Long term conformity assessment of radiation oncology practice standards

AN OPTIONS PAPER

August 2011

Radiation Oncology Reform Implementation Committee's Quality Working Group

Invitation to comment

This Options Paper describes a range of possible approaches by which radiation oncology facilities could be assessed for conformity with the Radiation Oncology Practice Standards (the Standards) in the future, including how these approaches could be implemented.

The Radiation Oncology Reform Implementation Committee's (RORIC) Quality Working Group (QWG) invites you to comment on these options, including the questions set out in each section of the paper.

A web-based Response Booklet has been prepared to assist you to provide your comments. This booklet includes each of the questions in the Options Paper and information about how to respond. The booklet is available to download on the Department of Health and Ageing's website (the Department's website) at: www.health.gov.au/ro . A copy is also included in the Options Paper at Appendix C.

If you would like to comment please:

Email the Response Booklet to: radiation.oncology@health.gov.au

OR

Write to the:

Chair, RORIC Quality Working Group
C/ Radiation Oncology Section
Department of Health and Ageing
MDP 853
GPO Box 9848
CANBERRA ACT 2601

Written comments would be appreciated by **16 September 2011.**

All written feedback received will be published on the Department's website.

It is preferred that written comments are provided by email or other electronic format. Electronic feedback should preferably be saved as an MS Word document (or other text based format) to assist administration and analysis of comments, and to fulfil the Department's obligations to provide information in the most accessible format possible. Hard copy feedback should be typed or written clearly using black ink.

Foreword

In 2002 the Report, *A Vision for Radiotherapy* by Professor Peter Baume (the Baume Report), identified a number of national safety and quality issues relating to radiation oncology.

In 2005, and in response to the Baume Report, the Department of Health and Ageing (the Department) funded the Royal Australian and New Zealand College of Radiologists (RANZCR) to work with the radiation oncology sector to develop a suite of practice standards for radiation oncology facilities (the Standards). In 2007/08, the Tripartite Committee, representing the three key professional groups involved in the delivery of radiotherapy, undertook to further refine and rationalise the Standards in readiness for consultation with the sector.

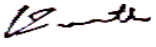
Following that consultation, a draft of the Standards was trialled in 2010 by the National Association of Testing Authorities, Australia (NATA) with funding support from the Department and with project oversight by the Quality Working Group (QWG) of the Radiation Oncology Reform Implementation Committee (RORIC). The trial assessed the suitability and applicability of the Standards and the readiness of the sector to implement them. That feedback has informed the finalisation of a first edition suite of the Standards, which are being launched at the August 2011 Symposium, *Beyond Bricks and Mortar – Building Clinical Cancer Services*, hosted by the QWG.

Much has been achieved in radiation oncology in the almost ten years since the Baume Report. Along with the opening of the Australian Clinical Dosimetry Service this year, the publication of the Standards by the Tripartite Committee is a significant milestone in the development of a quality framework for radiation oncology. The Standards are an important guide to good practice and an invaluable quality assurance and quality improvement tool particularly for those involved in establishing, staffing and operating new or expanded regional cancer centres.

Now that the Standards are published it is important to consider how the Standards might be implemented and measured in the long term. With the support of the Allen Consulting Group, this Options Paper has been prepared by the QWG, to provide you with information about possible approaches to assessing the Standards and to gather feedback about which approach is preferred and how it might be implemented.

This is the first phase of consultation on the long term implementation of the Standards. Your comments will help the QWG prepare advice for RORIC (which reports to the Australian Health Minister's Advisory Council (AHMAC) through its Clinical, Technical and Ethical Principal Committee (CTEPC)) about a preferred approach to implementing the Standards. Once this is determined, another phase of consultation will be undertaken to consider the impact of those arrangements, particularly the costs and benefits to the sector and the community.

I encourage you to take this opportunity to comment on the different models of conformity assessment outlined in the Options Paper. Advice about how to provide your feedback is included in the section, *Invitation to Comment.*



Leigh Smith
Chair, RORIC Quality Working Group August 2011

Contents

Section 1

Introduction

1.1 Development of the Standards

The 2002 Report, *A Vision for Radiotherapy*, by Professor Peter Baume (the Baume Report) identified a number of national safety and quality issues relating to radiation oncology.

The establishment of a quality program for radiation oncology was a recommended outcome of the Baume Report. The need for a suite of practice standards for radiation oncology facilities (the Standards), as part of the quality program, soon became apparent.

The Department began funding the development of the Standards in 2005. In 2007 the initial draft Standards were submitted to the Department. The Standards were then subject to further rationalisation and improvement on a collaborative basis across the radiation oncology sector. A draft of the Standards was settled in 2008.

A Tripartite Committee comprising representatives of the three main health professionals involved in the delivery of radiation treatment, developed the Standards:

- RANZCR, representing medical specialist radiation oncologists;
- Australian Institute of Radiography (AIR), representing radiation therapists; and
- Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), representing radiation oncology medical physicists.

The purpose of the Standards is to provide a framework for ongoing quality improvement in radiation oncology, which has strong support from radiation oncology practices and professionals. The International Society for Quality in Health Care (2004) sets out five principles for healthcare standards, which serve to explain the broader rationale for establishing standards:

- standards contribute to quality and performance improvement in the health organisation and the wider health system;
- the scope of standards is patient/client focused and encompasses the management and support infrastructure of that organisation or service;
- the content of standards is comprehensive and reflects all dimensions of quality;
- standards are planned, formulated and evaluated through a defined process; and
- standards enable consistent measurement.

The 16 radiation oncology practice standards are categorised in three sections, as shown in Box 1.

Box 1

OVERVIEW OF THE RADIATION ONCOLOGY PRACTICE STANDARDS

Facility Management

- Staff
- Workforce Profile
- Management of Radiation Oncology Patient Reports
- Data Management
- Facility Infrastructure
- Facility Process Management
- Equipment

Treatment Planning and Delivery

- Radiation Treatment Prescription
- Planning Procedures
- Dosimetry
- Radiation Treatment Delivery

Safety and Quality Management

- Safety, Quality and Improvement Processes
- Radiation Safety
- Incident Monitoring Program
- Dosimetric Intercomparison
- Clinical Trials Participation

Source: Tripartite Committee Radiation Oncology Standards, 2008

For each standard there is an overarching outcomes statement. The outcome statement is accompanied by criteria and commentary to assist interpretation and implementation, along with details of the evidence required to demonstrate that the outcome has been achieved. The criteria, commentary and required evidence components form the bulk of the Standards documentation (Tripartite Committee 2008, NATA 2011).

The ongoing development and maintenance of the Standards rests with the professions and will remain so irrespective of what governance arrangements might apply to any future conformity assessment arrangements.

1.2 Trial of the Standards

In 2009, NATA was engaged by the Department to undertake a trial of the draft suite of practice Standards. The Report on the trial is available at www.health.gov.au/ro_standards_trials. As NATA explains in the Report, the trial was undertaken during 2010. The objective of the trial was to assess the suitability and applicability of the Standards and the readiness of the sector to accept and implement the Standards. NATA reported that qualitative data derived from feedback given by organisations providing radiation oncology services was 'overwhelmingly positive'. Further stating that:

> *'The general consensus was that the Standards represent good clinical practice, are not onerous and are a sound guide for the provision of safe, quality radiation oncology services. Furthermore, no substantive changes to the Standards were identified, with suggested changes generally editorial in nature.'*

NATA also found that on average radiation oncology facilities possess about 75 per cent of the documentary evidence prescribed by the Standards, which suggests that most of the effort needed to meet the Standards is already embedded in existing practice.

Those standards have now been finalised taking into account the feedback from the Trial.

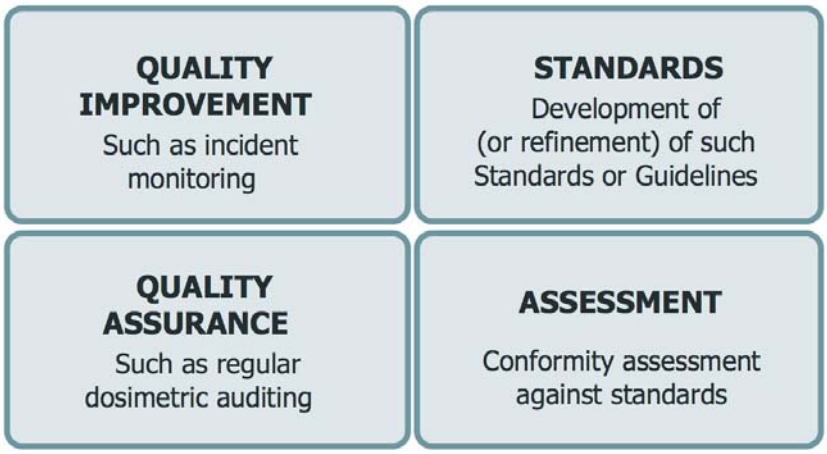
Quality framework

The Standards are best viewed as part of an overall quality framework as shown in Figure 1. The RORIC QWG, under direction from the Australian Health Ministers' Advisory Council, is developing the quality framework.

While this paper is focussed on conformity assessment, the four elements of the quality framework are interdependent. Conformity assessment contributes to ongoing quality assurance and quality improvement; and periodic review and refinement of the Standards. The National Health and Medical Research Council (1999) has advised of the importance of incorporating standards in quality assurance as an effective implementation strategy.

Figure 1

QUALITY FRAMEWORK



Source: Abel MacDonald and Tomas Kron presentation to EPSM 2010

1.3 National standards for health care safety and quality

The Australian Commission on Safety and Quality in Health Care (ACSQHC) was established by the Australian, state and territory governments to develop a national strategic framework and associated work program to guide improvements in safety and quality across the health care system in Australia.

The ACSQHC's role, as explained on its website, is to:

- lead and coordinate improvements in safety and quality in health care in Australia by identifying issues and policy directions, and recommending priorities for action;
- disseminate knowledge and advocate for safety and quality;
- report publicly on the state of safety and quality including performance against national standards;
- recommend national data sets for safety and quality, working within current multilateral governmental arrangements for data development, standards, collection and reporting;
- provide strategic advice to Health Ministers on best practice thinking to drive quality improvement, including implementation strategies; and
- recommend nationally agreed standards for safety and quality improvement.

The ACSQHC national standards focus on the safety and quality of health services. The Standards are presently subject to approval by Health Ministers. Section 3 and Section 6 of this paper consider the implementation of the radiation oncology practice standards in the context of the ACSQHC national standards.

1.4 This Options Paper

The purpose of this paper is to describe possible options for assessing conformity with the Radiation Oncology Practice Standards. It is hoped that this will generate discussion and written feedback about how in the future conformity against the Standards might be assessed, including possible governance arrangements and approaches to practice participation. We encourage interested parties to make written submissions in response to the questions posed throughout the paper. Advice about how to make a written submission is included in the section, *Invitation for Comment*.

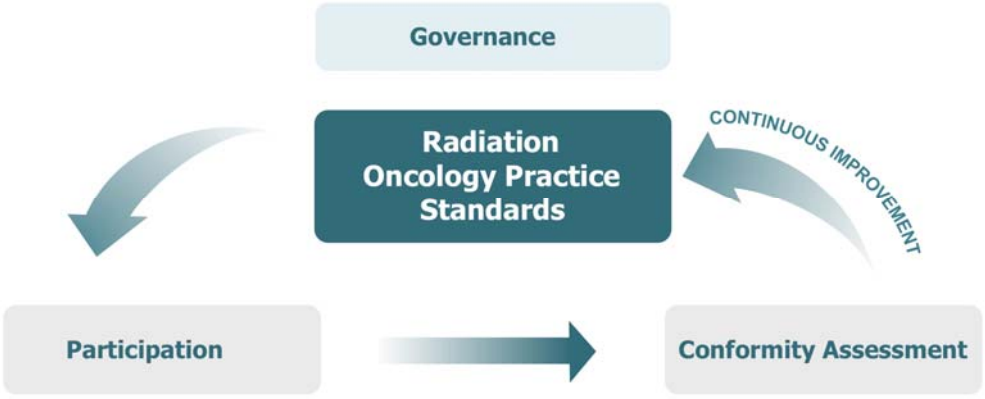
The written submission process will commence concurrently with the release of the Standards at the Quality Symposium *Beyond Bricks and Mortar – Building Quality Clinical Cancer Services* held in Melbourne in August. It is also hoped that this Options Paper will stimulate discussion at the Symposium.

In a regulatory context, conformity assessment would be referred to as compliance and enforcement. While conformity assessment may feature activities that resemble those found in a regulated scheme, a system of conformity assessment would be expected to have a high level of industry 'ownership', although this may co-exist with a strong role for key government agencies and an overall level of government oversight. As the options described in this paper indicate, there is a range of approaches to conformity assessment that vary in their level of prescription, governance and approach to assessment.

A full consideration of costs is not included in this Options Paper because it is about canvassing options and assisting stakeholders in shaping their preferences. A cost benefit analysis would be the next step once a preferred option has been identified. The relationship between the elements considered in the Options Paper is represented in Figure 2.

Figure 2

RELATIONSHIP BETWEEN ELEMENTS CONSIDERED



For each of the options, consideration is given to:

- the advantages and disadvantages;
- impact on stakeholders; and
- complementarity with existing regulatory or conformity assessment frameworks.

Selected examples are drawn from comparable international schemes (United States, Canada, United Kingdom and the International Atomic Energy Agency) and Australian practice areas of General Practice, Diagnostic Imaging, Pathology and Physiotherapy. Appendix A provides an overview of these models.

Discussion questions are provided throughout the document in shaded boxes and a consolidated list of the questions is provided at the conclusion of the paper.

The remainder of this paper comprises the following sections:

- Section 2 — Assessment options;
- Section 3 — Governance options;
- Section 4 — Participation options;
- Section 5 — Consolidation of options considered and high-level impact assessment; and
- Section 6 — Implementation.

Section 2

Assessment options

Options are described corresponding to three questions.

Who does the assessment?

- the practice (self assessment);
- peers; or
- external surveyors.

How are assessors/surveyors trained?

What is the assessment process?

- online remote assessment;
- onsite assessment; or
- combined remote and onsite assessment.

Assessment options are described prior to governance options and participation options, because arriving at the appropriate governance model may be guided by consideration of the preferred assessment model.

2.1 Self assessment

Self assessment by individual practices is an option for determining conformity with the Standards.

In a self assessment model, the practice would carry out its own assessment against the Standards. This option was suggested in the Report on the Trial of the Radiation Oncology Practice Standards (NATA 2011). Within a self assessment option, practices could determine their own system of self assessment. Tools and guidance could be provided to support more active participation. For instance, practices could agree to certain parameters, such as:

- frequency of self-assessment (every year, every two years or every three years);
- format of self-assessment (self assessment to be undertaken using a common assessment tool);
- record keeping (documentation relating to the self assessment is to be retained by the practice for an agreed period of time); or
- random audit (self assessment could be augmented by a sample of practices being subject to an audit to check self assessment documentation. This would require consideration of who does the audit, which is discussed in sections 2.2 and 2.3).

Furthermore, practices could be provided with a guide to assist them in reaching the level of performance that is required in order to conform with the Standards.

Considerations

Self assessment would have the advantage of giving practices discretion in determining how they will implement the Standards. The disadvantage of the option is that practices could ignore the Standards. For those practices that did attempt to make improvements, they may find this difficult due to the lack of detailed guidance of how to go about this. This option may lead to divergent approaches to implementation. Additionally, no information would be collected at a system wide level about quality improvement as a result of the Standards. As NATA (2011) notes, organisations may not have the resources or capacity to develop their own assessment tools.

The parameters outlined earlier in Section 2.1 would provide guidance to practices within a self assessment framework and would go some way to overcoming these disadvantages. A required self assessment frequency would ensure that practices take note of the Standards. A common self assessment tool and guide would provide for a higher level of consistency in implementation of the Standards. Record keeping and a random audit would enable data about conformity to be collected.

The disadvantage of any self assessment based approach is the lack, or relative lack, of external verification. Even with a random audit, only a sample of practices would be audited and there would be a time lag between the introduction of the Standards and the audit process. This would not be well suited to rapidly addressing any deficiencies identified through the audit process.

Examples

The pathology accreditation scheme in Australia allows practices to self assess once they have been found to be complying with the Standards over three consecutive cycles of accreditation. Self assessment in this case recognises consistent and demonstrated high performance in respect of the Standards.

A number of the other models reviewed for the purposes of this paper include a self assessment stage, without relying solely on self assessment (e.g. United Kingdom, International Atomic Energy Agency and the United States). These models are considered in more detail later in this section.

Of the international examples, under the *Quality Assurance Guidance for Canadian Radiation Treatment Programs* (Canadian Partnership for Quality Radiotherapy 2011) scheme, practices are responsible for implementing quality assurance programs and monitoring quality indicators.

Under the American College of Radiology[1]—American Society for Radiation Oncology Accreditation (ACR and ASTRO) partnership for radiation oncology practice accreditation, practices have access to self assessment and independent external expert audit, based on nationally recognised guidelines of ACR, ASTRO and the American Association of Physics in Medicine Task Group reports (ACR 2011).

The United Kingdom is a combined self-assessment/peer review model. The National Cancer Action Team (NCAT) of the National Health Service explains that for the self assessment stage, national evidence guides practices to meet the compliance requirements set out in the *Manual for Cancer Services*.

2.2 Peer assessment

Peer based assessment, involving radiation oncology practitioners from other practices undertaking assessment, is an option for conformity assessment.

A peer review model can involve peers reviewing written self assessment documentation. It can also involve peers undertaking the conformity assessment site visit. As radiation oncology is a cross functional discipline, the peer review team would likely include a representative of each of the three major disciplines.

Considerations

Advantages of peer assessment are that it provides the added rigour of having an objective external review of practice conformity, undertaken by people with experience and expertise. There is also a risk of conflict of interest in such a model. This can be addressed by drawing peers from practices that are not in direct competition with the practice being subject to assessment.

Peer review may be undertaken remotely or in a site visit. The remote option relying solely on the material provided by each facility assessed would provide a lower level of confidence than those options involving a site visit (NATA 2011).

Also, compared with a self assessment model, peer review requires added administrative effort and cost to organise and coordinate a peer network. The administrative effort would be greater in a site visit based model compared with a remote model. As NATA notes, the existence and willingness of sector experts with the requisite skills to undertake desktop review and onsite assessment cannot be assumed. Recruiting these people would require training and possibly payment.

Examples

In the United Kingdom, under the National Cancer Peer Review Program, peers review practice compliance against the *Manual for Cancer Services*. Peer review teams comprise a radiation oncologist, radiation medical physicist and radiation therapist (NCAT 2008). Peer reviewers undertake desktop validation of self assessments and conduct site visits.

[1] The American College of Radiology membership is comparable to the coverage of the Australian radiation oncology standards, as it includes radiologists, radiation oncologists, medical physicists, interventional radiologists and nuclear medicine physicians.

Similarly, the use of a team of peers including each of the major radiation oncology disciplines is the model used by the International Atomic Energy Agency Quality Assurance Team for Radiation Oncology (QUATRO).

It is also possible to include an independent assessor on the review team, accompanied by one or more peers. This is the approach used in the general practitioner scheme in Australia. The Royal Australian College of General Practitioners (RACGP) requires that two health professionals undertake survey and assessment for the purposes of accreditation, however only one of these surveyors must be a general practitioner. Similarly, the pathology and RANZCR/NATA medical imaging accreditation schemes include peer and non peer surveyors.

2.3 External surveyor assessment

Assessment by external surveyors, who specialise in assessing conformity with standards across different fields, is an option for conformity assessment.

Surveyors are recruited as trained assessment experts to contribute to the external review of compliance with practice standards and improve the safety and quality of care (Siggins Miller 2009). Surveyors may be employed by a specialist accreditation agency or they may be medical professionals who undertake surveyor work among their professional duties, usually for payment. Consequently, while external surveyor based assessment is presented here as an alternative to peer review, in practice there may be overlap, as surveyors may be peers, albeit with specialist surveyor accreditation.

The specialist assessment agencies include NATA, Quality in Practice (QIP), Health and Disability Auditing Australia (HDAA) and the Australian Council on Health Care Standards (ACHS).

Considerations

External assessment undertaken by a specialist surveyor provides a high level of separation between the practice and the organisation undertaking the assessment. External surveyors are experts in standards interpretation and measurement and bring this expertise to assessments undertaken by them.

The disadvantages of such a model are that it will probably be the most costly, particularly if it is based on site visits. The cost would be reduced if it were based on online remote assessment of documents submitted to the surveyor by practices. This model may also have difficulty in identifying a sufficiently qualified surveyor cohort. Surveyors would require sufficient technical knowledge of each of the radiation oncology disciplines. Ultimately, it may well be that a peer based approach is the only viable model for recruiting such a group. If desired, an external surveyor role could be incorporated in a peer-based model.

Examples

The diagnostic imaging scheme linked to the payment of Medicare benefits has three external assessors (NATA, QIP and HDAA). They accredit diagnostic imaging practices based on desktop audits. Practices may select which of the three agencies they wish to be assessed by. Although the scheme's current standards do not require onsite assessment, this could be a requirement in future versions of the Standards. Each accreditor operates independently within the guidelines provided by the Department using technical assessors and not peers (Department of Health and Ageing 2011).

Although not an example as such, the new Australian Clinical Dosimetry Service (ACDS) is relevant in considering conformity assessment of the Standards. As the overview of the ACDS provided in Box 2 suggests, the ACDS could have a future responsibility for assessing conformity against standard ten: dosimetry. This standard requires radiation oncology facilities to implement a dosimetry system, consistent with national and/or international standards, which ensures the safety and accuracy of the prescribed radiation dose for all clinical treatments. Alternatively, conformity assessment by other mechanisms could require a practice to demonstrate that it participates in the national dosimetry program.

Box 2

AUSTRALIAN CLINICAL DOSIMETRY SERVICE

ARPANSA has been funded to operate the Australian Clinical Dosimetry Service (ACDS) for three years on a trial basis with future funding arrangements to be determined following an evaluation in the third year of operation. Funding during this period is being provided under the Better Access to Radiation Oncology initiative. The ACDS was officially opened in February 2011. The purpose of the ACDS is to support improvement in radiation therapy in Australia by providing an independent dosimetric measurement and intercomparison service for external beam radiotherapy. The objectives of the ACDS are to:

- provide dosimetric auditing services to radiation oncology facilities in Australia for external beam radiotherapy
- provide independent validation of radiation dose measurement calculation and delivery for external beam radiotherapy;
- assist radiation oncology facilities to improve accuracy of dose delivery
- improve clinical dosimetric practice by providing support and advice on dosimetric activities; and
- maintain a national register of records of dosimetric information.

The ACDS offers a three level dosimetric audit service. These services measure linear accelerator output and specific treatment protocols. These audit services are free of charge to Australian facilities participating in the ACDS Trial. For the purposes of the Trial these audit services are limited to external beam radiotherapy.

Source: Department of Health and Ageing

Preparing surveyors for conformity assessment

Whether the assessor is a peer or an external surveyor, they need to be adequately prepared for this role. This usually involves some form of orientation, including training, and ongoing professional development.

A literature review of surveyor management undertaken for ACSQHC reported that candidates are typically required to take part in an approved surveyor training course, which may form a part of an orientation program. Training and orientation as a surveyor of an accrediting body includes learning about the accrediting body and its standards, the role of the surveyor, interpreting standards, assessing compliance and surveying techniques. A range of methods such as workshops, teleconferences, self study assignments and mock surveys are used in this initial training. Successful completion of training leads to time-limited certification as a surveyor (Siggins Miller 2009).

Examples

In the United Kingdom, the zonal coordinating team invites nominations of peer reviewers from the cancer networks. The cancer networks are then responsible for nominating an appropriate number of reviewers. These nominees then receive a short training course.

In the case of the general practitioner scheme in Australia, the RACGP requires that new surveyors are subjected to thorough orientation, supervision and mentoring in order to provide a consistent and credible service. Surveyors also undergo continuing professional development, with a focus on interpretation of the Standards.

Box 3

ASSESSOR ACCREDITATION REQUIREMENTS: GENERAL PRACTITIONER PRACTICE

GP and non-GP surveyors are required to demonstrate the following:

- contemporary knowledge of general practice, sufficient to make a reliable assessment of the competence of the general practice to provide safe, high quality products, processes or services;
- thorough knowledge of the RACGP Standards for general practices and relevant assessment method and documentation;
- familiarity with applicable legislation (e.g. drugs and poisons legislation, registration requirements, environment protection requirements);
- detailed knowledge of and experience in risk management, including the ability to analyse systems and their potential for failure;
- a health professional background with qualifications relevant to general practice;
- substantial technical experience in at least one area relevant to general practice (e.g. practice management);
- the ability to communicate effectively; and
- declaration of conflicts of interest (e.g. relationship with the general practice seeking external review such as previously employed by the general practice and/ or provided consultancy services to it).

Source: Royal Australian College of General Practitioners 2010

The ACHS has a group of surveyors who work with ACHS employees to provide a three day training program for newly recruited surveyors. The course is currently offered three times per year. The sessions are structured to give a simulated experience of the survey environment. Development days are offered to surveyors annually and bi-annually to survey co-ordinators.

Box 4

THE AUSTRALIAN COUNCIL ON HEALTHCARE STANDARDS

ACHS independently assesses health care service performance to promote safety. ACHS is an independent, not-for-profit organisation, collaborating with consumers, health care professionals, industry bodies and the broader community to develop the accreditation standards and quality improvement programs used by the majority of Australian hospitals and health care organisations. More than 1,300 individual health care organisations are members of ACHS quality improvement programs. While the ACHS programs relate to all forms of health service, radiation oncology is among the services included in ACHS surveys.

As of 30 June 2010 its surveyor workforce consisted of more than 400 dedicated senior healthcare practitioners with recent and broad experience in healthcare service provision and management.

Source: ACHS Annual Report 2010

2.4 The assessment process

Online remote assessment

Remote online assessment can be undertaken via an online questionnaire with the ability to upload responses, documentation and evidence to third party assessors. The assessors conduct a desktop assessment and provide feedback to the organisation. The process would be similar to the online questionnaire process used by NATA in the trial of the Standards, but could also include documentary evidence being submitted to the assessors (NATA 2011).

Considerations

The main advantage of online remote assessment is its cost effectiveness. It is also relatively unobtrusive for practices. The disadvantage is that the lack of a site visit precludes the opportunity to view actual practice activities, interview staff, undertake file audits and perform similar functions, which are not possible when reviewing documents remotely.

Examples

A number of schemes include a component of online remote assessment, but this is followed up by a site visit. The UK scheme provides such an example and this is described in the section entitled 'combination of remote and onsite assessment'. The diagnostic imaging scheme in Australia is based on a desktop audit. The NATA trial of the radiation oncology standards was based on review of documents provided by a sample of practices.

Onsite assessment

This option would involve an assessment team visiting the facility and reviewing relevant documents, processes and evidence as prescribed by the Standards. Visits could include a full assessment of each standard or a partial assessment (NATA 2011).

Considerations

The main advantage of onsite assessment is its ability to provide a comprehensive assessment. Through a site visit, the assessors can view the practice and its operation with their own eyes. They can undertake certain assessment activities, such as those alluded to in the considerations for the online option, which are not possible when relying on document review.

The disadvantage of onsite assessment is that it is more resource intensive compared with a remote assessment model, and therefore more costly to undertake. If undertaken without a preparatory stage involving the review of documents submitted by the practice, the site visits may need to be longer than desired. NATA (2011) noted that while facilities are on a learning curve about the Standards, assessment teams might have difficulty checking all requirements in a single day, and resolving issues could become protracted.

Examples

Internationally, the QUATRO process involves extensive onsite visits to radiotherapy centres. QUATRO audits may be both proactive (comprehensive reviews of the radiotherapy practice) and reactive (focused investigation in response to suspected or actual incidents). QUATRO proactive audits are undertaken over five days by a team of international experts. The design and coverage of the process reflects its use in countries with divergent levels of infrastructure and service quality. The audit methodology is designed for execution by a multidisciplinary peer review panel.

Combination of remote and onsite assessment

Several of the schemes reviewed feature combined remote and onsite assessment. The remote assessment is used to collect initial information, which is subject to analysis and validated during a site visit. The site visit can then direct time to more in depth exploration of quality practice. During the onsite visit, the team can randomly review patient files and observe other procedures. NATA (2011) advised that during the early years of the Standards a full day of assessment would be advisable following the online desktop reviews.

Considerations

Combining both remote and onsite assessment has the advantage of being a comprehensive approach. In NATA's (2011) view, this option provides the most thorough assessment process and should provide the highest level of confidence that the facility meets the requirements of the Standards.

The disadvantage of this option is that it is probably places the most burden on practices, as they need to complete and submit the documentary component, as well as prepare for and host the site visit component. From a resource perspective, this option requires the supporting infrastructure of an online portal in addition to the pool of assessors who review the documents and conduct the site visits.

Examples

In the UK practice scheme, the assessment process consists of three stages:

- internally validated self assessments — completion of an annual self assessment by the practice that delivers the particular cancer service;
- external verified self assessments — an external check of selected internally validated self assessments led by the zonal cancer peer review coordinating teams via a desktop review; and
- peer review visits — each year a targeted schedule of peer review visits will take place, the self assessment must be completed six weeks prior to the visit.

A similar three step process is evident in the voluntary Australian physiotherapy scheme. The practice initially performs a self assessment prior to the QIP nominated surveyor visiting the practice. Following the visit, the practice then completes the self-assessment and electronically submits the results to QIP. The peer surveyor then undertakes a four hour accreditation assessment. A practice accreditation report is then submitted to the QIP Accreditation Review Committee. If full accreditation is given to the practice, the practice continues quality improvement and compliance with standards and receives ongoing access to education and support from both QIP and the APA (QIP 2011).

The voluntary ACR — ASTRO practice accreditation process offered in the United States is another example. The application to become an accredited practice includes facility treatment and equipment information, staffing levels and qualifications, and physics Quality Assurance/Quality Control documentation. A one day onsite survey is then performed by board certified radiation oncologists and board certified medical physicists. The onsite survey is conducted over one business day for a single facility.

Questions

1. *What are the preferred assessment arrangements for the radiation oncology practice standards and why?*
2. *What role, if any, should existing accreditation agencies play in a model of conformity assessment for radiation oncology facilities?*

Section 3

Governance options

Options are described in response to the following question:

Which sector and organisation(s) should have overall responsibility for administering a program of conformity assessment?

- non-government (the radiation oncology profession);
  - through the Tripartite Committee;
  - through a lead professional body;
- partnership between non-government and government
  - through the RORIC QWG;
  - a hybrid of government and non government options; or
- government.

3.1 Elements of a program

In considering the governance of a program of conformity assessment, it is important to have a sense of the various elements of the program that require ongoing management. Suggested elements are outlined below. As the discussion of options makes clear, these elements could be the responsibility of one entity or there could be a sharing of responsibilities. Some of these elements might be the responsibility of a third party (such as an assessment agency) which is engaged to assess standards.

- *Rule making* — establishing and overseeing the rules for the operation of the program;
- *Administering assessment* — developing and maintaining support systems such as portals for document submission and assessment proformas;
- *Planning assessment* — planning the schedule of assessment, including a timeframe for each practice;
- *Managing assessment* — managing and monitoring any third party which undertakes assessment in accordance with the rules of the program;
- *Following up assessment outcomes and recommendations* — practices that have been asked to improve in certain areas to be assessed as conforming will require follow up to ensure these actions have occurred;
- *Maintaining the Standards* — feedback to the professions to inform development and maintenance of the Standards; and

- *Funding and incentives* — the above activities require resourcing and funding, which could be sourced from practices or governments or a combination of the two. Practice incentives to participate are discussed in Section 4.

3.2 Non government

There are two apparent options if responsibility for administering the scheme is to reside with the profession.

- through the Tripartite Committee; or
- through a lead professional body in agreement with the other professional bodies.

Through the Tripartite Committee

Under this option, the existing Tripartite Committee would be given ongoing responsibility for the conformity assessment program and related activities. The committee could be established as a legal entity in its own right. Alternatively the Department, on behalf of the Australian Government, could enter into a memorandum of understanding (MoU) with the three organisations represented on the committee. Under the MoU, the organisations would agree to retain the Tripartite Committee for this purpose.

Whichever way this outcome was arrived at, the respective roles and responsibilities of the Tripartite Committee, the Department and other stakeholders would require agreement.

The Tripartite Committee in addition to oversighting the conformity assessment program could be directly responsible for the assessments by recruiting and managing peers from the three radiation oncology disciplines. Peers could register as an assessor with the Tripartite Committee, which would train them and then schedule the assessments at facilities. Feedback from the assessments would be immediately available to the Tripartite Committee.

Considerations

Giving this responsibility to the Tripartite Committee has the advantage of continuity. The Tripartite Committee developed the Standards and consequently understands the content and objectives of the Standards. Stakeholders can be confident that this understanding will be reflected in implementation under the Tripartite Committee.

The disadvantage of the Tripartite Committee is the risk that it may not be viewed as sufficiently representative of the major stakeholders. As the other options indicate, key stakeholders include the Australian Government and state and territory governments. A further risk is that the Tripartite Committee would lack adequate resources to provide the various governance functions required. For this reason, the option suggests funding support for a secretariat.

Further consideration of the merits of this option would depend on whether an MoU or legal entity approach were used. MoUs would be simpler and represent a model that the Department and the professional bodies are accustomed to. A legal entity would only be needed if the Tripartite Committee needed to have certain powers that require a legal status.

Example

The Canadian Partnership for Quality Radiotherapy is an example of a collaborative approach to the development of a quality program. While government has a role as a stakeholder, the approach is driven by the professional organisations. The CPQR membership comprises the professional bodies and the Canadian Partnership Against Cancer.

Through a lead professional body with agreement to retain Tripartite Committee (or similar) as a non legal entity

Alternatively, one of the three professional bodies could be designated as responsible for overseeing the program. This would most likely be RANZCR given they are the largest of the three bodies. The involvement of the two professional bodies (AIR and ACPSEM) could be agreed with RANZCR, but RANZCR could have lead responsibility.

Under this option, the bodies could agree to retain the Tripartite Committee. However, the committee would not be established as a legal entity and the main MoU could be between the Department and RANZCR. RANZCR and the Tripartite Committee members could in turn agree to continue to participate on the committee.

One of the three bodies would take the lead role in providing the committee secretariat. If assessments (discussed in Section 2) were to be done by a cross disciplinary team with a representative from each of the three radiation oncology roles, this would further reinforce the tripartite nature of the arrangement in an operational sense.

Considerations

The advantage of this approach is its simplicity. The disadvantage of this model is it may not be viewed as providing a binding enough commitment to a tripartite structure.

Example

RANZCR has undertaken a similar role for the Standards of Practice for Diagnostic and Interventional Radiology and the Medical Imaging Accreditation Scheme (MIAC). This scheme is distinct from the diagnostic imaging accreditation scheme referred to previously, which is linked to Medicare. The medical imaging scheme managed jointly by NATA and RANZCR (much like the pathology scheme) is recognised by the diagnostic imaging scheme as a pathway to accreditation and Medicare eligibility.

3.3 Partnership between government and non government

A governance model where responsibility for administering the scheme is shared between the radiation oncology profession and government could feature:

- the RORIC QWG having a significant role in the scheme; or
- a hybrid of government and non government options.

RORIC QWG

The RORIC QWG could be given responsibility for overseeing the program, supported by a secretariat which could reside in the Department or a designated professional body, such as RANZCR. The QWG has provided project oversight of the trial of the Standards. RANZCR, AIR and ACPSEM are represented on the QWG along with Cancer Australia, consumer representatives and jurisdictional representatives.

Considerations

The advantage of this option is that governance resides in a body that includes a wide cross section of stakeholders. If this arrangement was preferred, membership of the QWG should be reviewed to ensure that all sector interests, including private sector interests are represented. Giving this responsibility to an existing committee, avoids the need to establish a new entity.

Although RORIC is a relatively large committee, the RORIC QWG is not, comprising eight members and two secretariat officers. There may be a view that placing this responsibility under RORIC (albeit through the QWG, which is a sub committee of RORIC) moves the balance of responsibility too far from the professional bodies.

Example

In the pathology accreditation scheme, NPAAC advises health ministers on matters relating to the accreditation of pathology laboratories. NPAAC is comprised of representatives from all states and territories, nominees from peak professional bodies and the Department. NPAAC is a ministerially appointed committee, hence it reports to Ministers.

NPAAC plays a key role in ensuring the quality of Australian pathology services and is responsible for the development and maintenance of standards and guidelines for pathology practices.

The accreditation process for pathology practices in Australia is carried out as a joint initiative between RCPA and NATA. NPAAC and NATA cooperate to facilitate the government's objectives pertaining to safety and quality.

Hybrid model

In a hybrid option, the professional bodies and government could take responsibility for different elements of the program. In considering a hybrid model, it is necessary to consider the main elements of the program. Consideration can then be given to the sharing of responsibility for the main elements. Possible elements of the program were listed in section 3.1, along with a brief description of what each might involve.

The profession would continue to be responsible for maintaining the Standards. Other elements could be assigned to either party but as an observation, for the program to be industry led, the professional bodies would need to retain lead or sole responsibility for most of the elements described.

Considerations

A hybrid model would have the advantage of being inclusive of both government and the professions. This would promote shared ownership of the scheme.

For such a model to be effective, the respective responsibilities of government and the professional bodies would need to be clear so as to avoid role confusion. The disadvantage of such a model is it is invariably more complex than an arrangement where one entity has lead responsibility for governance of the program, which is a feature of the other arrangements described.

Example

The United Kingdom is an example of a hybrid model, in the sense that the National Health Service, through NCAT, has overall responsibility for the system, but assessment itself is based on peer review and has a high level of industry ownership.

3.4 Government

There are three apparent options if overall responsibility for administering the scheme is to reside with government:

- new government entity;
- Department of Health and Ageing; or
- another existing government entity.

New authority

A new authority could be established and given responsibility for overseeing a program of conformity assessment. However, the merit of establishing a new body would need to be carefully considered given the relatively small size of the radiation oncology workforce. Additionally, the Australian Government (through the Department of Finance and Deregulation) has a policy position not to establish new entities when the role can be performed by an existing agency. The policy is set out in *Governance Arrangements for Australian Government Bodies* (2005), which is available online.

Considerations

A new authority would have the advantage of providing dedicated and well resourced oversight of the program. However, any proposal to establish such an entity would probably be challenged by the Department of Finance and Deregulation. This would slow the process and may lead to the agency not being approved.

Department of Health and Ageing

The Department could take direct responsibility for administering the program, perhaps on advice from an advisory body established for this purpose. If the later occurred this would be more akin to a partnership model as described in section 3.3. If the Department had direct responsibility for administering the program, it would develop the rules for the program and approve and manage (perhaps by Deed of Agreement) the entities which would assess radiation oncology facilities against the standards.

Considerations

If the Department undertook this role, it would be able to draw on its experience in other disciplines such as pathology and diagnostic imaging.

The disadvantage of this option relates to how it would be perceived by the sector which could have implications for the relationship between the Department and the professional bodies.

Examples

In the UK, although the profession retains strong ownership for the operation and maintenance of the scheme, overall administration is the responsibility of the National Health Service, through NCAT. NCAT employees do not undertake conformity assessment.

In the pathology scheme, the Department provides a secretariat service to the National Pathology Accreditation Advisory Council (NPAAC). In that scheme, NPAAC is the advisory body the scheme itself is jointly administered by the RCPA and NATA.

Another existing government agency

Cancer Australia

The Australian Government, through Cancer Australia, aims to provide leadership in cancer control to improve patient outcomes and enhance health service deliver. The agency also seeks to guide improvements across the continuum of cancer care. Given that radiation oncology is a cancer care service, Cancer Australia could potentially be given responsibility for overseeing a program of conformity assessment.

Cancer Australia is a statutory agency within the Health and Ageing portfolio. Such an expansion of the agency's role would need to be consistent with the *Cancer Australia Act 2006*. It is noted that among the specific functions listed, the Act also provides for Cancer Australia to undertake any function that the Minister directs it to perform (Cancer Australia Act Part 2, Section 7). For Cancer Australia to undertake this role, the Minister would need to agree for this to occur.

Australian Commission for Safety and Quality in Health Care

In addition to developing national standards for health care the ACSQHC is leading the national coordination of healthcare accreditation programs to assure the safety and quality of Australian health services. In the course of this national coordination role, it may also be possible for the ACSQHC to coordinate a radiation oncology conformity assessment program.

Considerations

Providing Cancer Australia with this responsibility would signal a change in the nature of its involvement in quality assurance. While Cancer Australia has previously worked with Cancer Service Networks to establish a quality assurance framework, such a role is quite different from having direct oversight of conformity assessment for a specific area of cancer service.

While assigning this governance responsibility to the ACSQHC could be considered an extension of its current role, equally it may not sit well with the Commission's broader remit which is to develop and implement the National Safety and Quality Health Service Standards.

Questions

3. *What is the preferred governance arrangement for a conformity assessment program for radiation oncology and why?*

4. *What is the appropriate role for government/s, professional bodies and accreditation agencies within a radiation oncology governance framework?*

Section 4

Participation options

Options are described in response to the following question:

Why do practices participate?

- they volunteer to do so;
- because they receive incentives to do so; and/or
- in response to regulatory requirements.

An option is considered voluntary if a practice has a real choice to not participate. Of the three approaches listed above, the latter two — particularly where there is a significant financial incentive — effectively make participation mandatory. Section 5 also considers whether the assessment of certain standards might be made mandatory.

4.1 Voluntary

Voluntary schemes rely upon practices being motivated to participate by a desire to signal they are a quality provider. For such a scheme to be effective a commitment to quality at the practice level is required, combined with a culture of continuous improvement across the radiation oncology profession and a strong preference for industry led assessment. Financial incentives are less likely to be a feature of a voluntary scheme.

Although participation in a scheme may be voluntary, upon committing to the scheme practices are subject to an assessment model. The rigour of the assessment model is not affected by the participation arrangements. Put another way, assessment under voluntary schemes can be extremely robust.

Considerations

An effective voluntary scheme has the advantage of a high level of practice commitment to the Standards and ongoing quality improvement. In a voluntary scheme with high levels of participation, adherence to the Standards comes to be seen as normal practice.

The disadvantage of a voluntary scheme is the risk of low participation. If few practices elect to participate, this renders a voluntary scheme ineffectual in contributing to general quality improvement across the sector. Early adopters who invest in improvements may feel disadvantaged compared to other practices, particularly if quality signalling does not directly result in increased profitability.

Examples

Participation is voluntary in a number of the examples examined, including the physiotherapy scheme in Australia and the radiation oncology schemes in the United States and Canada.

4.2 Health care funding contingent on participation

A conformity assessment program may be designed with financial incentives to encourage participation. The incentives may be designed so as to make participation a commercial imperative. A financial incentive-based option could include:

- a requirement that a practice be accredited to be eligible for Medicare rebates (as occurs with pathology and diagnostic imaging services in Australia); or
- a practice incentive program, under which practices receive payments from Government for participating in the scheme (as occurs with general practice in Australia).

Although not a direct financial benefit in the form of eligibility for a rebate or incentive payment, practices may also be encourage to participate on the basis of prudent risk management, which is based on minimising exposure to liability.

The National Health and Medical Research Council (1999) advises that many practitioners across all health services are concerned about their potential legal liability if a patient does not receive treatment as specified in practice guidelines. However, those practitioners who adopt standards will be afforded a measure of protection.

Considerations

A model in which funding is contingent on participation will achieve a high level of participation, particularly if the incentive structure provides an imperative to do so. A high level of participation will give confidence that Standards are contributing to ongoing quality assurance across the sector.

The potential disadvantage of such a model is that practices may not have the same level of ownership of the program, as they are effectively being obliged to undertake conformity assessment.

Examples

In the diagnostic imaging scheme, to be eligible for a payment under Medicare a diagnostic imaging service must be rendered from a site accredited to provide that service. The Location Specific Practice Number (LSPN) for the site is the mechanism by which Medicare Australia identifies accredited sites.

The HIA requires a pathology service to be provided in an accredited pathology laboratory in order to obtain Medicare benefits for pathology services (Medicare Australia 2011).

The general practice scheme features the Practice Incentive Program. Payments made through the program are in addition to other income earned by general practitioners and the practice, such as patient payments and Medicare rebates (AGPAL 2011). To be eligible to participate in the program, a practice must be accredited or registered for accreditation.

The United Kingdom scheme is not mandated by regulation but participation is almost universal. The scheme has a number of quality overlays, including the *Ionising Radiation (Medical Exposure) Regulations* and participation by many practices in the relevant British Standards Institution system. There is also an incentive to participate based on prudent risk management, for the same reason identified by the National Health and Medical Research Council in Australia. The role of the National Health Service in the UK is also different, in that the public sector is larger relative to the private sector.

4.3 In response to legislative requirements

Legislation or accompanying regulation may stipulate that a practice is required to participate in conformity assessment. There is a range of different approaches to the use of legislation and regulation. Legislation could be used to bring the scheme into effect, but the detail regarding the operation of the scheme could be a matter for industry to determine, rather than using accompanying regulations. There are some international examples where accreditation is a pre-condition for the licensing and operation of a health service.

Further sanctions for non-conformity with the Standards could be introduced to encourage compliance. Facilities found to not be complying could be publicly named, for example in the Department's annual report.

Considerations

A legislated requirement to participate in conformity assessment would represent a statutory model. This would provide for universal participation, which would ensure the application of the Standards in ongoing quality improvement.

The disadvantage of this option is the risk that it will be viewed as being at odds with a system with strong ownership by the profession. This would however depend on the legislative instrument used and the view of the radiation oncology sector. Those practices with a strong commitment to ongoing quality improvement based on common implementation of conformity assessment by all practices may endorse such a measure. It would ensure early adopters of conformity assessment, who invest in quality improvement, are not disadvantaged relative to others, as they might be in a voluntary scheme. Furthermore, while participation in conformity assessment could be a legislated requirement, the radiation oncology profession would always maintain ownership of the Standards.

A possible Australian funding model pertaining to Radiation Oncology

If financial incentives were to be attached to a program of conformity assessment, this could be done through either of the two existing funding streams for radiotherapy from the Australian Government.

- Firstly, the Australian Government is directly responsible for ensuring patient access to private services, through Medicare rebates to patients. Consequently, the diagnostic imaging accreditation model which uses LSPNs as the administrative mechanism for paying Medicare benefits could be implemented for radiation oncology. In practice, this would mean that a radiation oncology service would only be eligible for a payment under Medicare when it was rendered from an accredited site.
- Secondly, funding for radiation oncology capital equipment is provided separately through Health Program Grants. These grants constitute a capital reimbursement scheme, virtually unique to radiotherapy, which reimburses the capital (generally equipment) component of private services (Department of Health and Ageing 2002). In practice, if this option were implemented as an incentive for participation, one of the criteria for eligibility for health program grants would be participation in a program of conformity assessment, with Health Program Grant payments offsetting the costs of assessment.

In addition, states and territories are responsible for providing a right to access to public hospital services, using funding provided by the Commonwealth under the Australian Health Care Agreements in addition to the jurisdiction's own funds.

Considerations

Before either of these funding streams is used as a financial incentive for participation in a program of conformity assessment, consideration would need to be given to the administrative arrangements and the impacts on patients, facilities and governments.

Questions

5. *Should participation in a program of conformity assessment be voluntary or mandatory for radiation oncology facilities?*

6. *What incentives and/or sanctions, if any, would be preferable and more likely to be effective for radiation oncology?*

Section 5

Summary of options considered and impact assessment

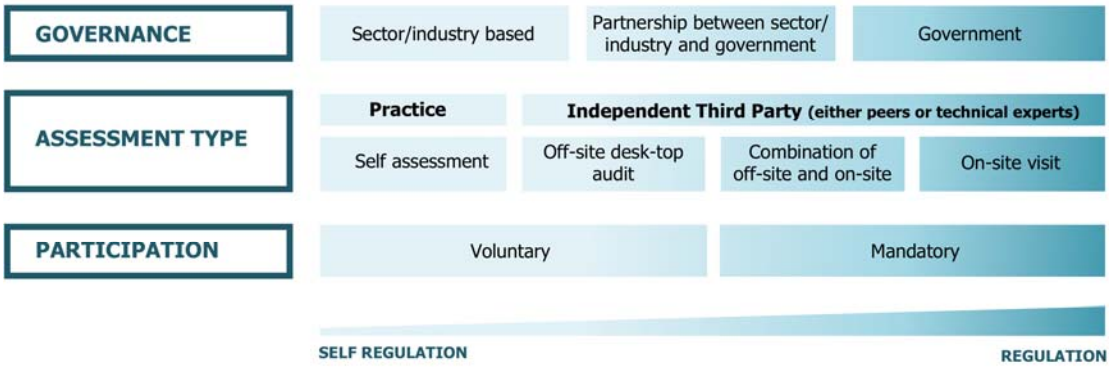
5.1 Overview of options

Conformity assessment can be considered along a spectrum, from voluntary self-assessment overseen by the professional bodies, to formal or legislative compliance obligations with government or regulator oversight.

In the preceding sections a number of options have been set out relating to how the Standards might be assessed, the governance arrangements for an assessment program and approaches to participation. A summary of the options is provided in the table below.

Figure 3

OVERVIEW OF OPTIONS



5.2 Four integrated models

Having considered each of the options described for each element of the scheme, four possible integrated options are outlined in the following sections. While many sub variations are available within each option, broadly speaking, the options represent a continuum from a more industry driven voluntary approach based on self assessment, to a more regulatory style mandatory approach based on external assessment.

For each of the options, a further consideration is the appropriate arrangement for reporting conformity assessment outcomes. Transparent reporting can provide practices with an added incentive to maintain high standards. This approach also provides assurance that assessment is being applied consistently. Under each option, assessment results could be made publicly available in summary form. The exact detail of the approach to disclosure is a matter for the profession to consider along with the entity overseeing the conformity assessment program.

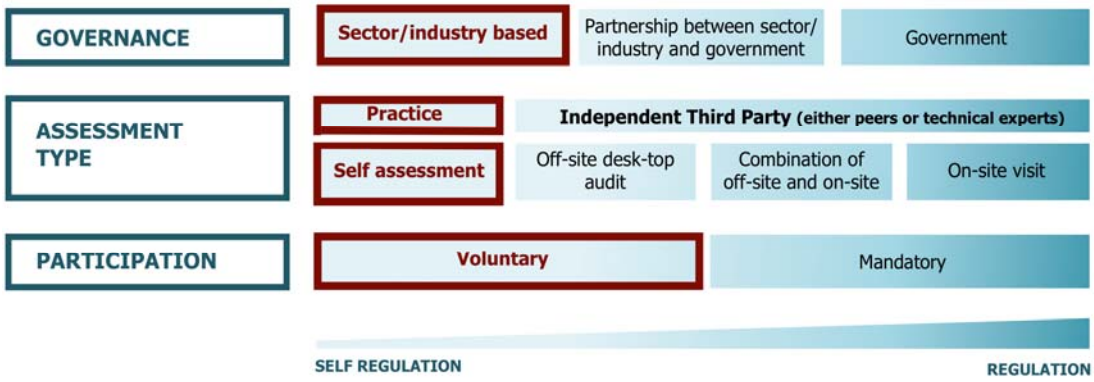
Option 1 — Self assessment based

This model would be based on practice self assessment with voluntary participation. The program would be overseen by industry through the Tripartite Committee. The RORIC QWG could have an advisory role so as to provide a mechanism for input from a broader range of stakeholders including the states and territories. Self assessment would be promoted through the provision of assessment aids such as questionnaires and templates to participating organisations. This could extend to the provision of an online tool, but without external review of the assessments (NATA 2011). In summary, key features of this option include:

- Tripartite Committee develops, implements and supports a program of self assessment for facilities;
- facilities participate voluntarily;
- no external incentives or sanctions, participation based on quality signalling and industry commitment to continuous improvement; and
- feedback from facilities can inform updates of the Standards by Tripartite Committee.

Figure 4

OPTION 1 — SELF ASSESSMENT BASED



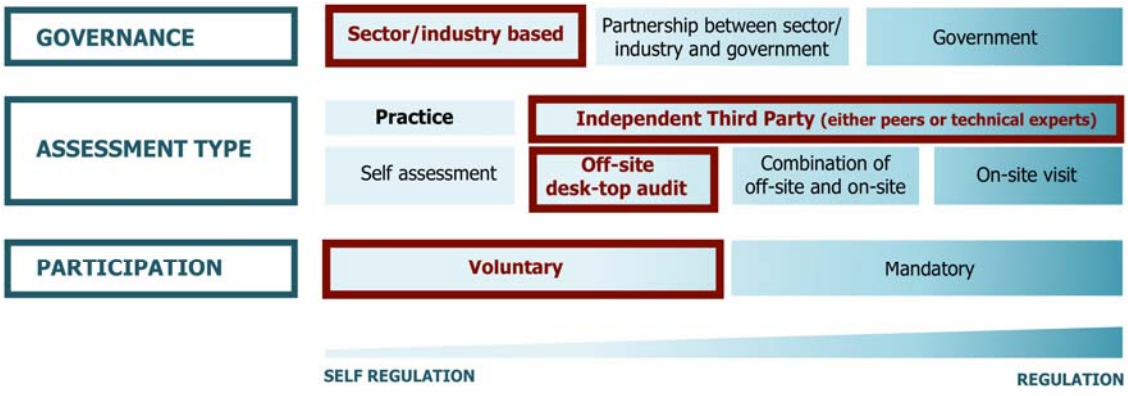
Option 2: Independently verified self assessment with voluntary participation

This model incorporates independently verified assessment and off site desk top audit. The RORIC QWG could have an advisory role so as to provide a mechanism for input from a broader range of stakeholders including the states and territories. The program is industry led and based on voluntary participation. The option could be based on external surveyor assessment or peer assessment, but if peer assessment were chosen, the peers would need to be trained and chosen in such a way as to ensure their independence. Although voluntary, the professional bodies would communicate their strong endorsement of the program and implore all practices to participate. In summary, key features of this model include:

- Tripartite Committee develops, oversees and monitors a desk top audit program;
- audits are undertaken by a third party (such as a certification/accreditation body or peers) which the Tripartite Committee has engaged for this purpose;
- participation is voluntary and documentation is submitted for review by the assessing organisation using technical assessors or peers;
- there are no direct financial incentives for participation or sanctions for non conformance; and
- feedback from facilities and/or independent third party assessor can inform updates of standards by Tripartite Committee.

Figure 5

OPTION 2: INDEPENDENTLY VERIFIED SELF ASSESSMENT WITH VOLUNTARY PARTICIPATION.



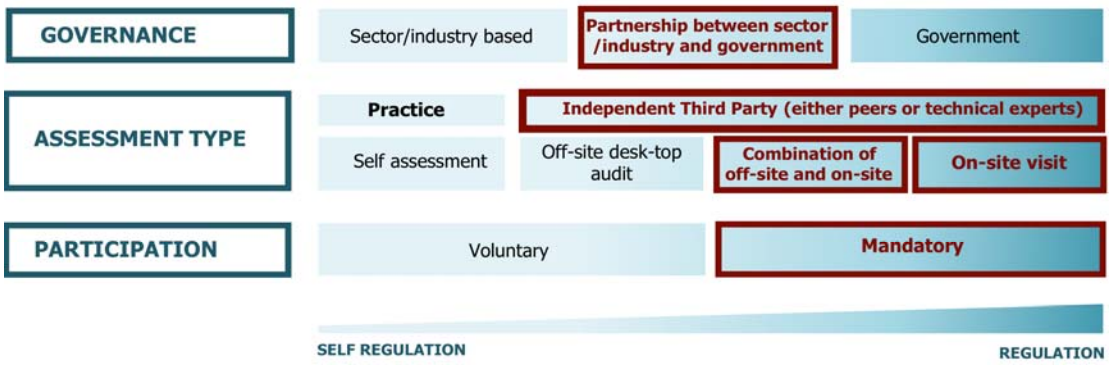
Option 3: Accreditation based: partnership arrangement

In this model, oversight of the assessment program is a partnership between the Tripartite Committee (or lead body) and the Department. The RORIC QWG could have an advisory role so as to provide a mechanism for input from a broader range of stakeholders including the states and territories. This program would be mandatory, requiring practices to be accredited to either provide services under Medicare or to qualify for Health Program Grants. In summary, the key features of this model include:

- oversight of the assessment program is undertaken in partnership between the Tripartite Committee (or lead body) and the Department;
- audits are undertaken by a third party (such as a certification/accreditation body) which the Tripartite Committee has engaged for this purpose;
- assessments involve a combination of off-site and on-site audits (a variation would be on-site only)
- assessment would involve technical assessors (provided by approved assessing bodies) and could also include peers (provided by the professions);
- assessment is linked either to the payment of Medicare benefits or Health Program Grants; and
- feedback from independent third party assessor can inform updates of standards by Tripartite Committee.

Figure 6

OPTION 3 — ACCREDITATION BASED: PARTNERSHIP ARRANGEMENT



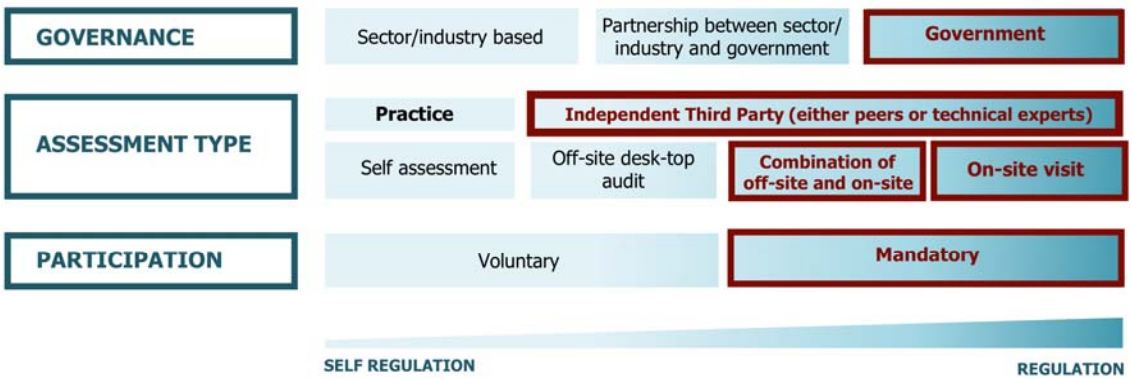
Option 4: Accreditation based: government led

Assessment would be undertaken independently and government would be responsible for oversight and governance. Industry would be responsible for maintaining the Standards based on feedback from the external surveyor. Through this mechanism, industry would provide advice to government on conformity assessment. Additionally, the assessment could include peers. In summary, key features of this option include:

- governance of the program rests with government as the rules for the assessment program are prescribed in legislation;
- government would approve any entity which is assessing facilities — these entities could be defined in legislation;
- assessments involve a combination of off-site and on-site audits (a variation would be on-site only);
- assessment would involve technical assessors (provided by approved assessing bodies) and could also include peers (provided by the professions);
- assessment is linked either to the payment of Medicare benefits or Health Program Grants; and
- feedback from independent third party assessor can inform updates of standards by Tripartite Committee.

Figure 7

OPTION 4 — ACCREDITATION BASED: GOVERNMENT LED



5.3 Stakeholder impact considerations

The main stakeholder groups are as follows:

- practices;
- governments;
- regulators;
- patients; and
- the wider community.

Practices

The perspective of each practice is likely to vary depending on their size, location, range of services offered, whether they are a private or public provider, their financial position and the extent to which they already have quality systems in place.

In assessing the impact on practices, a distinction is made between 'hub' and 'spoke' practices. The NATA trial (2011) reported that in a corporate structure a hub site would be considered as the organisation's head office or main site for administrative purposes. A spoke site would be considered a working facility taking administrative direction from the hub site. It is useful to distinguish between hub and spoke sites when assessing the impact of each option. A hub site manages administrative resources and provides support to spoke sites. A spoke site however may depend on a hub site for administrative support, and have limited administrative resources located at the facility.

It can reasonably be assumed that hub practices will be better equipped to implement changes brought about by conformity assessment requirements, while spoke practices may require more support to implement the requirements.

Government

While the Department of Health and Ageing is a major government stakeholder, the states and territories are significant stakeholders as they are providers and funders of radiation oncology infrastructure and services. The impact on the Department and state and territory governments is considered in terms of the level of administration required under each option.

Radiation safety regulators

State and territory governments are responsible for the state and territory regulations referred to in Table 1. ARPANSA is a significant stakeholder as the national regulator for radiation safety with specific guidelines related to radiation oncology.

Patients

Patients are obviously a key stakeholder group because the drive to improve quality and standards is based on improving patient care and safety. As mentioned in the introductory section, conformity assessment is part of an overall quality improvement framework. Consequently, in considering the impact on various stakeholders, those responsible for the scheme must be satisfied that it will achieve the overarching objective of quality improvement for patients.

Community

Over time increased confidence should also contribute to the wider community having a high level of confidence in the quality of radiation oncology services provided in Australia. That is not to say there is low confidence at present. The inclusion of this stakeholder group reflects that the services provided by radiation oncology practices affect many people beyond the individual patient.

Approach to assessment

The stakeholder impact on each of these groups of the four options described is considered in Table 1. Impact is assessed on a scale of low, medium or high.

For *practices, governments and regulators*, low is assumed to mean the impact is negligible, medium suggests the impact is noticeable but does not imply a major cost or the introduction of new systems, while a high impact suggests the impact has a material cost and accompanying revised processes or systems.

Table 1

STAKEHOLDER IMPACT ASSESSMENT

Stakeholder	Option 1 Self assessment based	Option 2 Ind. verified self assessment	Option 3 Joint assessment	Option 4 External assessment
Hub practices	Low	Medium	High	High
Spoke practices	Medium	Medium	High	High
Health and Ageing	Low	Medium	Medium	High
State and territory governments	Low	Medium	High	High
Radiation safety regulators	Low	Low	Low	Low

Patients and the wider community are considered separately, as this requires consideration of the likely impact on quality. The impact on quality is difficult to assess, because it depends on the level of participation under the voluntary programs. Furthermore, it is hard to anticipate a reasonable timeframe by which conformity assessment using the Standards will have a discernible impact on quality. Initiatives of this type may take a number of years to increase quality across the profession as a whole, and it should be recognised that the Australian radiation oncology sector is already operating at a high level of quality.

Notwithstanding these observations, it is reasonable to state that the mandatory options are more likely to achieve a discernible improvement in service quality in a shorter timeframe, compared with a voluntary option that achieves low participation. Commensurate with this, a model that achieves tangible quality improvement is also more likely to positively contribute to the level of community confidence in radiation oncology practice standards.

Questions

7. *Of the four conformity assessment models, which option is preferred and why?*

8. *Are there any specific stakeholder impacts that should be considered in designing a preferred model?*

Section 6

Implementation considerations

6.1 Implementation guidelines

As NATA noted, regardless of the option adopted, radiation oncology facilities will need to be educated about the requirements of the Standards. Their support will be needed during the transition to new arrangements.

The National Health and Medical Research Council has provided guidance on the development, implementation and evaluation of clinical practice guidelines or standards. A summary of key advice related to implementation and evaluation is summarised below.

Box 5

IMPLEMENTATION GUIDELINES

A variety of approaches has been shown to change clinicians' behaviour or health outcomes or both:

- using opinion leaders and clinical 'champions' in the media and for marketing
- endorsement by key clinical groups
- practice visits from influential experts
- educating patients
- provision of education materials
- seminars and conferences
- reminder systems incorporated in clinicians' daily work
- continuing quality assurance and data feedback
- local adaptation and incorporation
- local involvement and evaluation
- incentives.

Source: National Health and Medical Research Council 1999; A guide to the development, implementation and evaluation of clinical practice guidelines

6.2 Phasing in options

Stakeholders could consider phasing in options for implementation, such as:

- beginning with a voluntary scheme and retaining the option to transition to a mandatory scheme following a formative evaluation; or
- introducing conformity assessment for the Standards considered most critical because non conformity represents the highest level of risk, and deferring the assessment of the remaining standards to a later date.

Beginning with a voluntary scheme

Commencing with voluntary conformity assessment could be an effective way of easing practices into the scheme. This would provide the sector with the opportunity to embrace ownership of the scheme without being mandated to do so. Such an approach would enable an evaluation of voluntary conformity assessment to determine if this approach was resulting in quality improvement at the practice level.

Phasing in using a risk based approach

It is recognised that 'the Standards are interrelated and must be considered as a whole' (Tripartite Committee 2008). However, it may be possible to phase in the Standards by:

- advising practices that the Standards have become operational and they should work towards ensuring conformity with all standards; and
- indicating that initial conformity assessment will focus on the Standards considered most critical, based on assessment of risk in the event of non-conformance.

If a phased approach were pursued, it could also consider the alignment between the radiation oncology standards and the national standards for health services developed by the ACSQHC.

In implementing conformity assessment, it should be recognised that many practices participate in accreditation, certification and quality improvement processes. It might be possible to incorporate the radiation oncology practice standards into an existing program, or to recognise such a program as part of the assessment process.

6.3 Evaluation

Regardless of the implementation approach, an evaluation strategy will be required. Guidance on evaluation is outlined below.

Box 6

EVALUATION GUIDELINES

Evaluation of the guidelines should consider the following:

- How well were they disseminated?
- Is the general trend in clinical practice moving towards the guideline recommendations?
- Have the guidelines contributed to any specific changes in clinical practice?
- How have the guidelines affected consumers' knowledge and understanding?
- Have health outcomes changed?

A date should be set for revision of the guidelines. It is recommended that this occurs every three to five years and more often where the subject matter or circumstances are prone to rapid change.

Source: National Health and Medical Research Council 1999; A guide to the development, implementation and evaluation of clinical practice guidelines

6.4 Complementarity with existing frameworks

NATA noted that the Radiation Oncology Practice Standards were developed to co-exist in a complementary way with other frameworks. Complementarity should be an ongoing objective, and this is likely to require ongoing review and revision of the Standards as related quality and safety initiatives are pursued.

ACSQHC standards

The implementation of the ACSQHC standards is expected to affect the radiation oncology sector, although the precise impact is likely to differ from jurisdiction to jurisdiction, depending on the approach adopted. At a minimum, the introduction of the ACSQHC standards will require review of the radiation oncology standards to ensure consistency where appropriate. This has been the approach adopted by the RACGP for the general practice standards.

Role of state and territory governments

The appropriate role for state and territory governments requires consideration given their concurrent responsibilities contributing to health service funding, providing radiation oncology services, setting policy direction and overseeing radiation safety regulation.

As the discussion of options in Section 5 acknowledges, a direct role for state and territory governments could be achieved through the inclusion of an advisory body with state and territory representation. This would be a feature of the RORIC QWG option for example, as this committee could take on this advisory role. Alternatively, a new committee could be established for this purpose. Such a committee could include the state and territory governments, the Department and the three professional bodies.

State and territory regulations

Each state and territory has its own radiation safety regulations (Appendix B). This options paper has not undertaken a detailed comparison of the substance of these regulations. It is however important to recognise that in an Australian context, the state and territory regulations provide another layer of compliance requirements in addition to the ARPANSA requirements. A similar situation exists in the UK due to the IRMER regulations, which arose from the European jurisdiction. The existence of the state and territory regulations may influence stakeholders in determining if the conformity assessment model requires regulatory backing or if a voluntary based scheme will be adequate to provide the level of quality assurance and improvement that is sought.

ARPANSA

ARPANSA is responsible for protecting the health and safety of people, and the environment from the harmful effect of ionising and non ionising radiation. ARPANSA is part of the Health and Ageing portfolio, reporting to the Parliamentary Secretary to the Minister for Health and Ageing (ARPANSA website).

In this capacity, ARPANSA Radiation Protection Series 14 (2008) includes the Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation. This is accompanied by three safety guides:

- Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology;
- Safety Guide for Radiation Protection in Nuclear Medicine; and
- Safety Guide for Radiation Protection in Radiotherapy.

The ARPANSA codes of practice influence benchmarks for radiation protection and set fundamental requirements for radiation safety. These codes have been in place since 2008 and the authors of the standards would have been aware of them in drafting the radiation oncology practice standards. Unless ARPANSA revised the codes of practice or changes its approach, the introduction of radiation oncology conformity assessment is unlikely to present significant issues of complementarity or excessive complexity.

Questions

9. *Which, if any, of the 'phasing in' options is preferred and why?*

6.5 Conclusion

The design of an appropriate conformity assessment program represents a significant opportunity for the radiation oncology sector to continue the quality reforms that were prompted by the Baume Inquiry. As this paper indicates, there is a range of options available in arriving at a model, as well as an accompanying series of considerations in order to implement the preferred program. This paper has sought to present the options across a continuum from lighter to heavier touch approaches. In devising an approach, the objectives and guiding principles of a conformity assessment based program should remain at the forefront of considerations, namely:

- conformity assessment is a quality assurance function that contributes to continuous improvement; and
- while conformity assessment may feature activities that resemble those found in a regulated scheme, a system of conformity assessment would have a high level of industry 'ownership', although this may co-exist with a strong role for key government agencies and a level of government oversight.

Consolidated list of questions for comment

1. *What are the preferred assessment arrangements for the radiation oncology practice standards and why?*
2. *What role, if any, should existing accreditation agencies play in a model of conformity assessment for radiation oncology facilities?*
3. *What is the preferred governance arrangement for a program of conformity assessment for radiation oncology and why?*
4. *What is the appropriate role for government/s, professional bodies and accreditation agencies within a radiation oncology governance framework?*
5. *Should participation in a program of conformity assessment be voluntary or mandatory for radiation oncology facilities?*
6. *Which incentives and/or sanctions, if any, are preferable and more likely to be effective for radiation oncology?*
7. *Of the four conformity assessment models, which option is preferred and why?*
8. *Are there any specific stakeholder impacts that should be considered in designing a preferred model?*
9. *Which, if any, of the 'phasing in' options is preferred and why?*

Appendix A
Summary of other schemes

Key features of other schemes

Table A1 provides an overview of the features of the other Australian schemes considered in preparing this Options Paper.

Table A1

CHARATERISTICS OF OTHER AUSTRALIAN SCHEMES

	Pathology	Diagnostic imaging	Medical imaging	General practice	Physio
Assessment	Self assessment and onsite	Desktop audit	Onsite	Onsite	Self assessment and onsite
Assessment undertaken by	Accreditation agency (NATA) using Peer and non peer	Accreditation agency either (NATA, QIP and HDAA)	Peer review, NATA	Accreditation agency using a team of peers plus one non peer medical professional AGPAL or GPA plus	Accreditation Agency QIP
Governance	DoHA through NPAAC and the RCPA	DoHA and representatives from the sector	RANZCR	RACGP	APA
Participation	Mandatory for the payment of Medicare benefits	Mandatory for the payment of Medicare benefits	Voluntary	Mandatory for the PIP payment	Voluntary

The diagnostic imaging scheme is the regulated scheme overseen by the Department

The medical imaging scheme is operated by RANZCR and NATA and recognised for accreditation purposes

Table A2 provides an overview of the features of other international schemes considered.

Table A2

CHARACTERISTICS OF INTERNATIONAL SCHEMES

	US	Canada	UK	IAEA
Assessment	Onsite survey	Site visit	Submission of documents followed by onsite inspection	5 day onsite visit
Assessment undertaken by	Peers	Practice self assessment	Practice self assessment followed by peer assessment	Multi disciplinary team including the three radiation oncology roles
Governance	Jointly by ACR and ASTRO	CPQR on behalf of professional organisations	NHS, through NCAT in partnership with industry	IAEA and member governments
Participation	Voluntary	Voluntary	Mandatory	Voluntary (IAEA is invited by host government or facility)

Appendix B
State and territory regulations

Table B1

STATE/TERRITORY REGULATORY FRAMEWORK

State/Territory	Overseeing Authority	Legislation
Australian Capital Territory	ACT health	s.119 Radiation Protection Act 2006 and Radiation Protection Regulation 2007 See: **www.legislation.act.gov.au**
New South Wales	Department of Environment and Climate Change	s.36 Radiation Control Act 1990 and Radiation Control Regulations 2003 See: **www.legislation.nsw.gov.au**
Victoria	Department of Human Services	s.131 Radiation Act 2005 See: www.legislation.vic.gov.au and Radiation Regulations 2007 See: **www.austlii.edu.au**
Queensland	Department of Health	s.198 Radiation Safety Act 1999 and Radiation Safety Regulation 1999 See: **www.legislation.qld.gov.au**
Western Australia	Radiological Council	s.50 Radiation Safety Act 1975 See: **www.radiologicalcouncil.wa.gov.au** And Radiation (General) Regulations 1983 See: **www.austlii.edu.au**
South Australia	Environment Protection Authority	s.49 Radiation protection and Control Act 1982 and Radiation and Control (ionising Radiation) Regulations 2000 See: **www.legislation.sa.gov.au**
Northern Territory	Department of Health and Community Services	s.81 Radiation Protection Act 2004 See: **www.austlii.edu.au**
Tasmania	Department of Health and Human Services	s.76 Radiation protection Act 2005 and Radiation Protection Regulations 2006 See: **www.austlii.edu.au**

Appendix C
Response booklet

Either write or type your comments in the spaces provided. A MS Word version of this booklet can be downloaded from the Department's website: www.health.gov.au/ro

Further information about where to send your comments is included in the section *Invitation to Comment.* Comments would be appreciated by 16 September 2011.

1. What are the preferred assessment arrangements for the radiation oncology practice standards and why?

2. What role, if any, should existing accreditation agencies play in a model of conformity assessment for radiation oncology facilities?

3. What is the preferred governance arrangement for a program of conformity assessment and why?

4. What is the appropriate role for government/s, professional bodies and accreditation agencies within a radiation oncology governance framework?

5.	Should participation in a program of conformity assessment be voluntary or mandatory for radiation oncology facilities?

6.	Which incentives and/or sanctions, if any, are preferable and more likely to be effective?

7.	Of the four conformity assessment models, which option is preferred and why?

8.	Are there any specific stakeholder impacts that should be considered in designing a preferred model?

9.	Which, if any, of the 'phasing in' options is preferred and why?

NAME:

ORGANISATION:

ADDRESS:

EMAIL CONTACT:

DATE:

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