IANZ Position Statement
Compliance Requirements for Medical Imaging Monitors

The NZ mark of competence
Tohu Matatau Aotearoa

1. Purpose

To inform accredited organisations of the changes to the compliance criteria pertaining to display monitors, with respect to luminance levels, within medical imaging facilities.

2. Scope

The criteria as stated applies to all medical imaging accredited organisations.

3. Background

IANZ recognises the difficulty New Zealand medical imaging service providers may have in meeting current Royal Australian and New Zealand College of Radiologists (RANZCR) standards and associated International and/or national standards with respect to luminance levels of secondary/acquisition monitors, within any medical imaging environment, in order to achieve accreditation compliance.

The challenges to meeting compliance are influenced by:

- Ageing equipment
- Vendor parameters at manufacture and subsequent inability to calibrate to RANZCR stated luminance levels
- Cost and practicality of recalibration of display monitors routinely and repetitively
- Lack of clinical, diagnostic or technical evidence to support maintenance of higher luminance level compliance

4. Change

IANZ has agreed that the following criteria will safely and adequately address the compliance requirements for secondary/acquisition monitors within medical imaging facilities in New Zealand.

All accredited medical imaging providers are expected to comply with the following criteria:

1. A minimum value of 150cdm² is expected for all secondary/acquisition monitors within any accredited medical imaging practice.

   Note:
   Secondary/acquisition monitors are deemed to be any monitor that may be utilised for any type of clinical interpretation (such as Ultrasound, CT and MRI – often in ED and ultrasound departments) and on which images may be reviewed for appropriateness/acceptance. Acquisition monitors are most frequently utilised to determine whether images are clinically acceptable for reporting. Reporting is not undertaken from these monitors, but acceptance of the image is – thus the image is reviewed. Any monitors outside the service's accreditation (such as ED/GP or outpatient monitors) are not subject to review under accreditation.

2. Should any monitor/s fall below 150cdm², the following steps must be undertaken, with supporting evidence provided.
    - A clinical risk evaluation with respect to adverse outcomes for the patient through inadvertent missed diagnosis or other potential clinically adverse event related to resultant reporting arising from use of non-compliant monitors, in any way.
    - Evidence of clinical and executive review of such a risk evaluation.
    - Evidence of a clinically approved pathway for future examination provision utilising non-compliant monitors.

5. Assessment of Risk

The most significant risk to all parties is that an accredited organisation will not comply with accreditation requirements and, in the worst case, issue incorrect or invalid results, and that IANZ has failed to identify this because of ineffective assessment activity.

The magnitude of the risk will be assessed based on many indicators such as any critical risk to the safety and wellbeing of society, the industry or sector sensitivities, previous compliance performance, recent changes to accreditation requirements, changes within the accredited organisation, the internal quality control programmes of the accredited organisation, etc.

Based on the magnitude of the risk, appropriate assessment activities will then be selected to be undertaken at the surveillance assessment.

In all cases, IANZ will still retain the right to assess an accredited organisation, with or without Technical Experts, at any time should there be due cause to do so.

6. Implications

Each accredited organisation will be considered on a case-by-case basis and on its own merits.

7. Implementation

This notice is effective immediately (March 2023).