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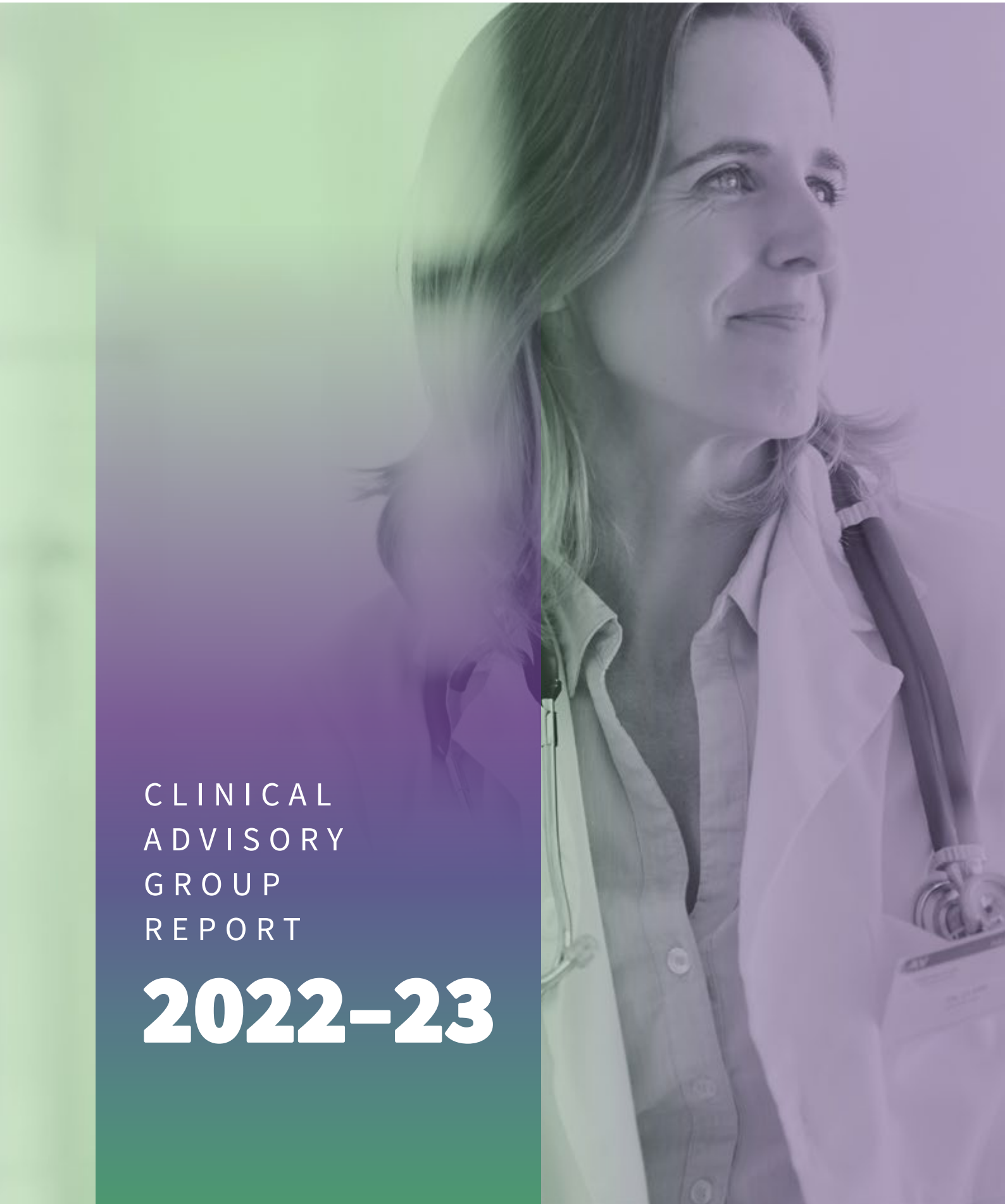


CLINICAL ADVISORY GROUP REPORT

2022–23

Letter of transmittal

19 December 2023

Dr Gillan Hirth
Chief Executive Officer
Australian Radiation Protection and Nuclear Safety Agency
619 Lower Plenty Road
Yallambie VIC 3085

Dear Dr Hirth

As agreed in the Terms of Reference for the ACDS Clinical Advisory Group 2023–2025, please find enclosed the Report of the ACDS Clinical Advisory Group 2022–23 that has been prepared in conjunction with the ACDS Year in Review Report 2022–23.

This report has been compiled by and is endorsed by the ACDS Clinical Advisory Group membership of:

- CAG members with affiliations:
- Dr Lucinda Morris, RANZCR
- Dr Louise Nardone, RANRCR
- Mr Adam Briggs, ACPSEM
- Dr Andrew Cousins, ACPSEM - New Zealand
- Dr Katrina Woodford, ASMIRT
- Ms Rebecca Thyne, NZIMRT
- Prof Joerg Lehmann, TROG
- Prof Tomas Kron, independent technical expert.

Yours sincerely

Dr Lucinda Morris
Chair of ACDS Clinical Advisory Group

Introduction

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has operated the Australian Clinical Dosimetry Service (ACDS) since 2011. The ACDS is a world class independent dosimetry auditing program that aims to provide a high standard of quality assurance and patient safety in radiation therapy across Australia and New Zealand.

The ACDS Clinical Advisory Group (CAG) is established by, and accountable to the CEO of ARPANSA as the ACDS's advisor. The CAG is responsible for providing clinical and scientific advice to the ACDS regarding out of tolerance audits, development of the audit suite, audit methods and phantoms. The CAG also reviews and provides feedback on ACDS performance metrics. Membership is made up of representatives from the public and private sectors and are nominated (based on experience and expertise) by following professional bodies:

- Radiation Oncologists – The Royal Australian and New Zealand College of Radiologists (RANZCR)
- Medical Physicists – Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)
- Radiation Therapists – Australian Society of Medical Imaging and Radiation Therapy/New Zealand Institute of Medical Radiation Technology (ASMIRT/NZIMRT)
- Clinical trials – The Trans-Tasman Radiation Oncology Group (TROG).

The chair of CAG is a radiation oncologist reflecting the clinical advisory role of the group. Meetings are held quarterly. Additional meetings are rapidly convened to discuss ACDS out of tolerance findings of concern. More information on the CAG is available at **arpansa.gov.au/cag**.

How audit findings have directly impacted patient care

Radiation therapy is vital and effective cancer treatment that contributes to 40% of all cancer cures. (Radiation Oncology Targeting Cancer, 2020). One in two people with cancer will require radiation therapy at some point in their treatment journey, whether it be for cure or quality of life (Radiation Oncology Targeting Cancer, 2020). Radiation therapy is more accurate and effective with fewer side effects than ever before, due to vast advances in the technology used to deliver treatment. With increased precision and ability to deliver ablative doses, the need to ensure that radiation oncology facilities are delivering the right dose of radiation to the right location has never been more critical.

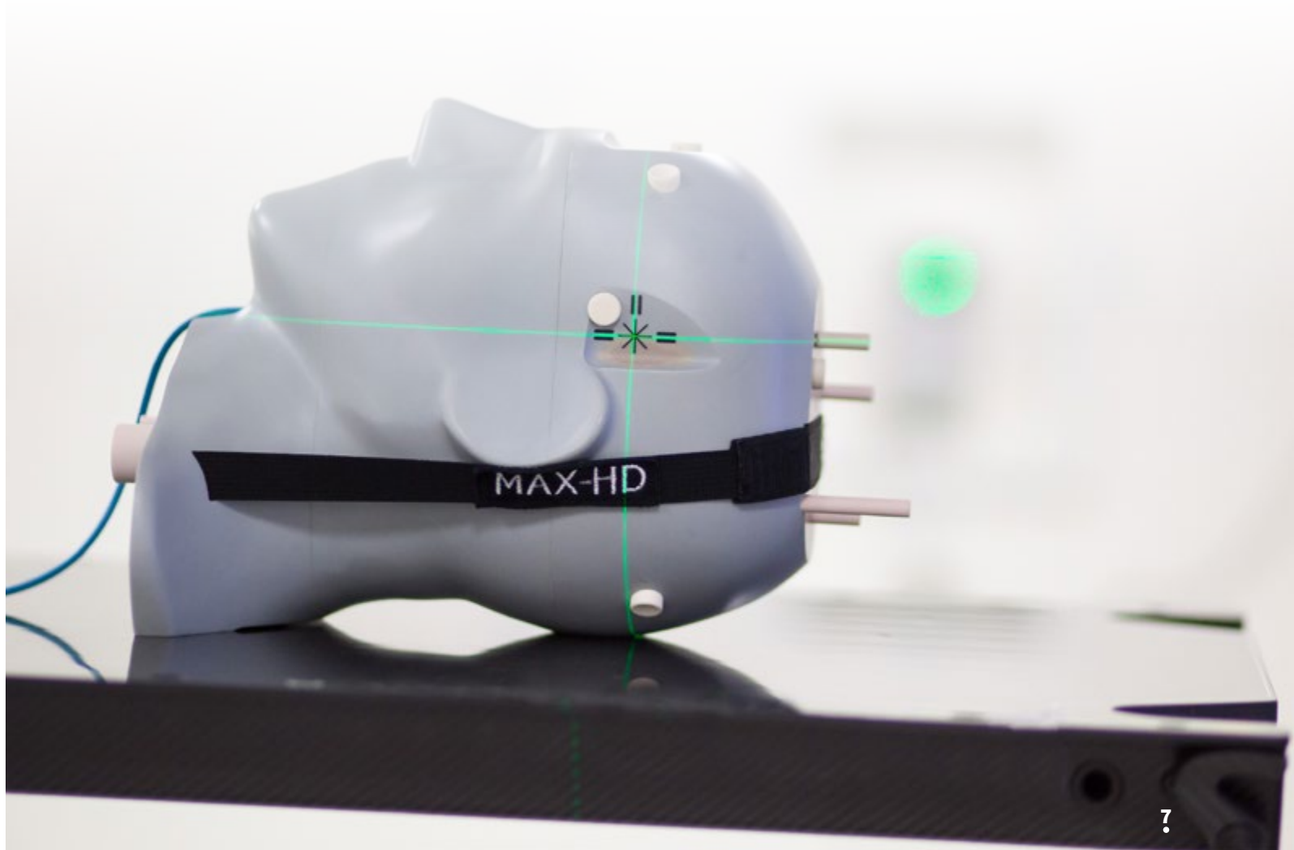
Radiation therapy dosimetry audits are vital to ensuring safe, high-quality care to people with cancer. ACDS audits are a quality improvement tool that replicate the whole or parts of a patient's pathway from treatment planning through to treatment delivery. The ACDS may make recommendations or work with facilities to resolve unexpected results while positive audits give confidence to the facility and their patients. Audits can identify potential harm to patients during pre-clinical tests and these may be remediated before any patients are treated. The ACDS works collaboratively with facilities, which encourages the uptake of new techniques and technologies by giving the facility confidence that an independent check has been performed. If an out of tolerance is detected, the ACDS provide advice and guidance on the rectification of any issues before a repeat audit is performed. Over FY 2022–23 the ACDS conducted 170 audits (63 remote, 107 onsite). There were also 5 Field trials and 4 Out-of-schedule Level III audits. The CAG reviewed 14 Out of Tolerance cases from 14 facilities. 9 onsite follow ups were performed.

Radiation Oncology clinical trials are the cornerstone of rigorous testing, development and implementation of new radiation therapy technologies and techniques. Quality assurance (QA) in radiation therapy clinical trials ensures the safety of participants, effectiveness of trial interventions and robustness of trial results. Radiation oncology centres participating in clinical trials must be able to demonstrate the ability to deliver trial radiation therapy interventions to a high degree of accuracy. ACDS audits are fundamental to this process, as they provide rigorous, independent auditing of contemporary radiation therapy techniques. The CAG continues to seek the advice and high level of expertise of the TROG representative in providing guidance to the ACDS regarding clinical trial audits.

Quality assurance in clinical trials and research

Clinical trials are essential in advancing the treatment of cancer patients, including in radiation oncology. Through trials new treatment technologies and techniques can be tested, developed and safely implemented. Quality assurance (QA) is an important component of radiation therapy clinical trials to ensure safety of participants, effectiveness of trial interventions and robustness of trial results. As part of the QA centres participating in radiation therapy clinical trials are required to demonstrate that they can accurately deliver trial radiation therapy interventions. In the clinical trials of the Trans-Tasman Radiation Oncology Group (TROG), ACDS audits continue to be fundamental to this process, as they provide rigorous, independent auditing of contemporary radiation therapy techniques. We note the advice and expertise of the CAG TROG representative to the ACDS regarding clinical trial audits is ongoing.

With TROG, the ACDS participates in international efforts to globally harmonise clinical trials QA (1). Through the work in audit design and results analysis the ACDS also originated research (2, 3) and participated in an Australian national guideline document (4).



Relevance of the existing suite

The ACDS continues to strive towards providing a comprehensive auditing service, providing a range of audits to cover the many conventional and specialised treatments provided by radiation oncology facilities. The clinical advisory group plays a key role in providing clinical expertise to the development of new audits and ongoing review of the current suite.

The ever-growing use of stereotactic ablative body radiotherapy (SABR) and its transition into mainstream practice created a need for a dedicated audit. After many years of development and field testing the SABR audit went live in FY 2021–22 and has had rapid uptake since. This level III audit covers three key anatomical sites (lung, soft tissue, spine) providing a tailored, in-depth assessment of this high-risk technique. During FY 2022–23, the ACDS conducted SABR audits at 34 facilities, measuring 71 SABR soft tissue cases, 59 SABR lung cases and 45 SABR spine cases. Four out of tolerance results were reported to the CAG during FY 2022–23 – 2 SABR soft tissue, one SABR lung and one SABR spine. These out of tolerances were discussed in detail by the CAG where recommendations were made, including follow-up measurements or consultation as required.

The ACDS audit suite continued to grow in FY 2022–23 with the addition of two new audits, Level Ib kV and Level III Stereotactic Radiosurgery (SRS), both going live on 1 July 2022. The Level Ib kV audit caters for low energy, kilovoltage x-ray units which are commonplace in many radiation oncology departments in Australia and New Zeeland and used to treat skin cancers. Two live audits were conducted in FY 2022–23. Stereotactic radiosurgery is characterised by delivering very high doses to small targets in the brain and necessitating a high level of accuracy and meticulous quality assurance from the departmental physicists. The Level III SRS audit was developed due to the increase in uptake of this technique by Radiation Oncology departments across Australia and New Zealand over the last decade. Once reserved for specialist centres only, SRS has been increasingly adopted by more facilities and conducted on standard linear accelerators as well as more specialised treatment units. The Level III SRS audit encompasses a number of cases ranging in complexity and incorporating the use of Magnetic Resonance Imaging (MRI). In FY 2022–23, 7 of these audits were conducted, 2 field trial audits from the previous financial year were reviewed and the CAG provided extensive deliberation on 5 out of tolerance results, highlighting the complexity of these treatments and the importance of independent dosimetry quality assurance.

Importance of field trial audits

Field trials are the final test of new audits before go-live with a representative subset of all centres which are likely to participate in the audits. Field trials typically are free of cost for participating centres but in return they would be asked to provide extensive feedback on audit scope, time and resource requirements, methodology and documentation. In addition to this it informs the setting of action levels as field trials can ensure that the levels are set in a way that they can be passed under real life conditions in a ‘field trial’. This is a process that anchors audits in reality, tests capability of the audit group and is used by several clinical audit networks around the world including ACDS and Imaging and Radiation Oncology Core (IROC) in Houston.

Field trials of audits are an integral part of audit development as they test the applicability of a new audit and identify any shortcomings. For participating centres, field trials are also an opportunity to support introduction of new technology in particular as field trials are likely to test audits for new and advanced technology.

A recent example is the introduction of an audit specifically for Stereotactic RadioSurgery (SRS) by ACDS. The audit takes a novel approach in including a scenario testing a single isocentre/ multi-metastases treatment, which is a technique that many facilities in Australia are currently considering for implementation. In this context, the use of field trials has not only benefits for ACDS but also for participating centres which results in a promotion of audits as a tool to support not only better day to day activity but also the introduction of new technology and techniques. Development of proton dosimetry audit capability is currently on hold until funding options are resolved.

The resources required by facilities to participate in the audit program

The CAG reviews customer feedback sought by the ACDS from facilities to ensure ongoing quality improvement of the service. Survey responses from 51 medical physicists and 7 radiation therapists were reviewed during FY 2022–23.

Key findings include:

Radiation therapists feedback

- All respondents agreed that audit involvement had improved their understanding of the role of clinical audits in ensuring patient safety.
- Time needed for treatment planning: responses ranged from 1 to 24 hours
- Time needed for treatment delivery: responses ranged from 4 to 9 hours.

Medical physicists feedback

- Time taken to complete physics planning tasks, including planning checks and patient specific QA ranged from 1 to 50 hours.
- 44/51 respondents agreed that ACDS audits increased the facility's confidence in the accuracy of its QA practices.

The global impact of ACDS audits and research for improving patient safety

ACDS collaborates with multiple international auditing bodies and is recognised as a peer amongst peak global auditing programs. Over the last decade the ACDS has had significant research output adding to the global body of knowledge related to dosimetry audits. A total of 24 national and international invited scientific and teaching presentations have been delivered by the ACDS team over FY 2022–23. These presentations have showcased the world-class ACDS audit program and reported on outcomes and ongoing development of the audit suite. The ACDS has also contributed the 4 peer reviewed publications regarding the audit program (ref 1–4). Beyond site or organisation specific information, the ACDS has detected system wide trends for various TPSs. This have become the basis for multiple publications, adding to the global body of knowledge and has potentially prevented embedded errors that may impact many thousands of patients.

The ACDS continues to be invited to assist the IAEA in delivering training programs for medical physicists around the world in audit methodology.

Conclusion

Dosimetry audit via the ACDS is fundamental to delivering safe, high-quality radiation therapy to people with cancer. The ACDS will continue to strive to support the radiotherapy community with an independent and comprehensive dosimetry audit service to ensure the highest level of quality and patient safety in radiotherapy across Australia and New Zealand.

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