INTERNAL ONLY

ISLHD POLICY COVER SHEET

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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Chief Information Officer
AUTHOR	Director Clinical Engineering
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FUNCTIONAL GROUP OR HUB	ISLHD, Clinical Engineering
NSQHS STANDARD	Standard 1
SUMMARY	This policy establishes governance for safety and functional testing of Medical Equipment and defines the frequency of testing and labelling within the ISLHD. The policy also encompasses equipment that is used for the safe introduction of interventional procedures into clinical practice.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

Feedback about this document can be sent to: ISLHD-CorporateGovernance@health.nsw.gov.au

Health
Illawarra Shoalhaven
Local Health District

Biomedical Equipment – Testing, Tagging and Labelling **ISLHD CORP PD 26**

1. POLICY STATEMENT

Medical Equipment used within the ISLHD will be subject to the practices for inspection, testing and labelling of medical equipment as defined in Australian Standard AS/NZS3551.

2. AIMS

- To establish the framework for safety and functional testing of Medical Equipment within the ISLHD.
- To clearly define the frequency of testing and labelling of Medical Equipment and equipment that is used for the safe introduction of interventional procedures into clinical practice.
- This policy must be adhered to in conjunction with the Safework NSW Code of Practice – Managing electrical risks in the workplace – August 2019.

Note: Medical Equipment testing is performed to AS/NZS3551, general electrical equipment is tested to AS/NZS3760 which has different applications and electrical safety requirements. This policy does not cover general electrical equipment**.**

3. TARGET AUDIENCE

Hub General Managers, Facility Managers, Department Heads, Nurse Unit Managers, Clinical and Nursing staff, Clinical Governance.

4. RESPONSIBILITIES

4.1 General principle for use of Medical Equipment

- No Medical Equipment within the ISLHD is to be used unless it has a current safety test label attached. This applies to all new purchases, equipment evaluations, rentals and loan equipment. In the case of rentals this may be in the form of the suppliers own label dated prior to dispatch.

4.2 Frequency of testing

- The frequency of testing is as defined in AS/NZS3551 and is determined during the equipment acceptance procedure. The testing interval is normally 12 monthly but can be varied under risk assessment outcomes or as per manufacturer's recommendations as per the Standard.
- The testing interval determined at acceptance will be entered into the equipment database to schedule ongoing inspections.

4.3 New, Evaluation, Loan or Rental equipment

- All equipment shall be tested on arrival at any ISLHD site prior to clinical use whether it is new, for evaluation or on loan. Rented equipment such as pressure relieving devices may forgo testing on arrival if systems are in place to ensure testing has been undertaken by the Supplier prior to dispatch.
- Service directors, Clinicians, Department Managers and Nursing Unit Managers are directly responsible in ensuring that equipment used within their areas has been acceptance tested and approved by Clinical Engineering prior to use.

4.4 Performance Verification testing

- Performance Verification testing will be undertaken at the intervals and in accordance with the tests deemed necessary during the acceptance procedure.
- In the case of equipment issued to home patients on long term loan, excepting dialysis equipment, it is the issuing departments responsibility to ensure the equipment is returned to Clinical Engineering for inspection in accordance with AS/NZS3551 before the testing due date.
- Equipment which cannot be located or cannot be accessed during routine testing by Clinical Engineering will be itemised on a report sent to the Department Manager at the end of the scheduled testing period. It is the responsibility of the Department Manager to ensure the itemised equipment is made available to Clinical Engineering for testing as soon as possible.
- It is the responsibility of the Department Manager to ensure all of their equipment is tested and that the dates indicated on the safety test labels are current.

4.5 Faulty equipment

- Faulty or damaged medical equipment shall be isolated and labelled in accordance with AS/NZS3551.
- Faulty equipment should be segregated and stored in a location where the equipment will not be used.
- Where it is suspected that faulty equipment may have contributed to an adverse patient outcome, the equipment along with all accessories and consumables associated with the equipment at that time will be immediately removed from service and isolated.

4.6 Patient-supplied equipment

- Patient-supplied equipment (such as CPAP devices) are to be inspected as per Policy ISLHD CORP PD 02 – ‘Patient-supplied Equipment’.

4.7 Records

- A summary report of all equipment tested can be requested by the relevant Department Manager at the end of the scheduled testing period.
- The numerical results of the Performance Verification tests are retained on file in the Clinical Engineering department and are not sent to the departments.
- All records, manuals and equipment assessment reports are to be retained in accordance with the General Retention and Disposal Authority: Patient Records (GDA17) and Administrative Records (GDA21)

5. DEFINITIONS

Acceptance Procedure: A set of processes, both administrative and technical, required to be performed before new medical equipment is released for clinical use.

Medical Equipment: Any instrument, apparatus or appliance, including software, whether used alone or in combination, together with any accessories necessary for correct operation that makes physical or electrical contact with the patient, or transfers energy to or from the patient, or detects such energy transfer to or from the patient, or is intended to diagnose, treat or monitor a patient.

Performance Verification: Testing the essential performance parameters of the medical equipment. This will require a range of physical, functional and electrical safety tests to confirm it is capable of performing safely and as intended by the manufacturer.

Safety Test Label: Labels attached to Medical Equipment and its associated detachable mains supply cable indicating the next test date, the service entity undertaking the test and that testing has been completed in accordance with AS/NZS3551.

6. DOCUMENTATION

Clinical Engineering – Equipment Database (ARMS)

7. AUDIT

Not Required

8. REFERENCES

a. AS/NZS 3551:2012 – Management programs for medical equipment
b. AS/NZS 3760:2010 – In-service safety inspection and testing of electrical equipment
c. Safework NSW Code of Practice – Managing electrical risks in the workplace – August 2019
d. General Retention and Disposal Authority: Patient Records (GDA17) and Administrative Records (GDA21)

9. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval / Date
Sep 2005	1	**Author:** Former NIHG Procedure revised by Manager NIHG BME in consultation with SESIH Clinical Biomedical Engineering Committee
		Approval / Date: Executive Management Committee, 27 Sep 2005
Dec 2006	2	**Author:** Changes to Section 5.6 Patients own equipment
		Approval / Date: SESIH Clinical Biomedical Engineering Committee, Dec 2006
Jul 2017	3	**Author:** Manager Clinical Engineering in consultation with the Districts Clinical Engineering Committee
		Approval / Date: Executive Director Finance and Corporate Services, Mar 2018
Feb 2021	4	**Author:** Director Clinical Engineering **Approval/Date:** Corporate Policy Recommendation committee/ March 2021 **Approval/Date:** Chief Information Officer / April 2021