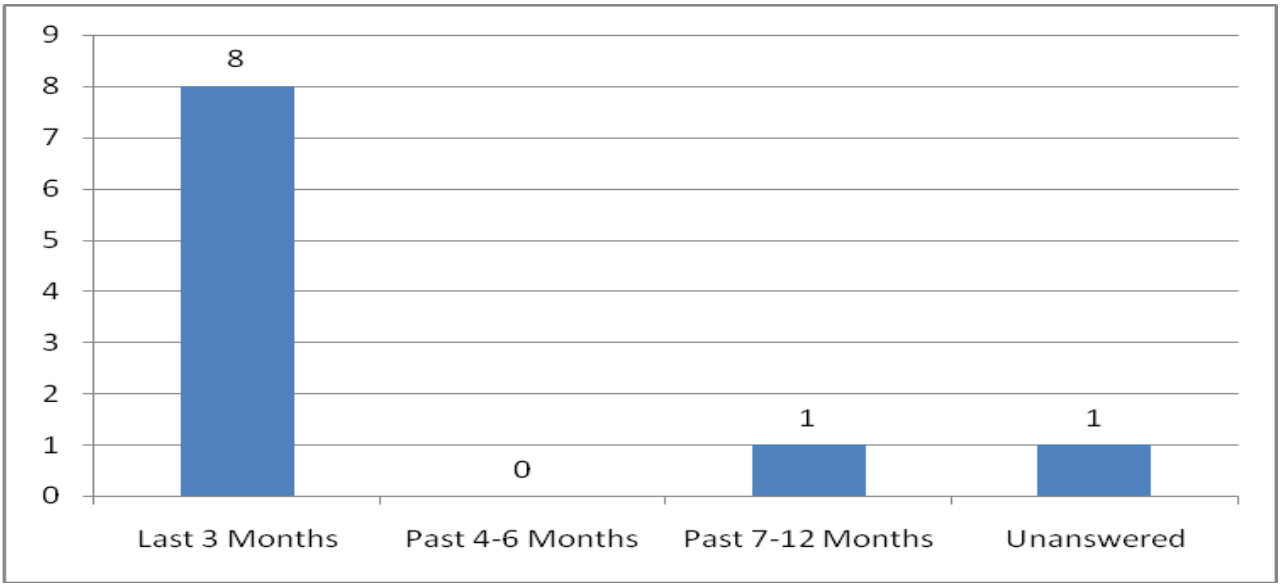
C24. How frequently does the committee meet?



Commentary
There is a wide variation in the frequency of meeting of the Incident Committees. The authors of this report would suggest that at least every six months would be appropriate.

Recommendation
The National Radiation Safety Committee should debate and develop recommendations on the frequency of meetings of Incident Committees in organisations which hold radiotherapy equipment.

C25. What was the date of the last meeting?



C26. What feedback mechanisms are in place?
C27. What is the procedure for informing patients of incidents?

Commentary
The feedback mechanisms described by the different organisations were not consistent with each other.

Recommendations
The National Radiation Safety Committee should provide guidance on optimal feedback mechanisms for Incidents, which include procedures for feedback to patients where appropriate.

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

	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.	4	40	6	60	0	0	0	0	0	0	0	0
D2. The **medical physicist** maintains systematic records of the assessments made.	9	90	1	10	0	0	0	0	0	0	0	0

Recommendation

It is the case that there should be 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. This is not the case in all aspects in six out of 10 organisations. In one organisation, the medical physicist was reported not to keep systematic records in all aspects. These organisations should review their arrangements.

	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.	9	90	1	10	0	0	0	0	0	0	0	0

Recommendation
The organisation, which reported that a written acceptance test has not been performed and reported by a medical physicist in all cases should review the items of equipment in question and remedy this situation (The identity of this organisation has been made known to the HSE which will enquire on the circumstances described in that organisation's survey response).

	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.	%
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.	9	90	1	10	0	0	0	0	0	0	0	0

Recommendation
The organisation which reported that either remedial action recommended by a medical physicist has not been acted upon, or written justification for its continued use has not been provided, should identify the item(s) of equipment in question and remedy this.

	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 evidence based practice, are in place for routine treatment of all common cancer sites	2	20	7	70	0	0	1	10	0	0	0	0
D6. These local protocols include referral criteria, an assessment of the benefits and risks to the individual, the operators and wider society.	2	20	5	50	1	10	2	20	0	0	0	0

Recommendation
Further work is needed in eight out of ten organisations on local protocols for routine treatment of common cancer types.

	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.	%
D7. Patients are reviewed at a multidisciplinary team meeting	8	80	1	10	1	10	0	0	0	0	0	0
D8. Peer review meetings are held for new patients	7	70	2	20	1	10	0	0	0	0	0	0

Recommendation
All patients should be reviewed at a multidisciplinary team meeting. Three out of ten organisations should review their arrangements in this respect.

	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.	%
D9. Each item of equipment has a written regime of quality control measures, related to the following: safety tests; mechanical/geometric tests; beam dosimetry; clinical dosimetry; in vivo dosimetry; record and verify or other network, imaging and advanced techniques as applicable. These control measures have specified timescales and circumstances in which the measurements should be made and records kept.	8	80	2	20	0	0	0	0	0	0	0	0

	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.	%
D10. These QC measures are recorded systematically in accordance with the timescales specified in the specified regime.	10	100	0	0	0	0	0	0	0	0	0	0
D11. Quality Assurance Programmes, written protocols and working instructions are established for every ionising radiation installation to prevent accidental exposures.	8	80	2	20	0	0	0	0	0	0	0	0

Recommendation
Further work is needed in two out of ten organisations on development of QC measures and the overall Quality Assurance Programme.

	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.	%
D12. The Practitioner in Charge (usually the medical/ clinical director) has recommended the referral criteria for treatment procedures undertaken.	5	50	3	30	0	0	0	0	2	20	0	0

Recommendation
The Practitioner in Charge in three out of ten organisations should ensure that there are referral criteria for all treatment procedures.

	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.	%
D13. Written criteria defining who may prescribe a course of radiotherapy is in place in your organisation, which includes a signature protocol. **Note: According to SI 478 and the Medical Council, a "prescriber" is a person who is registered as a medical practitioner under the Medical Practitioners Act 1978.**	10	100	0	0	0	0	0	0	0	0	0	0
D14. The prescription states: Patient name and ID, the treatment volume, number and position of fields, beam energy and type, diagrammatic representation of the treatment area, setting up information, total dose, dose per fraction and total time, name and signature of the radiation oncologist.	10	100	0	0	0	0	0	0	0	0	0	0
D15. All treatment plans are signed by the dosimetrist / physicist responsible and the prescribing radiation oncologist	10	100	0	0	0	0	0	0	0	0	0	0

	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. Verification films are checked and signed by the radiation oncologist	6	60	3	30	0	0	1	1	0	0	0	0

Recommendation

Four organisations should check its arrangements so that verification films are checked and signed by the radiation oncologist in all cases.

	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.	%
D17. All calculations are double checked by two independent staff members	10	100	0	0	0	0	0	0	0	0	0	0

	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.	%
D18. Protocol for checking data transfer	7	70	1	10	0	0	0	0	2	20	0	0

Comment
The two organisations which stated that this was not applicable to them stated that their equipment had integral data transfer.

Recommendation
Further work is needed by the one organisation out of ten, which stated that there is not a protocol for data checking data transfer in every case.

	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. The Medical Physicists take part in national or international external audits for beam dosimetry	10	100	0	0	0	0	0	0	0	0	0	0

	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.**	**%**
D19.1 Medical exposures undertaken are Justified and authorised by a named **practitioner**.	9	90	0	0	0	0	0	0	0	0	1	10

Recommendation

The HSE should enquire with the organisation, which did not answer question D 19.1, which was "Medical exposures undertaken are Justified and authorised by a named **practitioner**".

	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.**	**%**
D20. The **radiation oncologist** seek, where practicable, to obtain previous diagnostic and treatment information and records relevant to the definition of the treatment volume	7	70	3	30	0	0	0	0	0	0	0	0

Recommendation

The three organisations which stated that they do not obtain previous diagnostic and treatment information and records relevant to the definition of the treatment volume in every case should remedy this **urgently**.

	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. This includes all CT scans for treatment planning and treatment review, simulation, verification, portal imaging, EPIDS, IGRT	6	60	4	40	0	0	0	0	0	0	0	0

	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.	%
D20.1 The **practitioner** and **prescriber** seek, where practicable, to obtain previous diagnostic information and records relevant to the planned exposure.	8	80	1	10	0	0	0	0	0	0	1	10

Recommendation

The single organisations which stated that it does not obtain previous diagnostic and treatment information and records relevant to the definition of the planned procedure in every case should remedy this **urgently**.

	Yes		No		Unanswered	
	Number	%	Number	%	Number	%
D22. Audit is carried out periodically to evaluate total doses delivered per patient.	7	70	3	30	0	0

Recommendation
The three organisations which answered "No" to question D22, which was "Audit is carried out periodically to evaluate total doses delivered per patient", should review and change their practice to evaluate doses delivered to patients.

	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.	%
D23. 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.	4	40	0	0	0	0	0	0	5	50	1	10

Recommendation
The HSE should enquire with the organisation which did not answer D23, which was "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."

	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.	%
D24. 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)	6	60	0	0	0	0	0	0	4	40	0	0

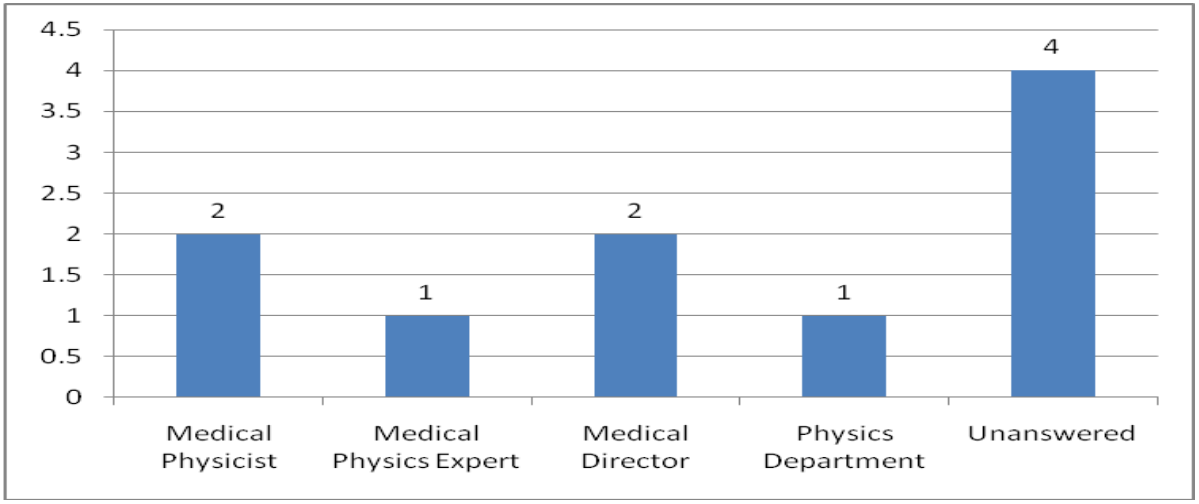
	Yes		No		Unanswered	
	Number	**%**	**Number**	**%**	**Number**	**%**
D25. Is the equipment performance tested after major maintenance by a Medical Physicist?	10	100	0	0	0	0
	Yes		**No**		**Unanswered**	
	Number	**%**	**Number**	**%**	**Number**	**%**
D26. Is there a preventative maintenance contract with manufacturers in place?	10	100	0	0	0	0

D27. If the answer to D26 is "No", who maintains the equipment?	Not applicable: All organisations have a preventative maintenance contract with the manufacturer.

	Yes		No		Unanswered	
	Number	**%**	**Number**	**%**	**Number**	**%**
D28. Has a replacement date been set for each item of equipment?	6	60	4	40	0	0
D29. Does your organisation have any items of x-ray equipment, which are being used beyond the replacement date?	2	20	8	8	0	0

	Yes		No		Unanswered	
	Number	**%**	**Number**	**%**	**Number**	**%**
D30. If "Yes" to **D29,** 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 and the Practitioner in Charge**?	1	10	1	10	8	80
D31. If **Yes** to **D29**, in relation to diagnostic equipment used as part of the planning or treatment process, has the image quality specifically been assessed and certified as being within acceptable limits by the **medical physics expert**?	2	20	0	0	8	80
D32. Has the clinical beam quality been assessed and certified as being within acceptable limits?	10	100	0	0	0	0

If Yes, by whom?



	Yes		No		Unanswered	
	Number	**%**	**Number**	**%**	**Number**	**%**
D33. If **Yes** to **D29**, has a new replacement date been established?	2	20	0	0	8	80

Recommendation

The subject of equipment replacement dates and use of equipment beyond this date should be reviewed in four out of ten organisations as they have not set such dates for all items of equipment. One out of 10 organisations should review its arrangements as one item is being used beyond its replacement date this continued use has not been certified.

	Yes		No		Unanswered	
	Number	%	Number	%	Number	%
D35. 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)	4	40	6	60	0	0

Commentary
This is acceptable, given the nature of the equipment described in the comments.

	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.	%
D36. Before or at the time of referral for treatment women of child bearing age are asked if they are pregnant or breast feeding and this is documented	8	80	1	10	0	0	1	10	0	0	0	0
D37. If pregnancy cannot be excluded a pregnancy test is authorised and, if positive, the decision is to continue with treatment, this is documented and signed by the patient and the radiation oncologist	8	80	1	10	0	0	0	0	0	0	1	10

Recommendation
Those organisations which could not answer “Yes in all aspects” to the question on pregnancy, should review their arrangements urgently to ensure that this is done in all cases and properly documented.

	Yes		No		N/A		Unanswered	
	Number	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
D38. Does your organisation participate in research/ clinical trials?	3	30	7	70	0	0	0	0
D38.1 The ethics committee approval has been given.	3	30	7	70	0	0	0	0
D38.2 Are in accordance with criteria as may be directed by Medical and Dental Councils and the Irish Medicines Board	3	30	7	70	0	0	0	0
D38.3 Written information has been given to the patient to explain the risks.	3	30	7	70	0	0	0	0
D38.4 Written consent is obtained from each patient.	3	30	7	70	0	0	0	0
D39.5 Doses are individually planned	3	30	7	70	0	0	0	0

Commentary

It is surprising that all organisations which undertake radiotherapy do not take part in research/clinical trials. The authors speculate that the reason for this is that the consultants who work in the main providers of radiotherapy services also work in these organisations and so the research is done in their main place of work, in high volume institutions.

SECTION E: INVENTORY OF DIAGNOSTIC AND INTERVENTIONAL EQUIPMENT

The following tables in Section E provide some valuable planning information for the HSE.

Item	Total in Ireland	Mean	Mode	Maximum	Minimum
Simulator	15	1.5	1	3	1
Linear Accelerators	27	2.7	2	8	1
Stereotactic	2	1	1	1	1
Treatment Planning System	16	1.6	1	3	1
Brachytherapy	6	0.6	1	2	1
High Energy x ray	2	0.2	1	1	1
Record and Verify System/ Patient Management System	10	1	1	1	1
Computed Tomography (CT)	2	0.2	1	1	1
Magnetic Resonance (MRI)	2	0.2	1	1	1
Nuclear Medicine/ PET	3	1.5	-	2	1
Radiology Ultrasound	2	0.2	1	1	1
Other	1	0.1	1	1	1

Table Showing Year Machines were Installed

Item	1988	1995	1996	1997	1999	2000	2001	2003	2004	2005	2006	2007	2008	Unanswered	Total
Brachytherapy	1	1						1			1			2	6
Computed Tomography (CT)									1		1				2
High Energy X-ray				1										1	2
Linear Accelerator		1	1		2		5		4	3	3	5	1	2	27
Magnetic Resonance (MRI)									1		1				2
Nuclear Medicine/PET									1	2	1				4
Radiology Ultrasound									1		1				2
Record and Verify System / Patient Management System					1		1		1	1	2	2	1	1	10
Simulator		2						2	3	1	2	3		2	15
Stereotactic													1		1
Treatment Planning System						1			2	2	5	4		2	16
Other				1											1
Total	1	4	1	2	3	1	6	3	14	9	17	14	3	10	88

Table showing year of replacement date

Item	2007	2008	2009	2010	2011	2012	2013	2015	2016	2017	2018	Data not set	Continuous upgrade	Unanswered	Total
Brachytherapy		1												4	5
Computed Tomography (CT)									1					1	2
High Energy X ray				1										1	2
Linear Accelerator		2	2		3			1		4	1	2		12	27
Magnetic Resonance (MRI)									1					1	2
Nuclear Medicine/ PET								1						3	4
Radiology Ultrasound									1					1	2
Record and Verify System / Patient Management System		1										1		8	10
Simulator	1	1						1	1	1		1		8	14
Stereotactic										1		1			2
Treatment Planning System						2			1			2	1	11	17
Other							1								1
Total	1	5	2	1	3	2	1	3	5	6	1	7	1	50	88

SECTION F: OVERALL COMMENTS FROM RESPONDENTS

Only one organisation submitted an overall comment. It was as follows:

"*The application and implementation of this statutory instrument should take account of the fast pace of technology and modern practice development*"

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