INTERNAL ONLY

ISLHD POLICY
COVER SHEET

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FORMER REFERENCE(S)	ISLHD OPS PD 09 & ISLHD OPS PD 10
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Executive Director Finance and Corporate Services
AUTHOR	Manager Clinical Engineering
KEY TERMS	Biomedical, Clinical Engineering, Evaluation, Loan, Rental
FUNCTIONAL GROUP OR HUB	District Wide
NSQHS STANDARD	Standard 1 Standard 8
SUMMARY	The purpose of this policy is to regulate and control the use of biomedical equipment within ISLHD sites under an evaluation, loan or rental agreement. It applies to all clinical departments and staff.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

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

Biomedical Equipment – Evaluation, Loan or Rental Of

ISLHD CORP PD 09

1. POLICY STATEMENT

The presence of biomedical equipment at ISLHD sites that are not owned and maintained by the organisation require controls to minimise risks and ensure the safety of patients, staff and visitors. This includes equipment used in the introduction of a new clinical practice or intervention.

2. AIMS

To ensure all biomedical equipment within ISLHD facilities meets relevant regulatory, safety, Work Health Safety (WHS), Infection Control and record management requirements and to minimise any safety, financial or legal risks such equipment may pose.

3. TARGET AUDIENCE

- All ISLHD staff wishing to evaluate, loan or rent biomedical equipment
- ISLHD Clinical Engineering
- Suppliers and their service agents

4. RESPONSIBILITIES

Evaluation Criteria

All biomedical equipment undergoing evaluation with a view to purchasing must meet the following criteria:

a) NSW Health guidelines for biomedical equipment i.e. the equipment is available for supply under a current HealthShare contract or is new technology or a product group not covered by an existing HealthShare contract. Exemptions from contracts can only be obtained by applying directly to HealthShare.
b) Be compliant with the NSW Health Goods and Services Procurement Policy.
c) Be compliant with the ISLHD biomedical equipment standardisation initiative and ensure the purchase is not in conflict with other ISLHD initiatives.
d) Include a Biomedical Specialist Review as part of the SCIS or the Clinical Equipment Standard Forms.
e) Include a WHS Specialist Review as part of the SCIS or the Clinical Equipment Standard Forms.

f) Include an Infection Control Specialist Review as part of the SCIS or the Clinical Equipment Standard Forms.
g) A Regulatory Compliance Declaration where appropriate.

Equipment for Evaluation

Prior to the evaluation of biomedical equipment:

a) Staff must obtain approval from their relevant Cost Centre Manager.
b) The authorised staff member will liaise with Clinical Engineering regarding equipment suitability, timing and Supplier contact details.
c) Clinical Engineering will liaise with the Supplier through use of either the SCIS or by way of the Clinical Equipment Standard Forms (the "Forms") and provide the Supplier with a NSW Health Deed for the Evaluation of Clinical Equipment (the "Deed") for completion.
d) The Supplier having completed the necessary sections of the "Forms" and the "Deed" will present the equipment along with all Relevant Documentation to Clinical Engineering.
e) Clinical Engineering will assess the supplied equipment, the "Forms", the "Deed" and Relevant Documentation ensuring its completeness and currency and sign the "Deed" on behalf of the public health organisation.
f) Clinical Engineering at a minimum will perform a visual inspection, electrical safety test and attach a Safety Test Label to the equipment before release for clinical use.

Equipment for Loan or Rental[1]

Prior to the loan or rental of biomedical equipment:

a) Staff must obtain approval from their relevant Cost Centre Manager.
b) The authorised staff member will liaise with Clinical Engineering regarding equipment suitability, timing and Supplier contact details.
c) Clinical Engineering will liaise with the Supplier through use of a NSW Health Deed for Loan of Clinical Equipment or Deed for Rental of Clinical Equipment (the "Deed") as appropriate.

[1] **Biomedical devices such as but not limited to pressure relieving mattresses and negative pressure wound therapy devices supplied under a current HealthShare rental agreement are excluded from these responsibilities.**

d) The Supplier having completed the necessary sections of the "Deed" will present the equipment along with all Relevant Documentation to Clinical Engineering.
e) Clinical Engineering will assess the supplied equipment, the "Deed" and Relevant Documentation ensuring its completeness and currency and sign the "Deed" on behalf of the public health organisation.
f) Clinical Engineering at a minimum will perform a visual inspection, electrical safety test and attach a Safety Test Label to the equipment before release for clinical use.

Equipment for Rental under a HealthShare Rental Agreement

For biomedical devices supplied under a HealthShare rental agreement:

a) Staff must obtain approval from their relevant Cost Centre Manager.
b) The authorised staff member will liaise directly with the Supplier regarding equipment suitability, rental timing and delivery.
c) Upon delivery of the rented device a visual inspection is to be conducted by the receiving staff member to ensure:
    i. The device matches the equipment ordered.
    ii. There are no obvious signs of physical damage to either the device or its mains cord.
    iii. A Safety Test Label is attached to the device and its main cord indicating currency of testing as per AS/NZS3551.

Additional Supplier Responsibilities

For all evaluation, loan or rental biomedical equipment:

a) Safe Work practices are to be attached to, or near, the equipment.
b) An operator's manual in clear, concise English must be supplied.
c) Training of staff who may use the equipment (all shifts if deemed necessary) will be undertaken by the Supplier.
d) The equipment is labelled with
    - "Evaluation Equipment" or "Rental Equipment" or "Loan Equipment", whichever is relevant.
    - The Supplier's name.
    - The Supplier representative's name and contact phone number.
e) Long term evaluation, rental or loan requires that the Supplier undertake safety and functional testing in compliance with AS/NZS3551 and provide copies of testing reports to Clinical Engineering if requested.

5. DEFINITIONS

Acceptance Testing: a set of processes described in AS/NZS3551 which shall be performed to verify correct and safe functioning of a medical device before it may be released for clinical use.

Biomedical Equipment: any instrument, apparatus or appliance, including software, whether used alone or in combination which makes physical or electrical contact with the patient, or transfers energy from or to the patient, or detects such energy transfer to or from the patient, and is intended to diagnose, treat or monitor the patient.

Clinical Equipment Standard Forms: A document issued by NSW Health that includes forms for presentation and indemnity, specialist review, evaluation results, evaluation committee recommendations and a "Deed" for either evaluation, loan or rental of Clinical Equipment.

Recent (as in Acceptance Testing): tested immediately before delivery or tested subsequent to use in other facilities and that testing is within the period specified by the manufacturer and AS/NZS3551.

Regulatory Compliance Declaration: Certificate of device registration by the Therapeutic Goods Administration (TGA) indicating conformance to relevant Type Approval Standards such as IEC60601 or their equivalent.

Relevant Documentation: Recent Acceptance Testing results performed by the Suppliers service agent and Operators manual. Additionally for equipment undergoing evaluation this also includes a comprehensive Technical manual, WHS declaration and any other documentation or software required by the Organisation to complete the evaluation.

Safety Test Label: Labelling attached to biomedical 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.

Supplier: An individual, organisation or company, which has or wishes to enter a contract or has accepted a purchase order to supply goods or services.

Supply Chain Information System (SCIS): A central facility for the lodgement, registration, record keeping and sharing of clinical product evaluation and exemption applications. It is comprised of the Clinical Product Evaluation Registry (CPER), the Health Quality Reporting System (HQRS) and the State Contract Exemption Application (SCEA).

6. DOCUMENTATION

- Acceptance Testing results - to be retained for a period of fifteen years
- Clinical Equipment Standard Forms
- Supply Chain Information System

7. AUDIT

Not Required

8. REFERENCES

- Australian Standard, AS/NZS3551 “Technical Management Programs for Medical Devices”
- International Standard, IEC60601-1-1 “Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems”
- NSW Work Health and Safety Act 2011, Part 2, Division 3, Section 25
- NSW Health – Goods and Services Procurement Policy
- NSW – General Retention and Disposal Authority – Public Health Services: Administrative Records – GDA 21

9. REVISION & APPROVAL HISTORY

Date	Revision No.	Author and Approval
Aug 2004	0	Manager Biomedical Services. Approved by the Area Policy and Procedure Committee 26th August 2004.
Apr 2005	1	Transferred to NIHG as a service procedure.
Sep 2005	2	NIHG Procedure revised by Manager Biomedical Services NIHG. In consultation with SESIAHS Clinical/Biomedical Engineering Committee. Approved by Executive Management Committee 27 Sept 2005.
Apr 2007	3	Revised and approved by SESIH Area Clinical/Biomedical Managers Committee on 10 April 2007 to reflect new/altered policy directives within NSW Health and SESIH.
Nov 2007	4	Manager, Biomedical Engineering, Southern Hospital Network. Updated Documentation section removing Area Form F006 Indemnity Form-Loan or Rental of biomedical equipment and Area Form F007 Clinical Equipment Evaluation indemnity and replaced with NSW Health Evaluation Forms – Clinical Equipment – Complete Kit with Indemnity which is available on the Health Support.
Aug 2011	5	ISLHD Manager Clinical Engineering. Updated from SESIAHS template to ISLHD template. Updated definitions, references and hyperlinks. Minor changes to procedures wording to reflect current practice and organisational changes.
Jul 2017	6	ISLHD Manager Clinical Engineering in consultation with the Districts Clinical Engineering Committee. Merged prior policies ISLHD OPS PD 09 & ISLHD OPS PD 10. Updated hyperlinks and minor wording changes. Included visual inspection for rental and loan devices.
Mar 2018	6	Approved by Executive Director Finance and Corporate Services.