MEDECINS SANS FRONTIERES
ÄRZTE OHNE GRENZEN

MSF-OCG BIOMEDICAL EQUIPMENT POLICY

MSF Section	**MSF-OCG, all missions**		
Policy title	Biomedical Equipment Policy – V1.1		
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Context

Technological developments have lead to a rapid increase in the availability of biomedical equipment which can support MSF's activities. The equipment often requires specialised knowledge to select, install, use and maintain. This places additional demands on infrastructure and HR, both in the field and at headquarters.

- Biomedical equipment directly affects the health and safety of both patients and staff. We must ensure that appropriate standards of safety and functioning are maintained.
- This equipment often becomes an essential part of MSF's operational activities and we must ensure continuity and quality of service.
- The cost of the equipment often represents a large investment, in some cases a significant part of a mission budget.

Biomedical equipment within MSF-OCG is a shared responsibility between the medical and logistics departments. The medical department has the role of prescriber and user. The logistics department has the role of supplier, installer, and maintainer. See also Annex I: Division of responsibilities (log/med validated in 2010).

Because biomedical equipment directly affects the health of patients this policy shall also be guided by the related documents on procurement, supply and donation of drugs and medical supplies.

Objective of the policy

The purpose of this policy is to establish the principles to be followed in order to ensure that all biomedical equipment used in MSF-OCG missions is suited to the activities and context and provides continued, high quality support for medical activities.

Scope of the policy

This policy applies to all biomedical equipment, owned or supported by MSF, in all MSF-OCG missions.

Definition of terms

Biomedical equipment	All equipment with a medical or laboratory related application (diagnosis or treatment) which requires an energy source (AC, battery, or mechanical), and requires preventative maintenance or periodic (re)certification.
Consumables	Items requiring periodic replacement (e.g. air filters, batteries etc).
Spares	Components which need to be replaced only in the event of a breakdown.
Preventative maintenance	Work which is carried out regularly to ensure continued functioning. This includes cleaning and exchange of consumables (medical responsibility) and additional periodic checks (logistics responsibility).
Corrective maintenance	Work which is carried out in order to repair an item of equipment which has malfunctioned. This is a logistic responsibility.
Country Specific Policy (**CSP**)	The CSP is a document written specifically for a mission which defines the overall policy as applied in the mission.

Related documents

(a) MSF-OCG Procedure for Selection & Procurement of Biomedical Equipment for missions
(b) MSF-OCG Procedure for Validation of Biomedical Equipment owned by others
(c) MSF-OCG Procedure for Biomedical Equipment Donations
(d) MSF-OCG Process of Innovation
(e) MSF Policy for the procurement of medical products (Jacques Pinel & Myriam Henkens, 22-05-2000)
(f) Supply of drugs and medical supplies, and management of pharmacies (MSF Internal Guidelines)

Content of the policy

1. Country Specific Policy *(CSP)*

1.1. The CSP - which clarifies aspects specific to the context - shall be drafted by the CoTL according to the template provided (see Annex II), submitted to HQ for validation, and then distributed to all staff. It shall be implemented by the CoTL, reviewed annually and updated when necessary.
1.2. A CSP may never contradict any aspect of the overall MSF-OCG Policy.
1.3. The CSP shall include all details of the equipment management at mission and project level.

2. Selection and procurement of equipment

2.1. Selection and procurement of biomedical equipment, spares and consumables shall be in accordance with the "MSF-OCG Procedure for the Selection & Procurement of Biomedical Equipment"
2.2. Biomedical equipment, spares and consumables shall normally be procured through MSF-OCG international supply channels and selected from the MSF-ITC catalogue according to the stated specification and justification requirements.
2.3. In exceptional cases it is permitted to procure through alternative channels, or select alternative equipment. In these cases HQ validation, compliance with the catalogue specification and justification requirements is still mandatory. The supplier shall be required to guarantee supply of spares and consumables, and provide a full support package.

3. Infrastructure and other investment requirements

3.1. Energy sources and systems shall be suitable for the equipment needs (power, voltage, stability, availability, protection, back-up, safety etc).
3.2. IT systems shall support effective use of equipment fitted with digital interface(s), and provide sufficient security for the data generated (data storage, back-ups, reliable accessibility, display quality of images etc).
3.3. The structure in which the equipment will be used shall be suited to the needs of the equipment and ensure the safety of patients and staff. This includes (but is not limited to) adequate foundation, protection from the elements, ventilation, protection of the surroundings from the equipment (e.g. x-rays) etc.
3.4. Sufficient resources (financial and HR) shall be reserved for both the initial investment and correct use and maintenance, to ensure quality of service and availability in accordance with the requirements of this policy.

4. Management of equipment

4.1. Division of responsibilities: Each project shall define one member of logistics staff with overall maintenance responsibility. They shall be the focal point for management of biomedical equipment. For each piece of equipment the responsibility of care shall be assigned to one member of medical staff. See also Annex I: Division of responsibilities.
4.2. All items of biomedical equipment shall be entered in the inventory and these records shall be updated to reflect status changes (location of use, spare stock, broken etc.).
4.3. Sufficient space and tools shall be allocated for servicing and administration in accordance with the requirements of this policy and the support documents.
4.4. Maintenance schedules (cleaning and preventative maintenance) shall be created for each project/facility and shall include all biomedical equipment. For each item of equipment the schedules will indicate the activity, the frequency, and the staff involved.
4.5. Preventative and corrective maintenance shall be carried out in accordance with the requirements defined in the support documents. The emphasis shall be on cleaning and preventative maintenance to avoid the need for corrective maintenance.
4.6. Any member of staff using an item of biomedical equipment shall be trained in correct and responsible use, hygiene, and care of the equipment.

4.7. Equipment which is not functioning correctly shall be removed from active use until it has been successfully repaired. Repair shall be done in accordance with the advice in the support documents or technical referent. Depending on the skills and experience available, repair work in the project, the capital, or return to the supplier for repair. If equipment is not repairable it shall be disposed of correctly, in accordance with the advice in the support documents.

5. Support of equipment belonging to others

5.1. Biomedical equipment not owned by MSF but foreseen to be used as part of a collaborative project shall be validated in accordance with the "MSF-OCG Procedure for Validation of Biomedical Equipment owned by others", in order to ensure suitability and availability of support.
5.2. A list of the equipment, and a clear definition of the agreements for its support and management, shall be included in the Memorandum of Understanding (MoU) with the project partner.
5.3. The equipment shall be integrated into the system of management for MSF's own biomedical equipment for the associated project. The requirements are the same as for MSF owned equipment (see item 4) except that a separate inventory shall be created for items owned by others.
5.4. If the existing equipment does not meet the validation criteria it should be replaced with MSF standard equipment according to the procedures for selection of new equipment (see item 2).

6. Receipt of donations

6.1. Donations will only be accepted if the equipment is in line with operational strategy, meets medical needs, is appropriate for the situation in which it will be used, and MSF is able to ensure continued service.
6.2. Prior to acceptance of donations validation is mandatory, in accordance with the "MSF-OCG Procedure for Biomedical Equipment Donations".
6.3. If the offered equipment does not meet the validation criteria but there is a confirmed medical need then MSF standard equipment shall be requested in accordance with the procedure for selection of biomedical equipment.

7. Donation of equipment to others

7.1. Equipment shall not be donated if MSF-OCG still intends to use and support it.
7.2. Equipment which MSF-OCG intends to donate without further support should only be donated if the recipient is able to use and maintain the equipment correctly.
7.3. The act of donation should be handled in accordance with the "MSF-OCG Procedure for Biomedical Equipment Donations".

8. Support materials, HR, training, standardisation and innovation

8.1. In its HR management MSF-OCG shall favour the maintaining and animation of a pool of biomed specialists (internal or external).
8.2. The support departments shall continue to develop and update procedures, technical guides and other information in support of field staff involved with biomedical equipment.
8.3. MSF-OCG shall continue to develop training materials and investigate external training options which comply with MSF-OCG policy and strategy.
8.4. Through participation in international working groups and platforms MSF-OCG will contribute to the development of standards in biomedical equipment which answer to operational needs.
8.5. All involved parties are encouraged to seek new innovations which could answer to field needs, identified or anticipated. When innovation offers a clear benefit it shall be evaluated, developed, and adopted in accordance with the document "MSF-OCG Process of Innovation".

ANNEX I : DIVISION OF RESPONSIBILITIES FOR BIOMEDICAL EQUIPMENT

<table>
<tr><th colspan="4">SELECTION & PURCHASE OF EQUIPMENT</th><th>BEFORE 1st USE</th><th>DURING USE</th><th>IN CASE OF PROBLEMS</th></tr>
<tr><td>Identify medical need</td><td rowspan="2">Discussion on possible solutions, paying attention to the requirements for:
- Energy/water needs.
- Structures/buildings.
- Staff (use and maintenance).
- Maintenance & spare parts.
- External service contracts.
- Budget (purchase, spares and servicing).
- Backup/Contingency alternatives.

Selected equipment must meet:
- Medical needs.
- Requirements for ensured continuity and quality of service.
- MSF Tech Standard and justification requirements (catalogue).

Deviation from MSF standard may require external service contracts and full spares & consumables supply package.</td><td>Order the equipment and a first supply of consumables and spare parts.</td><td></td><td rowspan="2">Define and put in place procedures for:
- Staff Responsibilities.
- Procedures for use.
- Procedures for cleaning.
- Procedures for maintenance.
- Back-up/Contingency plan.
(See support documents)

Conduct staff training.

Integrate equipment into Country Specific Biomed Policy</td><td>Perform cleaning and maintenance in accordance with the agreed procedures.
(See support documents)

Manage ordering of consumables and stock at health structure pharmacy level</td><td>Indentify the problem and provide LOG (as timely as possible) with:
- Full description
- Indication of urgency (depending on back-up options)</td></tr>
<tr><td></td><td>Follow the order through the supply system and give feedback on delivery to MED.

Prepare the project for use of the new equipment (i.e. energy, room/building layout, staff training, etc.)</td><td>Take delivery of the material and manage its installation.

Enter equipment in inventory.

If needed organise service contracts for preventive maintenance and ASS (after sales service)</td><td>Perform preventive and corrective maintenance in accordance with the agreed procedures.
(See support documents)

Manage ordering and stock of spare parts and stock of consumables at central stock level.

Ensure inventories are kept updated to reflect any changes in equipment (and status).</td><td>Assess problem and propose solution.
Pay attention to:
- Priority (depending on back-up options)
- Quality of repair (this is life-saving equipment!)

See support documents for details of:
- Repair procedures.
- Which medical equipment can be repaired in the field (and by whom), and which equipment should be returned to MSF-Logistique or supplier for repair.

Follow OCG/MSF-L procedures for return.</td></tr>
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Medical responsibility
Logistics responsibility
Joint responsibility, medical & logistics