SESLHD POLICY COVER SHEET

NAME OF DOCUMENT	Biomedical Equipment – Evaluation, Loan or Rental of
TYPE OF DOCUMENT	Policy
DOCUMENT NUMBER	SESLHDPD/335
DATE OF PUBLICATION	January 2024
RISK RATING	Low
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 1 – Clinical Governance
REVIEW DATE	January 2029
FORMER REFERENCE(S)	SESLHDPR/621 - Biomedical Equipment – Evaluation, Loan or Rental of Evaluation of Biomedical equipment PD 028 Procurement, loan or rental of biomedical equipment PD 029
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	General Manager, Corporate Services
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FUNCTIONAL GROUP(S)	Biomedical Engineering
KEY TERMS	Biomedical, Clinical Engineering, Evaluation, Loan, Rental
SUMMARY	The purpose of this policy is to regulate and control the use of biomedical equipment within SESLHD sites under an evaluation, loan or rental agreement. It applies to all clinical departments and staff.

Biomedical Equipment – Evaluation, Loan or Rental of

SESLHDPD/335

1. POLICY STATEMENT

The presence of biomedical equipment at South Eastern Sydney Local Health District (SESLHD) sites that are not owned and maintained by the organisation require controls to minimise risks and ensure the safety of patients, staff and visitors. It includes equipment used in the introduction of a new clinical practice.

2. AIMS

To ensure all biomedical equipment within SESLHD facilities meets relevant regulatory, safety, WH&S, infection control and record management requirements and to minimise any safety, financial or legal risks such equipment may pose to the SESLHD.

3. TARGET AUDIENCE

- All SESLHD staff wishing to loan or rent biomedical equipment
- SESLHD Biomedical and Clinical Engineering
- Suppliers and their service agents

4. PROCEDURE

4.1 Equipment for Evaluation, Loan or Rental[1]

Prior to the evaluation, loan or rental of 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, evaluation timing and Supplier contact details.
c) Clinical Engineering will liaise with the Supplier through use of either the Supply Chain Information System (SCIS) for evaluation equipment or by way of the Clinical Equipment Standard Forms.
d) The Supplier having completed the necessary sections of either the Clinical Product Evaluation Registry of the SCIS or the Clinical Equipment Standard Forms will then present the equipment along with all Relevant Documentation to Clinical Engineering.
e) **Clinical Engineering will table at the Hospitals Product Evaluation committee, if appropriate, the equipment for review and endorsement.**
f) Clinical Engineering will assess the supplied equipment and documentation ensuring its completeness and currency and sign the “Deed” on behalf of the public health organisation.
g) Clinical Engineering at a minimum will perform an electrical safety test on the equipment and label it appropriately for release into clinical use.

For rental pressure relieving devices supplied under a state-wide NSW Health agreement:

a) Staff to initiate visual inspection

[1] **Pressure relieving devices rented under a current NSW Health state wide agreement are excluded from these responsibilities.**

4.2 Evaluation Criteria

All equipment requiring 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 NSW Health contract or is new technology or a product group not covered by an existing NSW Health contract. Exemptions from contracts can only be obtained by applying directly to NSW Health.
b) Comply with the SESLHD equipment standardisation initiative and ensure the purchase is not in conflict with other SESLHD initiatives.
c) SESLHD WH&S requirements. The evaluation process must include an WHS Specialist Review as part of the SCIS or the Clinical Equipment Standard Forms
d) SESLHD Infection Control. The evaluation process must include an Infection Control Specialist Review as part of the SCIS or the Clinical Equipment Standard Forms
e) A Regulatory Compliance Declaration

4.3 Equipment for Loan or Rental

For all loan or rental biomedical equipment:

a) Safe Work practices must 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
    - "Rental Equipment" or "Loan Equipment"
    - The Supplier's name
    - The Supplier representative's name and contact phone number
e) Long term rental or loan requires that the Supplier undertake safety and functional testing in compliance with AS/NZS3551.

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 Australian Type Approval Standards or their equivalent.

Relevant Documentation: Regulatory Compliance declaration, Recent Acceptance Testing results performed by the Suppliers service agent, Service manual, Operators manual, Occupational Health and Safety declaration and a signed NSW Health Deed.

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 Systems (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 Evaluation form
- Supply Chain Information Systems

7. REFERENCES

- Australian Standard, AS/NZS3551 “Technical Management Programs for Medical Devices”
- Australian Standard, AS/NZS3200.1 “Approval and Test Specification – Medical Electrical Equipment”
- https://www.legislation.gov.au/Details/C2022C00082
- State Records NSW, General Retention and Disposal Authority – Public Health Services: Administrative Records GDA21

8. VERSION & APPROVAL HISTORY

Date	Version No.	Author and approval notes
May 2018	1	PD 028 – Evaluation of Biomedical Equipment and PD 029 – Procurement, loan or rental of biomedical equipment – combined to new procedure and updated - Approved by DCEC.
July 2018	1	Major Review – Draft for Comment Endorsed by Executive Sponsor
August 2018	1	Endorsed by Executive Council.
April 2020	1	Executive Sponsor updated.
30 January 2024	1.1	Minor review. Changed from procedure SESLHDPR/621 to policy template. Updated links and minor grammatical corrections.