The program at a glance

The current audit program includes **Level I, Level Ib, Level II** and **Level III audits**. A live audit is scored, and audits still in field trial, whether emergent or mature, are reported but not scored against the overall audit outcome. Mature field trials are reported with indicative outcomes.

### Level I
Determines absorbed dose to water per monitor unit for mega-voltage photon and electron beams under reference conditions. Optically Stimulated Luminescence Dosimeters (OSLD) are sent by post to the Radiation Oncology Facility (Facility). The OSLDs are irradiated by the Facility physicists and returned to the ACDS for processing. All clinical Linacs in a facility are tested.

The audit results are determined by the percentage deviation of the Facility Stated Dose Output from the ACDS Determined Dose Output, for each clinical beam. All beams on each Linac are tested, unless the Facility states that a beam is ‘Not Clinical’.

### Level Ib
Is conducted onsite by ACDS representatives and is typically offered for new linear accelerator installations or performed in response to a result for a Level I audit. To ensure a high degree of independence from the Facility, the ACDS provides external equipment and measurements whenever practicable. This audit is designed to measure static beams on a Conventional Linac, Halcyon™ including Ethos™, MR-Linac, Tomotherapy® and CyberKnife® systems and determines absorbed dose to water per monitor unit, for mega-voltage photon and electron beams, under the Facility’s reference conditions. Reference class electrometer and ionisation chambers are used with a water phantom. The determination is made using the IAEA TRS-398 Code of Practice. The ACDS uses ion chamber calibration factors determined in high-energy beams of similar quality (referred to as ‘directly measured’), as recommended by the code. The Level Ib audit consists of the following modalities:

- reference beams (photons and electrons)
- reference beams (photons FFF)
- small field output factors.

A kilovoltage field trial is available for 40-300 kVp radiotherapy beams, following the AAPM TG-61 dosimetry protocol, with optional applicator factor and HVL checks.
Determined absorbed dose to water, delivered to selected points and planes within a ‘slab’ geometry phantom. This is an audit of the beam model within a treatment planning system, where the phantom CT is supplied to the Facility for treatment planning and delivery. It includes a number of modalities, each with additional options and the Facility can choose to complete as many options in the audit as deemed necessary.

Multiple cases are planned for all modalities of the audit. Fields are fully prescribed by the ACDS and link directly to the ACDS Level III Audit. CT datasets are provided by the ACDS. Dosimetry measurements are made in a custom phantom of CIRS solid water, using a 2D ionisation chamber array as a primary detector and supporting measurements with CC13 ionisation chambers. The 2D array is calibrated against a Farmer type ionization chamber, which is traceable to the primary standard at ARPANSA.

<table>
<thead>
<tr>
<th>Modality</th>
<th>Conventional Linac</th>
<th>Halycon/Ethos</th>
</tr>
</thead>
<tbody>
<tr>
<td>3DCRT (Compulsory)</td>
<td>6X</td>
<td>6FFF</td>
</tr>
<tr>
<td>3DCRT (Optional)</td>
<td>10X, 18X, 6FFF, 10FFF</td>
<td></td>
</tr>
<tr>
<td>IMRT</td>
<td>6X, 10X, 6FFF, 10FFF</td>
<td>6FFF</td>
</tr>
<tr>
<td>VMAT</td>
<td>6X, 10X, 6FFF, 10FFF</td>
<td>6FFF</td>
</tr>
</tbody>
</table>

The Level III audit investigates the accuracy with which a Radiation Oncology Facility delivers dose to a simulated patient. An anthropomorphic phantom undergoes all steps within the Facility which a patient would experience for treatment with radical intent. Dosimetry measurements are made with an electrometer and ionisation chambers in a CIRS phantom. The ACDS uses ion chamber calibration factors determined in high-energy beams of similar quality as recommended by TRS-398.

The audit comprises multiple modalities and energies, components of which can be performed on a Conventional Linac, Halycon™, Ethos™, MR-Linac, Tomotherapy® or CyberKnife® system. Specialist (non-conventional) Linacs follow the general audit procedure, with system specific modifications.

***The SABR and adaptive modalities are currently in field trial and thus the results are reported but not scored.
**What is a field trial?**

A field trial is a preclinical developmental stage of an audit. Data gathered informs decision making on phantom design, detector use, correction factors and analysis techniques. Uncertainty budgets and the setting of pass/fail tolerances are refined as predicted tolerances are compared to measurements taken at participating facilities.

An audit moves from an emergent to mature field trial and then to a live audit, when there is enough data to ensure the robustness and accuracy of the audit. A mature field trial is when we have refined our procedures for delivering the audit, analysing the results and producing the report in a timely manner. There is enough data collected and experience gained such that the process of audit delivery, analysis and report writing is a smooth process and there is confidence in uncertainty budgets and final results. A proposed set of tolerances are derived, that the ACDS is confident can predict an out of tolerance outcome.

The Clinical Advisory Group (CAG) contributes to the decision making that determines when an audit is ready to become live.

**Mature field trials**

- With approximately 300 plans measured to date, the SABR field trial is a mature field trial with defined pass/fail tolerances; corrections for dose to bone, inhale lung and lung tumour are being incorporated into the data analysis code. The CAG and the ACDS are working to consider Red Flag protocol limits and this field trial is planned to go live in early 2021.
- Since the SRS phantom arrived in mid 2019 and 12 field trials have been performed to date, this field trial has now been promoted to mature status. Field trials resumed in September 2020 after a 6-month pause due to Covid-19 travel restrictions. Discussions with the CAG are underway, regarding tolerances and pass/fail metrics.
- The technical work for Lib small field dosimetry is now complete, with >200 beams measured since March 2019. Tolerances have been set for this field trial and it is now released as a live audit.
- kV Level Iib has 11 field trials since 2017 with pass/fail tolerances to be defined, prior to it’s release as a live audit.
- Halcyon™, Tomotherapy® and CyberKnife® field trials, use existing audit modalities and cases as applicable.
- The Level III online adaptive audit for the MR-Linac and Ethos™ systems, has had 4 fields trial performed to date, since the phantom inserts were modified in November 2019. The two new online adaptive audit cases are designed as extensions of an existing Level III IMRT/VMAT audit case.

**Emergent field trials**

- Two Gamma Knife® SRS cranial field trials have been completed.
“Action Level” audit outcomes are an occasional, but persistent source of feedback to the ACDS. The ACDS uses the Pass – Action Level classification to draw attention to outcomes that are unlikely to represent a significant error, but may benefit from closer scrutiny and are viewed as an opportunity for improvement. It provides both Facilities and the ACDS a level of informed discretion when determining appropriate follow up.

Audit outcomes are fundamentally binary, either “Pass” or “Out of Tolerance” (OT). The threshold is nominally derived from the calculated uncertainty budget, where the distribution of expected results is described in terms of standard deviation ($\sigma$). The OT threshold (>3 $\sigma$) makes it statistically unlikely the result occurred purely due to measurement uncertainty. A Pass outcome is further classified as “Pass - Optimal Level” (if within 1 $\sigma$) or “Pass - Action Level” (2-3 $\sigma$). Outcomes are continuously monitored for normality (an underlying assumption) and the frequency of each outcome. In practice, OT findings have been due to demonstrable dosimetric or procedural errors in almost all cases, not measurement uncertainties.

Follow up of an OT outcome follows a sequence of timelines, reporting, and follow-up determined by the severity and scope of the finding. Reporting points may include Chief Physicist, Medical Director/Head of Radiation Oncology, ARPANSA CEO and State regulators. All OT findings are reviewed by the ACDS Clinical Advisory Group (CAG). A ‘Red Flag’ event, occurs when the OT finding indicates the potential for significant clinical impact and a requirement for immediate intervention. This would be the case if the CAG recommends a facility cease or restrict patient treatment after reviewing the audit results.

The ACDS report includes explanatory comments and recommendations for follow up, which are made after careful consideration of all measurement outcomes within the audit, the Australia and New Zealand Data Set benchmarks, and detailed knowledge of the audit design. Any well-established behaviours will be identified and, typically, no further immediate follow up is requested. Less clear-cut cases may be discussed with the facility physics team, additional information may be requested and a follow up ACDS measurement may be offered.

The higher-level ACDS audits sample a limited yet challenging set of treatment scenarios. The potential to mitigate risk or improve quality must be balanced against unwarranted investigations that would draw time away from clinical needs. A Pass – Action Level outcome is still a Pass for the audit. An appropriate “action” can be as simple as additional facility scrutiny of the audit. A repeat measurement may often be the quickest means for definitive resolution, irrespective of any other investigations. Even two successive Pass Action results constitute two successive Pass outcomes.

The ACDS team are available for further discussion and assistance however, the decision to proceed with and the scope of any facility follow up to a Pass - Action Level outcome remains at the discretion of the organisation’s physics team.
Audit outcome criteria

Audit outcome

The audit results are determined by the percentage deviation of the Facility Stated Dose Output from the ACDS Determined Dose Output, for each clinical beam. All beams on each linac are tested, unless the Facility states that a beam is ‘Not Clinical’. Current result levels are given in Table 1.

<table>
<thead>
<tr>
<th>Result</th>
<th>Level</th>
<th>% Deviation (Facility stated dose / ACDS measured dose)</th>
<th>mm Deviation (Facility – ACDS)</th>
<th>Photon</th>
<th>Electron D_{max}</th>
<th>Electron R_{50} (6-16 MeV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pass</td>
<td>Optimal</td>
<td>≤ 2.6</td>
<td>≤ 3.4</td>
<td>≤ 2.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Action</td>
<td>&gt; 2.6 and ≤ 3.9</td>
<td>&gt; 3.4 and ≤ 5.1</td>
<td>&gt; 2.4  and ≤ 3.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Out of tolerance</td>
<td></td>
<td>&gt; 3.9</td>
<td>&gt; 5.1</td>
<td>&gt; 3.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1. General audit pass criteria

An overall audit outcome for each Linac is determined, which is equal to the poorest result of any individual beam.

Audit outcome

The audit results are determined by the percentage deviation of the Facility-Stated Dose Output from the ACDS-Determined Dose Output, for each clinical beam. Result Levels are given in Table 2. An overall audit outcome is determined, which is equal to the lowest result recorded for an individual beam.

<table>
<thead>
<tr>
<th>Result</th>
<th>Level</th>
<th>% Deviation (Facility stated dose / ACDS measured dose)</th>
<th>Photon</th>
<th>Electron</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pass</td>
<td>Optimal</td>
<td>≤ 1.4</td>
<td>≤ 2.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Action</td>
<td>&gt; 1.4 and ≤ 2.1</td>
<td>&gt; 2.2  and ≤ 3.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Out of tolerance</td>
<td>&gt; 2.1</td>
<td>&gt; 3.3</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. General audit pass criteria

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Field Size (cm)</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
<th>0.5 RNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimal level</td>
<td>≤ 1.1%</td>
<td>1.2%</td>
<td>1.7%</td>
<td>2.4%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Action level</td>
<td>&gt; 1.1% to ≤ 1.7%</td>
<td>&gt; 1.2% to ≤ 1.9%</td>
<td>&gt; 1.7% to ≤ 2.5%</td>
<td>&gt; 2.4% to ≤ 3.7%</td>
<td>&gt; 5% to ≤ 7.5%</td>
<td></td>
</tr>
<tr>
<td>Out of tolerance</td>
<td>&gt; 1.7%</td>
<td>&gt; 1.9%</td>
<td>&gt; 2.5%</td>
<td>&gt; 3.7%</td>
<td>&gt; 7.5%</td>
<td></td>
</tr>
</tbody>
</table>

Table 2a. Tolerances for small field output factors component of Lib with: % Deviation (Facility stated OF / ACDS measured OF)
Audit outcome criteria

Audit outcome

The outcome for an individual case is determined using the measured 2D dose map. An overall audit outcome for each modality is determined, which is equal to the worst case outcome for each modality.

For 3DCRT, the audit results are determined for each case using the dose variation between the Facility Stated Dose (planned dose) and the ACDS Measured Dose. A measurement case/plane is considered passed at the Optimal Level if the maximum absolute variation of the Facility stated plan dose from the ACDS measured dose is within 3.3% for all assessed points. It is considered passed at the Action Level if the maximum absolute variation is between 3.3% and 5%. It is considered Out of Tolerance if the maximum absolute variation is outside 5%.

For IMRT/VMAT, gamma criteria of 3%/3mm relative to 2Gy, with dose <20% suppressed, are assessed across the entire measurement plane for each case.

Measurement results that are reported but not scored include any deliveries which are restricted for clinical use, repeated measurements, alternative scoring options and supporting measurements.

<table>
<thead>
<tr>
<th>Modality</th>
<th>Metric</th>
<th>Criteria</th>
<th>Pass (Optimal Level)</th>
<th>Pass (Action Level)</th>
<th>Out of Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>3DCRT</td>
<td>Local dose variation</td>
<td>100% points</td>
<td>≤ 3.3%</td>
<td>&gt; 3.3% and ≤ 5%</td>
<td>&gt; 5%</td>
</tr>
<tr>
<td>IMRT and VMAT</td>
<td>Local dose variation</td>
<td>94% points*</td>
<td>γ1 at 3%/3mm</td>
<td>≥ 95%</td>
<td>&lt; 95% and ≥ 90%</td>
</tr>
<tr>
<td></td>
<td>Gamma Criteria</td>
<td>5%/2 mm</td>
<td>≥ 95%</td>
<td>&lt; 95%</td>
<td>&lt; 90%</td>
</tr>
<tr>
<td></td>
<td>Soft Tissue</td>
<td>70% isodose</td>
<td>γ1 at 3%/3mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>and Lung</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1D profile DTA</td>
<td></td>
<td>γ1 at 3%/3mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spine</td>
<td>50% isodose</td>
<td>γ1 at 3%/3mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1D profile DTA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>@ PTV/Spinal Cord</td>
<td></td>
<td>γ1 at 3%/3mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Junction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Local dose variation</td>
<td>100% points</td>
<td>γ1 at 3%/3mm</td>
<td>≥ 95%</td>
<td>&lt; 95% and ≥ 90%</td>
</tr>
</tbody>
</table>

Table 3. General audit pass criteria

Outcomes are attained for each modality the Facility chooses to include in the audit (see Table 4). Measurement results that are reported but not scored include out of field points, repeated measurements and deliveries restricted from clinical use.

Table 4. Scoring criteria for Level III audit

*An Out of Tolerance outcome will be given if a single point returns >8% local dose variation.
#SABR is currently in field trial and outcomes given are indicative only.
The audit cycle review

Current audits/cases

- Build ANZ Data Set
- Retire
- Retain for investigative use
- Retain for new installs
- End of cycle review
- Refinement of process and case set
- Start operational cycle

New audits/cases

- Concept development
- Clinical trial requirements
- Subscriber feedback
- Horizon scanning
- New clinical systems
- Emergent field trial
- Validation and commissioning
- Beta field trial
- Mature field trial
- Iterative refinement of process and case set
- Complementary products such as the ANZ Data Set are developed parallel to the core audits
- Establish future need
Feedback and review

Stakeholder feedback supports development of ACDS audits and contributes to the safety of radiotherapy patients. As such it is welcomed and encouraged.

Feedback from subscribers and stakeholders is essential to the cycle of audit review and development and the ACDS continues to actively seek feedback on both their products and their service delivery.

With the assistance of the CAG, the ACDS has developed a formal review process. In addition to the informal feedback and formal post audit surveys, there is now a request for review process, accessible via ARPANSA's website.

In the first instance, the facility representative is encouraged to discuss any issues or concerns with the director of the ACDS or the chief medical radiation scientist with the aim of a resolution. Alternatively, or in addition to this, there is the opportunity to either:

- request a further audit review
- dispute a review response by CAG
- provide feedback or a complaint.

Visit the feedback and review webform on our website.