

## Quality System Procedure Manual

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### Control of Inspection, Measurement, and Testing Equipment Procedure

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#### 1.0 Purpose:

To ensure that all inspection, measurement and testing equipment requiring calibration and re-calibration are identified and maintained.

#### 2.0 Scope:

This procedure applies to:

- Trillium Gift of Life Network (TGLN)

#### 3.0 Responsibilities:

Inventory Assistant (IA) or Administrative Assistant Provincial Resource Centre (PRC) - Organ is responsible for:

- tracking equipment which require calibration and when to send them out for calibration
- raising purchase orders for calibration services
- arranging transport to/from calibration services
- evaluating calibration certificates for out-of-tolerance conditions
- raising corrective actions to address out-of-tolerance data
- tracking equipment conditions to adjust calibration frequency, when required

#### 4.0 Procedure:

##### ***General***

- 4.1 Operations requiring periodic or ongoing inspections, measurements and tests are identified.
- 4.2 The type of inspections, measurements and tests undertaken by TGLN, the equipment used and calibration frequency for each type of equipment are specified.

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- 4.3 The calibration is determined by the manufacturer's recommendations and the usage of the equipment.
- 4.4 If the manufacturer's recommendation cannot be determined, the recommendation provided by the Equipment Supplier performing the calibration is also acceptable.
- 4.5 If the inspection, measuring and test equipment is used for "reference only", the equipment does not require calibration.
- 4.6 The information regarding TGLN's inspection, measuring and testing equipment is listed on the *Calibrated Equipment List*. See Exhibit 1.

#### **Calibration Process**

- 4.7 The IA or Administrative Assistant PRC – Organ shall prepare equipment for calibration prior to the calibration due date and ensure a suitable replacement is available during the time the piece of equipment will be out-of-service.
- 4.8 All calibrations must be performed to National Institute of Standards and Technology (NIST) traceable standards or equivalent.

#### **Non-Conforming Equipment**

- 4.9 The IA, Administrative Assistant PRC – Organ or designate will review the calibration certificate of the calibrated piece of equipment to determine if it was within tolerance and whether any adjustments were made to the piece of equipment to bring it within tolerance.
  - 4.9.1 If the piece of equipment was found to be out-of-tolerance, records shall be reviewed to determine if there was any adverse effect on any supplies, reagents, recovered organs or tissues.
  - 4.9.2 If it is found that the out-of-tolerance condition did impact supplies, reagents, recovered organs or tissues, then a corrective action will be raised in accordance with *Corrective and Preventative Action, QSP-14-1*.

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- 4.9.3 If the equipment was able to be adjusted back into tolerance, it shall be returned to service, but with the calibration frequency decreased by half. If the piece of equipment is found to be in-tolerance for two consecutive periods, it may be returned to its original calibration frequency.
- 4.9.4 If the equipment is not able to be adjusted back into tolerance, the equipment will be taken out-of-service and replaced.

#### **Review**

- 4.10 Periodic review of the *Calibrated Equipment List* is performed by the IA or Administrative Assistant PRC – Organ to ensure that all TGLN measuring, inspection and test equipment is calibrated according to the calibration schedule.
- 4.11 Any adjustments to calibration frequency, accuracy, precision, or tolerance limits shall be documented on the *Calibrated Equipment List*.

#### **5.0 Records:**

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Calibrated Equipment List	QSF-11-1	PRC	PRC	16 years
Calibration Certificates	-----	PRC	PRC	16 years

#### **6.0 References:**

- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. J5.000.
- Corrective and Preventative Action, QSP-14-1*

