This communique is to clarify to NATA Members and Technical Assessors the requirements in AS 3864.2 *Medical refrigeration equipment - For the storage of blood and blood products Part 2: User-related requirements for care, maintenance, performance, verification and calibration* relating to the calibration of blood fridges. In that document, Clause 2.4.1 states:

> "Any testing or calibration shall be performed according to the criteria set out in ISO/IEC 17025."

This is understood to be applicable specifically to the tasks detailed in Clause 3.7.2 (Temperature monitoring and alarm system calibration), 3.7.3 (Alarm reactivation test) and 3.8.3 (Spatial distribution check).

In order to satisfy this requirement, organisations using this equipment are expected to demonstrate that the calibration / testing providers performing the above activities have operated according to the criteria set out in ISO/IEC 17025 (also refer to Section 2.2 of NATA Policy Circular 11).

While use of accredited calibration providers is one way of satisfying the requirement, facilities are free to use non-accredited calibration providers whose service is suitable for the intended need.

Where the facility chooses to use non-accredited calibration providers whose service is suitable for the intended need, evidence of claimed traceability and measurement uncertainty for the calibration services provided must be available. This evidence will be reviewed by NATA at assessments of the facility.

The evidence the facility must maintain of the competence and claimed metrological traceability is likely to include but not be limited to the following (the numbers in brackets refer to the clause numbers of ISO/IEC 17025:2005):

- Audits of the calibration service provider (4.6.4 and 4.14);
- Documentation for competence of staff (5.2);
- Documentation for accommodation and environmental conditions (5.3);
- Records of calibration method validation (5.4.5);
- Procedures for estimation of uncertainty (5.4.6);
- Documentation for traceability of measurements (5.6);
- Documentation for assuring the quality of calibration results (5.9).

In practical terms, the facility would need to have evidence of an assessment of the calibration service provider similar to that which would be conducted by an accreditation body such as NATA or one which is signatory to the ILAC MRA.

Please note also that review of this material during the NATA assessment of the facility will require some additional effort by the assessment team, and this may add to the duration of assessments and involve additional fees reflective of the effort required.

Further enquiries may be directed to Mr Andrew Griffin, Deputy Sector Manager, Life Sciences in the Melbourne office on (03) 9274 8200.