Evaluation of the Australian Clinical Dosimetry Service

Final report

20 December 2013

Department of Health
Disclaimers

Inherent Limitations

This report has been prepared as outlined in the Introduction section. The services provided in connection with this engagement comprise an advisory engagement, which is not subject to assurance or other standards issued by the Australian Auditing and Assurance Standards Board and, consequently no opinions or conclusions intended to convey assurance have been expressed.

KPMG has indicated within this report the sources of the information provided. We have not sought to independently verify those sources unless otherwise noted within the report.

KPMG is under no obligation in any circumstance to update this report, in either oral or written form, for events occurring after the report has been issued in final form.

The findings in this report have been formed on the above basis.

Third Party Reliance

This report is solely for the purpose set out in the Introduction section and for the Department of Health’s information, and cannot be relied on by any other party. The report is dated 20 December 2013 and KPMG accepts no liability for, and has not undertaken work in respect of, any event subsequent to that date which may affect the report.

This report has been prepared at the request of the Department of Health in accordance with the terms of KPMG’s official order. Other than our responsibility to the Department of Health, neither KPMG nor any member or employee of KPMG undertakes responsibility arising in any way from reliance placed by a third party on this report. Any reliance placed is that party’s sole responsibility.

Electronic Distribution

Responsibility for the security of any electronic distribution of this report remains the responsibility of the Department of Health. KPMG accepts no liability if the report is or has been altered in any way by any person.
Executive Summary

The Department of Health (the Department) funded the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) through a Memorandum of Understanding (MoU) to operate the Australian Clinical Dosimetry Service (ACDS) on a trial basis for a four-year period from June 2010. In late 2012, the Department engaged KPMG to evaluate the ACDS trial, and provide advice on options for an ongoing national dosimetry audit service into the future.

This report presents the evaluation’s findings and outlines options and recommendations for the future.

PART ONE: Evaluation of the Australian Clinical Dosimetry Service

The context

Radiation therapy, or radiotherapy, is one of the main treatments for cancer which is a major cause of illness among the Australian population. This therapy is delivered via a variety of different techniques including external beam radiation therapy (EBRT). EBRT uses linear accelerator machines (linacs) for the delivery of prescribed radiation doses to patients, and is the focus of the ACDS. Within this technique, machine calibration according to standards, and dosimetry (measurement of radiation dose) are critical safety components.

Within Australia, there has been a rapid growth in the number of radiation oncology facilities and linacs, coupled with high demand for radiotherapy. Continued growth, projected key workforce shortages over time, continued expansion of radiotherapy techniques, and use of new technologies, indicate the need for effective quality assurance mechanisms to manage risk factors that may collectively increase the potential for errors and patient injury. This is reinforced by international lessons from accidental exposures in radiotherapy. Dosimetry audit is one component of an effective quality assurance approach.

The Australian Clinical Dosimetry Service

The ACDS trial was established to “support improvements in radiation therapy in Australia by providing an independent dosimetric measurement and inter-comparison service for clinical radiation therapy”. The total value of funding to the ACDS was $3,162,500 (including GST) over a four-year period. The trial’s operational phase commenced in January 2011, with services being provided free of charge to radiation oncology facilities that volunteered to participate in an audit. The ACDS was required to offer three levels of audit services, varying in complexity, during the trial, with the MoU setting out specific targets for the number of linacs to be audited at each level.

The evaluation

The evaluation used a mixed methods approach to address questions related to processes, outcomes and policy alignment and sustainability. The methods used were: a literature review; a review of ACDS documents and data; an online census survey of radiation oncology facilities; interviews with a sample of facilities and other key stakeholders; and a cost analysis. A pilot phase was used to test and refine the survey, interview guide and cost data collection tool. An Evaluation Advisory Group established by the Department provided advice and feedback on data collection tools and reports.
Process evaluation findings

The trial’s establishment phase was seen by ACDS staff as having been very challenging, but in retrospect, it appears that the time taken to develop detailed project plans, risk plans and audit plans, and to recruit appropriately qualified staff, was beneficial for the trial overall. With respect to its MoU, the available evidence indicated that the ACDS would meet or exceed its audit targets by December 2013, although the ACDS did not achieve two other requirements, namely the establishment and use of an audit panel, and the collection of detailed time and costs data for audits.

The ACDS had been well received by radiation oncology facilities and clinicians. There was a very high voluntary uptake of audits across the private and public sector, with about 87 percent of facilities participating in at least one audit during the trial. In terms of audit outcomes, there was a mix of audit results across all levels of audit, indicating the benefits of the service to identify a range of dosimetric quality issues prior to a possible error occurring.

The structure of the ACDS (including its placement within ARPANSA) and governance were perceived by key stakeholders as critical enablers for the success of the trial. That the service has been able to achieve its audit targets in a relatively short period, despite delays in critical staff recruitment, supports this view.

While there was a high degree of support from radiation oncology facilities, other stakeholders’ views of the service were more mixed. There is scope to improve working relationships between the ACDS and the state and territory health agencies and radiation protection bodies, particularly around clarifying the roles and responsibilities in respect of reporting obligations and co-operation more broadly.

Outcomes evaluation findings

The evaluation found that, although it had been operational for a relatively short period of time, the ACDS had made a positive, if not directly measurable, contribution to the improvement of radiotherapy dosimetric practice in Australia. Benefits included providing a level of assurance that internal quality assurance processes relating to dosimetry are working well, and increasing attention on these systems.

While the evaluation was unable to quantitatively measure the extent to which the ACDS had contributed to its key goals of assuring dose accuracy, or improving radiotherapy dosimetric practice, the ACDS has established an independent and valued dosimetry auditing service with a good reputation. Through its auditing activity, it has provided support and advice to assist radiation oncology facilities to, potentially, improve the accuracy of radiation dose delivery and improve clinical dosimetry practice – although the extent of this cannot be measured at this time.

Although stakeholders identified a number of areas in which there was the potential for improvement to the services provided, it was clear that most have high expectations of the ACDS. The service is valued, and the majority of stakeholders with whom the evaluation consulted indicated that they would like to see ACDS expanded over time to address more advanced techniques and technologies. They would also like to see ACDS more involved in contributing to the development of national standards for radiation therapy and quality benchmarks for services.

Evaluation findings on policy alignment, appropriateness and sustainability

The evaluation’s detailed assessment indicated that the ACDS is complementary to other existing dosimetry-related quality assurance systems. The ACDS model compares well against international peers and aligns with better practice principles for dosimetry audit. It is also appropriate for meeting the ‘need’
for an independent dosimetry audit regime. There are however a number of specific actions that could be implemented to better meet the objectives outlined in the MoU for the ACDS, such as provision of greater support to address errors or deficiencies detected through its audits and provision of national reporting of errors, trends and areas for improvement. Areas for improvement include: data collection in relation to time spent on audits; finalisation and accreditation of the Quality Management System; clearly defining protocols for managing fail results; governance improvements; and use of strategic and annual audit plans to improve the effectiveness and transparency of audit planning and scheduling.

In terms of financial sustainability, the evaluation has concluded that the current ACDS operating model would be likely to rely on a significant proportion of government funding to remain financially sustainable, if it were to continue. In terms of broader program sustainability, there are a number of areas of potential and actual program sustainability risk that the ACDS would need to improve in order to support its longer-term sustainability, if it were to continue. These include organisational capacity (related to recruitment and retention of staff as well as clinical skills currency), monitoring and review (including analysis of data as the audit results database develops), stakeholder engagement and communications, and longer-term strategic planning (including appropriateness of ongoing governance arrangements). The conclusion of the evaluation is that it would be possible to address all of these risks within the existing ACDS operating model – that is, none of the risks are insurmountable.

**Evaluation findings – costs and benefits**

**Cost analysis**

The detailed cost data available for analysis of the ACDS operating costs was not optimal and hence the analysis was highly reliant on ACDS estimates of staff time deployed on various activities. This was a limitation and the results therefore need to be considered with this in mind. Furthermore:

- The unit cost is a point in time measure that may not remain constant as it depends on the total future spend on facilities and development, and the quantum of future audit activity. For example, advice from ACDS staff indicates that some high value audit-related equipment has a useful life of approximately three years. This makes the average costs of delivering the audits per year highly variable.

- The facility cost data was based on a very small sample and should be interpreted with caution.

If the ACDS continues, more reliable cost data should be collected to better inform future cost analysis.

Based on the available information and ACDS time estimates, the estimated unit cost of delivering each audit type varied considerably over the trial period. Since the majority of audit-related activity occurred in 2013, the cost of labour spent on audit activity, total audit consumables and a share of general overheads from 2013 were used to estimate the cost of an audit.

Unit cost by audit type for 2012/13 for Level I was $5,114, Level Ib was $7,376, Level II was $6,854 and Level III was $7,618. A future unit cost was estimated for each audit type, using the six-month audit plan and financial projection data prepared by ARPANSA. The unit costs for Level Ib and Level II audits are forecast to be higher than the unit cost calculated in 2012/13.

The unit cost analysis demonstrated the relationship between the number of audits conducted and the proportion of staff time dedicated to delivering the audits. Both components had significant impacts on the unit cost. The unreliability of the staff allocation time data, relating to potential estimation errors, was
a significant limitation and explains, in part, the variation in unit cost. Improvements to data collection methods, particularly data relating to time and cost data for each audit type, would allow for more accurate description and analysis of audit costs in the future.

For facilities, the conduct of ACDS audits had between zero and $5,000 impact on their marginal financial position. During the evaluation interviews, facilities frequently said that they would be prepared to pay in the range of $500 to a ‘couple of thousand’ for the audits. Given that they generally do not perceive any costs at present, this is a good proxy for their views on the cost benefit trade off of the ACDS audits within their facility (i.e. excluding wider whole of system benefits). It is noted, however, that the facilities’ level of fee preparedness is significantly less than the direct cost of an audit to ACDS (irrespective of whether sunk costs are recovered), and hence any future ACDS fee approach would need to:

- target only partial cost recovery to be palatable, and hence ACDS would require continuing government subsidy;
- highlight hidden system benefits to make a higher fee palatable, to reduce the need for subsidy; or
- incorporate compulsion to ensure higher fees are paid and hence costs are recovered.

Analysis of costs and benefits

ARPANSA received $3,162,500 for operating the ACDS over four years, including a six-month establishment phase, a three-year operational phase, and a six-month transition phase. In the future, the estimated average cost of delivering a three-year audit cycle program involving one Level I audit and one Level II audit for 190 linacs (the estimated average number of linacs between 2013 and 2018), as well as one Level III audit across 76 facilities (based on facilities having an average of 2.5 linacs each) would be about $3,174,016 over three years, or about $1,058,005 per annum. This would provide for the delivery of Level I and II audits of each linac, and a Level III audit for each facility, based on the 2013/14 estimated unit costs. Costs for delivering Level Ib audits, or for developing and testing of new audits, would be additional to this amount.

There are a range of intangible benefits of the ACDS model, including ensuring alignment with international better practice, improving radiotherapy safety, increasing clinician confidence, and increasing patient confidence.

The estimated tangible benefits of the ACDS include avoided costs for compensation or litigation resulting from radiotherapy errors that may have been prevented through an independent audit program (value up to $15,000,000 per incident, based on international examples), potential for reduced liability insurance premiums, and statistical life years saved (value of $365,420 and $2,865,520 per annum, based on international evidence of error rates resulting in deaths and Australian Government values placed on statistical life years).

Therefore, the cost of delivering the ACDS audits during its trial period, and the cost of delivering a similar audit program in the future, are offset by the benefits arising from the service, including statistical lives saved and avoided costs.
PART TWO: Possible alternative approaches for a national dosimetry audit service

The evaluation found that a range of design features would influence the potential effectiveness of operational models and associated funding. These were: whether facilities’ future participation would be voluntary or mandatory; the frequency of audits to be conducted; whether audit scheduling would be cyclical or based on risk factors, such as being a newly commissioned linac; and whether there would be single or multiple audit providers.

Three potential operational models were identified for the Department’s consideration, and assessed for their individual strengths, weaknesses, benefits and risks. These models were:

- a national audit service with a single provider (the ACDS model);
- a national audit service subsumed into other existing quality assurance or accreditation services, with either single or multiple providers; and
- national peer audit networks, coordinated by single or multiple providers.

Three funding models were identified, and assessed. These were: full government subsidy; partial government subsidy with facility contribution; and full cost recovery.

PART THREE: Recommendations

The evaluation makes the following recommendations to the Department:

Future of a national dosimetry audit service

1. A national dosimetry audit service should continue.

2. ARPANSA should continue to be funded to provide the ACDS as the national dosimetry service. This will ensure the best use of equipment and resources already purchased and developed, and promote national consistency.

3. Due to the poor trial data around the unit costs of services, and the unclear impact on radiotherapy quality of various levels of audits deployed during the trial period, the service should be continued for a further three-year trial period in the first instance, with a view to it potentially becoming an ongoing service after that period concludes. A decision will need to be made at least six months prior to the end of that further trial period as to whether the service will continue. This decision will need to be informed by robust activity and outcomes data.

4. A cyclical audit approach should continue for all linacs and facilities during the further trial period.

5. If the service continues beyond the further trial period, it may be possible to transition to a risk-based audit program – if there is sufficient evidence and support for such an approach.

6. The costs of the Level I, Level II and Level III audits should be partially subsidised by government, with facilities paying a contribution towards the service as commonly occurs on other mandatory and voluntary quality assurance and audit programs. These arrangements can be re-assessed after the further trial period, when better cost data will be available.
7. Market research should be undertaken to determine whether facilities would be prepared to pay either the full costs of Level Ib audits, or the amount of the Level Ib cost that exceeds the amount of a Level I audit, given that this is a value added, ‘on demand’ service. It may or may not be necessary for these services to be subsidised by government.

8. Improved data collection during the further trial period is critical. At a minimum, this should include:
   - comprehensive data on audits conducted and audit outcomes at all levels of audit (preferably, these should be periodically reported in de-identified format); and
   - detailed information on the actual costs and staff time involved in conducting each level of audit so that accurate unit prices may be derived.

The adequacy of this data collection should be regularly reviewed during the further trial period, and appropriate sanctions applied if the required data is not being collected as required.

9. Participation in independent dosimetry audit should be mandatory for radiation oncology facilities in the future.

Specific improvements to the ACDS model

10. To ensure that appropriate data is collected (in line with recommendation 8) and the costs and benefits of the ACDS are able to be accurately captured and reported, ARPANSA should ensure that the necessary systems and processes are implemented as a matter of priority. This is likely to require additional business and commercial capability.

11. The Quality Management System should be finalised as a matter of priority. Once it has been completed, it should be audited and assessed against the ISO 9001:2008 standards by an accredited certification body. Achievement of the accreditation within a set period could be a condition of the further trial.

12. The risk management plan should be reviewed and revised at least annually. Again, this could be a condition of the further trial.

13. Clear processes and role delineation in appropriately managing fail results is required. Protocols need to be clearly defined, agreed and understood by all stakeholders, including jurisdictional regulators. A timeline for development of these protocols should be set and meeting this timeline should be a condition of the further trial.

14. Ongoing governance of the ACDS could be improved by: (i) restricting the role of the CAG to providing technical advice and input on clinical matters and advice on the development of audit methodologies, and (ii) forming a Management Advisory Group with a broader management focus and skill set to replace the MoU management group. These issues should be resolved within the first six months of the further trial period.

15. The effectiveness and transparency of ACDS audit planning and scheduling processes would be improved by the use of strategic audit plans and annual audit plans as outlined in this report. A strategic
audit plan and the first annual audit plan should be developed within the first six months of the further trial period.

16. The specific areas of program sustainability risk identified in this report should be addressed by the Management Advisory Group. Specifically, this relates to:

- building longer-term organisational capacity (including strategies for recruitment and retention of staff, as well as maintaining the required currency of clinical skills);
- monitoring and review (including analysis of data as the audit results database develops);
- improving stakeholder engagement and communications (including engagement with non-clinician stakeholders); and
- longer-term strategic planning.
Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Summary</td>
<td>i</td>
</tr>
<tr>
<td>Contents</td>
<td>1</td>
</tr>
<tr>
<td>Glossary</td>
<td>3</td>
</tr>
<tr>
<td>1. Introduction</td>
<td>5</td>
</tr>
<tr>
<td>PART ONE: Evaluation of the Australian Clinical Dosimetry Service</td>
<td></td>
</tr>
<tr>
<td>2. Background</td>
<td>7</td>
</tr>
<tr>
<td>2.1 Context</td>
<td>7</td>
</tr>
<tr>
<td>2.2 Trial of the Australian Clinical Dosimetry Service</td>
<td>13</td>
</tr>
<tr>
<td>2.3 Goal and objectives of the ACDS</td>
<td>16</td>
</tr>
<tr>
<td>3. Evaluation methodology</td>
<td>18</td>
</tr>
<tr>
<td>3.1 Approach</td>
<td>18</td>
</tr>
<tr>
<td>3.2 Challenges and limitations</td>
<td>19</td>
</tr>
<tr>
<td>3.3 Evaluation Advisory Group</td>
<td>20</td>
</tr>
<tr>
<td>3.4 Data collection methods</td>
<td>20</td>
</tr>
<tr>
<td>3.5 Pilot testing of the data collection tools</td>
<td>25</td>
</tr>
<tr>
<td>3.6 Clinical dosimetry expertise</td>
<td>25</td>
</tr>
<tr>
<td>4. Establishment and implementation of the ACDS</td>
<td>26</td>
</tr>
<tr>
<td>4.1 Overview of this chapter</td>
<td>26</td>
</tr>
<tr>
<td>4.2 Establishment of the ACDS</td>
<td>26</td>
</tr>
<tr>
<td>4.3 Service delivery</td>
<td>34</td>
</tr>
<tr>
<td>4.4 Effectiveness of enabling structures and processes</td>
<td>35</td>
</tr>
<tr>
<td>4.5 Summary of key points</td>
<td>39</td>
</tr>
<tr>
<td>4.6 Suggested actions / areas for improvement</td>
<td>41</td>
</tr>
<tr>
<td>4.7 Conclusions</td>
<td>41</td>
</tr>
<tr>
<td>5. Outcomes of the ACDS</td>
<td>44</td>
</tr>
<tr>
<td>5.1 Overview of this chapter</td>
<td>44</td>
</tr>
<tr>
<td>5.2 Quality of the service (as perceived by stakeholders)</td>
<td>44</td>
</tr>
<tr>
<td>5.3 Relevance (alignment with other quality assurance processes)</td>
<td>48</td>
</tr>
<tr>
<td>5.4 Impact (improving radiotherapy dosimetric practice)</td>
<td>49</td>
</tr>
<tr>
<td>5.5 Summary of key points</td>
<td>51</td>
</tr>
<tr>
<td>5.6 Conclusions</td>
<td>51</td>
</tr>
<tr>
<td>6. Policy alignment, appropriateness and sustainability</td>
<td>53</td>
</tr>
<tr>
<td>6.1 Policy alignment</td>
<td>53</td>
</tr>
<tr>
<td>6.2 Appropriateness</td>
<td>55</td>
</tr>
</tbody>
</table>
## Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACDS</td>
<td>Australian Clinical Dosimetry Service</td>
</tr>
<tr>
<td>ACPSEM</td>
<td>Australasian College of Physical Scientists and Engineers in Medicine</td>
</tr>
<tr>
<td>ARPANSA</td>
<td>Australian Radiation Protection and Nuclear Safety Agency</td>
</tr>
<tr>
<td>Brachytherapy</td>
<td>Radiotherapy administered/delivered using sealed, biologically inert radioactive sources interstitially as an implant or superficially as a mould</td>
</tr>
<tr>
<td>CAG</td>
<td>Clinical Advisory Group</td>
</tr>
<tr>
<td>DoH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>Dosimetry</td>
<td>The calculation and design of radiotherapy treatment plans for oncology patients</td>
</tr>
<tr>
<td>EAG</td>
<td>Evaluation Advisory Group</td>
</tr>
<tr>
<td>EDA</td>
<td>Explanatory Data Analysis</td>
</tr>
<tr>
<td>EBRT</td>
<td>External beam radiotherapy delivered using linear accelerators</td>
</tr>
<tr>
<td>Facility</td>
<td>In this report, refers to a radiation oncology department/service based at a single geographical site – i.e. one facility = one site (noting that in practice some facilities have multiple sites or campuses; under this definition each of those sites or campuses would be classified as a separate facility). This is consistent with the approach taken by the ACDS in scheduling audits.</td>
</tr>
<tr>
<td>IMRT</td>
<td>Intensity-modulated radiation therapy</td>
</tr>
<tr>
<td>Linac</td>
<td>Linear accelerator used to deliver external beam radiotherapy</td>
</tr>
<tr>
<td>MoU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>OSLD</td>
<td>Optically stimulated luminescent dosimeter</td>
</tr>
<tr>
<td>TEAP</td>
<td>Training, Education and Accreditation Program</td>
</tr>
<tr>
<td>TLD</td>
<td>Thermoluminescent dosimeter</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>The medical use of ionising radiation to permanently damage the DNA of localised malignant cells in cancer patients</td>
</tr>
<tr>
<td>ROMP</td>
<td>Radiation Oncology Medical Physicinot</td>
</tr>
</tbody>
</table>
RORIC  Radiation Oncology Reform Implementation Committee
RO     Radiation Oncologist
RT     Radiation Therapist
1. Introduction

The Department of Health (the Department) funded the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) under a Memorandum of Understanding (MoU) to operate the Australian Clinical Dosimetry Service (ACDS) on a trial basis over a period of up to four years (including an establishment phase, operational phase and transitional phase) from 28 June 2010. In October 2012, the Department engaged KPMG to undertake an external evaluation of the ACDS trial, and provide advice on options for an ongoing national dosimetry audit service into the future.

**Part one** sets out the methodology, findings and conclusions from the evaluation of the ACDS, including suggested actions to improve the trial service. This includes findings against a process evaluation of the ACDS trial, an outcomes evaluation, an assessment of the policy alignment and sustainability of the model, and an assessment of costs and benefits.

**Part two** explores possible alternative approaches to delivering a national dosimetry audit service in the future.

**Part three** sets out the recommendations arising from the evaluation.

The **appendices** include the evaluation instruments and detailed results from specific evaluation activities (see separate document).

**Structure of this report**

- Chapter 2: outlines the background and context to the ACDS trial, rationale for the model, and the goals and objectives of the ACDS.
- Chapter 3: provides an overview of the evaluation methodology, including the evaluation questions and data collection methods.
- Chapter 4: presents the findings of the process evaluation.
- Chapter 5: presents the findings of the outcomes evaluation.
- Chapter 6: discusses the policy alignment (including appropriateness and alignment to better practice) and sustainability of the ACDS trial model.
- Chapter 7: outlines the assessment of costs and benefits of the ACDS trial model.
- Chapter 8: sets out preliminary considerations for an ongoing, national dosimetry audit service.
- Chapter 9: explores possible alternative approaches for a national dosimetry audit service.
- Chapter 10: provides a framework for cost effectiveness analysis of a future ongoing national dosimetry audit service.
- Chapter 11: sets out the evaluation recommendations.
PART ONE:

Evaluation of the Australian Clinical Dosimetry Service
2. Background

This chapter describes the context and rationale for the ACDS trial, as well as the goals and objectives of the ACDS trial.

2.1 Context

Cancer is a major cause of illness in Australia. In 2012, it was estimated that more than 120,700 Australians would be diagnosed with cancer in that year alone.¹ The most commonly diagnosed cancers for men are prostate, bowel, melanoma and lung cancer. The most commonly diagnosed cancers for women are breast, bowel, melanoma and lung. Lung cancer is the most common cause of death from cancer for both males and females. In recent years, the mortality rate due to cancer has fallen (although survival rates are not consistent across cancer types or population groups), suggesting that this is due to increased effectiveness of treatment and earlier diagnosis (which is partly attributable to population screening).

Radiotherapy treatment of cancer

Radiotherapy, or radiotherapy, is the medical use of radiation such as x-rays, gamma rays, electron beams or protons to kill or sufficiently damage cancer cells and stop them from growing or multiplying further. Radiotherapy is designed to deliver a lethal dose to the cancer cells in the area to be treated but limit the radiation to the normal cells to as little as possible so that they can survive and recover to normal function.

Radiotherapy is one of the main modes of cancer treatment along with surgery and chemotherapy.² In 2011-12, 57,246 patients received radiotherapy services subsidised through the Medicare Benefits Schedule; of these, 97.85% were external radiotherapy beam services.³

Distinguishing features of radiotherapy include the need for:

- A large team of professionals, comprising:
  - radiation oncology medical physicists (ROMPs) who work with the specially trained service engineer to repair and calibrate the linear accelerator according to relevant national and international standards. ROMPs are responsible for dosimetry (measurement of radiation dose) and ensuring the accuracy of the radiotherapy dosimetry chain (from planning and simulation, through to treatment and verification);
  - radiation oncologists (ROs), who are responsible for the patient’s medical safety during radiotherapy, prescribe the radiation treatment technique and doses, approves the treatment plan and follows-up patients under their care after the treatment is finished; and

- radiation therapists (RTs), who devise the treatment plan to deliver the RO’s prescribed dose and sets up and treats the patient according to the planned treatment using the radiotherapy machine;¹⁴

- Installing an expensive, complex linac and its accessories which must be housed in a purpose-built radiation-shielded facility;⁵ and

- Patients being treated daily over several weeks.

Patients may receive radiotherapy in a variety of ways – externally, internally or systematically.⁶ External radiation therapy is the primary means of treatment in Australia. There are a number of other external beam treatments, including:

- Three-dimensional conformal radiation therapy (3-D CRT), which uses imaging techniques to obtain the three-dimensional shape of the patient’s anatomy and the cancer site(s). This enables better targeting of the radiation beam to the cancer site and reduces radiation damage to nearby normal tissue;

- Intensity-modulated radiation therapy (IMRT), can be produced by the linac’s computer-controlled beam shaping device to deliver a three-dimensionally shaped dose. The IMRT technique can provide much higher, more precisely shaped radiation doses to the tumour site and limits the patient’s normal tissue dose more efficiently;

- Image-guided radiation therapy is an enhanced version of 3-D CRT and IMRT which uses imaging to take into account tumour motion during treatment exposure, thereby further increasing precision; and

- Stereotactic ‘radiosurgery’ which involves using the linac to produce a very high dose with a very small beam of radiation that is ‘knife like’ (thus the surgery terminology). This technique is used for non-malignant cases at risk of aneurisms in the brain and for cancer patients who may have small metastatic masses in the brain, lung or liver.

Internal radiation is delivered using brachytherapy by either low or high dose techniques. This involves the use of biologically inert sealed radioactive sources in the form of an implant or insertions placed near the tumour.

Systemic radiation therapy is delivered in liquid or capsule form (such as radioactive iodine for thyroid cancer).

The ACDS trial relates only to the independent dosimetry audit of external radiation beam therapy (excluding IMRT, IGRT and stereotactic techniques).

---

¹⁴ Department of Radiation Oncology, Newcastle Mater Misericordiae Hospital (2006) National level III dosimetry program lead-in project: Report on a collaborative investigation managed by the Department of Radiation Oncology, Newcastle Mater Misericordiae Hospital, New South Wales, Australia, 2003-2006.

⁵ The Department of Health estimates that establishment of a new two linac facility can cost from $8 million to $12 million for equipment alone – and this does not represent the majority of costs for the service given the lifespan (about 10 years) of the equipment and the maintenance requirements.

Radiation oncology in Australia

Based on information provided by the Department, as at January 2011 there were 59 existing radiation oncology facilities in Australia:

- 34 of these were public facilities and 25 were private.
- There were 139 linacs in operation across those facilities (94 in public facilities and 45 in private facilities).

By June 2013, there were 66 operational facilities:

- 39 were public facilities and 27 were private.
- There were 168 linacs (112 public and 56 private).

With planned public and private expansion that the Department is aware of in coming years, the number of linacs is expected to increase to a total 214 by 2018. Based on national radiotherapy planning parameters, this number of linacs would be sufficient to treat 96 per cent of the projected number of cancer patients in 2018 that would benefit from radiotherapy as part of their treatment. The total number of linacs needed in Australia by 2021 (but not yet funded/planned) is projected to be 241.

This rapid growth in linacs and radiation oncology facilities, alongside high demand for radiotherapy treatment, projected key workforce shortages over time\(^7\)\(^8\), continuing expansion of radiotherapy techniques and further use of new technologies indicate a number of risk factors that may collectively increase the potential for errors and patient injury. These risks highlight the need for effective quality assurance approaches.\(^9\)\(^10\)

Risks in linac calibration and the radiotherapy treatment chain

If the initial calibration of the linac treatment machine is incorrect, then this may lead to an increased number of patients receiving serious treatment complications when the radiation dose is higher than intended (an overdose) or failure to cure the patient’s cancer when the dose is lower than intended (an under dose). An under dose is equally critical since this may lead to cancer recurrence, further patient suffering and significantly reduced probability of survival. Based on information provided by members of the Evaluation Advisory Group, the ‘window’ of dose accuracy between the occurrence of under dose and overdose effects is considered to be in the order of +/- 2% for the initial treatment machine calibration.

There are other inaccuracies that can occur in the treatment chain. The dose calculations for planning the treatment and directional inaccuracies when setting up and delivering the x-ray dose each time over several weeks should be kept within a +/-5% tolerance. All sources where errors occur should be carefully

---


\(^8\) Health Workforce Australia (2013) *National cancer workforce strategic framework*, Adelaide: HWA.


checked and monitored throughout a patient’s treatment course. The need for this tight control over the accuracy of treatment from beginning to end is even more important for the most recent new techniques such as IMRT and stereotactic radiosurgery when the dose prescribed is much greater than that used for conventional radiotherapy and is closer to the dose level where tissue complications can arise.

Intermittent (and random) errors may occur for any patient receiving radiotherapy but, if the initial calibration of the linac is incorrect, then all patients treated on that machine will have received a treatment dose error. These kinds of errors may not be detected for some time and so can affect the proper treatment of a large number of patients (given that linacs typically treat four patients an hour when in operation), with potentially severe consequences.

Dosimetry

Dosimetry is a key component of radiotherapy. It involves a medical physicist measuring and calibrating the radiotherapy equipment for the radiation dose that patients will receive. Using the theoretical method to calculate this dose by computer, the radiation therapists specially design radiotherapy treatment plans for each oncology patient. Dosimetry inter-comparisons are arranged to ensure the delivery of radiation dose is accurate and consistent to a similar level of accuracy in other radiotherapy centres. The purpose of this procedure is to ensure that the patient receives the prescribed dose as accurately as practicable, is consistently accurate in all treatment centres internationally and is to reduce the risk of overdose or underdose.

Auditing dosimetry practices in clinical settings ensures the quality of radiotherapy treatments for patients is consistent with other high quality advanced centres internationally and improves dosimetric practice in both individual settings and across jurisdictions. Dosimetry audits can also identify inadequacies in a facility’s treatment procedures, planning methods or quality assurance programs.

Dosimetry in its broadest sense is the measurement of how much ionising radiation dose a person receives when exposed to a radioactive substance or radiation apparatus. In medicine, the principles of radiation dosimetry focus also on ensuring accurate measure and delivery of an intended exposure or absorbed dose. This includes ensuring that the radiation is directed in a safe, controlled accurate means. The use of x-rays in radiation oncology is an important mode of treatment for cancer patients and is used extensively in diagnostic imaging modalities in nuclear medicine and radiology, computerised tomography and plain x-rays.

The number ‘dialled up’ on the linac to deliver the treatment is called a monitor unit and all linacs must be individually calibrated to deliver an accurately known dose per monitor unit. Quality assurance processes to monitor the machine’s treatment parameters governing the dose are then required to ensure that it is accurately maintained over time.

Contemporary radiation therapy treatment planning is based on applying a theoretical model to describe the absorption of the radiation in the patient. This is a complex process with many factors applied to the calculation using a computer-based system or manually applied by the radiation therapist. The aim of this pre-treatment state is to produce a plan to provide optimal dose delivery (i.e. maximum dose to the tumour site and minimum dose to the surrounding normal tissue structures). Therefore, dosimetry quality assurance processes also need to be carried out to test the accuracy of the algorithm and its correction factors used in the planning system. This involves comparing the calculated dose plans with actual measurements taken on a simulated patient’s treatment technique exposed in a phantom of tissue
equivalent material. This ensures that the calculated dose distribution on the plan agrees within acceptable accuracy with what the patient would receive during the treatment. If the measurement does not agree with the dose calculation, then further work would be needed to identify which of the factors may be causing the error. Unfortunately, different treatment techniques can involve different correction factors and cause a different range of errors in the plan’s dose distribution. Therefore, a wide variety of simulated phantoms are required to test the validation procedure between calculation and measurement. Ongoing quality assurance is then required whenever a planning software program is upgraded (upgrades can introduce errors not previously there and represent an ongoing risk to the accuracy of a facility’s dosimetry control).

To ensure that the linac dose output is accurate, it needs to be measured frequently against an accurately calibrated secondary standard. Primary standards and secondary standards are tools that measure absolute radiation dose. A primary standard is held in a central laboratory approved by the National Standards regulator and is the tool that other, more portable instruments are measured against. In Australia, the primary standard is held at the ARPANSA in Melbourne.

It is common for the instruments that measure radiation dose to differ slightly, so each may have a different calibration factor when compared to the primary standard. The known calibration factor compared with the primary standard can be used to calculate dose readings from the secondary standard and to compare or check linac dose calibrations.

Many radiation oncology departments have secondary standard ionisation chambers and electrometer that have been calibrated against the primary standard and are used as the local standard dosimeter for this work. Other ionization chambers and electrometer connected to it (the field instrument) are cross-calibrated against this local secondary standard. The field instruments are used to regularly check the dose, shape and quality of the radiation beams of their linacs. The local secondary standard dosimeter is normally not regularly used and is stored separately for safe keeping. It is reserved for cross-calibration of field instruments and for new treatment machines.

However, it is possible to introduce error if any of these readings are incorrect and remain undetected. Therefore, access to accurately calibrated secondary standards, and to a primary standard laboratory, are important parts of the dosimetry quality assurance chain.

**Dosimetry inter-comparisons / audits**

International analysis of lessons learned from accidental exposures in radiotherapy has identified a number of areas of risk, including: resources (staff shortages or inadequate training, particularly around the use of new equipment, new technology or new modalities); human factors (including failure to apply critical safety steps and activities, miscommunication, and poor documentation); equipment failures or maintenance problems (relatively uncommon in terms of frequency, but with potentially severe consequences for many patients); and problems at the human-equipment interface (including inadequate understanding of malfunction alarms). The analysis concludes that effective quality assurance mechanisms are vital to manage these risks, and states that quality management systems should include

---

calibration of sources, clinical dosimetry within facilities, quality assurance of medical exposures and records, as well as regular and independent quality audits and ‘frequent inter-comparison’ of equipment.

In an Australian context, the need for an effective quality assurance system inclusive of acceptance testing (e.g. on commissioning of equipment), regular constancy testing, preventative maintenance, and dosimetric calibration and recalibration of equipment by a qualified expert on at least an annual basis, is also emphasised in the ARPANSA Safety Guide for Radiation Protection in Radiotherapy.12

The ARPANSA Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (a regulatory document that covers the practices of radiotherapy, diagnostic and interventional radiology and nuclear medicine) requires independent calibration of all radiation equipment for proposed clinical techniques by a qualified expert prior to its clinical use, as well as re-checking and re-calibration of equipment by a qualified expert at regular intervals as specified in national or international protocols against relevant national standards.13

Rationale for a national dosimetry audit service in Australia

In Australia, the 2002 Baume Inquiry identified the need for a national quality program overseen by a national body, and incorporating a radiation oncology facility accreditation program, an independent dosimetry audit program, and an adverse incident-monitoring program.14 In response to the Baume Inquiry, the Australian Health Ministers’ Advisory Council (AHMAC) established the Radiation Oncology Reform Implementation Committee (RORIC) in 2003 to progress national radiation oncology reforms recommended by the report. RORIC provided a formal mechanism for jurisdictions and other stakeholders to collaborate on national radiation therapy reforms and facilitated the planning and implementation of patient outcome improvement strategies for radiotherapy services. Following a review of AHMAC committees, RORIC was disbanded in March 2013.

One of the initiatives endorsed by RORIC was the development of radiation oncology practice standards. The Department funded the development of practice standards by the Tripartite Committee (a peak group comprising the Royal Australian and New Zealand College of Radiologists, Australian Institute of radiologists and the ACPSEM). The final voluntary standards were officially launched in August 2011. They provide a framework for ongoing quality improvement in radiation oncology and are available to all facilities as a guide to good practice. To coincide with the launch of the standards, an options paper proposing different models of conformity assessment was also released for comment.

The 2008 Delaney Review, which detailed the findings of an investigation into an incident of systemic under-dosing at the Royal Adelaide Hospital, also made a number of recommendations for mitigating the risk of future adverse incidents in radiation oncology treatments which included improved data collection systems, addressing staff shortages and development of a national dosimetry audit service. Given this report and two high profile cases of the incorrect dosing of Australian patients (the first in which 869

patients were under-dosed and the second in which 75 patients were over-dosed), the national dosimetry audit service trial was established outside the practice standards which were still in development. Work on the implementation of the standards is still ongoing, pending the outcome of the ACDS trial.

A number of clinicians suggested to the evaluation that the practice standards could form the basis of a mandatory radiation oncology facility accreditation scheme. The standards relate to facility management, treatment planning, and safety and quality. The standards require, inter alia, that facilities have a quality assurance program for radiotherapy equipment (page 16), documented dosimetry including independent checks of all clinical dosimetric data by a ROMP (page 21), and documentation that the facility has successful participated in ‘an external dosimetric inter-comparison with a non-affiliated organisationally separate service within the last two years’ (page 29).

2.2 Trial of the Australian Clinical Dosimetry Service

The trial of the ACDS commenced its operational phase in January of 2011. The trial service is auspiced by ARPANSA and fully-funded by the Department under an MoU. The services to be provided, objectives and key performance indicators were developed by the Department with advice from the RORIC Quality Working Group.

The ACDS provides independent dosimetric measurement and inter-comparison of external beam radiotherapy. Radiation oncology facilities participate on a voluntary basis and receive the audit services free-of-charge from the ACDS. The ACDS has offered three levels of dosimetric audit during the trial.

- **Level I:** An independent measurement of linear accelerator output at one point under reproducible reference conditions in a regular rigid homogenous phantom. This is a postal audit. The detectors and all associated equipment are sent out by the ACDS to the facilities being audited, which irradiate them according to the relevant ACDS audit protocol and send them back. The ACDS confirms whether the linac delivers the specified level of radiation, as measured by the international standard measure for absorbed radiation (1 Gray). This is the simplest level of audit.
  - Initially the ACDS provided this service in 2011 using thermoluminescent dosimeters (TLD) or chips, but moved to the use of optically stimulated luminescent dosimeters (OSLD) in July 2012.
  - The Level I audit is an extension of the TLD service the International Atomic Energy Agency has been offering internationally for a few decades. In 2003, ARPANSA took on the role of providing Level I audits for facilities in Australia under a fee-based service (the fee was a contribution rather than a full user pays amount, and was based on the number of beams measured) until the ACDS commencement in January 2011.

---

15 The dosimetry audit service trial – the ACDS – is only one aspect of the wider, integrated quality program for radiation oncology as per the original Baume recommendation; many stakeholders made this observation during the evaluation consultations. Consideration of the need for a national radiation oncology quality program, including facility accreditation, is beyond the scope of this evaluation, but the strength of stakeholder views on this issue is noted.

16 Descriptions of audit levels based on information accessed on 28 July 2013 at www.arpansa.gov.au/services/ACDS/ACDSaudits.cfm
• **Level Ib**: This onsite audit is a variant of the Level I audit and is designed for new facilities or existing facilities with new linacs. This level of audit is not specified in the MoU but was developed by the ACDS in response to a perceived demand from the sector; it is being delivered in addition to the other audit levels required under the MoU and without additional funding. Level 1b provides a more accurate independent measurement than the Level I audit and involves the ACDS visiting the requesting facility to perform onsite measurements. The measurements are performed in the centre's own water tank. All other dosimetry equipment is brought in by the ACDS.

• **Level II**: An independent measurement of linear accelerator output at multiple points in multiple beams with increasing complexity. This audit is conducted onsite and is more complex than the Level I audit. It considers the planning process as well as testing the characteristics of the beam and accuracy of the planning system. The audit uses a 2D array of detectors to measure dose in a plane normal to the mean direction. The dose received by the chip is measured against the national primary standard.
  
  – The Level II audit commenced field trials in May 2012 and was released from March 2013.

• **Level III**: An independent end-to-end assessment simulating a patient’s treatment path using a synthetic human upper torso in place of a patient. The synthetic upper torso is constructed from tissue equivalent plastic, machined to represent a generic human upper torso and includes lung, bone and tissue equivalent materials, and is known as 'a phantom'. The plastic phantom is imaged with a computed tomography (CT) scan, the key internal structures on the images outlined and the radiation plan is designed according to a protocol defined by the ACDS. The planning is verified according to the local procedures at which point the entire radiation plan is sent through to the linear accelerator where it will be re-checked. Finally, the phantom is irradiated following the prescribed plan while measurements are taken within the phantom by the ACDS. The predicted and measured radiation doses are compared and scored.
  
  – This is the most complex level of audit. It is conducted onsite and the entire planning and treatment chain is measured.
  
  – Level III field trials commenced in February 2012 and became operational in July 2012.

The MoU sets out targets for the different audit levels. These targets were developed by the RORIC Quality Working Group in 2009. During the operational period of the trial from January 2011 to December 2013, the ACDS’s specified targets are:

• **Audits for at least 80 per cent of existing linear accelerators** (that is, linacs which were existing as at 1 January 2011)
  
  – Of this 80 per cent, no more than 60 per cent are to be level I audits, and the remaining 40 per cent are to have level 2 audits.
  
  – In addition, level 3 audits are to be undertaken on no less than 15 linacs which have had a level I or level II audit.

• **Audits for at least 50 per cent of new linear accelerators** (a linac which did not exist at 1 January 2011)
  
  – Level I and Level III audits are to be conducted where a new planning system is implemented.
− Level I and Level II audits are to be conducted where an existing planning system is being utilised.

− Audits on new linear accelerators are to be given priority in audit plans.

There are no targets for the level Ib audits which are not specifically referred to in the MoU. The figure below indicates the methodologies of and integration between the different audit levels.

Audit levels have been designed to be part of an integrated (and ongoing) audit program: Level II audit test capabilities provide a foundation for Level III audits as well as a fallback approach when questionable Level III outcomes arise. Similarly, issues arising with a Level II audit may be investigated with a Level I, or anomalous Level 1 results may be investigated with a Level Ib.

The ACDS audit methodologies and operational protocols are maintained in a three-tier Quality Manual based on the ISO 9001:2008 quality management systems standard. The protocol for reporting audit outcomes to facilities is available on the ACDS website. All outcomes fall into one of three ranges (acceptable/optimal, acceptable/actionable or out of tolerance). Ranges are derived from a probability distribution specific for each measurement point. Each is characterized by a standard deviation or $\sigma$ value.

Table 1: ACDS audit outcomes action matrix (all audit levels)

<table>
<thead>
<tr>
<th>Range</th>
<th>Audit outcome</th>
<th>ACDS action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptable range (measurements within agreed clinically determined limits)</td>
<td>Difference ≤ 2 σ</td>
<td>Audit measurements recorded. Report finalised and provided to facility.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Optimal</td>
</tr>
<tr>
<td>Acceptable range (measurements within agreed clinically determined limits)</td>
<td>2 σ &lt; Difference ≤ 3 σ</td>
<td>Audit repeated, measurements recorded and compared to international limits. Continued clinical use of linac.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Actionable</td>
</tr>
<tr>
<td>Outside the acceptable range</td>
<td>Difference &gt; 3 σ</td>
<td>Immediately investigate and assist facility to take corrective action. May recommend to the facility suspension of clinical use of linac/beams until discrepancy resolved and/or other actions as advised.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Out of Tolerance</td>
</tr>
</tbody>
</table>

Source: ACDS audit outcomes protocol

2.3 Goal and objectives of the ACDS

The goal of the ACDS is ‘support improvements in radiation therapy in Australia by providing an independent dosimetric measurement and inter-comparison service for clinical radiation therapy’.\(^\text{18}\)

The objectives of the ACDS are to:

- provide dosimetric auditing services to radiation oncology facilities 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 dosimetry practice by providing support and advice on dosimetric activities; and
- maintain a national register of records of dosimetric information.

Figure 2 provides a program logic model for the ACDS trial.

\(^{18}\) Cl 7.1, ACDS Memorandum of Understanding

© 2013 KPMG, an Australian partnership and a member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative (“KPMG International”), a Swiss entity.

All rights reserved.

The KPMG name, logo and ‘cutting through complexity’ are registered trademarks or trademarks of KPMG International.

Liability limited by a scheme approved under Professional Standards Legislation.
Figure 1: Program logic model for the ACDS trial

Impact of ACDS:
External beam radiotherapy is effective and safe

Outcomes:
Assurance that radiation oncology facilities deliver accurate dosage
Radiotherapy practice is improved

Key program objectives:
ACDS provides external validation of radiation dose measurement calculation and delivery
ACDS provides advice and support on dosimetric activities

Outputs:
- Audits are undertaken in accordance with defined methodologies, consistent with international best practice and standards
- Participating facilities are provided with their audit results, and receive advice to improve practice
- National register for records of dosimetric information informs practice improvement

- Level 1 audits completed for 60% of linacs
- Level 1a audits completed as agreed (non-MOU)
- Level II audits completed for 40% of linacs
- Level III audits completed for 20% of linacs

- Panel of auditors established and trained by ACDS
- Dosimetric audits of radiation oncology facilities for external beam therapy are undertaken in a planned and timely manner
- Sufficient radiation oncology facilities are recruited to the auditing program
- Audit methodologies and protocols developed
- Access to primary standards

Key operational objectives:
ACDS is effective, efficient and sustainable

Inputs:
ACDS funding model is appropriate
ACDS operating model is appropriate
ACDS has appropriate business systems, structures and processes established
ACDS has appropriate governance (including clinical governance) systems in place
ACDS engages appropriately skilled and trained staff to undertake dosimetric auditing
ACDS has developed and maintains a national audit plan, guidelines, templates and tools
Clinical Advisory Group has appropriate representatives and meets regularly
ACDS staff have access to relevant education and training
National register for records of dosimetric information is established

Source: KPMG derivation of MoU requirements
3. Evaluation methodology

This chapter describes the methodology used to conduct the evaluation the ACDS, including an overview of the approach, description of the evaluation questions, and outline of the data collection methods.

3.1 Approach

There were four objectives for the evaluation:

- to assess the impact of the ACDS in supporting improvements in radiotherapy in Australia;
- to analyse the ACDS outputs and processes;
- to assess the appropriateness, efficiency and effectiveness of the ACDS; and
- to consider future arrangements for operating and funding a national dosimetric auditing program after the ACDS trial (including continuing/improving the trial service, and other alternatives).

In order to address each of these objectives, the evaluation was conducted at three levels. Key evaluation questions were identified for each level of evaluation. These were outlined in an evaluation framework which guided the data collection and analysis.

- **Level 1 – Process evaluation:** This involved assessment of the extent to which the ACDS had met its objectives and delivered the required services, as well as the effectiveness of the enabling structures and processes. The process evaluation addressed the following key questions:
  - What did the ACDS do, and with what resources?
  - How did it go, and what was learnt?

- **Level 2 – Outcomes evaluation:** This involved assessment of the extent to which ACDS had contributed to its intended outcome of improving radiotherapy in Australia. The outcomes evaluation addressed the following key questions:
  - What did the ACDS achieve?
  - What were the key lessons learnt?

- **Level 3 – Policy alignment and sustainability assessment:** Drawing on the level 1 and 2 findings, as well as a cost analysis and risk assessment, this involved an assessment of the ongoing appropriateness of the ACDS trial model and consideration of areas to improve the service (should it be continued). The assessment addressed the following key questions:
  - Should a national auditing service continue?
  - Can the services be improved or delivered in another way?
  - What else could or should be done to meet the objectives?
  - What are the risks?
  - Is the service sustainable?

This assessment also contributed to the consideration of alternative operating and funding models for an effective, efficient national dosimetry audit program in the future (outlined in part two of this report).
3.2 Challenges and limitations

There were three significant methodological challenges and limitations for the evaluation.

**Inability to directly link ACDS activities to health outcomes and clinical impacts:** There is no data available which would credibly allow for the direct linkage of ACDS activities to health outcomes and clinical impacts. The literature suggests that this is a common issue with international dosimetry audit services. Whilst it is possible to identify cases where patient injuries or deaths resulted from dosing errors in international jurisdictions, and in some of those cases the lack of independent dosimetry audit was identified as a key contributing risk factor for the incident, it is extremely difficult to demonstrate that an independent dosimetry audit program would have prevented (as opposed to minimising) those risks. For example, in some of the international cases, the errors had been identified through audits but the facilities had not addressed the identified problems. This raises systemic issues of quality monitoring and management that extend beyond the delivery of an independent dosimetry audit service alone.

**Measuring the extent to which the ACDS contributed to improving radiotherapy in Australia:** Improving external beam radiotherapy is the key intended outcome for the ACDS. Measuring this requires an understanding of the extent to which radiotherapy practice and safety has improved since the introduction of the ACDS, and determining the extent to which any such improvements may be attributable to the ACDS. However, there was no baseline against which any changes to dose accuracy or practice improvement could be measured: in effect, the ACDS has established the baseline for dose accuracy during its trial period.

Given the absence of a baseline quality indicator against which ‘improvement’ could be objectively measured prior to and since the commencement of ACDS, it was necessary for the evaluation to collect qualitative data from participating facilities and other expert informants (professional bodies, jurisdictions) to gauge their views on the extent to which ACDS had contributed to improving radiotherapy. The evaluation also reviewed a range of documentation and literature which provided a limited amount of primarily qualitative information about the baseline from which improvement could be measured.

In assessing the impact of the ACDS in improving radiotherapy, the evaluation, therefore, was restricted to considering the reported contribution of the ACDS to supporting a professional culture of quality assurance and continuous improvement in radiotherapy, rather than measuring actual improvement from an agreed quantitative baseline.

**Obtaining reliable cost data to establish unit prices:** The evaluation was asked to assess both the current costs of the ACDS (for ACDS operations and costs incurred by participating facilities), and the projected costs of the service in the future, by establishing a unit price per audit level.

The MoU between the Department and ARPANSA for the ACDS trial included a requirement for the collection of detailed cost data that would have allowed an accurate collection of the unit pricing of audits – had the information been collected. Unfortunately, that information was not collected by ARPANSA, and the evaluation had to rely on retrospective estimations of how auditors’ time had been used to derive a unit price. These estimations were then compared to annual budget expenditure information. The results must be reviewed with caution.
3.3 Evaluation Advisory Group

An Evaluation Advisory Group (EAG), established by the Department, acted as a steering committee for the evaluation. The EAG provided advice and commented on key deliverables and data collection tools. The EAG met four times in person during the evaluation: to discuss the work plan and evaluation methodology (10 December 2012); to discuss the pilot evaluation report and literature review (25 March 2013); and twice to discuss the draft final evaluation report (15 August 2013 and November 2013). The EAG also convened via teleconference to discuss and provide feedback on the key preliminary findings from the evaluation on 15 July 2013. Membership of the EAG is included at Appendix A.

3.4 Data collection methods

Six core data collection methods were used to address the evaluation questions. This section describes each of the data collection methods. The detailed data collection and analysis framework (including mapping of the methods to each of the evaluation questions and identified aspects within each question) is at Appendix B.

Literature review of better practice dosimetry audit models

A literature review was undertaken in February 2013 to provide an update on recent advances in research relating to radiotherapy dosimetry auditing and better practice (noting that a previous review was undertaken in 2009 as part of the business model development for the ACDS)\(^\text{19}\). The review focused on identifying and analysing any new information and evidence relating to different models of dosimetric audit services and models of funding of dosimetric audit services, and identifying elements of better practice.

The review targeted literature published in English since 2005 relating to practices in the UK, USA, Europe and Japan (although the review was unable to locate sufficient literature in relation to Japan). The following databases were searched: the Cochrane Library; Science Direct; Medline; Health Policy Reference Centre; and British Medical Journal. A search using the Google search engine was also undertaken to identify any additional publicly available information.

The review findings were discussed with both the EAG (see section 3.5 below for more information on this group) and the ACDS and were used to inform the subsequent evaluation data collection, as well as to derive ‘better practice principles’ for independent dosimetry audit which informed the policy alignment and sustainability assessment and the development of possible alternative dosimetry audit models outlined in part two of this report. A summary of the key findings is at Appendix C.

Review of ACDS documents and data

This involved the systematic review and analysis of a range of documents and data from the ACDS and the Department, including:

- the MoU between the Department and ARPANSA to operate the ACDS trial, as well as six-monthly operational reports provided by the ACDS to the Department under the MoU arrangements (28 July 2011, 30 December 2001, 30 June 2012);

• meeting papers for the MoU management group quarterly meetings (n=9) and the ACDS Clinical Advisory Group quarterly meetings (n=7);
• ACDS budget and summary of expenditure for 2011 and 2012 and prorated for 2013;
• the ACDS Quality Manual, including the audit methodologies and protocols;
• 2011 and 2012 project plans for the ACDS;
• 2012 risk assessment and risk management plan for the ACDS;
• annual audit plans;
• review of a sample of de-identified audit outcomes reports for each level of audit;
• organisational and management structure for the ACDS within ARPANSA; and
• ACDS conference presentations, journal articles, communication materials and promotional materials.

Online survey of radiation oncology facilities

An online survey was distributed to all radiation oncology facilities in Australia in April 2013 (n=64).20 Email contact details for relevant persons within the facilities were provided by the Department.

The survey instrument was an online, self-administered questionnaire with a range of multiple-choice questions and some free text options. Respondents were asked to provide some factual information about their experience of ACDS audits conducted within the radiation oncology facility in which they work, and to express opinions based on those experiences including:

• the extent to which they found the audit outcomes and recommendations constructive, and the degree to which they considered the ACDS had an impact on radiotherapy practice in their facility;
• views on the perceived benefits and value of the ACDS compared to the time and costs involved;
• views on the relative importance of independent dosimetry audit;
• overall satisfaction with the ACDS model of independent dosimetry audit; and
• willingness to participate in independent dosimetry audits in the future, including under different funding models to that used in the ACDS trial (i.e. if the services involved a partial or full fee contribution).

Two versions of the instrument were developed and refined after a validity and reliability pilot testing process: a primary survey, which was distributed to self-nominated key contact persons (usually senior medical physicists) at every radiation oncology facility in Australia, and a secondary survey, which key contact persons were able to forward onto any number of their colleagues within the facility. The surveys were largely identical, except that the primary survey included a number of additional questions about the nature of the facility and its staffing profile.

The surveys were distributed on 19 April 2013. Weekly reminder emails were sent during the period that the survey was open. The survey closed on 10 May 2013.

20 There are approximately 66 facilities in operation at the time of writing, but only 64 were operational at the time of the survey.
For the primary survey, there were 44 individual responses from staff across 38 radiation oncology facilities (more than one staff member responded from some facilities). The response rate was 58.4 per cent of all facilities that received the survey. All respondents to the primary survey were medical physicists.

For the secondary survey, there were 21 individual responses from staff across 15 radiation oncology facilities (again, more than one staff member responded from some facilities). The response rate was 23 per cent of all facilities that received the survey. 85 per cent (n=18) of respondents to the secondary survey were medical physicists; the other 14 per cent (n=3) described their role as either radiation therapist or radiation oncologist.

Results of the surveys were combined for analysis. There were 65 individual responses to the primary and secondary surveys combined, 67 per cent (n=43) of which were from the primary survey. These individual responses represented 41 radiation oncology facilities – resulting in a combined facility response rate to the surveys of 63 per cent of all facilities that received the survey.

The profile of combined primary and secondary survey respondents was as follows:

- 95 per cent (n=82) of all respondents were medical physicists;
- 57 per cent (n=49) of respondents reported that there were two linacs operating at their facility (20 per cent had 4 linacs; 8 per cent had 3 linacs; 6 per cent had 5 linacs; 5 per cent had 6 linacs; and 3 per cent reported having just one machine in their facility);
- 76 per cent (n=65) of respondents were in a facility that had been operating linacs for more than 5 years at that site;
- 67 per cent (n=58) of respondents were from public facilities (the other 33 per cent were from private facilities); and
- 65 per cent (n=56) of respondents were from metropolitan-based facilities (the other 35 per cent were in regional facilities).

Copies of the survey instruments are at Appendix D and Appendix E. The survey results are set out at Appendix F.

Interviews with a sample of radiation oncology facilities

Interviews were conducted between May and June 2013 with a sample of radiation oncology facilities. The purpose of the interviews was to gain qualitative insights into the operation of the ACDS and key stakeholder perceptions of outcomes achieved, the value of the service and its contribution to the objective of improving radiotherapy dosimetric practice. All interviews were conducted in-person by evaluation team members at the facilities.

Criteria for selecting the interview sample were as follows:

- a mix of private and public facilities;
- at least one metropolitan facility in each jurisdiction (i.e. 8 in total);
- at least four regional facilities (each from a different jurisdiction);
- at least one facility that had had an actionable audit rating at some point;
• at least one facility that had had an out-of-tolerance audit rating at some point;
• a mix of facilities that had participated in different levels of audit;
• at least one multi-site facility;
• at least one facility with experience in multiple levels of audit;
• at least one newly established centre; and
• a focus on more recent audit participants (to avoid raising issues that may have already been addressed by the ACDS).

The Department assisted the evaluators to identify potential facilities using these criteria.

A total of 14 facilities participated in the interviews (a total of 15 facilities were invited to participate). The profile of facilities which participated is as follows:

• three facilities in Victoria, two facilities each in New South Wales, Queensland, Western Australia and South Australia, and one facility each in Tasmania, the Northern Territory and the Australian Capital Territory (n=14);
• nine public facilities and five private facilities (n=14); and
• seven facilities were in regional areas (including those in ‘isolated’ city locations) and seven in major metropolitan locations (n=14).

A semi-structured interview guide was used for the interviews. This tool was pilot tested for validity prior to use and refined in response to the pilot testing feedback. The interview questions were provided to interviewees in advance of their interview.

Interviews were conducted in-person with key staff at the facilities to understand their experiences of participating in ACDS audits. Facilities were also asked to provide information to assist with the evaluation’s cost analysis, relating to the time and costs involved in ACDS audits that they had participated in.

Key themes from the interviews are set out in Appendix G.

**Interviews with other key stakeholders**

Interviews were conducted with 19 key stakeholders to gain qualitative insights into the operation of the ACDS and perceptions of outcomes achieved the value of the service and its contribution to the objective of improving radiotherapy dosimetric practice. Semi-structured interview guides were used for the interviews. Tools used for interviews with jurisdictions and other stakeholder groups were pilot tested for validity and refined in response to that testing prior to use. Tools used for interviews with the Department and the ACDS and ARPANSA were not pilot tested prior to use. In all cases, the interview questions were provided to interviewees in advance of their interview.

All state and territory health departments and radiation safety agencies in all states and territories were invited to participate in an interview (n=16). A total of 13 jurisdictional interviews were conducted. The majority of these interviews were conducted in-person.

The relevant departments and agencies were:

• Australian Capital Territory: Health Protection Service;
Nine other key stakeholder groups, identified with input from the Department, were invited to participate in an interview. Five of these organisations participated in an interview and a sixth provided a written submission.

The six stakeholder groups which participated were:

- Australian Association of Private Radiation Oncology Practices;
- Australian Commission on Safety and Quality in Health Care;
- Australasian College of Physical Scientists and Engineers in Medicine;
- Australian Institute of Radiography;
- CanSpeak; and
- Royal Australian and New Zealand College of Radiologists.

The majority of these consultations were conducted by telephone.

The evaluation also conducted two group interviews with staff from ARPANSA and the ACDS (all available ACDS staff were involved with the interviews), and one group interview with senior staff from the Department. In addition, a member of the evaluation team attended one meeting of the ACDS MoU Management Group in Canberra.

Key themes from the interviews are set out in Appendix G.

**Assessment of costs and benefits**

The evaluation undertook an analysis of the ACDS costs, including a detailed review of planned and actual annual budgets, review of resourcing allocations to audit and non-audit tasks, interviews with key ACDS and ARPANSA staff. The evaluation also included an assessment of costs and benefits, which included a thorough review of evidence relating to benefits and risks of dosimetry audit services and an analysis of
the operating costs of the ACDS to validated cost/benefit assessment indicators (notably the Australian Value of a Statistical Life Year measure).

3.5  

Pilot testing of the data collection tools

The evaluation included a pilot phase, conducted from December 2012 to March 2013. This allowed for testing of the evaluation tools with a small number of stakeholders; specifically, the online survey of facilities, interview guides, and cost data collection tool. The testing allowed for the review and refinement of the tools, as necessary, prior to the full evaluation, to ensure that the tools were reliable, valid, and met the information requirements of the evaluation framework.

Details of the pilot testing are included at Appendix H.

3.6  

Clinical dosimetry expertise

In addition to the advice from the EAG, the evaluation had access to specialist clinical dosimetry advice from Dr Sean Geoghegan, Chief Medical Physicist at The Canberra Hospital. Dr Geoghegan provided input to the development of the evaluation framework, the literature review, and undertook a technical review of the ACDS Quality Manual particularly focussing on the audit methodologies and protocols (the findings of that review are summarised in the process evaluation chapter and are included in full at Appendix I).

The Canberra Hospital has participated in some ACDS audits, and was one of the facilities included in the interview sample for the evaluation. The interview with Dr Geoghegan was conducted separately to the interviews with other staff members, to manage any perceived conflicts of interest given his involvement in the evaluation.

Dr Geoghegan was not directly involved in the development of the evaluation findings or the development of this report, and he did not have access to any evaluation materials other than those specifically mentioned above (the evaluation framework, literature review and the ACDS Quality Manual).
4. Establishment and implementation of the ACDS

This chapter outlines the findings from the process evaluation.

4.1 Overview of this chapter

This chapter addresses the following evaluation questions and aspects:

- What did the ACDS do, and with what resources?
  - This includes consideration of the establishment processes, protocols and procedures developed, and services delivered.
- How did it go? What was learnt?
  - This includes consideration of the achievement of service targets (audits delivered), and the effectiveness of the enabling structures (including equipment and tools, governance and management, and service planning and reporting).

Evaluation evidence informing this chapter was gathered primarily through a review and analysis of key ACDS and MoU documents, and through interviews with the ARPANSA and the ACDS and the Department of Health.

4.2 Establishment of the ACDS

The ACDS trial service was auspiced by ARPANSA and fully-funded by the Department under a MoU. The MoU included an establishment phase to December 2010 and an operational phase from January 2011. The MoU states that the purpose of the service is to support improvement in radiation therapy by providing an independent dosimetric measurement and inter-comparison service for clinical radiation therapy. The services to be provided, objectives and key performance indicators under the MoU were developed by the Department, with advice from the RORIC Quality Working Group.

Placement of the ACDS within ARPANSA

There were a number of factors which contributed to the decision to establish the ACDS within ARPANSA:

- the national primary standard for clinical dosimetry is maintained at ARPANSA and a co-located ACDS would have direct access to the primary standard and the medical reference linac;
- ARPANSA had experience delivering dosimetric audits, having delivered fee-based Level I postal audits in Australia since 2003;
- there were concerns about the capacity to recruit suitable staff to the ACDS and it was considered that ARPANSA would have the ability to provide suitable ‘back up’ resources and expertise; and
- the ACDS would have access to ARPANSA’s supporting structures including accommodation, financial management systems and human resource management systems.

Other alternatives for operation of the ACDS that were considered included placement of the service within a university or a host radiation oncology facility. The host facility option had been proposed in an earlier trial of Level III dosimetric inter-comparison (although it was not clear under that proposal who would audit the host facility). The host facility option was not pursued because of concerns about the
independence of such an arrangement – that is, whether other facilities would perceive an independent dosimetry audit service hosted by another facility as being sufficiently independent. The university option was not pursued due to a perceived lack of required facilities and personnel.

A number of stakeholders interviewed for this evaluation indicated that they had initially been concerned about the placement of the ACDS within ARPANSA on the basis that an audit service is not generally located within a regulator as matter of good practice (although ARPANSA noted that it is not in fact a direct regulator of hospitals and radiation oncology facilities). However, of stakeholders who expressed these initial reservations, many agreed that the co-location was working well and that access to the standards laboratory and the research linac were an enabler of the service. This structure was positively received overall. The majority of stakeholders also perceived ARPANSA to be more independent than a host radiation oncology facility or university option.

ACDS staff reported that the relationship with ARPANSA has been a critical success factor, particularly with the provision of financial management and staff management processes.

**Funding**

The funding for the ACDS is set out in schedule 3 of the MoU. The ACDS was entirely supported by funding from the Department through the Better Access to Radiation Oncology budget measure and audit services were provided to facilities free of charge during the trial period. The total value of funding to the ACDS is $3,162,500 (GST-inclusive) over the four-year trial period. Payments were made on the basis of the ACDS meeting milestones as outlined in the MoU.

The rationale for the Department fully-funding the service without a fee to facilities for services or a contribution from jurisdictions was threefold. Firstly, providing the services free to facilities was seen as a mechanism to encourage high uptake and participation (100% of facilities approached by the ACDS to participate in the audits did agree to participate). Secondly, it was seen as appropriate for the service to be fully-funded during the trial given it was time-limited, as other funding options to be considered following an evaluation. Thirdly, it was seen as an expedient way to establish the trial quickly.

Funding levels were adequate to deliver the agreed services during the trial period (including delivery of the additional level Ib audits – noting that these services were ‘additional’ to the MoU requirements as such, but they did count towards the overall MoU audit targets for audits of new linacs).

**Establishment phase**

The MoU specified that the trial was to be delivered in three phases with a number of deliverables in each phase. The first phase (establishment) involved achievement of the following by 1 December 2010:

- recruitment of ACDS personnel;
- establishment of a Clinical Advisory Group (CAG) to provide clinical advice on the development of suitable audit methodologies and protocols;
- development of audit methodologies for all levels of audit;
- procurement of the equipment required to operate the service;
- engagement with facilities to foster their participation (in line with the targets set out in the MoU);
development of service delivery procedures including project plan and risk management plan, audit plan, and communication strategies; and

establishment of an audit panel.

Recruitment of ACDS personnel

During the establishment phase, ARPANSA was required to fulfil the MoU requirements using its personnel and resources (i.e. prior to recruitment of ACDS personnel). The target timeframes for recruitment of ACDS personnel proved overly ambitious within the six-month establishment period. This was not unexpected given the demand for medical physicists in clinical roles, and the ACDS was eventually able to recruit the required complement of suitably qualified staff. As at 30 June 2013, the ACDS was composed of the following staff:

• Director (senior medical physicist) – the position description indicates that this role involves the planning, direction and management of a small team of scientific and technical staff to actively engage with the medical professions to provide a high level audit service for external beam radiotherapy, and collaborate in the assessment of radiotherapy dosimetry, requiring qualifications in medicine or in a branch of the physical sciences.

• Auditors (senior medical physicist) – the position description indicates that this role involves overseeing services ranging from postal audits to site visits, including linac output measurements, treatment dose assessment using phantoms, and quality system audits, requiring the incumbent to develop or procure phantoms for the assessment of the entire treatment delivery process, and determine measurement methodologies. The incumbent of the position requires expertise to prioritise treatment sites and radiotherapy techniques which require an audit service. In terms of qualifications and experience, the position requires more than five years experience as a physicist in megavoltage dosimetry with a sound understanding of the processes and techniques involved in dose assessment and quality systems in radiotherapy. Extensive experience of clinical dosimetry, particularly in areas of emerging technologies being implemented in Australian radiotherapy treatment centres, is considered desirable (note that the position description for this role was slightly updated during the trial period as new vacancies arose).

• Physics technician – the position description indicates that this role is responsible for linac operation, maintenance, quality assurance programs, scheduling and integration of users’ equipment with the linac, requiring a technical degree or diploma with a major in electronics, physics or engineering and a demonstrated knowledge and understanding of the science of linear accelerators.

• Administrative support – the position description indicates that this role involves assisting the Director of the ACDS and staff in liaising with radiotherapy centres in promoting the ACDS, and providing administrative and technical assistance as required.

The position descriptions appear to be suitable expressions of the key requirements for the ACDS staff, and are broadly in line with the expectations indicated by most stakeholders in terms of the qualifications and expertise they would expect of staff in a national dosimetry service. Some clinical stakeholders feel the requirements are not high enough, and suggest that all auditors should be qualified medical physicists and should preferably hold relevant professional body credentials/accreditations.
Development of audit methodologies

The MoU required the development of audit methodologies for all levels of audit prior to the operational phase. This proved challenging. The development and testing time for Level II and III audits were delayed in part because of the staffing recruitment delays, and in part because the design and testing processes took longer than anticipated (the Level I audit methodology was already well-established prior to the ACDS). However, audit methodologies for all levels were developed and tested in sufficient time to allow for the delivery of all required audits within the MoU timeframes.

Development of service delivery procedures

The ACDS developed a number of protocols and procedures to guide the establishment and operation of the service, including:

- The ACDS Quality Manual – this manual forms the core of the ACDS operations and was subject to continuous development and improvement during the trial period. It included the audit methodologies and protocols for managing audit results. The audit methodologies were developed by the ACDS with support from its CAG and, initially, the RORIC Quality Working Group. The Department also had a role in approving the methodologies, but did not play a role in developing the content.
  - The quality management system (QMS) utilised by the ACDS is based on the ISO 9001:2008\(^{21}\) standard developed by the International Organisation for Standardisation. A complete QMS aids in the continuity of services when training new staff in service delivery.
  - At the time it was reviewed for the evaluation (May 2013), the ACDS QMS was still under development. Appropriately, priority had been on developing the components of the Quality Manual dealing with the audit methodologies and protocols for reporting and following up audit results.
  - Although the ACDS QMS is incomplete, the technical aspects of the supporting documents which are finalised and in production can be assessed independently of the overarching QMS. An independent technical review of these documents was undertaken as part of the evaluation. A number of suggested improvements were identified. Summary points and suggested actions from the technical review are indicated in Figure 3 below. The full review and suggested actions are set out in Appendix I.
  - It is suggested that the QMS of the ACDS, once finalised, should be audited and assessed against ISO 9001:2008 by an accredited certification body recognised in Australia.

---

**Figure 2: Technical review of the ACDS Quality Management System**

**Technical review of the ACDS Quality Management System: Summary points**

A technical review of the ACDS quality management system and related documentation was undertaken by Dr Sean Geoghegan in May 2013. The scope of this technical review was to:

- review the ACDS audit methodologies and procedures;
- comment on the extent to which these are consistent with contemporary better practice and international standards; and
- provide suggestions to improve the alignment with contemporary better practice and international standards.

The audit methodologies are outlined in the three-tier ACDS Quality Manual. This review paid particular attention to Tier 3 in which the operational instructions on providing the dosimetry audit services are described. A Tier 0 exists within the ACDS quality system and is used by the ACDS to describe the organisation of the Quality Manual.

**Review findings**

The quality management system (QMS) utilised by the ACDS is based on the ISO 9001:2008 standard developed by the International Organisation for Standardisation. The ISO 9000 standards describe the establishment and maintenance of quality management systems which help organisations meet the needs of customers in delivery of services and products. ISO 9001:2008 defines the requirements of quality management systems that meet the standard and is the document against which an organisation is assessed for that organisation to be awarded accreditation under the ISO 9000 family of standards.

A significant risk of an incomplete QMS is that much of the system’s knowledge may not be adequately documented. Insufficient documentation puts the continuity of a service in jeopardy if a critical staff member holding specialised knowledge is no longer available. A complete QMS aids in the continuity of services when training new staff in service delivery.

The ACDS QMS lacks complete documentation in the areas listed below (the ISO 9001:2008 section references are given in brackets):

- Management (4.1, 4.2.1, 4.2.2, 5.1 – 5.5);
- Document control (4.2.3);
- Records (4.2.4);
- Review (5.6);
- Resourcing and competencies (6);
- Planning and communication (7.1, 7.2);
- Design control (7.3);
- Procurement (7.4);
- Operational control (7.5);
- Measurement and monitoring (7.6);
- Analysis and improvement – satisfaction (8.1, 8.2); and
- Analysis and improvement – conformance (8.3 – 8.5).

Those requirements of ISO 9001:2008 missing from or requiring further development in the ACDS QMS are generally associated with the management of the QMS and operational aspects of service delivery, and are not associated with the technical aspects of service delivery.

The one major technical aspect of the ACDS Tier 0 and Tier 1 QMS documents that is missing relates to the management of the dosimetry equipment used by the ACDS. Specifically, procedures for ensuring the traceability of the dosimetry chains to the primary standards for their ion chambers, hydrometer, barometer and hygrometer are not documented. The

---

The same is true of the optical stimulation luminescent dosimeters (OSLDs), although the evidence cited is stronger with direct mention of a Co-60 source (presumably the ARPANSA standard source) used to calibrate the OSLDs. This lack of documentation within the ACDS QMS does not represent an actual technical gap because appropriate calibration arrangements are described in a peer reviewed publication prepared by the ACDS.  

**Suggested actions**

1. The ACDS develops a succinct Policy Statement meeting the requirements of a QMS defined by ISO 9001:2008.
2. The ACDS clearly document the dosimetry calibration chain to the relevant primary standards within their QMS.
3. The ACDS review the design control requirements of the ISO 9001:2008 standard in view of managing the development of their audit systems.
4. If the ACDS service is continued then the ACDS works to finalise the documentation that is part of the ACDS QMS as soon as possible and develop the QMS suitable for assessment against ISO 9001:2008 eliminating unnecessary reference to older versions of the ISO 9001 standard and older versions of internal documents.
5. The QMS of the ACDS, once finalised, should be audited and assessed against ISO 9001:2008 by an accredited certification body recognised in Australia, if the service is continued.
6. The ACDS programs into the ACDS QMS a schedule and ongoing quality assurance and quality control programs for the systems, making specific mention of the brands and models of the equipment and the version numbers of related software.
7. The ACDS documents in the ACDS QMS the resetting (bleaching) procedure for the OSLDs (nanoDots), including instructions to remeasure the sensitivity of the nanoDots following bleaching.
8. The ACDS considers procuring and using 150–200 W Tungsten Halogen lamps with filters to reset their OSLDs (nanoDots).
9. The ACDS documents the location of original OSLD data and reference to these data locations in the various Excel workbooks used in the ACDS QMS so that any changes to basic data can be more easily tracked and controlled.
10. The ACDS develops a unified staff competencies table covering the services provided by the ACDS.
11. All documents forming the ACDS QMS are named and numbered and a listing of the current version of these documents is provided in the QMS so that version control can be maintained.
12. The ACDS identify and document a design control process to manage the addition of audit protocols to accommodate existing and future radiotherapy techniques and technology including intensity modulated radiotherapy (IMRT), volume modulated arc therapy (VMAT), stereotactic radiosurgery (SRS) and flattening filter free beams.
13. The documentation provided to facilities by the ACDS as part of an audit includes information on the impact of delaying the return of the audit OSLDs on the uncertainty budget.
14. The factsheet provided as part of the Level Ib audit should be updated to conform to the 2σ and 3σ values defined in the ACDS protocol for audit outcomes.
15. The ACDS is to continue to refine the Level II audit documentation.
16. The ACDS should refine the uncertainty budget following an analysis of several (at least six) Level III audits to arrive at a best estimate of the standard uncertainty for various representative dose points measured as part of the audit.
17. Once the Level III audit process is validated in the pelvis and thorax, the ACDS should procure and develop a Level III audit procedure for head and neck sites.

---

• ACDS project plans for 2011 and 2012, and 2012 risk assessment and risk management plan – these comprehensive plans were developed by the ACDS. They set out the projected work plan for the ACDS, risk analysis (including internal risks such as staffing and external risks such as funding) and risk management strategy based on an assessment of risk likelihood and consequence. These plans are appropriate and useful management tools, but the risk management plan in particular needs to be regularly reviewed and revised as needed. Based on the information available to the evaluation, the risk assessment appeared only to have been updated in May 2011 and June 2012. The risk management controls in place were appropriate.

• Annual audit plans (2011, 2012 and 2013) – these were developed by the ACDS and document the proposed audits to be conducted each year and, for 2012 and 2013, include a table summarising the target number of existing linacs to be audited each year tracked to the target numbers identified in the MoU, which assists in planning and monitoring progress against the MoU targets. However, the source of the total number of existing linacs is not cited in the plans. Also, it would be helpful to have a similar table for the new linacs to be audited. Finally, there is no reference in the audit plan to the use of risk profiling or other prioritising criteria to select facilities for audit (the MoU requires that priority be given to newly commissioned linacs, and that the type of audit to be performed vary based on whether a new or existing planning system is being used; the ACDS also identified other potential risk criteria which it used to plan audits – this rationale is not evident in the audit plan documents). For these reasons, it is difficult to link the audit plan to the MoU targets.

• Operating reports (July 2011, December 2011, June 2012) – these reports from ACDS to the Department describe the ongoing progress towards achieving targets and updates on the number of audits performed in the preceding period. They also outline any issues or problems encountered and actions taken to resolve these. Reporting on the number of completed and planned audits in current and future periods could be improved with the addition of a simple table, updated with each report, specifying the number of audits at each level completed for that period and projected for the next period.

• Publications and conference presentations – four journal articles and a number of conference presentations by ACDS were reviewed, indicating that the MoU requirement to promote the ACDS in relevant forums were fulfilled.

• Audit outcomes data – the evaluation reviewed a de-identified extract from the national register of records of dosimetry audits.

• Audit outcomes reports – a sample of de-identified audit reports was reviewed (seven Level I reports, four Level Ib reports and four Level III reports). The report formats have significantly improved over time. Reports with actionable findings included suggestions for addressing identified issues. References were made to previous audits where the facility had already participated in other ACDS audits. However, some of the reports do not include key dates such as when audits were performed and/or exposures taken and when reports were written.

Audit panel

The MoU required the ACDS to establish an audit panel of suitably qualified persons to conduct the ACDS audits in line with the established audit guidelines and service delivery procedures. The ACDS was to provide a list of the auditors, a needs analysis of training requirements and an outline of when training
would be conducted to the Department by December 2012. The role and composition of the audit panel was not clearly articulated in the MoU, but discussions with ACDS indicate that the panel was to consist of independent and experienced physicists working in existing facilities who could be temporarily seconded to ACDS to conduct onsite audits. Discussions with the Department suggested that it was not necessary under the MoU that panel auditors be practicing medical physicists, but rather it was the responsibility for ARPANSA to determine the appropriate qualifications.

In practice, although some training of suitable audit panellists did occur, the audit panel concept proved challenging for a number of reasons during the trial period:

- the small pool of potential panellists (senior and experienced physicists) and the high demand for their services in clinical practice;
- limited availability of the panellists to be seconded from their facilities to undertake audits, within the notification timeframes provided by the ACDS (suggesting that such an arrangement may have been more successful with a longer lead time);
- lack of clarity over employment and insurance (i.e. whether the ACDS or the seconding employer was responsible for insurance); and
- concerns by the CAG and MoU management committee about the potential for inconsistency in undertaking the audits (resolved by agreeing to have a process whereby an ACDS lead auditor would ensure the audit methodology was to be implemented consistently across sites), as indicated in the CAG and MoU management committee meeting minutes and verified in evaluation interviews.

In the end, some audit panellists were trained for some audit levels (partially satisfying the MoU requirements), although none of these trained panel auditors undertook any audits during the trial period.

Although the audit panel envisaged by the MoU did not eventuate, another form of a panel did arise when one ACDS auditor decided to take up a position in a clinical practice role, and secured an agreement from the ACDS and his new employer that he would continue to work as a part-time ACDS auditor so long as he did not conduct audits in his facility’s jurisdiction to avoid conflicts of interest. This is seen by the ACDS as being a potentially effective arrangement for the future (i.e. a clinician could work with the ACDS for a period, then return to clinical practice and maintain a part-time auditing role with the ACDS).

**MoU – operational and transitional phases**

The second phase of the MoU (operational) involved achievement of the following:

- provide the agreed dosimetry audit services;
- data collection;
- report to the MoU management committee on achievement of MoU milestones outlined in the MoU on number and type of audits conducted, key findings and proposed changes to the audit methodology or service delivery procedures;
- convene Clinical Advisory Group (CAG) meetings;
- promote the ACDS at key professional meetings; and
- participate in external evaluation.
All of these activities have occurred. In terms of data collection, the evaluation understands that there is now an ACDS data set of Level I results which could be analysed (the evaluation has seen an earlier de-identified version of the database in which these results are maintained). To date, however, there has not been enough Level II or Level III audits to analyse the audit outcomes data.

The MoU included a requirement that audits should be apportioned equally over the three-year operational phase. This was not possible due to the delays in developing the Level II and Level III audits.

The final phase (transitional) involves activities to be defined following the evaluation and a decision on the future of the service beyond the trial.

### 4.3 Service delivery

#### Operational phase

**Delivery of audits**

Overall, the MoU audit targets have been or will be met or exceeded. At June 2013 the ACDS had conducted 209 audits on linacs across 58 facilities (87 per cent of the 66 facilities).²⁴

By November 2013, 236 linacs had been audited.

*Table 2: Linacs audited during ACDS trial*

<table>
<thead>
<tr>
<th></th>
<th>2010/11</th>
<th>2011/12</th>
<th>2012/13</th>
<th>2013/14</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>12</td>
<td>40</td>
<td>69</td>
<td>11</td>
<td>132</td>
</tr>
<tr>
<td>Level Ib</td>
<td>0</td>
<td>0</td>
<td>33</td>
<td>3</td>
<td>36</td>
</tr>
<tr>
<td>Level II</td>
<td>0</td>
<td>0</td>
<td>37</td>
<td>5</td>
<td>42</td>
</tr>
<tr>
<td>Level III</td>
<td>2</td>
<td>13</td>
<td>5</td>
<td>6</td>
<td>26</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>14</strong></td>
<td><strong>53</strong></td>
<td><strong>144</strong></td>
<td><strong>25</strong></td>
<td><strong>236</strong></td>
</tr>
</tbody>
</table>

Source: ACDS

In terms of the results of the audits, the majority of outcomes were found to be within tolerance. Overall then, if the ACDS trial is looked upon as a ‘snapshot’ of dosimetric quality in Australia, it can be concluded that the general standard of dosimetric practice in Australia is high. This could not have been said prior to the ACDS trial.

However, there were some ‘fail’ results at each level of audit (particularly the more comprehensive Level II and Level III audits). Some of these results were followed by re-testing which had a different outcome (i.e. on re-testing the linac was found to be within tolerance).

²⁴ Note that some facilities have participated in multiple audits.
There is a lack of clarity amongst stakeholders (including facilities) around how or if an out of tolerance result would be escalated by the ACDS, in the event that a facility failed to address the identified issues. The ACDS has a clear protocol on this, which involves escalation within the facility if required (but not outside of it), but this protocol is not widely understood by stakeholders. These protocols should be clearly defined and understood by all stakeholders, including jurisdictional regulators, to improve the overall understanding of the role of the ACDS.

4.4 Effectiveness of enabling structures and processes

Facility recruitment processes

By June 2013 the ACDS had conducted audits across 58 radiation oncology facilities (roughly 87 per cent of the 66 facilities existing across Australia at that time).

The ACDS developed its audit program based on (a) the priority criteria set out in the MoU, and (b) flexibly-applied risk profiling criteria which evidence suggested may contribute to the potential for dosimetric errors. In the early part of the trial, these potential risks were identified as:

- new facilities delivering clinical services for the first time (highest priority);
- isolated facilities with new linacs;
- existing facilities with new linacs; and
- other facilities, based on the time since their most recent Level I audit (including ARPANSA Level I audits conducted prior to the ACDS).

Additional risk criteria which were taken into consideration in prioritising facilities to invite and/or to participate in an audit included: facilities with a single physicist (including a visiting as opposed to resident physicist); stand-alone facilities not part of a wider organisation; regional facilities; and facilities with potential ‘legacy issues’ (such as staff turnover, very old internal processes and protocols that were developed by former staff, satellite centres established by former staff etc.). In practice, the ACDS found that some of these factors proved to be less of a risk than anticipated: for example, single physician and isolated centres often seemed to be very aware of their risks and had taken steps to mitigate them, whereas in contrast some well-established metropolitan centres with a stable staff profile appeared to sometimes have fallen into a pattern of doing what they always had done which actually could make them a higher risk than the isolated facility.

Identified facilities were recruited by direct invitation. One hundred per cent of facilities invited to participate agreed to participate in an audit. During the interviews for the evaluation, the ACDS indicated that demand for audits was much higher than their capacity to supply and exceeded the MoU targets. Interviews with facilities confirmed this: several facilities that had participated in one or two levels of audit indicated that they also wanted to participate in other levels of audit.

Overall, the recruitment process was effective for the purposes of the trial.

Equipment and tools

The ACDS had access to sufficient equipment to deliver the required audits. Much of the required equipment was purchased specifically for the ACDS trial. A more detailed discussion of the equipment used and its fitness for purpose is included in the technical review at Appendix I of this report.
Governance and management

There were three components to the ACDS governance during the trial period:

- internal governance within ARPANSA;
- external governance via the MoU management group (comprising the ACDS, ARPANSA and the Department); and
- technical governance via the Clinical Advisory Group (CAG).

These processes proved generally fit for purpose during the trial period. They were perceived by key staff within the ACDS, ARPANSA and the Department to be critical success factors for the achievement of the audit targets and delivery of the trial objectives.

The internal governance within ARPANSA meant that the ACDS had ready access to corporate, financial, human resources and legal supports during the trial, as well as clear internal management lines. Had the ACDS been established as a standalone service, or had it been hosted by another organisation, they may not have had the same level of access to such support.

It is more difficult to measure the effectiveness of the MoU management group. Key staff from the Department and the ACDS and ARPANSA reported that the MoU management group, and the associated reporting responsibilities, was a useful mechanism to ensure the trial was implemented as intended, that performance indicators were met, and that problems were resolved quickly; both parties reported that the MoU management group was a critical success factor for the ACDS trial.

However, despite these views, the observation of the evaluation is that this governance structure must be reviewed if the ACDS becomes a continuing service. The MoU management group was focussed on project management and measuring performance against targets during the trial, rather than an overall management of the ACDS. A particularly notable failing of the MoU management group was its inability to enforce the collection and analysis of cost data to the level of detail specified in the MoU (this included ‘personnel and auditor hours in performing each audit including the type of personnel and the proportion of their time, direct costs to ARPANSA in performing each audit and any other service delivery activity, and costs (direct or indirect) incurred by facilities participating in each audit’). The failure to collect this information represents non-compliance with the terms of the MoU, and the management group might have been expected to have addressed this. Had the information been collected as specified, it would be possible to have a clear understanding of the unit price for an audit by the end of the trial. As the information was not collected – and the MoU management group failed to ensure that the information was being collected over the three year operational period – the evaluation had to rely on estimations of time spent on audits by the ACDS staff. If the service is to continue, better efforts must be made to collect this information.

The CAG appeared to be a more successful group. The role of the CAG was broadly defined in the MoU as:

- providing advice on and assisting with the development of the audit methodology and service delivery procedures;
- providing advice on and assisting in the interpreting of the results of Level I, Level II and Level III audits;
- identifying the relevant range of treatment techniques for Level III audits;
• confirming phantom and measurement techniques developed by ARPANSA for Level III audits for priority treatments;
• providing advice on the skills and experience required for the panel of auditors and confirming the selection of auditors;
• providing advice on the training of auditors; and
• through the Department, consulting with the RORIC Quality Working Group.

The membership of the CAG comprised:
• a radiation oncologist;
• a radiation therapist;
• a medical physicist;
• a Trans Tasman Radiation Oncology Group (TROG) representative;
• a RORIC representative; and
• the senior radiation physicist of the ACDS.

During the trial period, the CAG meetings were focused on the processes and protocols of the ACDS audits. The meetings focused on ensuring the ACDS met best practice for dosimetric audit in addition to providing general advice regarding auditing procedures, processes and documentation.

Ongoing governance of the ACDS could be improved by (a) restricting the role of the CAG to providing technical advice and input on clinical matters and advice on the development of audit methodologies, and not on the management of the service or similar non-clinical matters, and (b) forming a Management Advisory Group with a broader management focus to replace the MoU management group.

A Management Advisory Group with the right composition of members and skill-sets could focus less on measuring progress against project plan milestones, and more on the development and implementation of strategies and business plans, effective strategic and annual audit planning, staff planning, critically assessing and improving cost data and audit outcomes data analysis, and assisting to develop audit benchmark results for reporting to the sector. To do this, the Management Advisory Group would need to include people with expertise in areas such as financial management and reporting, data analysis and reporting, strategic planning, and resource management. These skills are not currently represented on the MoU management group.

A Management Advisory Group could also provide a forum for wider stakeholder engagement. For example, it might include representatives such as jurisdictional health and/or radiation safety agencies, the Australian Commission on Safety and Quality in Healthcare, a data analysis expert, and a cancer consumer representative.

Financial management and reporting issues

Key staff within the Department expressed concerns that the level of financial and performance reporting by the ACDS during the trial period was inadequate. In particular, there were concerns about a lack of detail on how much staff time and other costs were required to conduct each audit. The evaluation was also hampered by this lack of information. As noted above, it was a requirement under the MoU that this
information should have been recorded by the ACDS, and the failure to collect this information makes it
difficult to accurately calculate the unit price of an audit. If the service continues, collection of accurate
cost and time data should be a priority.

The Department also expressed concerns that there was a general lack of non-clinical skills within the
ACDS, citing a lack of business management, financial management and other similar skills. The evaluation
notes, however, that these skills were accessed through ARPANSA. Furthermore, these issues could be
addressed through the changed arrangements for the management committee suggested above.

Annual and strategic audit planning

As indicated in the discussion of facility recruitment earlier in this chapter, the ACDS took a purposive
approach to identifying and recruiting facilities for audits during the trial period. Some attempt was made
to risk profile facilities in order to prioritise audits, and to schedule the various levels of audit – although,
given the lack of actual data on dosimetry quality prior to the ACDS trial, this risk profiling was necessarily
crude. In terms of scheduling the audits, the ACDS utilised a whiteboard to plan audits requiring onsite
visits, so that several audits could be conducted in the same geographic areas and make the best use of
staff travel time, and to ensure that the MoU performance targets were met in terms of the number and
spread of audits. Overall, this scheduling approach was pragmatic and effective for the purposes of the
trial.

However, if the ACDS becomes an ongoing service, a more sophisticated approach to audit planning and
scheduling should be used. The first question to be resolved is whether audits should be conducted on a
cyclical or risk basis.

- **Under a cyclical model, all facilities would be audited over a period of time. This is the future model
advocated by the ACDS – it proposes a three-year cycle, whereby every facility would have a Level I,
Level II and Level III audit at least once over a three-year period (Level IB audits would remain
available on request). Many clinical stakeholders also advocate a cyclical audit program, although
their opinions differ as to the frequency: most suggest a Level I annually, biennially or triennially
(most of the literature suggests biennially), with Level II and III every three to five years, or earlier if
required (i.e. if Level I results suggest it would be beneficial). This type of system is used in some high-
risk regulated sectors. It may be more costly than a risk-based model – because more audits are
conducted than may be necessary.

- **Under a risk based model, Level I audits would be conducted on a regular basis (say, every two years)
or on a random basis, with Level II and III audits conducted on the basis of identified risk factors (i.e.
changes to planning systems, significant changes of personnel or equipment etc. – the actual risk
factors would need to be determined by suitable experts and agreed within the sector). This type of
system is often used in entry controlled sectors (that is, industries where compliance with standards
or regulations must be demonstrated in order to obtain an operating licence or accreditation – an
‘entry control’ – and the level of compliance monitoring, including audits, is then determined on the
basis of assessed risk). This model can be more cost effective than a cyclical model – because there
are fewer overall audits, and they are targeted to facilities at higher risk – but it can only be effective
where there are clear, agreed risk factors. It also depends on effective entry controls.
In the case of the ACDS, it may be more effective to have a cyclical model for the first few years, given the lack of clear evidence to support a risk-based model – it would be possible to transition to a risk-based model over time.

Once it is known how many facilities and linacs will be audited over a period (say, a three-year period), best practice would be to develop an audit strategy. Once the audit strategy has been developed, annual audit plans can be developed. The ACDS did develop annual audit plans during the trial, but these were driven by the MoU performance targets, rather than having been informed by an audit strategy.

The purpose of the multi-year (e.g. three-year) audit strategy is to outline the manner in which audits will be conducted, including goals and objectives for the audit program, how facilities and linacs will be selected for audit, and how risk profiling will be conducted (if applicable). In the case of the ACDS, the document could be expected to cross-reference to the Quality Management System (particularly the audit methodologies and protocols) and the ACDS risk management plan. Key components of the audit strategy would include:

- the role and objectives of audits;
- management and governance framework for conduct of audits, including accountabilities and reporting lines;
- process for scheduling audits (including risk profiling criteria, if applicable);
- format and templates for audit reports and other documents;
- mechanisms for coordination with relevant stakeholders (including facilities, jurisdictional health agencies, jurisdictional radiation safety agencies and clinical bodies); and
- key performance indicators for the audit program (these would likely replace the KPIs in the current MoU).

The annual audit plans would set out the proposed audit schedule for each year in detail. Typically it would be more than a spreadsheet of intended audit sites and dates, and would draw on the strategic plan to reflect the rationale for annual audit schedule. This would be based on an environmental risk assessment as well as areas of particular interest or concerns to the management group or the CAG (for example, it may be informed by trends that have been identified in previous years’ audit results that suggests more or less attention should be paid to certain areas).

The annual audit plan should also be fully costed, including staff time, travel time and other related costs. This highlights the importance of having an accurate unit price for each audit, including an accurate record of required staff time to complete each level of audit.

### 4.5 Summary of key points

<table>
<thead>
<tr>
<th>Establishment of the ACDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Some stakeholders were initially concerned about the placement of the ACDS within ARPANSA, but these concerns were allayed once the service became operational.</td>
</tr>
<tr>
<td>- Ready access to support and existing structures within ARPANSA was seen by the ACDS to be a critical success factor in establishing the ACDS and achieving the trial objectives.</td>
</tr>
<tr>
<td>- Funding levels appeared to be adequate to deliver the agreed services during the trial period.</td>
</tr>
</tbody>
</table>
The MoU provided a clear timeframe and schedule of services to be delivered, and a clear governance structure for the ACDS trial period. The reporting requirements within the MoU promoted accountability and regular monitoring and review of progress against the targets.

However, the targets in terms of proportion of linacs to be audited were somewhat confusing, written in an overly complex manner and potentially open to interpretation as to how many existing and new linacs there were at a point in time.

There were delays in staff recruitment and development of audit methodologies, but these did not impact on the overall ability of the services to meet its requirements under the MoU.

The Quality Management System (including the audit methodologies and protocols for communicating with facilities and reporting audit outcomes) is still under development.

Project plans and risks management plans were appropriate and effective.

Audit outcomes reports have significantly improved over time, indicating a continuous improvement approach and use of feedback from facilities to refine templates.

Development of the audit panel proved challenging for a variety of reasons and ultimately it was not established as intended.

The audit panel approach may be worth exploring again in the future, but in the short to medium term it would appear that this approach is unlikely to be viable unless there was significant ‘buy-in’ from employers to the idea and they agreed to regularly release practicing physicists to fulfil an audit panel role.

Service delivery

The MoU targets for numbers of audits at each level will be met or exceeded by December 2013.

Overall – if the ACDS trial is looked upon as a ‘snapshot’ of dosimetric quality in Australia – it can be concluded that the general standard of dosimetric practice in Australia appears to be very good. That said, there was a mix of audit results across all levels of audit, indicating the benefit of the service to identify a range of dosimetric quality issues prior to a possible error occurring.

There is a lack of clarity amongst stakeholders around how or if an out of tolerance result would be escalated by the ACDS (although the ACDS has a clear protocol on this, involving escalation within the facility if required but not outside of it).

Effectiveness of enabling structures

Facility recruitment processes were successful, with about 87 per cent of facilities participating in at least one ACDS audit during the trial.

The ACDS had sufficient access to equipment and tools to deliver its services.

Governance and management processes were generally fit for purpose during the trial period.

Audit planning and scheduling was effective for the trial period, but a more strategic approach should be adopted if the ACDS becomes an ongoing service.
4.6  Suggested actions / areas for improvement

Establishment of the ACDS

- The QMS should be finalised. Once it has been completed, it should be audited and assessed against the ISO 9001:2008 standards by an accredited certification body.
- The risk management plan should be regularly reviewed and revised as needed.

Service delivery

- Clear processes and role delineation in appropriately managing fail results is required. Protocols need to be clearly defined, agreed and understood by all stakeholders, including jurisdictional regulators.

Effectiveness of enabling structures

- Ongoing governance of the ACDS could be improved by: (a) restricting the role of the CAG to providing technical advice and input on clinical matters and advice on the development of audit methodologies, and (b) forming a Management Advisory Group with a broader management focus and skill set to replace the MoU management group.
- In the future, the effectiveness and transparency of ACDS audit planning and scheduling processes would be improved by the use of an audit strategy and annual audit plans.

4.7  Conclusions

Returning to the specific evaluation questions:

What did the ACDS do, and with what resources?

The total value of funding to the ACDS was $3,162,500 (including GST) over a four-year period.

The ACDS will meet or exceed its targets by December 2013.

Two notable aspects of the service which were not achieved as per the MoU were the establishment and use of an audit panel, and the collection of detailed time and costs data for audits.

How did it go? What was learnt?

The ACDS has been well-received by radiation oncology facilities and clinicians. There has been a very high voluntary uptake across the public and private sector.

If the ACDS audit outcomes are viewed as a snapshot of Australian dosimetric quality taken over a three-year period, it can be inferred that the standard of dosimetric practice in Australia is very good.

In terms of audit outcomes, there was a mix of audit results across all levels of audit, indicating the benefit of the service to identify a range of dosimetric quality issues prior to a possible error occurring.

In terms of meeting the MoU objectives, the table below provides a summary assessment based on the audit outcomes.
Table 3: Summary assessment of performance against MoU objectives

<table>
<thead>
<tr>
<th>MoU objective</th>
<th>Process evaluation assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing dosimetric auditing services to radiation oncology facilities in Australia for external beam radiotherapy</td>
<td>Objective has been met – the services have been provided</td>
</tr>
<tr>
<td>Provide independent validation of radiation dose measurement calculation and delivery for external beam radiotherapy</td>
<td>Objective has been met - independent validation of radiation dose measurement and delivery of external beam radiotherapy has been provided</td>
</tr>
<tr>
<td>Assist radiation oncology facilities to improve accuracy of dose delivery</td>
<td>Unclear – there is evidence that audit reports offer advice to improve accuracy of dose delivery, but there is no conclusive evidence of the extent to which this advice is implemented by facilities (considered further in the next chapter)</td>
</tr>
<tr>
<td>Improve clinical dosimetric practice by providing support and advice on dosimetric activities</td>
<td>Unclear – there is no conclusive evidence of the extent to which ACDS supports improvements in clinical dosimetric practice (considered further in the next chapter)</td>
</tr>
<tr>
<td>Maintain a national register of dosimetric records.</td>
<td>Objective appears to have been met (dosimetric records have been maintained, but the register database itself is still under development at this time)</td>
</tr>
</tbody>
</table>

Source: KPMG assessment

Some of the key lessons learnt from a process perspective were:

- The structure of the ACDS (including its placement within ARPANSA) and governance were perceived by key stakeholders as critical enablers for the success of the trial. That the service has been able to achieve its audit targets in a relatively short period, despite delays in critical staff recruitment, supports this view.

- The establishment phase of the ACDS trial was seen by ACDS staff as having been very challenging, but in review it appears that the time taken to develop detailed project plans, risk plans and audit planning, and to recruit appropriately qualified staff, was beneficial for the trial overall.

- A laudable success of the trial is the high participation rate by facilities. This indicates a high degree of support from radiation oncology facilities.

- Other stakeholders have more mixed views on the service. Working relationships between the ACDS and the state and territory health agencies and radiation protection bodies could be improved, particularly around clarifying the roles and responsibilities in respect of reporting obligations and cooperation more broadly.
There is concern and a lack of clarity amongst some stakeholders – particularly the jurisdictional radiation safety agencies and health departments – around how (and if) an out of tolerance fail result would be escalated beyond a facility by the ACDS. The ACDS has a clear protocol for escalating results within the facility, but not outside of it. There is no protocol for what, if any, action the ACDS would or should take if the director of the facility (the highest point at which the issue would be escalated by the ACDS under its protocol) failed to take corrective action.

Jurisdictional stakeholders (radiation safety agencies and health agencies) indicated their preference for a mechanism whereby the ACDS was required to report such results to them. The ACDS was of the view that such a mechanism was neither required nor appropriate for a voluntary quality assurance service. The ACDS noted that there are jurisdictional regulations requiring facilities to self-report such issues (making the reporting issue one for the director of the facility). The ACDS was also concerned that such a requirement would confuse the ACDS’s audit functions with those of a regulator.

Better engagement with these stakeholder groups could mitigate this lack of clarity and increase broader understanding of and support for the role of the ACDS.
5. Outcomes of the ACDS

This chapter outlines the findings of the outcomes evaluation.

5.1 Overview of this chapter

This chapter considers the effectiveness of the ACDS by addressing the key outcomes evaluation questions:

- What did the ACDS achieve?
- What were the key lessons learnt?

In considering achievements of the ACDS, the evaluation focused on the perceived quality and value of the service, the relevance of the service including its alignment with other quality assurance processes, and its contribution to the goal of improving radiotherapy dosimetric practice.

Evaluation evidence informing this chapter was gathered primarily through the online survey of radiation oncology facilities, interviews with radiation oncology facilities and other stakeholders, review and analysis of key ACDS and MoU documents, and interviews with the ARPANSA, the ACDS and the Department.

5.2 Quality of the service (as perceived by stakeholders)

From the perspective of the ACDS itself, a primary achievement was its establishment as a quality assurance service for Australian radiation oncology facilities. This process of establishment took a sizeable portion of the trial period. Key challenges to be overcome included recruiting staff, designing the ACDS quality management system and audit methodologies and establishing functional relationships with radiation oncology facilities. The ACDS also identified the achievement of universal participation in the program (that is, 100 per cent of facilities invited to participate did participate), meeting its MoU targets, and establishing a well-respected reputation as key achievements of the trial.

As noted in the previous chapter, the ACDS appears to be on track to meet or exceed its MoU targets in terms of the number of audits to be performed. Achievement of numerical targets, however, must be considered alongside the quality, relevance and impact of the service.

The survey results provide insight to the reasons that facilities decided to participate in the ACDS trial. ACDS services being free of charge during the trial period was cited as a positive influence on the decision to participate by the majority of facilities (this was also verified in the facility interviews), but it was not the most important factor: the perceived importance of an independent dosimetry audit and the ability to have internal dosimetry confirmed against national benchmarks were seen as more important influences.

In the survey results, the perceived importance of dosimetry audit as a quality assurance mechanism was cited by respondents as the most significant motivation behind their participation across all the audit levels, closely followed by the opportunity to compare internal dosimetry practices against a national benchmark, the quality of ACDS audit service and that the service was free of charge.

For all levels of audit, the most commonly cited ‘strongly agree’ reasons for participating were that ‘independent dosimetry audit is an important quality control tool’ and ‘the ACDS can confirm that our internal dosimetry audit conforms with national benchmarks for other radiation facilities’. This is
illustrated in the following tables (note the numbers in these tables relate to the total number of respondents that answered that question – percentages are not used due to the small sample size of 65 total respondents; it should also be noted that not all survey respondents answered all questions).

**Table 4: Reasons for participating in Level I audit**

<table>
<thead>
<tr>
<th>The following statements ask you to consider why you decided to participate in the Level 1 audit. Please consider the extent to which you agree or disagree with each of the statements</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent dosimetry audit is an important quality control tool</td>
<td>41</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>The ACDS offers a high quality dosimetry audit</td>
<td>26</td>
<td>17</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>The ACDS can confirm that our internal dosimetry conforms with national benchmarks for other Australian radiation oncology facilities</td>
<td>29</td>
<td>17</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Participation was required</td>
<td>11</td>
<td>12</td>
<td>9</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>The postal audit process was straightforward and simple</td>
<td>17</td>
<td>25</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>The audit was offered free of charge</td>
<td>19</td>
<td>16</td>
<td>10</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

*Source: Survey of radiation oncology facilities, April-May 2013*

**Table 5: Reasons for participating in Level Ib audit**

<table>
<thead>
<tr>
<th>The following statements ask you to consider why you decided to participate in the Level 1b audit. Please consider the extent to which you agree or disagree with each of the statements</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent dosimetry audit is an important quality control tool</td>
<td>17</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>The ACDS offers a high quality dosimetry audit</td>
<td>12</td>
<td>7</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>We had not participated in onsite dosimetry audits before</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>The ACDS can confirm that our internal dosimetry conforms with national benchmarks for other Australian radiation oncology facilities</td>
<td>13</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Participation was required</td>
<td>6</td>
<td>6</td>
<td>10</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>The audit was offered free of charge</td>
<td>13</td>
<td>7</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Source: Survey of radiation oncology facilities, April-May 2013*
Table 6: Reasons for participating in Level II audit

<table>
<thead>
<tr>
<th>The following statements ask you to consider why you decided to participate in the Level 2 audit. Please consider the extent to which you agree or disagree with each of the statements</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent dosimetry audit is an important quality control tool</td>
<td>7</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>The ACDS offers a high quality dosimetry audit</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>We had not participated in onsite dosimetry audits before</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>The ACDS can confirm that our internal dosimetry conforms with national benchmarks for other Australian radiation oncology facilities</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Participation was required</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>The audit was offered free of charge</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: Survey of radiation oncology facilities, April-May 2013

Table 7: Reasons for participating in Level III audit

<table>
<thead>
<tr>
<th>The following statements ask you to consider why you decided to participate in the Level 3 audit. Please consider the extent to which you agree or disagree with each of the statements</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent dosimetry audit is an important quality control tool</td>
<td>14</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>The ACDS offers a high quality dosimetry audit</td>
<td>12</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>We had not participated in onsite dosimetry audits before</td>
<td>7</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>The ACDS can confirm that our internal dosimetry conforms with national benchmarks for other Australian radiation oncology facilities</td>
<td>10</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Participation was required</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>The audit was offered free of charge</td>
<td>8</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: Survey of radiation oncology facilities, April-May 2013

Facilities were also asked about their motivation for participating in the ACDS audits in the evaluation survey and interviews. Similarly to the survey findings, a number of common factors were identified:

- perceived independence of the ACDS service;
- expertise of the auditors;
- service’s connection to the Primary Dosimetry Standards Laboratory (ARPANSA);
- service’s alignment with best practice; and
- the service being free.
A number of internal motivators for participation were also identified:

- desire to confirm internal quality assurance processes;
- desire to align their facility with ARPANSA recommendations;
- opportunity to increase the number of linacs that could be audited in some way i.e. additional to the auditing already undertaken by the facility (particularly for large facilities); and
- opportunity to gain useful information and comparison to support internal self-improvement.

The survey results and facility interview data indicated that facilities that had participated in an ACDS audit were generally satisfied or very satisfied with the quality of the audit, including the pre-audit processes, conduct of the audit and post-audit phases. Facilities generally reported in the survey and at interview that their expectations of the service had been met or exceeded, particularly for the Level Iб and Level III audits (refer to Appendix F for more detail of these survey results broken down by audit level).

A small number of facilities were not satisfied with the follow-up after an audit, particularly (but not only) where the audit had a fail result. These facilities rated as poor or very poor the timeliness of the audit report, the credibility of the audit findings, and the usefulness of the report recommendations.

Some facilities reported problems with the conduct of audits, with a number receiving unexpected audit results which upon retesting proved to be ‘false positives’. Some facilities that recorded a fail result on the initial test and a pass result on the subsequent re-test still ended up with a ‘fail’ notice on their written report from the ACDS.

In particular, difficulties with both design and implementation of the Level II audit methodologies were reported. Level II audits were described as “problematic”, as some facilities found them very difficult and time consuming, and it appears that many underestimated the preparation time required ahead of arrival of the ACDS team. In some cases this led to a fail result. Issues associated with the Level II audits were identified by both the ACDS and a number of radiation oncology facilities. These included incompatibilities between the ACDS and facility equipment or approaches (e.g. the Level II audit process is unable to account for variations between linacs of different manufacturers, or the known limitations of particular machines) and the testing of beams in isolation (which rarely occurs in practice).

One facility reported receiving a Level II audit result with a standard deviation of greater than 3 per cent. In response, the facility reviewed the planning cases for over 700 patients but failed to detect any cases that matched the results of audit. Ultimately, the facility concluded that the audit did not account for the known limitations of the linac. This feedback was given to ARPANSA, but a definitive reason for the error was not determined. The inflexibility of the audit procedure meant that this facility invested significant staff time reviewing its records in an attempt to verify the fault.

“There were some issues with the Level II audit as there were problems with the chamber. The components that the ACDS brought with them were for a different model chamber. This was solved by improvising. It would have been better if there had been more communication between us prior to the audit to ensure that everything was prepared.”

Medical physicist, public radiation oncology facility
Other minor concerns included a lack of appropriate opportunity to follow up and clarify results with ACDS following a fail result. Some facilities also reported some problems with communications from ACDS, especially during the early days of the service. These appear to have been remedied over time, with most facilities satisfied with ACDS communication. This was generally supported by the document review conducted as part of this evaluation, which showed an improvement in the clarity of written communication materials (including audit instructions and reports) over time.

Although some radiation oncology facilities reported concerns about the time required for participating in the more intensive audits, others stated they expected the time would decrease over time as physicists become more familiar with audit procedures and require less time to understand their requirements.

### 5.3 Relevance (alignment with other quality assurance processes)

The ACDS operates in a sector with a well-established and strong culture of safety and quality. Notably, radiation oncology facilities have implemented extensive quality management systems that include frequent (e.g., daily, weekly, monthly, six monthly and annual) dosimetry checks along with other quality assurance mechanisms. In addition, many have engaged in some form of external auditing previously, such as peer-to-peer or international auditing by the Radiological Physics Center (RPC).

In acknowledging these controls, clinician stakeholders also observed that given the complexities relating to the calculation and delivery of radiation therapy doses, errors may be introduced at a range of points across the treatment chain. Therefore, an external quality assurance service such as ACDS is considered to be a valuable adjunct to the existing quality assurance regime established for each facility.

There is very strong support across the radiation oncology sector for independent dosimetry auditing. All but one respondent to the facility survey indicated they considered dosimetry auditing to be extremely (69 per cent) or very (29 per cent) important (see Table 8). This view was consistently expressed by respondents from across public and private, metropolitan and regional, and large and small facilities.

<table>
<thead>
<tr>
<th>In general, what level of importance do you place on dosimetry audits?</th>
<th>Total</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely important</td>
<td>45</td>
<td>69%</td>
</tr>
<tr>
<td>Very Important</td>
<td>19</td>
<td>29%</td>
</tr>
<tr>
<td>Somewhat important</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>65</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

*Source: Survey of radiation oncology facilities, April-May 2013*

Stakeholders valued the presence of an external service with recognised expertise as a mechanism for testing the accuracy of their dosimetry within their facilities. The location of ACDS within ARPANSA, which ensures access to the primary standards laboratory, was also seen as an important component of the model.

One stakeholder interviewed also noted that, as internal quality assurance tests may not cover every linac within a facility during a year, participation in ACDS auditing extends their ability to conduct dosimetry audits for more machines within the one facility.
At interview, facilities described the ACDS as being complementary to existing internal quality assurance processes. Some stakeholders even went as far as suggesting that in the long term, participation in ACDS audits may offer additional protection against litigation relating to adverse treatment outcomes by providing further evidence of quality assurance and control.

Some overlap between the ACDS audit program and that offered by international services such as the RPC can be observed. For those facilities that participate in clinical trials, particularly public tertiary facilities, they are required to undertake relevant dosimetry audits at levels equivalent to ACDS Levels I, II or III (depending on trial) to be eligible to participate. These stakeholders would like to see the ACDS obtain recognition from major services such as the RPC to avoid duplication of this kind of audit activity. The evaluation does not see this as a viable objective in the immediate future (i.e. the next three to five years), but, if the ACDS does become an ongoing service, it could be pursued in the longer-term.

### 5.4 Impact (improving radiotherapy dosimetric practice)

The evaluation was unable to quantitatively measure the extent to which the ACDS had contributed to its key goals of assuring dose accuracy, or improving radiotherapy dosimetric practice. In particular, there was no quantitative evidence of reduced errors. There was no evidence of any change in facility risk profiles or impact on patient outcomes (positive or negative) attributable to the ACDS. This was not unexpected given the limited data available and the relatively short period in which the service has been operational.

There was also no baseline against which any changes to dose accuracy or practice improvement could be measured. In effect, the ACDS pilot has established the Australian baseline for dose accuracy during its trial period. Now that such a baseline exists, it would be useful for the ACDS to publicly report on some of those findings. This is information that all stakeholders are very keen to receive as a form of benchmarking to get a sense of how radiation oncology facilities are performing in comparison to their peers.

Stakeholders commonly stated that they were unable to definitively comment on the impacts of the ACDS on dosimetric practice in the absence of any feedback or information about the number and outcomes of the audits performed by the service. However, they were able to make some general comment based on their facility level experience.

- Most survey respondents indicated that ACDS has made a positive contribution to improving dosimetric practice in their facility, even though fewer than 50 per cent of facilities indicated in the survey that the ACDS audits have helped to improve their ability to provide more accurate dosage or improve the dose accuracy of radiotherapy equipment (see Figure 3).

- Similarly, 51 per cent of respondents reported that ACDS provided advice and support regarding implementation of audit recommendations, which may reflect a more limited number of facilities receiving actionable recommendations. For both these items, public facilities were more likely than private facilities to believe that the ACDS made a positive impact.
Figure 3: Survey respondent views on the outcomes of ACDS audits

Source: Survey of radiation oncology facilities, April-May 2013

About 60 per cent of facilities indicated in the survey that they believed that audits have had an impact on facility competence regarding the dosimetry aspects of equipment, and on dosimetry practice overall. Furthermore, 75 per cent of respondents believed that the process of participating in auditing itself had contributed to staff development and knowledge. These responses suggest one of the key outcomes of the ACDS has been focusing internal attention on dosimetry quality assurance.

For each aspect, there was a large cohort of respondents who neither agreed nor disagreed with statements about the impact of the ACDS. While it is likely some of these responses indicate uncertainty about the impact of ACDS dosimetry practices, it is also plausible that many responses reflected the view of facilities whose auditing outcomes reflected delivery of radiation doses within expected tolerances during the auditing process.

The other major impacts of the ACDS are less tangible. Stakeholders commonly commented that a benefit of the ACDS is that it provides independent, expert validation of dosimetry practices, which in turn provides some confidence regarding internal quality assurance systems. Stakeholders also noted that the presence of the ACDS has improved awareness and attention to dosimetry accuracy, and contributed to the sector’s overall culture of safety and quality.
### 5.5 Summary of key points

#### Quality
- Facilities generally reported that their expectations of the ACDS had been met or exceeded, particularly for Level Ib or Level III audits.
- Some facilities were not satisfied with the follow-up after an audit, particularly (but not only) where the audit had had a fail result.
- Some facilities questioned the accuracy of audit results which were recorded as a fail result.
- Particular challenges were encountered in designing and delivering Level II audits.

#### Relevance
- The Australian radiation therapy sector has a well-established and strong culture of safety and quality.
- Clinician stakeholders perceived the national dosimetry audit service provided by the ACDS as a valuable adjunct to the existing quality assurance regime established for radiation oncology facilities.

#### Impact
- The evaluation was unable to quantitatively measure the extent to which the ACDS had contributed to its key goals of assuring dose accuracy, or improving radiotherapy dosimetric practice.
- There was little evidence that the ACDS had contributed directly to practice change.
- Survey responses suggest that a key outcome of the ACDS has been focusing internal attention on dosimetry quality.
- The ACDS has made a positive, if not directly measurable, contribution to the improvement of radiotherapy dosimetric practice in Australia. Cited benefits include providing a level of assurance that internal quality assurance processes relating to dosimetry are working well, and increasing attention on these systems.

### 5.6 Conclusions

In returning to the specific evaluation questions:

**What did the ACDS achieve?**

In the relatively short period of time the ACDS has been operational, it has made a positive, if not directly measurable, contribution to the improvement of radiotherapy dosimetric practice in Australia. Benefits include providing a level of assurance that internal quality assurance processes relating to dosimetry are working well, and increasing attention on these systems.

While the evaluation was unable to quantitatively measure the extent to which the ACDS had contributed to its key goals of assuring dose accuracy, or improving radiotherapy dosimetric practice, the ACDS has established an independent and valued dosimetry auditing service with a good reputation. Through its auditing activity, it has provided support and advice to assist radiation oncology facilities to, potentially, improve the accuracy of radiation dose delivery and improve clinical dosimetry practice – although the extent of this cannot be measured at this time.
At present ACDS audits only extend to 2-D CRT external beam radiation therapy, and other common techniques such as brachytherapy, IMRT, VMAT or stereotactic radiation therapy are not covered. Yet given these are newer and more complex treatments, errors in relation to their delivery are also more likely to occur. The demand for audit services covering these other techniques will only increase over time.

The stakeholder interviews also highlighted that the ACDS has had limited penetration beyond medical physicists in engaging with radiation therapy clinicians (e.g. oncologists and radiation therapists), as well as state and territory departments of health and regulators. For the service to remain relevant into the future, it will need to improve its engagement with these other stakeholders. This may include involving radiation therapists with audits, and/or involving non-clinical stakeholders such as jurisdictions and consumer representatives in the ACDS governance model.

What were the key lessons learnt?

Feedback from the ACDS and radiation oncology facilities has highlighted some of the challenges of establishing a dosimetry auditing program. A key observation is that the development and rollout of new auditing services takes a long time, and testing and refining new procedures with radiation oncology facilities is important. If the ACDS is to expand its services to address additional radiation therapy techniques and technologies, significant lead times will be required. Likewise, if another organisation were to be engaged to deliver dosimetry auditing services in Australia, in place of the ACDS, the gains of the last four years risk being lost.

This pilot period also highlights the importance of working flexibly with services to both schedule and deliver dosimetry audits. One of the principles of quality improvement – that it is a continuous process – is more than apt here. There has been a need to continue to extend and refine protocols based on feedback and experience. A lack of clarity on the part of many facilities about procedures for undertaking audits (especially Level II and III audits), as well as about what actions would be taken in the event of out of tolerance findings, was observed. Some facilities also reported concerns about the timeliness of ACDS reports communicating the results of the audits.

No stakeholder had received information about ACDS’ performance against its MoU targets, nor about the overall outcomes of dosimetry auditing in Australia. Stakeholders were particularly keen to receive some form of benchmarking data to assess their performance beyond a simple pass / fail result. In addition, the lack of engagement by the ACDS with state and territory health authorities caused particular consternation for these stakeholders. Therefore, communication is an area that could be improved.

Lastly, it is apparent that most stakeholders have high expectations of ACDS. The service is valued, and the majority of stakeholders consulted for the evaluation indicated that they would like to see it expanded over time to address more advanced techniques and technologies. Stakeholders would also like to see ACDS more involved in contributing to the development of national standards for radiation therapy and quality benchmarks for services.
6. Policy alignment, appropriateness and sustainability

This chapter draws from the findings of the process and outcomes evaluation to assess the ongoing policy alignment, appropriateness and sustainability of the ACDS.

6.1 Policy alignment

In the context of this evaluation, ‘policy alignment’ refers to the alignment of the ACDS operating model with Australian and international standards and policies for radiotherapy quality management, including identified better practice for independent dosimetry audit as a component of quality management.

The ACDS was established after many years of lobbying from the radiation therapy sector. The Baume report, together with the incidents relating to the Royal Adelaide Hospital and Coffs Harbour Hospital, proved to be the catalysts leading to establishment of the service. Over the last four years, ACDS has worked to establish an independent national dosimetry auditing service.

A number of commentators have pointed to significant improvements to radiotherapy safety and quality since the 1980s and 1990s. While internal systems are most significant for achieving safety and quality type outcomes for patients (as per advice from the Australian Commission on Safety and Quality in Healthcare), these improvements have been directly linked to their involvement in quality assurance programs and, more specifically, in dosimetry auditing.25,26,27

Nonetheless, the risk of errors occurring and being built into dosimetry systems remains. Errors may be introduced due to failures of either humans or equipment, and once introduced, may remain undetected for some time and result in harm to patients through under or over-dosing. These risks are well understood by the radiation therapy sector, and hence support for external dosimetry auditing provided by an independent, expert agency is very strong.

The ACDS is complementary to existing dosimetry related quality assurance systems. Radiation oncology facilities conduct frequent internal dosimetry checks as part of extensive internal quality assurance programs, and many are engaged in some form of external auditing (e.g. by RPC or peer services) prior to participation in the ACDS program.

From a structural perspective, the ACDS model compares well against the international peers such as: the National Physical Laboratory (NPL) (operated by the Institute of Physics and Engineering in Medicine, IPEM, in the United Kingdom); Quality Assurance Network for Radiotherapy (EQUAL) (operated by the European Society for Therapeutic Radiotherapy and Oncology, ESTRO, in France); and the Radiological Physics Center (RPC, located at the MD Anderson in the United States of America). Of these models, it is noted that only the UK model could be described as a ‘mandatory’ model per se.

Each of these services has adopted a different model for promoting quality and safety in radiotherapy. However, a number of core quality assurance techniques stand out – particularly the combined use of postal dosimetry measurement and more intensive onsite review of the broader treatment chain. Literature indicates there is a strong evidence base for utilising these approaches in dosimetry auditing, especially when combined with other measures such as a strong quality assurance system and sharing of results and learnings.

A number of ‘better practice’ features were observed in the literature and as adopted by other international services (refer to the literature review at Appendix C for more detailed discussion and references). The identified features include:

- Specification of the standards, performance measures and tolerances radiotherapy services are expected to meet.
- Alignment of external audit services with internal quality assurance systems to ensure radiotherapy services have ownership and ongoing responsibility beyond the review cycle, and to avoid duplication and gaps.
- Use of external auditors to provide a reference point as well as external accountability and transparency. External auditors may be either peers working in other radiation oncology facilities or expert external auditor reviews. Commentary in the UK literature indicates the latter approach produces more accurate and hence consistent outcomes than a peer review model.
- Calibration of dosimetry measurements against a Secondary Standards Dosimetry Laboratory (SSDL) to enable validation against a standardised measurement and promote consistency.
- Employment of a combination of auditing techniques.
- Provision of a mixture of onsite (e.g. treatment chain review) and remote assistance (e.g. through use of postal phantoms, remote review of documents and data, and providing access to best practice plans, data and dose modelling). While the IAEA and EqualEstro models do not include onsite visits, this level of contact is considered by some authors to provide a better level of support.
- Provision of support to address any errors or deficiencies, based on a quality improvement approach rather than a compliance enforcement or punitive approach.
- Sufficient attention to quality and safety while minimising as far as possible the time and workload burden of participating in the quality assurance processes. Typically, this may involve annual postal audits (e.g. TLD or OSLD) together with more intensive audit activity occurring on a less frequent basis (e.g. triennially or where indicated as necessary due to quality concerns).
- Participation in national and international reporting systems of incidents and near misses to contribute to collective learning. Reporting systems should be based on a no-blame and anonymous dissemination approach.
- Flexibility that enables the radiotherapy service to tailor its quality assurance / management system and respond to new technologies and techniques. Advanced technologies can operate with many more degrees of freedom and in a wider range of potential clinical implementations than for conventional systems, and add significantly to the problem of excessive and unrealistic testing requirements on multi-modality linacs. Overly prescriptive approaches to quality assurance have difficulty covering all situations. Thus, whilst a prescriptive approach remains valid and valuable for
much of the technology and procedures currently in place, new and different approaches need to be developed in parallel for advancing technology. These must be risk- and evidence-based, process orientated rather than device and procedure orientated, multi-disciplinary in nature, resource and risk optimised and flexible enough to cope with current and anticipated changes in technology. Process orientated examples of quality assurance include risk based analysis, process mapping, and application of failure modes and effects analysis (FMEA) and fault tree analysis (FTA).

The ACDS reflects the majority of these principles. Notably, however, it could be argued the ACDS presently provides only limited support in addressing any errors or deficiencies detected through its audits, as demonstrated by stakeholder responses to the survey. The ACDS does provide assistance through its auditing service and report recommendations, but does not go beyond in terms of actively advising or assisting services to calibrate or commission linacs. Although some facilities have requested this level of additional assistance, the ACDS has argued such support may compromise its independence as an external auditing service.

The other area where the ACDS has had limited impact is in the provision of national reporting of errors, trends and areas for improvement detected during the trial period. Stakeholders were universal in requesting this sort of support, and the ACDS has expressed willingness to provide this sort of service in the future. They would need additional capacity to do this.

### 6.2 Appropriateness

‘Appropriateness’ refers to whether the identified need which underpinned the original establishment of the service still remains, and whether the goals and objectives of the service remain an appropriate operational response to that identified need.

In considering the ongoing need for a national dosimetry audit service, it is noted that establishment of such a service was originally proposed as a key mechanism (within a suggested wider radiotherapy quality assurance framework) to manage known dosimetry risks. This followed several incidents where those risk events occurred and there were impacts on patient safety. As noted earlier in this report, at the time that the ACDS became operational in 2011, there was no baseline data to indicate the level of dosimetry accuracy nationally (and hence the future likelihood of dosimetry risks occurring), the risk profile of radiation oncology facilities, or even the general effectiveness of dosimetry practice nationally. The ACDS was established in response to a need identified by stakeholders, which was accepted by government, for a national dosimetry audit service to help improve radiotherapy dosimetric practice. There was no evidence on the extent to which radiotherapy dosimetric practice needed to be improved, but there was an accepted assumption that application of a nationally consistent, independent dosimetric audit program would contribute to this desired improvement.

---

29 Delaney, G, Oliver, L and Coleman, R (15 August 2008) Review of the radiation incident at Royal Adelaide Hospital report (online), accessed on 26 July 2013 at www.health.sa.gov.au/DesktopModules/SSA_Documents/LinkClick.aspx?tabid=46&table=SSA_Documents&field=ID&it=817&link=T%3A%SC_Online+Services%SCWeb+Admin%5CIndividual_site_correspondence%5CProject+Correspondence%5CRAH%5CDelaney-Rev
In reviewing this logic, there is no evidence to suggest any significant change to those circumstances. The ACDS audits have sought to establish the evidence base on the level of dosimetry accuracy nationally – this did not exist before. That evidence base suggests that the level of dosimetry accuracy is high. However, it is noted that not all linacs have been audited yet. It is also noted that a number of actionable and fail audit results have been detected at all levels during the trial period: this supports the assumptions that underpinned the initial rationale for the ACDS.

The next consideration is whether the service remains an appropriate response to the identified ‘need’. There was very strong support and advocacy of the ACDS expressed by the majority of expert clinical stakeholders consulted by the evaluation – including those who were critical of some aspects of the service. These stakeholders clearly view the ACDS model as an appropriate response to the need.

In addition, as noted previously, the ACDS model is consistent with the international evidence and identified better practice principles for a dosimetry audit service.

It can be concluded that the ACDS in its current form is an appropriate response to the ‘need’ for an independent dosimetry regime. However, this does not mean that the ACDS model is the only possible response; other models might also be appropriate (refer to part two of this report for further consideration of this question).

There is an important qualification to be made here: the nature of the need for a national dosimetry audit service is not static. The radiotherapy environment is dynamic, and thus any dosimetry audit must be able to respond to that dynamism in order to remain an appropriate response to the need. Stakeholders and researchers have pointed to the rapid development of new radiotherapy technologies and techniques over the last decade such as IMRT, brachytherapy, three-dimensional computed tomography (CT) based planning, multi-leaf collimation (MLC), improved immobilisation, and more sophisticated planning software.30,31 These new treatment approaches have increased the likelihood of errors, and have introduced new complexities for quality assurance and dosimetry audits (which are being forced to catch up). The need for flexibility and responsiveness in quality assurance and dosimetry systems has been emphasised by both stakeholders and the literature. In introducing new quality assurance checks, stakeholders also cautioned that radiotherapy services as well as the ACDS not be overloaded from a workload perspective. On this basis, the capacity for the ACDS to provide audits in areas of new technologies and non-external beam techniques will impact its longer-term appropriateness.

Finally, it is important to note that dosimetry audit forms only one aspect of a safety and quality assurance system. The Australian Commission for Safety and Quality in Health Care (ACSQHC) commented during consultations for this evaluation that quality assurance in relation to the equipment, people and environment aspects of care delivery also needs to be considered. Given that radiation therapy is delivered in a multi-factorial environment, it is difficult to attribute changes or improvements in practice to a single service. It was also noted that while the service may lead to more accurate dosimetry, this may not necessarily lead to better patient outcomes. Lastly, the ACSQHC cautioned that the ACDS is equipment, not patient-centric model that operates in relatively high degree isolation to other quality assurance systems. An alternative approach would be to strengthen accountabilities within facilities for

radiation safety and quality. Potentially, this could be achieved through the application of agreed radiation oncology service standards, and/or through a peer network dosimetry audit model.

This view indicates that the ACDS, or any other isolated model of independent dosimetry audit, may not be considered appropriate by some stakeholders unless it forms part of an integrated, holistic and consistent quality assurance model.

Despite the ACSQHC’s concerns, the ACDS can be seen as an appropriate model for Australia’s needs. The ACDS model compares well to other benchmark international models examined and the better practice principles identified during the literature review. During the trial period, considerable work and progress has been made towards establishing a sound organisation with scientifically rigorous dosimetry auditing technology and procedures.

As cautioned by the ACSQHC, however, there is an ongoing need to ensure that the ACDS, or any other form of dosimetry audit service, is integrated with existing quality assurance systems and that facility level accountabilities are not lessened in any way due to its establishment, should the ACDS be continued.

6.3 Sustainability

There are three aspects to ‘sustainability’ that are relevant to the ACDS: financial sustainability (whether the service can continue after its initial government funding ends), broader program sustainability (whether the service is sufficiently well-developed and supported to continue beyond a trial), and participation levels (whether a sufficient proportion of radiation oncology facilities will participate in the audits so that it remains relevant to and valued by key stakeholders).

Financial sustainability

Financial sustainability in the context of a government-funded trial service such as the ACDS relates to the capacity to maintain and continue the service after an initial funding period concludes to ensure the service achieves long-term, ongoing successes. This requires the firm establishment of effective processes, resources, partnerships and the securing of a long-term funding stream. There may be a need to amend aspects of a service or program to ensure that the services can still be delivered after a period of government funding ends.

Broader elements of program sustainability

There are broader elements of service or program sustainability aside from financial sustainability. The Centre for Public Health Systems Science at Washington University in St Louis has developed a Program Sustainability Framework which defines program sustainability capacity as the ability to maintain a program and its benefits over time. It identifies eight domains of sustainability, which can be scored

---

33 Washington University in St Louis (2012) Program sustainability framework and domain descriptions (online), accessed on 30 July 2013 at https://sustaintool.org/
using a licensed assessment tool. One of the domains relates to funding, but the framework recognises that funding is not the only element of a sustainable program or service.

A description of the framework domains and a general assessment of the ACDS, drawn from the evaluation findings, are set out in the following table.

Table 9: Assessment of ACDS against the Program Sustainability Framework

<table>
<thead>
<tr>
<th>Program sustainability domain</th>
<th>Domain description</th>
<th>Assessment of the current ACDS model against the program sustainability domains</th>
</tr>
</thead>
</table>
| Political support             | Internal and external political environments support the program                  | • The ACDS has strong advocacy support from clinical stakeholders and is well-supported within ARPANSA.  
• The level of political support from other non-clinical stakeholders is mixed – stakeholders are generally supportive, but stress its place within a wider quality assurance framework.  
• Most stakeholders feel somewhat in the dark about what the ACDS has actually achieved and what has been learnt from the audits. This influences political support for the service.  
• **Overall assessment:** This is a potential sustainability risk for the ACDS. Political support for the ACDS is mixed. This could be strengthened through improved engagement with non-clinical stakeholders. |
| Funding stability             | A consistent financial base is established for the program.                       | • A stable financial base for the ACDS is yet to be determined.  
• **Overall assessment:** This is a potential sustainability risk for the ACDS. |
| Partnerships (stakeholder engagement and collaboration) | Connections are cultivated between the program and key stakeholders. | • The ACDS has developed effective connections with radiation oncology facilities and clinical stakeholders (particularly medical physicists) during the trial period. It has also developed effective connections within the Department of Health (beyond the MoU management group).  
• There is considerable scope to improve connections with other clinical groups (notably radiation therapists) and other stakeholders (notably jurisdictional health and radiation safety agencies, other government agencies involved in health quality and safety, and private hospitals).  
• Effective partnerships with all of these groups is required to ensure ongoing support for the ACDS, and shared understanding of the role and purpose of the ACDS, should it continue. This |

---

<table>
<thead>
<tr>
<th>Program sustainability domain</th>
<th>Domain description</th>
<th>Assessment of the current ACDS model against the program sustainability domains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program evaluation</td>
<td>Program monitoring and assessment informs planning. Results of program reviews are documented.</td>
<td>• Six-monthly operational reports during the trial period have provided a generally effective mechanism for monitoring the service and for planning to meet the trial goals and objectives. • Processes would, however, need to be strengthened, should the ACDS continue. Specifically, there would need to be regular and documented analysis and use of audit outcomes data to inform future planning, service development and service delivery. • <strong>Overall assessment:</strong> This is a potential program sustainability risk. Ongoing mechanisms for program monitoring and assessment are required to support long-term sustainability of the ACDS, should it continue.</td>
</tr>
<tr>
<td>Organisational capacity</td>
<td>Internal supports and resources are available to effectively manage the program.</td>
<td>• The ACDS had access to effective internal supports and resources (including those within ARPANSA) to manage the trial period. If the service continued in its current form, these supports and resources would presumably continue. • If the service continues, however, there could be some challenges in maintaining ongoing organisational capacity beyond a time-limited trial period. • These challenges relate primarily to staffing: retaining suitably qualified staff; recruiting additional suitably qualified staff if the service offering is expanded in the future (i.e. audits of IMRT etc); and ensuring that staff retain current clinical knowledge. • <strong>Overall assessment:</strong> This is a sustainability risk for the ACDS. Detailed staff planning (including strategies for recruitment, retention and professional development to maintain currency of skills and clinical practice) would be required to ensure future organisational capacity and support long-term sustainability of the ACDS, should it continue.</td>
</tr>
</tbody>
</table>

would also contribute to improved political support, improved communications.

- **Overall assessment:** This is a sustainability risk for the ACDS. Improved connections with stakeholders, beyond medical physicists, is required to support long-term sustainability of the ACDS, should it continue.
<table>
<thead>
<tr>
<th>Program sustainability domain</th>
<th>Domain description</th>
<th>Assessment of the current ACDS model against the program sustainability domains</th>
</tr>
</thead>
</table>
| Program adaptation            | Action is taken to adapt the program to ensure ongoing effectiveness. | • The ACDS has clearly demonstrated that it can adapt its services to ensure ongoing effectiveness (improving the Level I audit process through the change from TLD to OSLD; introducing the Level Ib audit in response to client demand; expanding the development and field testing periods of the Level II and III audits whilst still maintaining an overall work plan to meet targets; effective use of the CAG to develop and refine processes and procedures; continuous improvement and updating of the Quality Manual in response to client feedback; refinement of its ‘risk profiling’ criteria for facilities in response to audit findings).  
  • **Overall assessment:** This is less of a sustainability risk for the ACDS. Program adaptation has been demonstrated and is a key strength of the ACDS. This will contribute to its long-term sustainability, should it continue. |
| Communications                | Strategic communications with stakeholders and the public about the program. | • As indicated above, all stakeholders feel somewhat in the dark about what the ACDS has actually achieved and what has been learned from the audit results. This highlights a strong desire by stakeholders for more information about the ACDS (including analysis and dissemination of aggregated audit result findings, and promulgation of learnings).  
  • The ACDS could strengthen its service and its perceived value by stakeholders, should it continue. This would require enhanced and structured communications with a focus on all stakeholders (not just radiation oncology facilities).  
  • It was clear during the evaluation that many stakeholders did not understand the ACDS’s protocols for managing out of tolerance audit findings, and some stakeholders were unclear about whether or how the ACDS interacted with regulators.  
  • **Overall assessment:** This is a program sustainability risk. Improved and structured communications planning is required to support long-term sustainability of the ACDS, should it continue. |
Program sustainability domain | Domain description | Assessment of the current ACDS model against the program sustainability domains
--- | --- | ---
**Strategic planning** | Using processes that guide the program’s direction, goals and strategies. | - The ACDS undertook adequate strategic planning to support its trial phase and achieve the required MoU outcomes. Longer-term strategic planning would need to be undertaken to support future sustainability of the ACDS, should it continue.  
- **Overall assessment:** This is a potential program sustainability risk. Further strategic planning is required to support longer-term sustainability of the ACDS, should it continue.

Source: KPMG analysis based on Program Sustainability Framework (Washington University at St Louis, 2012)

The assessment indicates that there are several areas of potential and actual program sustainability risk that the ACDS would need to improve in order to support longer-term sustainability, if it were to continue. These include longer-term organisational capacity (related to recruitment and retention of staff as well as clinical skills currency), monitoring and review (including analysis of data as the audit results database develops), stakeholder engagement and communications, and longer-term strategic planning.

Based on this assessment, the conclusion of the evaluation is that it would be possible to address all of these risks within the existing ACDS operating model.

**Facility participation levels to support sustainability of the ACDS**

The third aspect of sustainability considered here relates to the minimum required levels of participation in the audit program by radiation oncology facilities. Participation rates will influence the extent to which the service is valued, and thus supported, by stakeholders. Depending on the future funding model, participation rates would also influence the financial sustainability of the ACDS (this aspect is discussed further in part two of this report).

The conclusion of the evaluation is that it is necessary to achieve 100 per cent participation in the audit program by public and private radiation oncology facilities, in order to maintain and extend the benefits and value of the service as articulated by stakeholders. This particularly relates to the use of a nationally consistent dosimetry audit approach, and to the development and analysis of a national data set of dosimetry audit results over time.

Participation rates are closely related to the funding model (whether facilities would be expected to pay a fee for the service, and the level of that fee), and whether participation is voluntary or mandatory.

In terms of the funding model, the evaluation survey and interview data suggest there could be a decrease in voluntary participation if facilities were asked to make a partial contribution to the cost of the audits (an amount was not specified), and a marked decrease under a full fee/user pays model.
### Figure 4: Likelihood of future participation under different funding models

<table>
<thead>
<tr>
<th>How likely is it that you would participate in a future national dosimetry audit program if the funding model was different?</th>
<th>Extremely likely</th>
<th>Very likely</th>
<th>Somewhat likely</th>
<th>Not very likely</th>
<th>Not likely at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit service fully subsidised by government (i.e. current approach)</td>
<td>38</td>
<td>13</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Audit service partially subsidised by government, with a financial contribution by facilities</td>
<td>8</td>
<td>23</td>
<td>20</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Audit service partially subsidised by government, with in-kind contribution by facilities (i.e. provision of peer auditors)</td>
<td>7</td>
<td>12</td>
<td>27</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Audit service not subsidised by government (i.e. facilities to pay full cost of service)</td>
<td>4</td>
<td>8</td>
<td>24</td>
<td>12</td>
<td>4</td>
</tr>
</tbody>
</table>

Source: Survey of radiation oncology facilities, April-May 2013

### 6.4 Summary of key points

**Appropriateness**
- The ACDS is an appropriate model for meeting the ‘need’ for an independent dosimetry audit regime.
- Other approaches may also be appropriate.

**Policy alignment**
- The ACDS is complementary to existing dosimetry related quality assurance systems.
- The model compares well against the international peers and aligns with better practice principles for dosimetry audit.

**Sustainability**
- There is strong stakeholder support for the role of the ACDS in providing dosimetry auditing.
- However, there are a number of areas of potential and actual program sustainability risks that the ACDS would need to improve in order to support its longer-term sustainability.
- The current ACDS operating model would likely rely on a significant proportion of government funding to remain financially sustainable, if it were to continue.
- Participation rates (and thus the sustainability of the service) are closely related to the funding model, and whether participation is voluntary or mandatory. The evaluation evidence suggests that participation rates would decrease under a voluntary system with a funding model which required a full or partial fee for services to be paid by facilities.
6.5 Conclusions

Returning to the specific evaluation questions:

**Should a national auditing service continue?**

The policy alignment and appropriateness assessment outlined above supports continuation of a national auditing service.

**Can the services be improved or delivered in another way?**

The process and outcomes evaluation findings in previous chapters suggest a number of ways that the service could be improved, if the current ACDS model is continued. There are also other alternatives for delivery of these services; some of these are considered in part two of this report.

**What else could or should be done to meet the objectives?**

The evaluation findings suggest three actions that could be taken to better meet the objectives that are outlined in the MoU:

- Continue a national auditing service for a further period and ensure rigorous data collection to allow analysis of the accumulating audit results data set which will help to develop a clear picture of:
  - the ‘baseline’ for dosimetry practice quality in Australia;
  - any changes to practice over time that may indicate improvement from that baseline; and
  - an evidence-based dosimetry risk profile around which any longer-term auditing and other radiotherapy quality management processes can be framed (if needed).
- Use appropriate policy levers (if needed) to promote 100 per cent participation in the national auditing service to strengthen the rigour and reliability of that data set.
- Develop a broader national radiotherapy quality framework, inclusive of dosimetry and independent audit as well as other elements such as facility management, and patient experience and outcomes – recognising that an integrated, nationally consistent approach to quality management and assurance is needed to truly meet the aspirational objectives and intended outcomes set out in the MoU.

**Is the service sustainable? What are the risks?**

In terms of financial sustainability, the conclusion of the evaluation is that the current ACDS operating model would likely rely at least on a significant proportion of government funding to remain financially sustainable, if it were to continue.

In terms of broader program sustainability, there are a number of areas of potential and actual program sustainability risk that the ACDS would need to improve in order to support it longer-term sustainability, if it were to continue. These include: organisational capacity (related to recruitment and retention of staff as well as clinical skills currency); monitoring and review (including analysis of data as the audit results database develops); stakeholder engagement and communications; and longer-term strategic planning (including appropriateness of ongoing governance arrangements). The conclusion of the evaluation is that it would be possible to address all of these risks within the existing ACDS operating model – that is, none of the risks are insurmountable.
7. Cost analysis

This chapter outlines the findings from an analysis of the costs associated with the ACDS during its trial period.

7.1 Overview of this chapter

This chapter includes an analysis of operating costs for the ACDS (including analysis of the costs related to audit development and testing, delivery of the audit program through conduct of the audits, amenities and overhead costs), description of the unit costs of the audits, future cost scenario modelling for a range of conditions based on the unit costs, as well as an analysis of the costs incurred by radiation oncology facilities that participated in the ACDS audits.

Limitations

As noted earlier in this report, the detailed cost data available for analysis of the ACDS operating costs was not optimal and there was some reliance on ACDS estimates of staff time deployed on various activities. The results therefore need to be considered with this in mind. Furthermore:

- The unit cost is a point in time measure that may not remain constant as it depends on the total future spend on facilities and development, and the quantum of future audit activity. For example, advice from ACDS staff indicates that some high value audit-related equipment has a useful life of approximately three years. This makes the average costs of delivering the audits per year highly variable.

- The facility cost data was based on a very small sample and should be interpreted with caution.

If the ACDS continues, more reliable cost data should be collected to better inform future cost analysis.

7.2 Operating costs for the ACDS

The costs of the ACDS 2010/11 to 2012/13

An analysis of ACDS operating costs for the period 2010/11 to 2012/13 shows that the audit costs (inclusive of development and testing, as well as delivery of the audits) grew significantly across the three year period as the ACDS progressively moved from its establishment and audit design stages into an audit delivery phase.

Amenity/Facilities costs cover a range of costs incurred by the ACDS in relation to its core operations, such as establishing operational capacity for audit design and delivery. It includes items such as stores and supplies, and non-capitalised infrastructure. These costs peaked in 2011/12, reflecting the full establishment of the ACDS.

Overhead costs cover the range of costs associated with the ACDS being hosted within ARPANSA. These costs relate to human resource management, information management, legal, finance, property, corporate and technical services. At about 20 per cent of the total ACDS cost, this is the most significant cost group that the ACDS incurs after labour costs. KPMG has not conducted any value for money assessment of these charges.
The table below summarises the ACDS’s expenditure by year from establishment in 2010/11 to the end of 2012/13.

Table 10: ACDS expenditure, by year

<table>
<thead>
<tr>
<th>Cost category</th>
<th>2010/11</th>
<th>2011/12</th>
<th>2012/13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labour costs</td>
<td>$116,803</td>
<td>$489,087</td>
<td>$570,860</td>
</tr>
<tr>
<td>Audit costs (direct consumables)</td>
<td>$10,585</td>
<td>$27,024</td>
<td>$67,105</td>
</tr>
<tr>
<td>Facilities cost</td>
<td>$20,662</td>
<td>$66,196</td>
<td>$157,153</td>
</tr>
<tr>
<td>Communications costs</td>
<td>$12,478</td>
<td>$34,284</td>
<td>$42,003</td>
</tr>
<tr>
<td>Conferences / Training</td>
<td>$9,161</td>
<td>$3,397</td>
<td>$18,855</td>
</tr>
<tr>
<td>Overheads costs</td>
<td>$23</td>
<td>$195,238</td>
<td>$197,069</td>
</tr>
<tr>
<td><strong>Total Costs</strong></td>
<td><strong>$169,712</strong></td>
<td><strong>$1,015,227</strong></td>
<td><strong>$1,053,045</strong></td>
</tr>
</tbody>
</table>

Source: ACDS cost account data 2010/11 to 2012/13 and ACDS / KPMG cost categorisation

Notes:
- The figures for 2010-11 reflect that the ACDS did not come into operational effect until significantly later in that year and that the organisation continued to grow into 2012-13.

The cost movements across individual cost groups on a year on year basis, and the related overall change in organisational cost profile, is demonstrated in the figure below. The decreases in facility expenditure is related to lower audit-related equipment purchases.
Figure 5: Cost movements across cost groups, year by year

Source: ACDS cost account data 2010/11 to 2012/13 and ACDS / KPMG cost categorisation

The figure below demonstrates how, between 2011/12 and 2012/13, the ACDS’s operational cost profile moved from an establishment phase to a more operational audit environment where the balance of non-labour and overhead costs moved from amenities costs to audit delivery costs.

Figure 6: Operational cost profile, year by year

Source: ACDS cost account data 2010/11 to 2012/13 and ACDS / KPMG cost categorisation
Analysis of labour costs – profile of ACDS staffing, 2010/11 to 2012/13

The ACDS provided an estimation of staff time spent on a range of activities between 2010-11 and 2012-13. The estimate differentiated between:

- time spent on developing audits;
- time spent on undertaking audits, covering both the initial field-testing and subsequent operation, categorised across audit types;
- general ACDS establishment and management activities; and
- external body liaison, covering the MoU and activities with: ARPANSA, Department of Health, and external stakeholders (jurisdictional and industry).

The following table summarises the resultant estimates of ACDS time, expressed in full time equivalent (FTE) terms.

Table 11: ACDS staff activity distribution, by year

<table>
<thead>
<tr>
<th>Estimated FTE</th>
<th>2010/11</th>
<th>2011/12</th>
<th>2012/13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit development</td>
<td>0.52</td>
<td>1.76</td>
<td>0.83</td>
</tr>
<tr>
<td>LI testing and full operation</td>
<td>0.25</td>
<td>0.84</td>
<td>1.01</td>
</tr>
<tr>
<td>LI b testing and full operation</td>
<td>0.05</td>
<td>0.50</td>
<td>0.17</td>
</tr>
<tr>
<td>LII testing and full operation</td>
<td>0.00</td>
<td>0.25</td>
<td>0.98</td>
</tr>
<tr>
<td>LIII testing and full operation</td>
<td>0.10</td>
<td>0.31</td>
<td>0.17</td>
</tr>
<tr>
<td>ACDS establishment &amp; mgt</td>
<td>0.36</td>
<td>0.54</td>
<td>0.64</td>
</tr>
<tr>
<td>External body liaison</td>
<td>0.32</td>
<td>0.59</td>
<td>0.89</td>
</tr>
<tr>
<td><strong>Total FTE utilised in year</strong></td>
<td><strong>1.60</strong></td>
<td><strong>4.79</strong></td>
<td><strong>5.03</strong></td>
</tr>
<tr>
<td><strong>Total Audit testing and operation</strong></td>
<td><strong>0.40</strong></td>
<td><strong>1.89</strong></td>
<td><strong>2.67</strong></td>
</tr>
<tr>
<td><strong>Audit as a percentage of total FTE</strong></td>
<td><strong>25 per cent</strong></td>
<td><strong>39 per cent</strong></td>
<td><strong>53 per cent</strong></td>
</tr>
</tbody>
</table>

Source: ACDS estimates of FTE activity 2010/11 to 2012/13

The estimates of FTE consumed in each activity are based on general estimates of the amount of time on activities and relative balances of these between different areas within the context of the known total amount of FTE that was available in those years. This type of estimation:

- requires time to be allocated to a single activity, which in practice may be time that addresses more than one activity;
- uses iteration of estimation to get to a correct total FTE; and
- relies on memories rather than specific time records.
As such, the estimation will contain potentially significant levels of error, and as such should be read as indicative only. Irrespective of that qualification, the changing profile of FTE time year on year is consistent in general terms with the profile of costs seen in the preceding section.

The estimates of FTE spent on audit activities show consistent growth year on year in both the absolute and relative time spent on audit activity, reflecting the already noted move of the ACDS in the later parts of the three year period into a more audit based activity phase.

The figure below further illustrates those movements, highlighting:

- an increase in audit activity and a rebalancing from audit design to audit delivery; and
- the relative decrease in time spent on management and liaison as the ACDS moved into longer term operations and achieved some benefits from economy of scale.

Figure 7: ACDS staff activity distribution, by year

![Graph showing ACDS staff activity distribution by year](source: ACDS estimates of FTE activity 2010/11 to 2012/13)
Table 12 summarises the level of audit activity by audit type and financial year. The 2012/13 year reflects ACDS fully operational.

Table 12: Audit activity, by type, 2010/11 to 2012/13

<table>
<thead>
<tr>
<th>Audit type</th>
<th>2010/11</th>
<th>2011/12</th>
<th>2012/13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I (linacs)</td>
<td>12</td>
<td>40</td>
<td>69</td>
</tr>
<tr>
<td>Level II (linacs)</td>
<td>-</td>
<td>-</td>
<td>33</td>
</tr>
<tr>
<td>Level III (facilities)</td>
<td>-</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>Level Ib (linacs)</td>
<td>2</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>Total audits</td>
<td>14</td>
<td>53</td>
<td>121</td>
</tr>
</tbody>
</table>

Source: ACDS

7.3 Unit costs of audit

A combination of the costs and time estimates data presented in the preceding sections allowed an estimate of the unit cost of delivering audits. The evaluation has calculated a unit cost for each audit type based on:

- total labour cost spent on audit activity, allocated across audit types in proportion to the estimated profile of FTE auditing times across types;
- total audit consumables (including travel costs) in proportion to the audit type; and
- a share of general overheads allocated under the same basis.

On the basis that they are not directly related to delivery of audit service, the following costs were excluded from the calculation of audit unit costs:

- advertising costs (categorised as ‘promotion’ costs);
- conference costs (conference attendance costs); and
- salary costs other than those related to audit testing and operation (see Table 11). ACDS establishment, recruitment, development and management (including undertaking DoH reporting requirements, and participation in CAG) have been excluded.

The following table summarises the unit costs for each audit type between 2010/11 and 2012/13 based on all costs and activities in the three years 2010/11 to 2012/13.
Table 13: Unit costs of audit (2010/11 to 2012/13)

<table>
<thead>
<tr>
<th>Audit type</th>
<th>2010/11</th>
<th>2011/12</th>
<th>2012/13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>$3,752</td>
<td>$10,703</td>
<td>$5,144</td>
</tr>
<tr>
<td>Level II</td>
<td>-</td>
<td>-</td>
<td>$6,854</td>
</tr>
<tr>
<td>Level III</td>
<td>-</td>
<td>-</td>
<td>$7,618</td>
</tr>
<tr>
<td>Level Ib</td>
<td>$4,055</td>
<td>$12,500</td>
<td>$7,376</td>
</tr>
</tbody>
</table>

Source: KPMG analysis

Note that the time spent on Level II and III audits in 2010/11 and 2011/12 did not directly contribute to the completion of an audit, hence the nil activity data in those years.

The calculated unit costs show unexpectedly high unit costs for Level Ib audits, relative to other audit types. Despite having lower activity, the 2012/13 unit cost for Level Ib was lower than the 2011/12 unit cost. These higher unit costs are likely to reflect errors in the time estimations noted above.

7.4 Future costs scenarios

The table below models future costs based on financial and activity data supplied to KPMG. Note that:

- Activity data is based on the audit plan developed by ARPANSA for the six-month period January to June 2014.
- Financial data is based on ARPANSA projections for the six-month period January to June 2014. The same method described above has been used to derive the unit costs reported below.

Table 14: Audit unit costs for future costs scenarios

<table>
<thead>
<tr>
<th>Audit type</th>
<th>2013/14 (6 months)35</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I (audit is per linac)</td>
<td>$4,654</td>
</tr>
<tr>
<td>Level II (audit is per linac)</td>
<td>$7,678</td>
</tr>
<tr>
<td>Level III (audit is per facility)</td>
<td>$6,986</td>
</tr>
<tr>
<td>Level Ib (audit is per linac)</td>
<td>$9,331</td>
</tr>
</tbody>
</table>

Source: KPMG analysis

35 Unit costs for each level of audit is based on 6-months (January to June 2014) of forecast financial and activity data

© 2013 KPMG, an Australian partnership and a member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative (“KPMG International”), a Swiss entity. All rights reserved. The KPMG name, logo and ‘cutting through complexity’ are registered trademarks or trademarks of KPMG International. Liability limited by a scheme approved under Professional Standards Legislation.
The unit costs for Level Ib and Level II are higher than the unit cost calculated in 2013/14. While some variation is expected (related to yearly increases in salary costs and general operating expenses), the variation is higher than expected, particularly for Level Ib audits. The level of variability confirms the limitations of the activity data estimates, and the method and accuracy of allocating staff time to various activities.

Based on 2012/13 staff costs, the cost of ACDS management and stakeholder liaison time (i.e. non-audit time, excluding time for establishment and development), is approximately $100,000 per year.

The use of these unit costs in future scenario planning depends on the following:

- Whether historic establishment and development costs are treated as sunk
- The level of future audit program development (where cost will no longer be treated as sunk and could be amortised across stated future activity levels) – such as development of new audits for IMRT, etc
- The volume of future audit activity (the allocation of overhead costs over larger numbers of audits where some costs are likely to be fixed, will lead to lower unit costs)
- The level of resourcing required. While the staffing profile impacts the number and types of audits conducted, it also impacts the allocation of indirect costs, such as general overheads. ARPANSA allocate overhead costs to ACDS personnel on an FTE basis (the allocation is approximately $50,000 per FTE).

### 7.5 Costs incurred by audit participants

The data in this section is based on a limited sample of data from eight facilities that completed a cost collection tool that looked at the direct costs incurred from undertaking an audit and any related opportunity costs. As such it should be interpreted with caution.

#### Direct costs

##### Labour costs

The following table summarises the labour time and related costs incurred by a facility from undertaking an audit by audit level:

*Table 15: Labour costs incurred by participating facilities*

<table>
<thead>
<tr>
<th>Audit type</th>
<th>Average staff hours required</th>
<th>Implied staff cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>7.0</td>
<td>$486</td>
</tr>
<tr>
<td>Level Ib</td>
<td>10.0</td>
<td>$694</td>
</tr>
<tr>
<td>Level II</td>
<td>16.0</td>
<td>$1,111</td>
</tr>
<tr>
<td>Level III</td>
<td>18.4</td>
<td>$1,274</td>
</tr>
</tbody>
</table>

*Source: KPMG facility cost data survey, administered May-June 2013*
Please note the estimated staff cost was based on an average hourly staff rate of $69.44 or $125,000 per annum based on a mixture of physicists and radiation therapists who participate in audit activities.

No facility reported that marginal staff costs were incurred due to the audits taking place in overtime hours or temporary staff being employed.

**Other costs**

No facility reported any specific additional non-labour costs being incurred as a result of an audit.

**Opportunity costs**

**Lost income**

Three facilities reported taking their linac off line as a result of the audit. The table below reports on the reported offline times and estimated costs.

*Table 16: Opportunity costs incurred by participating facilities*

<table>
<thead>
<tr>
<th>Facility</th>
<th>Audit type</th>
<th>Hours offline</th>
<th>Clients foregone</th>
<th>Lost income</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Level I, IB, and II (undifferentiated)</td>
<td>8.5</td>
<td>35</td>
<td>$15,050</td>
</tr>
<tr>
<td>B</td>
<td>Level III</td>
<td>2.5</td>
<td>11</td>
<td>$4,730</td>
</tr>
<tr>
<td>C</td>
<td>Level III</td>
<td>3.0</td>
<td>12</td>
<td>$5,160</td>
</tr>
</tbody>
</table>

*Source: KPMG facility cost data survey, administered May-June 2013*

The lost income shown above is based on an income rate of $430 per patient treatment that was provided by one survey respondent. This treatment income rate was consistent with anecdotal evidence heard during site visits conducted as part of the wider evaluation.

These opportunity costs need to be considered with caution, however, given they are based on the reported experiences of just three facilities. The survey also asked facilities how long, if at all, their linac was unavailable during usual treatment hours as a result of an ACDS audit. The majority of respondents said there was no impact on patient treatment hours.

It was more likely that facilities with only one linac would incur the opportunity costs.
Table 17: Number of hours linac was unavailable for patient treatment

<table>
<thead>
<tr>
<th>Was your linac unavailable for patient treatment during usual patient treatment hours for your recent ACDS audit? (all levels combined)</th>
<th>Number of facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, there was no impact on patient treatment because audit processes were conducted after hours or during scheduled down time</td>
<td>52</td>
</tr>
<tr>
<td>Yes, the linac was unavailable for less than 1 hour during a period it would usually have been available for patient treatment</td>
<td>2</td>
</tr>
<tr>
<td>Yes, the linac was unavailable for between 1 and 4 hours during a period it would usually have been available for patient treatment</td>
<td>14</td>
</tr>
<tr>
<td>Yes, the linac was unavailable for between 5 and 8 hours during a period it would usually have been available for patient treatment</td>
<td>2</td>
</tr>
<tr>
<td>Yes, the linac was unavailable for 8 hours or more during a period it would usually have been available for patient treatment</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: Survey of radiation oncology facilities, April-May 2013

Foregone expenditure

No facility reported any specific non-labour costs being foregone as a result of an audit.

The conduct of ACDS audits has between zero and about $5,000 impact on the marginal financial position of facilities.

During interviews conducted as part of the evaluation, facilities noted that:

- The ACDS audit activity time generally displaced other quality activity time and hence is not viewed as an additional impost. Furthermore, time spent on quality assurance is already built into the assumed work profile of staff and the ACDS audits used this time.

- Forgone income is the largest impact of the ACDS audit. This was likely to be more relevant for Level III audits than in other audit levels. However, the impact of this is also influenced by the number of linacs a facility has: the more linacs available, the less impact on patient services, as ACDS testing can by undertaken in times where a linac may be unutilised or where its patients can be moved to another machine.

The lack of cost impost on facilities is likely to be the most significant reason why they did not express any strong views on the cost of audits in either the survey or interviews conducted for the evaluation.

During the evaluation interviews, facilities frequently said that they would be prepared to pay in the range $500 to a ‘couple of thousand’ for the audits. Given that they generally do not perceive any costs at present, this is a good proxy for their views on the cost benefit trade off of the ACDS audits within their facility (i.e. excluding wider whole of system benefits).

It is noted, however, that the facilities’ level of fee preparedness is significantly less than the direct cost of an audit to ACDS (irrespective of whether sunk costs are recovered), and hence any future ACDS fee approach would need to:

- target only partial cost recovery to be palatable, and hence ACDS would require continuing government subsidy;
- highlight hidden system benefits to make a higher fee palatable, to reduce the need for subsidy; and

© 2013 KPMG, an Australian partnership and a member firm of the KPMG network of independent member firms affiliated with KPMG International Cooperative (KPMG International), a Swiss entity. All rights reserved. The KPMG name, logo and ‘cutting through complexity’ are registered trademarks or trademarks of KPMG International. Liability limited by a scheme approved under Professional Standards Legislation.
• incorporate compulsion to ensure higher fees are paid and hence costs are recovered.

These issues are discussed further in part two of this report, where a range of possible funding models are considered.

7.6 Summary of key points

- The unit cost of delivering each audit type varied considerably over the trial period.
- While the first two years were largely establishment years, year three delivered the majority of audit-related activity, so provides a better reflection of the cost of an audit. Unit cost by audit type for 2012/13 for Level I was $5,114, Level Ib was $7,376, Level II was $6,854 and Level III was $7,618.
- A future unit cost was calculated for each audit type, using six-month audit plan and financial projection data prepared by ARPANSA. The unit costs for Level Ib and Level II are higher than the unit cost calculated in 2013/14.
- The unit cost analysis demonstrated the relationship between the number of audits conducted and the proportion of staff time dedicated to delivering the audits. Both components had significant impacts on the unit cost.
- The unreliability of the staff allocation time data, relating to potential estimation errors, was a significant limitation and explains, in part, the variation in unit cost.
- Improvements to data collection methods, particularly data relating to time and cost data for each audit type, will allow for more accurate description and analysis of audit costs in the future.
- The conduct of ACDS audits has between zero and about $5,000 impact on the marginal financial position of facilities.
- Facilities viewed ACDS audit activity time as displacing other quality activity time and hence not an additional impost.
- Forgone income was viewed by facilities as the largest impact of the ACDS audit. This was likely to be more relevant for Level III audits than other audit types and for facilities with fewer available linacs.
- Facilities frequently said that they would be prepared to pay in the range $500 to a ‘couple of thousand’ for the audits. This being significantly less than the direct cost of an audit.
8. Assessment of costs and benefits

This chapter outlines an assessment of costs and benefits associated with the ACDS during its trial period.

8.1 Overview of this chapter

The evaluation was required to undertake an economic and resource evaluation, including a cost-benefit analysis, to underpin advice about the cost of operating a national auditing program and alternative funding options. This chapter sets out the results of a costs and benefits assessment of the ACDS; the costs and benefits of possible alternative approaches for delivering a national dosimetry audit service are considered in part two of this report.

8.2 Costs under the ACDS model

Costs to government of a fully-subsidised service

During the ACDS trial, the Australian Government fully-funded the service at a total cost of $3,162,500 (including GST). Based on data supplied by ARPANSA to forecast the activity levels and financial cost for the six-month period January to June 2014, the average price for an audit will be:

- Level I: $4,654
- Level Ib: $9,331
- Level II: $7,678
- Level III: $6,986

A reasonable allowance for the cost of ACDS management and stakeholder liaison time (i.e. non-audit time, excluding time for establishment and development), is approximately $100,000 per year (based on 2012/13 staff costs).

In terms of estimating future costs, it is necessary to make assumptions about the frequency of audits. The ACDS’s preferred future model involves a three-year audit cycle, whereby each linac would have a Level I and Level II in one of the three years and each facility would have a Level III audit in the other year, while Level Ib audits would remain available on demand. This model has been assumed as the future model for costing purposes by the evaluation. Only the costs of Level I, Level II and Level III audits have been considered (Level Ib audits, and development and testing of any new audits, would need to be funded separately).

At June 2013, there were 168 linacs in operation and this is expected to grow to 214 by 2018. Assuming an average of 190 linacs over the three year period, the total audit cost per linac of a three-year cycle with one Level I and one Level II audit would be $2,343,080.

At June 2013, there were 69 facilities with an average number of 2.5 linacs per facility, according to current ACDS facility data. The average number of facilities over the three year period (assuming an average 2.5 linacs per facility) would be 76. The per facility cost of conducting one Level III audit across each of the 76 facilities over the three-year cycle is $530,936.

An allowance of $300,000 is also made for management and liaison costs.
This brings the total cost of a three-year cycle covering all linacs and all facilities with allowances for management and liaison costs to $3,174,016. The total program cost can be compared to the cost of one new linac machine which is about $3,500,000 (according to advice from the EAG).

**Costs to facilities of a fully-subsidised service**

As explored in the previous section, facilities generally did not perceive there to be any significant costs associated with their participation in ACDS audits. There was some minimal evidence of foregone expenditure from linac down time, and there was some staff hours required – but this was not considered to be a significant impost.

### 8.3 Comparison of costs to similar programs

The cost of a Level I ACDS audit in 2012/13 was $5,114. In comparison, the fee payable by facilities for a Level I audit conducted by ARPANSA prior to the ACDS trial, was around $600 per audit – but ARPANSA has advised that this fee was below cost recovery, and so it is not a direct comparison.

Fees for a Level I audit from the RPC in the US is between $650 and $1,000 – but again, it is not a direct comparison because the fee is only intended to offset shortfalls in government funding for the service (i.e. it is a contribution or co-payment, not a cost recovery amount). The former ARPANSA service fee and the RPC service fee are indicators of what facilities might be prepared to pay as a contribution towards a Level I audit, rather than benchmarks for the actual price of delivering the service.

The RPC does also deliver equivalent Level II audits and Level III audits, specific to particular clinical trials, but the costs of these services vary depending on the particular trial.

In terms of Level III audits, the 2004-08 Australasian multi-centre dosimetric intercomparison trial provides a comparison for the ACDS Level III costs (‘the Newcastle trial’). The cost of a Level III ACDS audit in 2012/13 was $7,618 per facility. In comparison, the average cost of conducting a Level III equivalent audit across 37 sites during the Newcastle trial was $6,216 per facility. While the two costs are not exactly comparable in terms of what costs are included or excluded, the unit cost of the ACDS Level III audit is within 25 per cent of the ‘Newcastle trial’ benchmark for a Level III audit.

### 8.4 Benefits of a national dosimetry service

**Intangible benefits**

A number of intangible or unquantifiable benefits of the ACDS service can be observed.

**Alignment with international better practice**

Independent dosimetry audit is recognised as better practice for radiotherapy quality assurance in the international literature. The ACDS model provides one option for delivering such a service.

---


Improved safety of radiotherapy

The evidence shows that regular, independent dosimetry audit as part of a broader quality assurance program can improve the safety of radiotherapy practice.39

Clinician confidence

Survey and interview evidence to the evaluation suggests that increased clinician confidence is a key benefit of the ACDS. As an example of how this confidence can translate into systemic benefits, clinicians at one facility interviewed for the evaluation said that they were more willing to participate in clinical trials or explore new treatment techniques that could benefit their patients, after they had participated in ACDS audits and it had been independently confirmed that they had ‘the basics’ right.

Patient confidence

Another intangible benefit is increased patient confidence in radiotherapy treatment, which may increase their willingness to be treated and in turn reduce cancer morbidity and mortality.

As an example of this, staff at one of the larger facilities interviewed for the evaluation described how patients are often intimidated by the linacs and concerned about the use of radiation treatment. To offset this, the facility has started providing information sessions for new patients where they explain to them how the equipment works and the quality assurance processes designed to keep patients safe. The facility has incorporated the independent audits provided by ACDS into this information session, which has provided patients with additional comfort.

Tangible benefits

Avoided costs

There are a number of potential avoided costs associated with improved quality of radiotherapy associated with independent dosimetry audits. These include avoided costs for compensation payments to patients or their families as a result of injuries or deaths arising from under- or overdoses of radiation or other errors during the treatment process, and potentially reduced insurance premiums.

Internationally, a number of significant radiotherapy errors have been found to be at least partially attributable to a lack of independent or peer dosimetric audit, including:

- Overexposure of 426 patients over 22 months resulting in deaths and several complications (USA, 1974-76).40
- Under dosage of 1,045 patients of whom 492 developed cancer recurrence as a probable result of the under dose, due to undetected errors in the planning system (UK, 1982-90).41

---

38 Thomas, R et al (undated) The role of the National Physics Laboratory in monitoring and improving dosimetry in UK radiotherapy, NPL, Middleton
40 Thomas, R et al (undated) The role of the National Physics Laboratory in monitoring and improving dosimetry in UK radiotherapy, NPL, Middleton
41 ibid
• Over dosage of 27 patients of whom 15 died as a direct result, and another 2 died as a partial result, due to an undetected faulty repair to a linac (Spain, 1990).42

• Over dosage of 115 patients at least 17 of whom died as a result, due to a faulty timer undetected during beam calibration (Costa Rica, 1996).43

• Over dosage of 450 patients at least 12 of whom died as a direct result and many others suffered severe complications due to undetected errors in the computer system and other failures in the treatment chain (France, 2004-06).44 45

• Over dosage of 223 patients over a one-year period due to malfunctioning computer equipment (Trinidad, 2011)46.

The radiation overdoses in Epinal, France which resulted in 12 deaths and several complications for hundreds of patients, resulted in criminal charges for manslaughter against clinicians plus fines of between €10,000 and €20,00047. The facility was not subject to independent audit.

The family of a lung cancer patient in Miami, USA who died as a result of radiation overdose resulting from a planning system error received compensation of $15 million, of which $2 million was paid by the clinicians (the limit of their insurance policies) and the balance by the manufacturer of the linac.48

Also in the US, a patient who suffered severe permanent injuries due to an error in the placement of equipment, received a compensation payment of $500,000 from the clinicians’ malpractice insurance49. Also in the US, an examination of 621 radiation therapy accidents in New York from 2001 to 2008 found hundreds of errors that could have been detected by audits (notably to do with planning system errors, incorrect use of devices to shape or modulate beams, or incorrect positioning of beams), some of which resulted in deaths or catastrophic and irreversible injuries to patients – the compensation amounts paid for these errors was frequently confidential, but in many instances could be anticipated to have been significant.50

These incidents do need to be viewed in their international context. Compensation payments in the US can be quite high compared to other jurisdictions; in other countries compensation payments for radiotherapy dosage errors resulting in death or injury can be relatively low (in countries such as Finland, for example, which has a no-fault, non-litigious social insurance scheme for medical errors and where the

42 ibid
43 Ibid
46 Caricoma News Network (2011) Hospital responds to overdose of radiation to cancer patients, 9 July
49 Abramson Smith Waldsmith (2013) $500,000 mediated settlement for negligently planned radiation therapy (online), accessed on 18 October 2013 at http://www.aswlcp.com/
median compensation paid is less than $2,000)\textsuperscript{51}, or relatively rare (in the UK, injuries resulting from dosage errors may not compensable unless medical negligence is proven)\textsuperscript{52}.

**Insurance premiums**

Based on trends in other sectors and internationally, it is likely that liability insurance premiums could be reduced for facilities and/or practitioners participating in regular independent quality audits such as ACDS audits.

**Life years saved**

The Australian Government best practice regulation guidance on estimating benefits of reducing the risks of death indicates that, based on Australian and international research, a credible estimate of the value of a statistical life year is $151,000\textsuperscript{53}.

Based on advice from the EAG, the average external beam radiotherapy patient is approximately 60 years old. As the average Australian lifespan is 82 years,\textsuperscript{54} the number of life years that may be ‘saved’ through prevention of radiotherapy errors is 22 years, which is the difference between the average patient age and the average Australian lifespan. At $151,000 per statistical life year, a simple calculation values 22 life years at $3,322,000.

Internationally, 15 deaths per 1 million radiotherapy treatment courses can be attributed to radiotherapy errors.\textsuperscript{55} This means there is a 0.0015% chance of death due to error. Applying this likelihood:

- In Australia, there are 57,246 radiotherapy patients per annum, based on 2011-12 MBS data (1 patient = 1 treatment course, usually).
- 0.0015% of Australian patients is 0.86 deaths per annum.
- 0.86 of $3,332,000 (the value of 22 years calculated using the Value of a Statistical Life Year measure) is $2,865,520 per annum. This is higher than the annual operating cost of the ACDS during the trial period, and higher than the anticipated annual cost (about $1,058,005 for a national dosimetry service operating on a three-year audit cycle).

However, the 15 deaths per 1 million treatments is an international figure, which is inclusive of developing countries and other countries that may not have the same high standards of dosimetry practice as Australia. If we compare Australia only to the UK, where there are only 2 deaths per 1 million treatment courses, the cost benefit assessment is as follows:

- If there are 2 deaths per 1 million treatments, this means there is a 0.0002% chance of death due to error.

---


\textsuperscript{52} Hansard (UK), HC Deb 24 June 1997 vol 296 cc507-8W


\textsuperscript{54} http://abs.gov.au/AUSSTATS/abs@.nsf/Lookup/4102.0MainFeatures10Mar+2011

\textsuperscript{55} Ahmad, SS (2012) ‘Advances in radiotherapy’, *BMJ* 2012;345:e7765 doi 10.1136/bmj.e7765 (Published 4 December 2012)
0.0002% of the 57,246 Australian patients is 0.11 deaths per annum (based on 2011-12 MBS data).

0.11 of the VSLY for the 22 life years saved is $365,420 per annum. This is lower than the anticipated annual cost (about $1,058,005) for a national dosimetry service operating on a three-year audit cycle.

8.5 Comparison of costs and benefits

The following table compares the costs and benefits of the ACDS.

Table 18: Comparison of costs and benefits

<table>
<thead>
<tr>
<th>Costs of the ACDS</th>
<th>Intangible benefits</th>
<th>Tangible benefits (estimated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs during the trial period</td>
<td>Alignment with international better practice: Independent dosimetry audit is recognised as better practice for radiotherapy quality assurance in the international literature.</td>
<td>Avoided costs: Compensation for injuries or deaths associated with dosage errors.</td>
</tr>
<tr>
<td>Total cost over four years was $3,162,500 (including GST). Average audit cost per linac (based on 2012-13 activities):</td>
<td>Improved safety of radiotherapy: The evidence shows that regular, independent dosimetry audit as part of a broader quality assurance program can improve the safety of radiotherapy practice.</td>
<td>Avoided costs: Reduced insurance premiums for clinicians and facilities.</td>
</tr>
<tr>
<td>• Level I: $5,144</td>
<td>Clinician confidence: Survey and interview evidence to the evaluation suggests that increased clinician confidence is a key benefit. This has a range of potential systemic benefits.</td>
<td>Lives saved: Assuming at least 0.11 deaths per annum are due to radiotherapy errors (based on Ahmad, 2012).</td>
</tr>
<tr>
<td>• Level Ib: $7,376</td>
<td>Patient confidence: Another intangible benefit is increased patient confidence in radiotherapy treatment, which may increase their willingness to be treated, and in turn reduce cancer morbidity and mortality.</td>
<td>International literature indicates that independent dosimetry audit can reduce errors and improve quality, reducing likelihood of death or injuries.</td>
</tr>
<tr>
<td>• Level II: $6,854</td>
<td></td>
<td>Value: Between $365,420 and $2,865,520 per annum (based on Ahmad, 2012 and Department of Finance and Deregulation, 2008).</td>
</tr>
<tr>
<td>• Level III: $7,618</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Likely future service costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cost for three year cycle of 190 linacs/76 facilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• $3,174,016 total over three years (inc $300,000 mgt and liaison) ($1,058,005 pa).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: KPMG
8.6 Conclusions

The cost of operating the service over the multi-year trial period was $3,162,500.

The likely average annual cost of delivering a three-year audit cycle program for 190 linacs across 69 sites would be about $3,174,016 over three years, or **about $1,058,005 per annum** (note this is the cost of delivering Level I, II and III audits and is based on the estimated 2013/14 unit costs; costs for delivering Level Ib audits, or for developing and testing of new audits, would be additional to this amount).

Intangible benefits of the ACDS include ensuring alignment with international better practice, improving radiotherapy safety, increasing clinician confidence, and increasing patient confidence.

Estimated tangible benefits of the ACDS include avoided costs for compensation or litigation resulting from radiotherapy errors that may have been prevented through an independent audit program (value **up to $15,000,000 per incident**, based on international examples), potential for reduced liability insurance premiums, and statistical life years saved (value of **between $365,420 and $2,865,520 per annum**, based on international evidence of error rates resulting in deaths, Australian Government values placed on statistical life years, and estimations of the life years potentially saved).

The cost of delivering the ACDS audits during its trial period, and the cost of delivering a similar audit program in the future, are offset by the benefits arising from the service, including statistical life years saved and avoided costs.
PART TWO:

Possible alternative approaches for a national dosimetry service
9. Alternative approaches for a national dosimetry audit service

This chapter sets out possible alternative approaches for delivering a national dosimetry audit services.

9.1 Overview of this chapter

The evaluation was asked to consider other possible approaches for delivering an ongoing national dosimetry audit, including options for future funding arrangements. This involves assessing the relative merits of different options for operating and funding a national dosimetric audit program beyond the trial.

This chapter describes possible alternative approaches for operating and funding a dosimetric audit service that were identified during the evaluation, and in consultation with the Department and the EAG. The chapter concludes with an analysis of the costs, benefits and risks of the alternative approaches.

9.2 Preliminary considerations

There are a number of preliminary considerations and issues to be resolved before determining the most appropriate operational form and funding model for a national dosimetry audit service. These are discussed below.

**Mandatory or voluntary participation**

The first issue to be resolved is whether facilities would participate on a mandatory or voluntary basis. Stakeholders expressed strong views on this question during the evaluation, suggesting that the potential benefits of the program could only be achieved if it obtained full coverage (which may not be achieved under a voluntary model), and that the costs of the program could only be managed if there was full coverage (otherwise the unit price per audit could increase to an unsustainable level).

Clinicians, radiation safety agencies and health quality assurance stakeholders firmly supported a mandatory scheme. However, health agencies (including the Department) and the ACDS itself preferred a voluntary model, citing concerns about over-regulation, compliance costs and red tape.

Based on the international evidence, examples of other health quality assurance schemes that include audit-based compliance monitoring, and the structure of audit services in other sectors, the evaluation is of the view that a mandatory program with full coverage of all linacs is preferable.

In terms of an appropriate mechanism for mandating participation, the evaluation notes the suggestion by a number of clinicians that eligibility for MBS payments for radiation therapy services could be subject to demonstrated compliance with the radiation oncology practice standards; these standards include a requirement for independent dosimetry audit at least every two years. This is similar to processes already in place for other areas of health including diagnostic imaging and pathology. In those schemes, facilities do not receive MBS payments unless they are accredited and/or meet the required standards. Services are required to pay a fee for compliance monitoring services (such as audits), and they may or may not have a choice of audit service provider.
Another mechanism suggested by some stakeholders was to make compliance with the standards and/or participation in independent dosimetry audits a linac licensing condition administered by radiation safety agencies.

**Examples of similar services with mandatory participation**

- National Pathology Accreditation Advisory Council (NPAAC) develops accreditation materials for pathology services. Accreditation is a requirement to access MBS payments for pathology. Mandatory audits against the standards are conducted by a single service provider. Accredited facilities pay annual fees of between $6,564 and $7,877 to cover audit assessments and site visits.

- The Diagnostic Imaging Accreditation Scheme requires providers of certain types of diagnostic imaging to be accredited in order to access MBS payments. There are three approved accreditation service providers. Facilities are accredited for four years. Accreditation is based on a desktop review and costs range from about $500 to $3,000 depending on the size of the facility seeking accreditation.

- The National Safety and Quality Health Service standards are mandatory for most public and private hospitals, including day surgeries, under state and territory hospital licensing requirements. Facilities are accredited for three year periods and must undertake regular audit-type activities each year during the three-year cycle. Facilities have a choice of 10 accreditation providers, which determine the associated fees.

**Frequency of audits**

The next issue to be resolved is the frequency of the audits, as this will impact both on the desired operational form of the national dosimetry audit service, and on the funding model.

The literature does not offer definitive guidance on the optimal frequency of independent dosimetry audits, other than that they should be ‘regular’.\(^{56}\) The ARPANSA *Safety Guide for Radiation Protection in Radiotherapy* suggests that equipment should be recalibrated by a ‘qualified expert’ on ‘at least an annual basis’.\(^{57}\) The (currently voluntary) radiation oncology practice standards require an external dosimetric inter-comparison with a non-affiliated organisationally separate service (at least every) last two years.\(^{58}\)

As indicated earlier in this report, the ACDS’s preferred future model is a three-year audit cycle, whereby each linac would have a Level I, Level II audit in one of the three years and each facility would have a Level III in the other year, whilst Level IB audits would remain available on demand. This is a similar approach to that used with the pathology, diagnostic imaging and hospital accreditation schemes mentioned above. Therefore, this approach has been used as the basis for the following analysis of options.

---


Cyclical or risk based audit scheduling

Linked to the issue of audit frequency is whether the audits are planned and delivered on a cyclical basis (that is, all facilities are subject to audits within a given period of time – as per the three-year cycle proposed by the ACDS), or whether the audits are planned and delivered on the basis of risk assessment.

For the purpose of this analysis, it has been assumed that the audits will be conducted across all linacs on a cyclical basis – at least over the next three-year period or so. However, it may be possible to move to a risk-based audit program in the future, once there is agreement on what the risk factors are and how they should be weighted, and adequate data is collected to assess the risk. Under such a model, Level I audits might be conducted on a regular basis (say, every two years, as per the facility standards) or on a random basis, with Level II and III audits conducted on the basis of identified risk factors (i.e. changes to planning systems, significant changes of personnel or equipment etc. – the actual risk factors would need to be determined by suitable experts and agreed within the sector). This model can be more cost effective than a cyclical model – because there are fewer overall audits, and resources are targeted to facilities at higher risk – but it can only be effective where there are clear, agreed risk factors.

Single or multiple audit providers

Once the issues of mandatory or voluntary participation, audit frequency and whether audits will be cyclical or risk-based have been addressed, consideration should be given to whether the audit service should be provided by a single service or multiple services. The advantage of a single provider is that it promotes national consistency, and, in the case of the ACDS model, it realises benefits from its co-location with the ARPANSA primary standard. The advantage of multiple providers is that it offers choice to facilities, and potentially more competitive pricing of services. In the case of dosimetry audit, however, there is a question about whether there would be a suitable market for audit service providers given the need for considerable investment in equipment and access to a linac and the primary standard.

9.3 Assumptions

There are a number of assumptions that underpin all of the alternative approaches considered in this chapter.

- Any approach must support a national approach to dosimetry audit – this means use of nationally-consistent audit methodologies, protocols and standards linked to the national standards laboratory, and a national register or database of audit outcome results. However, this does not necessarily mean that the audit service must be delivered by a single national organisation.

- Any approach should support the collection and analysis of audit outcomes data – collection of data (the dosimetric audit results register) will allow for benchmarking and risk profiling of facilities and, over time, it will potentially support research on Australian dosimetry practice. Again, this does not necessarily mean that the audit services need to be delivered by a single national organisation.

- Any approach should have the potential to expand audit activity to other radiotherapy techniques in the future – although the focus of the service is currently on external beam radiotherapy, the ongoing appropriateness and acceptability to stakeholders of a national dosimetry audit service will depend on its capacity to move into auditing other areas of demand over time.
9.4 No national dosimetry audit service

There is an option to conclude the ACDS after the trial and not continue with a national dosimetry audit service. Although this option was not advocated by any of the stakeholders consulted during the evaluation, and it is not supported by the evaluation evidence, for completeness the Department has requested that the evaluation consider this option.

**Key features and rationale for this approach**

Under this approach, the ACDS would be terminated at the end of the trial period. It would not be replaced by another form of national dosimetry service. Facilities would retain responsibility for performing their own dosimetry audits as required by regulations and their quality assurance program. Facilities could choose to participate in other inter-comparison arrangements if they wished to, or were required to do so to qualify for participation in clinical trials, etc.

The rationale for this approach is that the trial has shown the level of dosimetry practice in Australia to be generally high. Regulations for the use of medical radiotherapy equipment and voluntary radiation oncology practice standards provide guidance for facilities on the quality assurance programs they should be using to maintain their equipment and treatment chains (including use of dosimetry audits).

It would be difficult to maintain a dosimetric audit records register under this approach. It might be possible to have a system whereby facilities voluntarily reported audit results operated as part of the radiation incident reporting register or through some other body such as AIHW or a university, but participation rates with such a mechanism could be low (administrative burden, perceived lack of relevance).

**Strengths of this approach**

- Emphasises that facilities are responsible for their own quality assurance and quality management program.
- Cost savings for government.

**Weaknesses of this approach**

- Does not support the better practice principles of external audit linked to national standards.
- Most facilities would not be able to access the equipment needed for Level II and III audits.
- Loses the momentum and gains made during the ACDS trial.
Overall assessment

Table 19: Assessment of alternative 1

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Savings for the Australian Government of about $1,000,000 per annum by not funding a national dosimetry audit service.</td>
<td>• Does not support a nationally consistent approach to audit.</td>
</tr>
<tr>
<td>• Emphasises facility responsibility for their own quality assurance and management.</td>
<td>• Does not align to international better practice principles and evidence.</td>
</tr>
<tr>
<td>• Recognises the relatively lower risks of radiotherapy in Australia, based on the results of the ACDS trial showing overall very good dosimetric practice.</td>
<td>• Is not supported by clinical stakeholders.</td>
</tr>
</tbody>
</table>

Source: KPMG

Possible variants of this approach

• Variant 1: a pared back ‘advisory service’ could be funded, at a significantly lower cost than a full dosimetry audit service, to provide advice and tools to facilities to help them undertake their own dosimetry audits. Such a service could be hosted by a university, a radiation oncology facility, ARPANSA, the Department, a host jurisdiction health agency or radiation safety agency, or an outsourced private provider.

• Variant 2: provide direct funding to facilities to assist them in purchasing independent dosimetry audit services from overseas providers (which may be in the vicinity of $1,000 per facility every two years for a Level I audit from the RPC). This is potentially more cost effective arrangement, but it would likely limit the scope of coverage to Level I audits as Level II and Level III audits are not widely available outside of clinical trial preparation.

9.5 Alternative operating models for a national dosimetry audit service

Three alternative operating models have been identified:

• Model 1: National audit service with a single dedicated provider (ACDS model)
  - Variant 1: Current provider (ACDS placed within ARPANSA)
  - Variant 2: Different provider (outside of ARPANSA)
  - Variant 3: National panel of part-time auditors (based within hospitals).

• Model 2: National audit service subsumed into other existing QA or accreditation services, single or multiple providers
  - Variant 1: Single service provider
  - Variant 2: Multiple audit providers, with a central agency responsible for maintaining audit protocols and collating national audit results reporting.
• Model 3: National peer audit networks, coordinated by single or multiple providers
  - Variant 1: Link with existing networks
  - Variant 2: Central coordination body.

These are discussed in turn below, followed by a comparison of benefits and risks for each alternative.

9.6 Operating model 1: ACDS model

Key features and rationale for this approach

This model is similar to the successful RPC model in the US.

Under this approach, the ACDS service as established for the trial would be continued and become an ongoing service. The audit program (frequency and use of routine or risk base audits) and funding model would need to be determined. A full participation rate is assumed – as noted above, this may or may not require mandating participation through legislation. Under this approach, suggested improvements highlighted in part one of the evaluation report are adopted to assist the ACDS transition from a time-limited trial service to an ongoing service.

The rationale for this approach is that the ACDS has a high level of stakeholder acceptance which may contribute to improved radiotherapy dosimetric practice. Continuing the service would consolidate gains made during the establishment and initial rollout of the ACDS trial, including making use of procedures and equipment that have been developed specifically for the service. The ACDS model also compares favourably to international dosimetry audit models and aligns to identified better practice principles for independent dosimetry audit. The ACDS would also maintain and build upon its register of dosimetry records.

Strengths of this approach

• High level of stakeholder acceptance.
• Builds on the gains and momentum of the trial.
• For variant 1, makes good use of equipment and protocols procured and developed for the trial (there may be difficulties with equipment under variants 2 and 3).
• Aligns well to better practice.
• Compares well to international models.

Weaknesses of this approach

• Resource intensive and relatively costly.
• Current model has a number of sustainability risks that would need to be resolved (see earlier discussion in this report).
• May weaken other quality assurance activities currently undertaken by facilities.
**Overall assessment**

**Table 20: Assessment of operating model 1**

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Could operate under a range of funding models.</td>
<td>• May not work with a full cost recovery model, due to the high unit price of audits and providing a full coverage, cyclical audit service.</td>
</tr>
<tr>
<td>• Could operate under a mandatory or voluntary model.</td>
<td>• Participation may be lower under a voluntary model.</td>
</tr>
<tr>
<td>• If ACDS, makes use of equipment already purchased for the trial.</td>
<td>• If another provider, start-up costs and equipment purchase would be duplicated.</td>
</tr>
<tr>
<td>• If ACDS, benefits from direct access to the ARPANSA primary standard.</td>
<td>• If another provider, would need to negotiate access to the ARPANSA primary standard.</td>
</tr>
<tr>
<td>• Model is strongly supported by clinical stakeholders.</td>
<td>• Model is less strongly supported by some non-clinical stakeholders.</td>
</tr>
<tr>
<td>• Model supports future expansion into audits of new technologies and techniques.</td>
<td>• Additional funding would likely be required for new audit development.</td>
</tr>
<tr>
<td>• Aligns well to international better practice standards.</td>
<td>• May lessen individual facility responsibility for quality assurance and quality management (due to reliance on cyclical independent audits).</td>
</tr>
<tr>
<td>• Supports a nationally consistent approach through the use of a single audit service.</td>
<td>• If the service provider is not a government entity, there would be insurance related risks (in that insurance would not be available or the cost of insurance may be prohibitive). In contrast, government entities are generally covered by government self-insurance.</td>
</tr>
</tbody>
</table>

**Source: KPMG**

**Possible variants of this approach**

• Variant 1: Retain the current single service provider (ACDS placed within ARPANSA).
• Variant 2: Procure a different single service provider (outside of ARPANSA).
• Variant 3: Retain the current provider to maintain audit materials and protocols, but develop a national panel of part-time auditors to conduct the audits. This model could lead to more competition in the cost of audits, it is also likely to have higher administrative burden and cost to manage the program.
9.7 Operating model 2: Subsume into an accreditation scheme

Key features and rationale for this approach

This model is similar to the successful diagnostic imaging accreditation, pathology provider accreditation scheme or national health standards accreditation scheme in Australia.

Under this approach, the requirement for independent dosimetry audit would either (a) be incorporated into existing health care standards, or (b) be incorporated in specific practice standards for radiotherapy, and facilities would require accreditation against these standards to access MBS benefits or obtain/retain linac licenses. Participating in the audits would be a requirement of the accreditation. This type of system is usually mandatory. Incorporating the audit functions into an accreditation scheme could involve stronger entry controls (i.e. for new linacs and/or new facilities), with licensing fees that would cover at least a portion of the costs of the accreditation as well as the costs of compliance monitoring (i.e. audits).

There could be a single accreditation provider/auditor (for example, the pathology accreditation scheme has a single service provider) or multiple accreditation providers/auditors (for example, there are three providers under the diagnostic imaging and ten under the health care standards accreditation schemes). Under a multiple-provider scenario, a body would still be required to develop and maintain audit protocols and tools to maintain national consistency. Centralised reporting of audit outcomes would also be required.

The rationale for this approach is that it is consistent with common practice for entry-controlled standard-based accreditation and audit, would particularly lend itself to a future move to risk-based auditing, and has the options for multiple audit providers. Strengths of this approach

- For variant 1, makes good use of equipment and protocols procured and developed for the trial (there may be difficulties with equipment under variants 2).
- Aligns well to better practice.
- Compares well to other accreditation and audit systems.
- Supports a future move to risk-based auditing

Weaknesses of this approach

- Compliance costs for providers
- May not be effective under a voluntary model
- Requires regulation (i.e. accreditation standards)
- May be difficult or costly to maintain and administer national consistency and data reporting under variant 2
Overall assessment

Table 21: Assessment of operating model 2

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Could operate under a range of funding models</td>
<td>• May be difficulties in supporting a nationally consistent approach under variant 2</td>
</tr>
<tr>
<td>• Model is similar to other services that stakeholders are already familiar with</td>
<td>• Start-up costs and equipment purchase would be duplicated under variant 2</td>
</tr>
<tr>
<td>• Aligns well to international better practice standards</td>
<td>• Audit provider(s) would need to negotiate access to the ARPANSA primary standard under variant 2</td>
</tr>
<tr>
<td></td>
<td>• Model may not support future expansion into audits of new technologies and techniques (who would develop the audits? Who would fund them?)</td>
</tr>
<tr>
<td></td>
<td>• If the service provider is not a government entity, there would be insurance related risks (in that insurance would not be available or the cost of insurance may be prohibitive). In contrast, government entities are generally covered by government self-insurance.</td>
</tr>
</tbody>
</table>

Source: KPMG

Possible variants of this option

• Variant 1: Single service provider.
• Variant 2: Multiple audit providers, with a central agency responsible for maintaining audit protocols and collating national audit results reporting.

9.8 Operating model 3: National peer networks

Key features and rationale for this approach

This model is similar to the successful UK peer networks model.

Under this approach, formalised peer audit networks would be established. It would involve networks of facilities (public and private) grouped regionally or by another method such as by size and type of facility (and potentially across jurisdictions) performing inter-comparison audits on each other.

The rationale for this approach is that the model has proven to be relatively effective in the UK and it could be a more cost effective model than a standalone independent dosimetry audit service such as the ACDS trial model (at least in terms of the direct costs to the Australian Government). That said, there would be considerable costs to facilities as they would need to make staff available to perform the audits.
To maintain a nationally consistent approach, a body (possibly ARPANSA, or the Department, or a university, or a host facility) would need to maintain national standards against which the audits could be conducted, as well as maintaining and promulgating the audit protocols. This body may need to pay fees to ARPANSA to use the primary standard.

It could be possible to maintain a dosimetric audit records register under this approach. Peer reviewers could report audit results to a central register. The register could be operated as part of the existing radiation incident reporting register, or through some other body such as AIHW or a university.

One unresolved issue would be how to assure consistency across the application of the audits, and who would train the peer auditors. Another unresolved issue is how the networks would be formed, and who would administer them.

**Strengths of this approach**

- Reinforces facility responsibility for quality assurance.
- Builds on examples of existing informal networks in some parts of Australia.
- Aligns well to better practice.

**Weaknesses of this approach**

- Potential challenges in maintaining/promoting national consistency.
- Logistical, political and geographical challenges in forming networks.

**Assessment of this approach**

*Table 22: Assessment of operating model 3*

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Could operate under a range of funding models.</td>
<td>Participation may be lower under a voluntary model.</td>
</tr>
<tr>
<td>Could operate under a mandatory or voluntary model.</td>
<td>May be difficulties in supporting a nationally consistent approach.</td>
</tr>
<tr>
<td>Model is supported by some stakeholders.</td>
<td>Challenges in accessing equipment across networks.</td>
</tr>
<tr>
<td>Aligns to international better practice standards.</td>
<td>Networks would need to negotiate access to the ARPANSA primary standard.</td>
</tr>
<tr>
<td></td>
<td>Model may not support future expansion into audits of new technologies and techniques (Who would develop the audits?)</td>
</tr>
</tbody>
</table>

*Source: KPMG*
Possible variants of this approach

- Variant 1: A central body responsible for administering the networks, including the provision of audit methodologies and tools, equipment, management of the database and provision of auditor training. This could be a new, purpose-specific body; an existing body (such as ACPSEM or the ACQSHC); or a 'host' institution/facility or jurisdiction.

- Variant 2: Rather than establishing new networks, fund existing radiation oncology and radiation therapy professional training networks, Medicare Locals or health and hospitals networks to facilitate and coordinate the dosimetry peer review networks, collect the audit results data, and collate and disseminate the results reports to stakeholders.

9.9 Alternative funding models

Three alternative funding models have been identified:

- Funding model 1: Fully subsidised by government.
- Funding model 2: Partially subsidised by government, with facility contribution.
- Funding model 3: Full cost recovery.

These models have been designed so that they can apply to any of the operational model alternatives discussed above.

9.10 Funding model 1: Fully subsidised (as per ACDS trial)

Key features and rationale for this approach

Under this approach, government would continue to fully fund the national dosimetry audit service as it has done during the trial period. Facilities would receive the full range of audits free of charge (noting that the frequency of audits is yet to be determined).

- Funding could be shared between the Australian Government and state/territory jurisdictions.
- A base level of core services could be fully funded (e.g. Level I, II and III audits) with additional services (e.g. Level Ib) being provided on a cost recovery basis. There would need to be agreement about what constituted a ‘core’ service.
- The model could be transitional.

Strengths of this approach

- Strongly supported by stakeholders.
- Supports full participation (potentially without the need for legislation to mandate participation).
- Recognises the difficulty in pricing services given the lack of clarity over audit unit costs.

Weaknesses of this approach

- Cost impact for government.
Cost implications

Table 23: Cost implications of funding model 1

<table>
<thead>
<tr>
<th>Estimated costs to government</th>
<th>Estimated costs to facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under a mandatory model</td>
<td>Under a mandatory model</td>
</tr>
<tr>
<td>$3,174,016 total over three years based on three-yearly audit cycle of Level I, Level II and Level III audits. Additional funding for Level Ib and development of new audits, and promotion etc, if required.</td>
<td>Linac down time and staff time only.</td>
</tr>
<tr>
<td>Voluntary model (assuming 50% participation)</td>
<td>Voluntary model (assuming 50% participation)</td>
</tr>
<tr>
<td>$1,587,008 total over three years. Additional funding for Level Ib and development of new audits, and promotion etc, if required.</td>
<td>Linac down time and staff time only.</td>
</tr>
<tr>
<td>Voluntary model (assuming 25% participation)</td>
<td>Voluntary model (assuming 25% participation)</td>
</tr>
<tr>
<td>$793,504 total over three years. Additional funding for Level Ib, development of new audits and promotion etc, if required.</td>
<td>Linac down time and staff time only.</td>
</tr>
</tbody>
</table>

Source: KPMG

9.11 Funding model 2: Partially subsidised with facility contribution

Key features and rationale for this approach

Under this approach, government would partially fund the national dosimetry service and facilities would be asked to pay a contribution towards the costs of the audits. For costing purposes, the level of contribution has been determined based on the information obtained during the evaluation about facilities’ willingness to pay, and comparison to international benchmarks (where available).

Average facility contributions have been nominally set as $4,125 per three-year audit cycle, composed of:

- Level I at $500 per linac;
- Level II at $750 per linac;
- Level III at $1000 per facility;
- Total facility contribution of three-year cycle (assuming 2.5 linacs per facility): **$4,125 over three years**.

This model does not assume any additional contributions for follow-up services or re-testing following a fail audit result.

Level Ib has not been included in the costings, given the ambiguity about the actual costs of that service, but given that it is proposed to be retained as an ‘on demand’ service, it might be feasible for it to be
provided on a full cost recovery basis given that it is supplementary to the proposed ‘core’ cycle of Level I, II and III services.

**Strengths of this approach**

- Most facilities indicated they would be willing to pay a contribution for dosimetry audit services.
- Arguably, payment of some fee towards audit services would encourage the better practice principle of facility responsibility and ownership for quality assurance.

**Weaknesses of this approach**

- For private sector facilities, the costs would likely be passed onto health insurers and/or patients as additional gap fees.
- May discourage smaller facilities from participating (this could be managed by adjusting the fee based on facility size).

**Cost implications**

Table 24: Cost implications of funding model 2

<table>
<thead>
<tr>
<th>Estimated costs to government</th>
<th>Estimated costs to facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Under a mandatory model</strong></td>
<td>Under a mandatory model</td>
</tr>
<tr>
<td>$2,860,516 total over three years.</td>
<td>$313,500 over three years ($4,125 per facility).</td>
</tr>
<tr>
<td>Additional funding for Level Ib and development of new audits, and promotion etc, if required.</td>
<td>Plus additional contribution for Level Ib where requested.</td>
</tr>
<tr>
<td></td>
<td>Plus linac down time and staff time.</td>
</tr>
<tr>
<td><strong>Voluntary model (assuming 50% participation)</strong></td>
<td>Voluntary model (assuming 50% participation)</td>
</tr>
<tr>
<td>$1,430,258 total over three years.</td>
<td>$156,750 over three years ($4,125 per facility).</td>
</tr>
<tr>
<td>Additional funding for Level Ib, development of new audits and promotion etc, if required.</td>
<td>Plus additional contribution for Level Ib where requested.</td>
</tr>
<tr>
<td></td>
<td>Plus linac down time and staff time.</td>
</tr>
<tr>
<td><strong>Voluntary model (assuming 25% participation)</strong></td>
<td>Voluntary model (assuming 25% participation)</td>
</tr>
<tr>
<td>$868,629 total over three years.</td>
<td>$106,875 over three years ($4,125 per facility).</td>
</tr>
<tr>
<td>Additional funding for Level Ib, development of new audits and promotion etc, if required.</td>
<td>Plus additional contribution for Level Ib where requested.</td>
</tr>
<tr>
<td></td>
<td>Plus linac down time and staff time.</td>
</tr>
</tbody>
</table>

*Source: KPMG*
9.12 Funding model 3: Full cost recovery model

Key features and rationale for this approach

Under this approach, government would not fund the service and facilities would be required to fully fund the cost of audit services they used. Note that this approach would likely not be viable under a voluntary participation model, given that the threshold price facilities indicated they would be prepared to pay for an audit was considerably lower than the apparent unit cost of the audits. However, working on the assumption that the service will have 100 per cent participation (through mechanisms to be determined), the user pays model is one form of funding model that may still be considered.

Potentially, a full cost-recovery model could also include additional charges for follow-up services or re-testing following a fail audit result. It is noted, however, that some level of follow-up and re-testing occurred during the trial, and is thus already factored into the audit unit costs as calculated.

Strengths of this approach

- Arguably, payment of a fee for audit services would encourage the better practice principle of facility responsibility and ownership for quality assurance.

Weaknesses of this approach

- There are no other international examples of a full cost recovery dosimetry audit service.
- Per facility fees would be very high – about $41,726 per facility for a three-year audit cycle.
- Administrative cost may be prohibitive given the relatively small population of facilities.
- Costs would likely be passed onto health insurers and/or private patients as additional gap fees.
- May discourage smaller facilities from participating.
Cost implications

Table 25: Cost implications of funding model 3

<table>
<thead>
<tr>
<th>Estimated costs to government</th>
<th>Estimated costs to facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Under a mandatory model</strong></td>
<td><strong>Under a mandatory model</strong></td>
</tr>
<tr>
<td>Funding for development of new audits, and promotion etc, if required.</td>
<td>$3,174,016 total over three years (approximately $41,763 per facility).</td>
</tr>
<tr>
<td></td>
<td>Plus linac down time and staff time.</td>
</tr>
<tr>
<td><strong>Voluntary model (assuming 50% participation)</strong></td>
<td><strong>Voluntary model (assuming 50% participation)</strong></td>
</tr>
<tr>
<td>Funding for development of new audits, and promotion etc, if required.</td>
<td>$1,552,631 total over three years.</td>
</tr>
<tr>
<td></td>
<td>Plus linac down time and staff time.</td>
</tr>
<tr>
<td><strong>Voluntary model (assuming 25% participation)</strong></td>
<td><strong>Voluntary model (assuming 25% participation)</strong></td>
</tr>
<tr>
<td>Funding for development of new audits, and promotion etc, if required.</td>
<td>$776,316 total over three years.</td>
</tr>
<tr>
<td></td>
<td>Plus linac down time and staff time.</td>
</tr>
</tbody>
</table>

Source: KPMG

9.13 Comparison of alternative approaches

The following matrix provides a comparative assessment of benefits and risks of each of the alternative approaches.
Table 26: Comparison of alternative approaches to a national dosimetry audit service

<table>
<thead>
<tr>
<th>Model</th>
<th>Variant</th>
<th>BENEFIT: Operative under a range of funding models</th>
<th>BENEFIT: Operative under both mandatory and voluntary participation</th>
<th>BENEFIT: Promoting National consistency</th>
<th>BENEFIT: Enables future expansion into new types of audits</th>
<th>BENEFIT: Promotes improvement in radiotherapy dosimetric practice</th>
<th>BENEFIT: Promotes facility responsibility for QA</th>
<th>RISK: Lack of Stakeholder acceptability - clinic/Radiotherapy agencies, radiation safety, peak bodies</th>
<th>RISK: Not aligned to better practice principles</th>
<th>RISK: Administrative burden</th>
<th>RISK: Fails to address issues identified in trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pre ACDS trial</td>
<td>Return to the pre-trial state where facilities are responsible for own audit and QA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Low</td>
<td>High</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>2. ACDS Trial Model, plus improvements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The ACDS service as established for the trial would be continued and become an ongoing service with suggested improvements implemented.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>Continue with ACDS (within ARPANSA)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>1.2</td>
<td>Different provider (outside ARPANSA)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>1.3</td>
<td>Audit Panel</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>3. Subsume into existing QA System</td>
<td>Requirement for audit would be either incorporated into existing health care standards or specific practice standards for radiotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1</td>
<td>Single service provider</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
</tr>
<tr>
<td>3.2</td>
<td>Multiple auditors</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>4. Peer Networks</td>
<td>Formalised peer audit networks would be established. Involves networks of facilities grouped and performing intercomparison audits on each other.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>Central body administration (i.e. ACPSEM)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>2.2</td>
<td>Link in with existing training networks</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
</tr>
</tbody>
</table>

Source: KPMG
The following matrix provides a comparative assessment of benefits and risks of each of the alternative approaches. We have rated the threat level of each risk using the risk assessment key below.

**Figure 8: Risk assessment key**

![Risk assessment key diagram](source: KPMG)
10. Framework for future cost effectiveness assessment

The evaluation was asked to provide advice on options for a full cost benefit assessment or cost effectiveness assessment of a national dosimetry service in the future (should such a service be continued beyond the ACDS trial).

A first, vital step would be to ensure that there is sufficient, robust cost data available. This evaluation was significantly constrained by the failure of the ACDS and the MoU management committee to ensure that cost and time data required under the MoU was actually collected, and thus the cost analysis was reliant on estimations which lacked robustness. Any future cost benefit or cost effectiveness assessment will need a solid base of reliable cost data – including accurate unit prices for the audits.

Once mechanisms are in place to collect the required cost data, consideration can be given to whether a cost benefit assessment or a cost effectiveness assessment is most appropriate. Given the nature of this particular type of service, it would be appropriate to apply a cost effectiveness analysis (CEA) over a cost benefit analysis (CBA) to the national dosimetry service. The reasons for this are:

- Quantifying the benefits achieved by a national dosimetry audit service is difficult. A CEA allows for non-monetary units of measurement, such as “lives saved”, while a CBA forces the user to monetise the benefits.

- While a national dosimetry audit service is likely to have multiple impacts, such as improved health service processes and procedures, and increased patient confidence, the main intended outcome is the delivery of safe radiotherapy services. A CBA is more suited to identifying the net benefit of a program that has multiple outcomes.

- CEA is useful where a desired outcome has been agreed, and the main issue is how to achieve this at the lowest cost.\(^{59}\)

Cost effectiveness calculates the ratio of the amount of the “effect” of a program for a given amount of cost incurred (i.e. the amount of cost required to achieve a given impact, such as lives saved). The main difference between a CEA and CBA is in how the benefits of the program are expressed; in a CEA, benefits are not in monetary units so it does not provide an absolute measure of the benefit to the economy of the project.

The box below summarises the approach to conducting a CEA and a CBA. The ‘framework’ for analysis (cost effectiveness or cost benefit analysis) is reliant on the intended outcome/s of the program.

---

Steps in cost effectiveness and cost-benefit analysis

1. Specify the framework for analysis
2. Decide whose costs and benefits should be recognised
3. Identify and categorise costs and benefits
4. Project costs and benefits over the life of the program
5. Monetise (attach dollar values to) costs
6. Quantify benefits in terms of units of effectiveness (for CEA) or monetise benefits (for CBA)
7. Discount costs and benefits to obtain present values
8. Compute a cost-effectiveness ratio (for CEA) or a net present value (for CBA)
9. Perform sensitivity analysis
10. Make recommendations as appropriate.

Source: Cellini & Kee (2010) and Department of Finance and Deregulation (2013).

Future considerations

Cost effectiveness analysis should use disaggregated data, where assumptions about key factors such as program activity or direct costs are made explicit, making it easier to perform sensitivity analysis. It also allows for greater analysis of the relationship between costs and outcomes. While the approach taken in this cost analysis utilises activity data which allowed for this analysis, the unreliability of staff estimates on audit activity make sensitivity analysis difficult. The collection of this data in the future would allow for more accurate depiction of cost, and therefore the effectiveness of a national dosimetry audit service.

Clarifying assumptions used in the analysis relies on identifying how the analysis is to be used. This will determine which costs (the implementer or society as a whole) to include to maximise the cost-effectiveness of the program. The approach taken in this cost analysis presented the costs borne by health services (opportunity costs of having radiotherapy machines shutdown) as well as the costs incurred to the implementer (the Department).

An obvious challenge to assessing the cost effectiveness of a national dosimetry audit service is that program costs are largely upfront, whereas the benefits accrue over an extended period of time; for patients undergoing radiotherapy, the major benefit is the safe delivery of radiation. The outcomes of unsafe radiation dosage may take decades to be identified. Therefore, while it is easy to capture the cost of delivering the program over a three year period, it is difficult to capture the benefits over the same period.

The table below summarises the type of data that should be captured to perform this analysis. The collection of radiotherapy service data is likely to improve in the future as innovative and sophisticated

---

methods become embedded in radiotherapy practice. For example, the UK is developing tools which utilise electronic data to link patient data to other databases (such as cancer registries) to determine the survival curves by diagnosis and by consultant.\textsuperscript{61} This technology will also permit departmental audit to be an automatic undertaking using nationally agreed standards. Importantly, the technology should allow for the quantification and analysis of the late effects of radiotherapy on normal tissue\textsuperscript{62} which support cost effectiveness research.

**Table 27: Future data collection**

<table>
<thead>
<tr>
<th>Component</th>
<th>Data</th>
</tr>
</thead>
</table>
| Activity data | • Audit activity by audit type (facility and linacs).  
|             | • The number and nature of audit fails (errors in linac configuration etc).  |
| Financial   | • Detailed cost data, including audit consumables and equipment costs by audit type.  
|             | • Detailed labour cost data derived from a timesheet or job recording system. This should allow labour cost data to be filtered by activity (non-audit/audit), staff member and audit type (if applicable).  
|             | • Indirect costs (such as overhead) based on consumption rather than an arbitrary FTE basis.  |
| Outcomes    | **Participants – health services**  
|             | • Any measurable improvement in health service practice.  
|             | **Participants – patients**  
|             | • Quantitative measure of extent of activity (e.g. patients treated in audited facility/machine).  
|             | • Estimates of adverse incidents, measured in lives saved and/or years lost.  
|             | • Avoided costs of accessing other services due to error in radiation dosage (e.g. hospitalisation, rehabilitation) or patient compensation.  |

*Source: KPMG*

\textsuperscript{61} The Royal College of Radiologists (2006), *Radiotherapy does-fractionation.*

\textsuperscript{62} The Royal College of Radiologists (2006), *Radiotherapy does-fractionation.*
PART THREE:

Recommendations
11. Recommendations

The evaluation was asked to consider what else could or should be done to meet the objectives of a national dosimetry audit service. The evaluation findings suggest three actions that could be taken to better meet the objectives:

- Continue a national auditing service for a further period and improve all aspects of data collection so that the costs and benefits of the service may be more clearly assessed.
- Use appropriate policy levers (if needed) to promote full participation in the national auditing service.
- Consider developing a broader national radiotherapy quality framework, inclusive of dosimetry and independent audit as well as other elements such as facility management, and patient experience and outcomes – recognising that an integrated, nationally consistent approach to quality management and assurance is needed to truly meet the aspirational objectives and intended outcomes set out in the MoU.

Table 28, below, is a summary of the recommendations to the Department of Health:

Table 28: Recommendations for the Department of Health

<table>
<thead>
<tr>
<th>#</th>
<th>Recommendation</th>
<th>Section reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Future of a national dosimetry audit service</strong></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>A national dosimetry audit service should continue.</td>
<td>6.2</td>
</tr>
<tr>
<td>2.</td>
<td>ARPANSA should continue to be funded to provide the ACDS as the national dosimetry service. This will ensure the best use of equipment and resources already purchased and developed, and promote national consistency.</td>
<td>6.2</td>
</tr>
<tr>
<td>3.</td>
<td>Due to the poor trial data around the unit costs of services, and the unclear impact on radiotherapy quality of various levels of audits deployed during the trial period, the service should be continued for a further three-year trial period in the first instance, with a view to it potentially becoming an ongoing service after that period concludes. A decision will need to be made at least six months prior to the end of that further trial period as to whether the service will continue. This decision will need to be informed by robust activity and outcomes data.</td>
<td>6.5</td>
</tr>
<tr>
<td>4.</td>
<td>A cyclical audit approach should continue for all linacs and facilities during the further trial period.</td>
<td>8.6 and 9.2</td>
</tr>
<tr>
<td>5.</td>
<td>If the service continues beyond the further trial period, it may be possible to transition to a risk-based audit program – if there is sufficient evidence and support for such an approach.</td>
<td>8.6 and 9.2</td>
</tr>
<tr>
<td>#</td>
<td>Recommendation</td>
<td>Section reference</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>6.</td>
<td>The costs of the Level I, Level II and Level III audits should be partially subsidised by government, with facilities paying a contribution towards the service as commonly occurs on other mandatory and voluntary quality assurance and audit programs. These arrangements can be re-assessed after the further trial period, when better cost data will be available.</td>
<td>9.11</td>
</tr>
<tr>
<td>7.</td>
<td>Market research should be undertaken to determine whether facilities would be prepared to pay either the full costs of Level Ib audits, or the amount of the Level Ib cost that exceeds the amount of a Level I audit, given that these are a value added, ‘on demand’ service. It may or may not be necessary for these services to be subsidised by government.</td>
<td>9.11</td>
</tr>
<tr>
<td>8.</td>
<td>Improved data collection during the further trial period is critical. At a minimum, this should include:</td>
<td>6.5</td>
</tr>
<tr>
<td></td>
<td>• comprehensive data on audits conducted and audit outcomes at all levels of audit (preferably, these should be periodically reported in de-identified format); and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• detailed information on the actual costs and staff time involved conducting each level of audit so that accurate unit prices may be derived.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The adequacy of this data collection should be regularly reviewed during the further trial period, and appropriate sanctions applied if the required data is not being collected as required.</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Participation in independent dosimetry audit should be mandatory for radiation oncology facilities in the future.</td>
<td>6.3</td>
</tr>
</tbody>
</table>

**Specific improvements to the ACDS model**

<p>| 10. | To ensure that appropriate data is collected (in line with recommendation 8) and the costs and benefits of the ACDS are able to be accurately captured and report, ARPANSA should ensure that the necessary systems and processes are implemented as a matter of priority. This is likely to require additional business and commercial capability. | 4.4 and 6.3        |
| 11. | The Quality Management System should be finalised as a matter of priority. Once it has been completed, it should be audited and assessed against the ISO 9001:2008 standards by an accredited certification body. Achievement of the accreditation within a set period could be a condition of the further trial. | 4.2                |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Recommendation</th>
<th>Section reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.</td>
<td>The risk management plan should be reviewed and revised at least annually. Again, this could be a condition of the further trial.</td>
<td>4.2</td>
</tr>
<tr>
<td>13.</td>
<td>Clear processes and role delineation in appropriately managing fail results is required. Protocols need to be clearly defined, agreed and understood by all stakeholders, including jurisdictional regulators. A timeline for development of these protocols should be set and meeting this timeline should be a condition of the further trial.</td>
<td>4.3</td>
</tr>
<tr>
<td>14.</td>
<td>Ongoing governance of the ACDS could be improved by: (i) restricting the role of the CAG to providing technical advice and input on clinical matters and advice on the development of audit methodologies, and (ii) forming a Management Advisory Group with a broader management focus and skill set to replace the MoU management group. These issues should be resolved within the first six months of the further trial period.</td>
<td>4.4</td>
</tr>
<tr>
<td>15.</td>
<td>The effectiveness and transparency of ACDS audit planning and scheduling processes would be improved by the use of strategic audit plans and annual audit plans as outlined in this report. A strategic audit plan and the first annual audit plan should be developed within the first six months of the further trial period.</td>
<td>4.4</td>
</tr>
</tbody>
</table>
| 16.| The specific areas of program sustainability risk identified in this report should be addressed by the Management Advisory Group. Specifically, this relates to:  
   • building longer-term organisational capacity (including strategies for recruitment and retention of staff, as well as maintaining the required currency of clinical skills);  
   • monitoring and reviewing (including analysis of data as the audit results database develops);  
   • improving stakeholder engagement and communications (including engagement with non-clinician stakeholders); and  
   • longer-term strategic planning. | 6.3                |
APPENDICES

Refer separate document