C9 BIOMEDICAL ENGINEERING

C9.1 SERVICE DESCRIPTION

C9.1.1 Scope of Services

Biomedical Engineering will provide a "full-service" range of biomedical engineering services to the Hospital and the Cancer Centre. Biomedical Engineering will manage all service related to medical devices and medical device systems, excluding major radiation therapy equipment which will be maintained by Clinical Physics staff and all equipment managed by Plant Services, as described in Section E8.

Services to be performed within the component consist of two main elements as follows:

- Medical Technology Management
- Quality Monitoring

Medical Technology Management consists of:

- Inspection on all incoming medical devices to assure proper performance and compliance with pertinent Service Standards and regulations, as well as appropriate interface with the Health Authorities Information Systems.

- Perform an acceptance test on all medical devices before use. This inspection and acceptance testing verifies performance of these devices as per manufacturers' specifications. This includes, but is not limited to, the following areas:

  - Electrical safety
  - CSA standards
  - Radiation protection standards
  - Anaesthesia gas standards
  - Operational specifications
  - Operational manuals
  - Service manuals
  - Accessories
  - Verification of all details of purchase orders (i.e., features as ordered)
  - Health Authorities IS standards (e.g., Dicom, HL7, etc.)

- Install and/or manage the installation of all medical devices and medical device systems in accordance with Health Authorities and manufacturers recommendations. All installations and management of medical devices will be undertaken in a cost effective manner

- Provide a technology assessment and evaluation service on all medical devices, as required under Applicable Law and Health Authority Policies. Includes participating in planning for new technologies, assessment of technology being considered for acquisitions, participating with the specification preparation for new technology for the RFP process (or as required for ongoing needs), and capital planning for the replacement of technology. Provide facility planning consultation services for incorporation of new technologies with regards to installation/renovation requirements.

- All medical devices are maintained in accordance with the manufacturer's recommendations and that all equipment in each room/area is available for its intended use.

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- Investigate and log all actions taken with regard to all Events/unusual occurrences and hazard alerts/recall notices involving Medical Devices. An organized process is used to manage all notifications, alerts, etc. This information is available to staff via a database.

- Tracking all vendor services and contracts for technology support. All services history, modifications, updates, either hardware or software are tracked utilizing a medical technology database which interfaces with the Health Authorities databases.

- Training of staff on all new technologies or initial technology installations and the basis for ongoing management, as well as interface with vendors for all relevant education activities they may provide.

- Maintaining a risk management program with respect to patient safety and medical device hazards. This shall include, but not be limited to:

  - Recalls
  - Incidence reporting and follow-up, alerts, notifications, modifications, upgrades (hardware and software)
  - Internal notification to users of all risk issues, maintenance of a database of all risk Information
  - Suggesting changes/additions to the medical devices inventories and providing any supporting documentation in regards to such suggested changes/additions.
  - Participation of other safety programs such as:
    - radiation protection program
    - trace gas analysis for OR/recovery areas
    - electrical safety in clinical areas

Quality Monitoring consists of:

- Development, maintenance, and implementation of a system for recording and acting on customer feedback and satisfaction with respect to the Biomedical Engineering Services, including the conduct of a customer user satisfaction survey/questionnaire.

C9.1.1.1 *Current Trends*

- *Medical devices and medical device systems in general are becoming more computer software driven.*

- *Past individual medical devices and medical device systems are being integrated into multiple function devices.*

- *Equipment continues to become more sophisticated and complex.*

C9.1.2 Scope of Education Services

The Health Authorities participate in the BCIT Biomedical Technology apprenticeship and mentoring program, which may involve two to three students at a time over several weeks.

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C9.1.3 Scope of Research Services

Any research taking place within this component in the future will be accommodated within the service space provided.

C9.1.4 Specific Exclusions

This specification excludes biomedical engineering services/requirements provided elsewhere, including:

- Radiation therapy equipment, which is serviced either by an outside service contract, or by in-house Clinical Physics staff [see section A1(h)].

C9.2 OPERATIONAL DESCRIPTION

C9.2.1 Minimum Hours of Operation

Hours of operation for the component are as follows:

- Monday to Friday 07:30 – 16:30. After hours: on call.

C9.2.2 Patient Management Processes

Not Applicable

C9.2.3 Patient Information Management

Not Applicable

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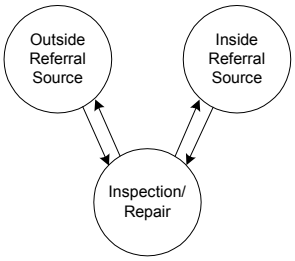
C9.2.4 Staff Work Processes

C9.2.4.1 Zoning
The component will be organized in 2 main zones:

- Service area
- Office/technologists work area

C9.2.4.2 Service Area
This area will serve as the main equipment receiving and staging area as well a location for larger repairs and cleaning. Equipment may be received from the main hospital loading dock in Materiel Services or from any area within the Facility. The room will be equipped with a floor drain, fume hood and have access to the parts storage room. An entrance, large enough to accommodate the passage of large equipment, is required from both the main hallway and into the Office/Workroom Area.



Process Flow Diagram

C9.2.4.3 Office/Workroom Area
Equipment will arrive directly from the Service Area. In this area technologists perform general repair, acceptance testing, calibration and preventative maintenance services on portable equipment. They require convenient and sufficient access to both electrical and data outlets at the workbench. This area must have direct access to the Service Area.

C9.2.5 Materiel Services

Refer to Output Specifications, Section 4: Facility Management Services, subsection E7 Materiel Services, and Section 2: Clinical Services, subsection C8 Sterile Processing Services.

C9.2.6 Linen/Housekeeping Services

Refer to Output Specifications, Section 4: Facility Management Services, subsections E5 Housekeeping Services and E6 Laundry/Linen Services.

C9.2.7 Equipment Asset Management

The Health Authorities biomedical engineering program uses a regional database to identify all medical devices and track purchase dates, service histories, modifications, and service contracts.

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C9.3 ACTIVITY INDICATOR

C9.3.1 Hospital Activity

Unit	Minimum Projected Yearly Activity
Medical Imaging	
X-Ray (exams)	54,500
Nuclear Medicine (exams)	9,000
Laboratory (units)	5,500,000
Renal Dialysis Chairs	15
ECG (exams)	27,100
Vascular Stress Tests	2,200
EEG (tests)	1,500
Inpatient Days	96,122
Inpatient Beds	300
Surgical Cases	14,000

	Work Order Count	Hours	%
Administration	24	2,056	11%
Education	98	987	5%
Acceptance/Incoming	443	1,127	6%
Projects	75	1,400	7%
Repair	2,540	8,234	42%
Risk Management	45	256	1%
Scheduled Maintenance	2,282	4,428	23%
Technology Assessment	98	689	4%
Vendor Service Management	24	234	1%

C9.3.2 Cancer Centre Activity

Biomedical Engineering will manage all service related to medical devices and medical device systems, excluding major radiation therapy equipment which will be maintained by Clinical Physics.

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C9.4 PEOPLE REQUIREMENTS

This component will have a total staff complement in the range of 9 FTE, consisting of 7 biomedical technologists, 1 manager, and 1 clerk.

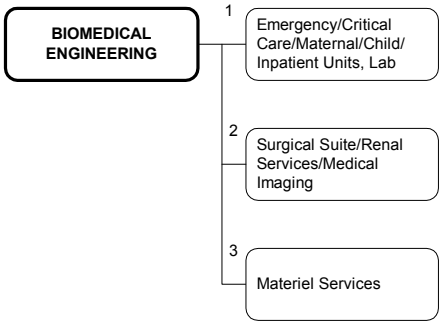
It is anticipated that the key functional areas in the component will need to accommodate the following maximum number of people.

Functional Areas	Patients	Staff	Visitors	Others	Total
Lab/Office Area	-	8-10	1-2	-	9-12
Service Area	-	8-10	1-2	-	9-12

C9.5 DESIGN CRITERIA

C9.5.1 Key External Relationships

The following key relationships will be achieved in the priority order as numbered for the purposes stated:



1 Provide <u>direct</u> access by <u>general</u> circulation to the Emergency/Critical Care/Maternal/Child/Inpatient Units and Laboratory) for movement of staff and equipment on an immediate basis.

2 Provide <u>convenient</u> access by <u>general</u> circulation to the Satellite Biomedical Engineering Workshops in the Surgical Suite, Renal Services, and Medical Imaging for staff movement.

3 Provide <u>convenient</u> access by <u>general</u> circulation to Materiel Services (Receiving dock area) for the movement of staff and equipment

C9.5.2 Key Internal Relationships/ Environmental Considerations

The following will be achieved:

C9.5.2.1 <u>Finishes and Floors</u>
Must provide durable finishes for moving equipment.

C9.5.2.2 <u>Work Benches</u>
Access to data and electrical outlets and durable for repairing equipment, tools and chemicals.

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C9.5.2.3 Doorways, Hallways, Traffic Patterns
Must accommodate efficient and safe movement of large equipment.

C9.5.2.4 Lighting
Provide task lighting at all workstations to facilitate precision work. WCB guidelines or similar will apply.

C9.5.2.5 Flexibility
Provide flexibility to add 1 or 2 workstations in the future.

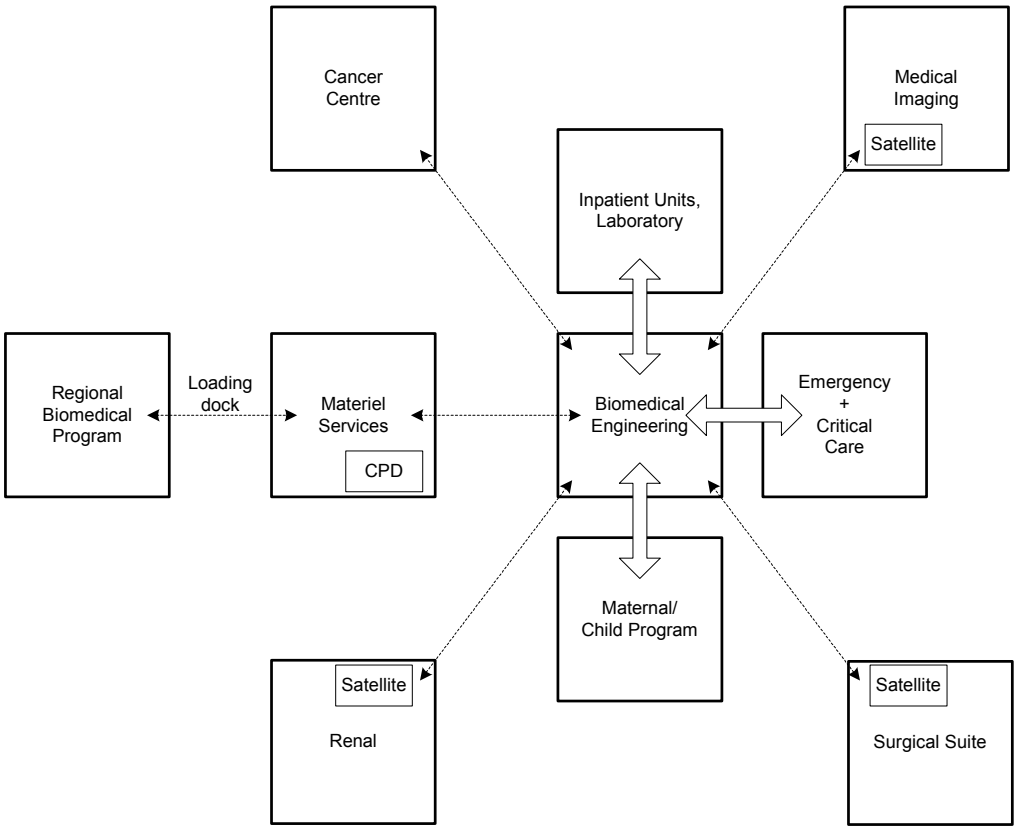
C9.5.2.6 Piped Gases and Electrical Strip
Provide piped gases and continuous electrical strip to all workstations (compressed air, medical air, oxygen and vacuum).

C9.5.2.7 Ventilation
Provide at least one fume hood at a selected workstation.

C9.5.2.8 Floor Drain
Provide a floor drain in the wet area.

C9.5.2.9 Component Functional Diagrams
The spatial organization of this component will be generally as shown in the diagram below.

Macro Relationship Diagram



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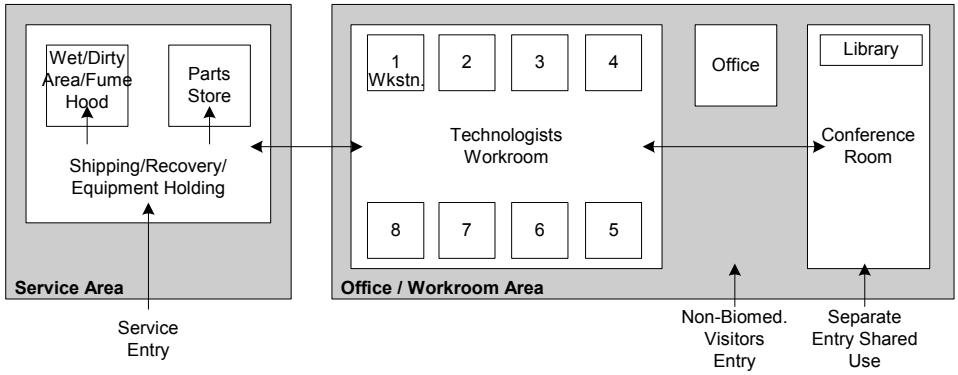
Micro Relationship Diagram



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C9.5.3 Schedule of Accommodation *(Note: Spaces listed in parentheses ( ) are spaces supporting services provided by Project Co and are included in the total net square metres.)*

Ref	Space	Area Requirements units	nsm/unit	Nsm
	Office/Workroom Area			
01	Office, Manager	1		9.0
02	Conference Room	1		15.0
03	Workroom, Technologists	1		75.0
	Subtotal			84.0
	Service Area			
04	Shipping/Receiving/Equipment Holding Room	1		15.0
05	Wet/Dirty Area	1		8.0
06	Parts Storage Area	1		20.0
	Subtotal			58.0
	Total			**142.0**

C9.6 DESIGN GUIDANCE

Project Co is referred to:

- Occupational Health & Safety Act
- NCCSL Design Guidelines, latest edition (for fume hood requirements)

C9.7 OTHER SPECIFICATIONS

Biomedical engineering services are primarily based in the Biomedical Engineering component, however, other specifications that will be consulted are:

Not Applicable.