

REPUBLIC OF RWANDA



MINISTRY OF HEALTH

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GUIDELINES FOR HEALTH CARE EQUIPMENT DONATIONS

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BACKGROUND

Rwanda has seen impressive economic growth which has resulted in various gains across the health sector. However, the healthcare needs of the population have been changing over time, and an increase in healthcare equipment is needed. The majority of this equipment are purchased, but a portion of this equipment is donated. Although donations of healthcare equipment may help to improve the efficiency of health facilities, instances exist where healthcare equipment donations cause more problems than benefits. For example, some donated equipment arrives with no installation or service manuals and limited availability of spare parts. Further, in some cases, the donated healthcare equipment is no longer useful. Recognizing that not all healthcare equipment donations benefit the healthcare system, the Ministry of Health (MoH) is developing guidelines to define the requirements of healthcare equipment donations to Government institutions and private health facilities. Through these guidelines, the MoH is aiming to improve the healthcare equipment donation process for both donors and recipients to ensure that all donated equipment achieves its intended objective within the healthcare system.

PURPOSE AND SCOPE

The purpose of these guidelines is to streamline the process for managing healthcare equipment donations to improve healthcare services provided to the population of Rwanda. These guidelines are intended to be used by both the donor and recipient of the healthcare equipment donation. Further, these guidelines apply to both in-country (e.g. one health facility donating equipment to another health facility) and out-of-country healthcare equipment donations.

The MoH through Rwanda Biomedical Center (RBC) is responsible for managing medical technology and infrastructure, including management of all donations related to healthcare equipment in Rwanda.

Any donation whether initiated by the MoH, health facility (private or public) or any other third party should be coordinated by the MoH to ensure all policies and guidelines are followed.

ACRONYMS

CE European Conformity
FDA Food and Drug Administration
MoH Ministry of Health
RBC Rwanda Biomedical Center



DEFINITIONS

Donation: A gift given by physical or legal persons, typically for charitable purposes and/or to benefit a cause. A donation may take various forms, including services and new or used goods.

Recipient: A beneficiary of the donated healthcare equipment. Recipient can be a public or private health facility or any third party who will receive a donated healthcare equipment.

Donor: A person, organization, or government who donates healthcare equipment in kind or monetary terms.

Healthcare equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers and end users. Healthcare equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Healthcare equipment excludes implantable, disposable or single-use medical devices.

Stakeholder: Any third party who supports or is consulted during the process of acquiring healthcare medical equipment donation.

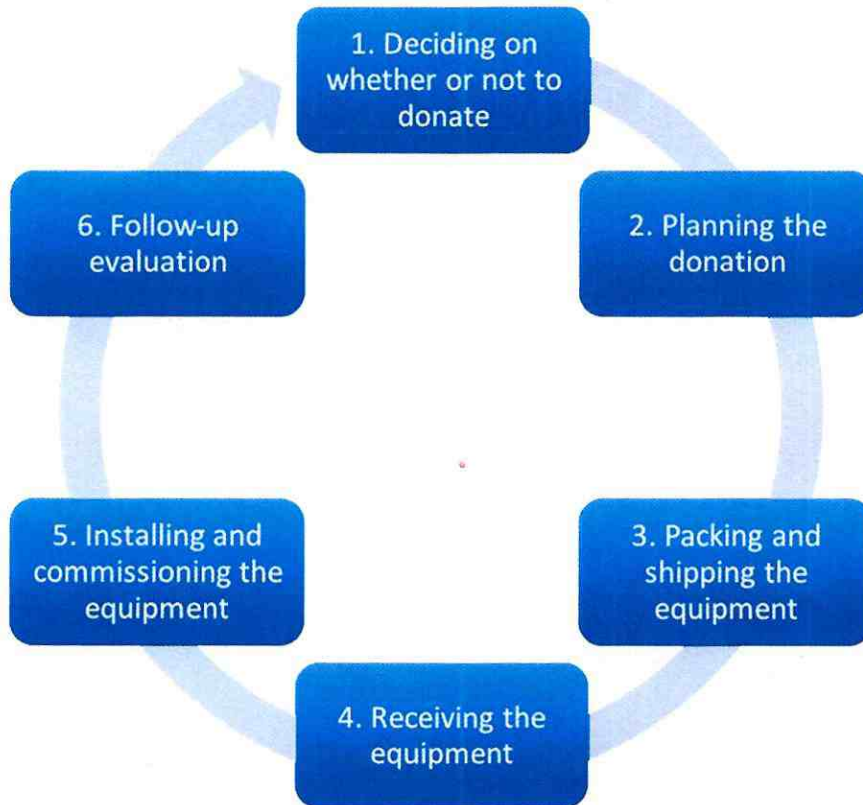
Complex Healthcare Equipment: Healthcare equipment that requires specific expertise for quality and safety controls.

Reception Team: A specific team appointed by competent authority to receive the donated healthcare equipment.



Cycle for Health Care Equipment Donation

These guidelines address the following key steps within the donation process:



1. *Deciding whether or not to donate*

The donation process can be initiated by a donor, recipient, or third party. Donations can be in the form of healthcare equipment or a financial donation, which the MoH can use to purchase the healthcare equipment. A financial donation is preferable, as it enables the MoH to ensure that the healthcare equipment is of high quality and has maintenance support, spare parts and consumables, and after sale services. Further, the MoH can also ensure availability of training on proper use of the healthcare equipment and harmonization and sustainability with existing equipment.

When deciding whether or not to receive a donation, the recipient and the donor shall ensure the following criteria are met:

- a. The healthcare equipment responds to an identified need, which can be based on the institutional experience or data collected from healthcare facilities.
- b. The healthcare equipment is appropriate to the setting of the health facility (i.e. climatic and environmental conditions and adequate infrastructure).
- c. The healthcare equipment meets existing safety and performance specifications provided by the manufacturer and promulgated by international bodies, such as European Conformity (CE) or the Food and Drug Administration (FDA).
- d. The healthcare equipment is affordable and cost-effective, including operation and maintenance costs in terms of spare parts and consumables.



- e. The healthcare equipment is user-friendly with updated and upgradeable software in one of the official languages.
- f. The equipment has a sufficient remaining life span (at least seventy percent or 70% of the life span provided by equipment manufacturer).
- g. The healthcare equipment conforms to the recipient's policies, plans and guidelines.
- h. The healthcare equipment can be affordably and safely disposed of in accordance to the national policies and guidelines.
- i. The decontamination of healthcare equipment is easily performed by end users with affordable and accessible cleaning supplies for infection control.
- j. The healthcare equipment can be maintained locally (i.e. the availability of human resources with the needed expertise).
- k. The healthcare equipment has adequate aftercare support to ensure the sustainability of the donated equipment.

All donations have to follow the above criteria. The recipient should not feel obliged to accept a donation that does not fulfil the above prescribed requirements.

Further, additional caution should be taken when considering donations of complex equipment requiring specialized training to operate and maintain, a strong supply chain for consumables, and significant changes to infrastructure for proper functioning of the equipment.

Recipient Specific Responsibilities

The following are recipient specific responsibilities, depending on the nature of the healthcare equipment:

- Conduct needs assessment of existing healthcare equipment to identify gaps to respond to the national policies and strategies.
- Ensure appropriateness of equipment in terms of health facility level, running costs, technical design and technology (affordable cost, low energy consumption, standardized with other equipment, simplicity of operation, minimal number of accessories required, and availability of necessary operating supplies, particularly disposable).
- Provide comprehensive specifications for needed equipment.
- Conduct a critical assessment of the healthcare equipment to ensure quality and safety and local and international standards and requirements are met.
- Ensure that all resources needed are available at the health facility, including needed expertise to operate and maintain the equipment.
- Ensure the costs of transport to the health facility, custom duties, and any other charges associated with importation are fully funded either by the donor or the recipient.
- Ensure the following requirements are met for proper use of the healthcare equipment: installation location, safety requirements (such as shielding), accessibility, floor loading capacity, space and electrical power (voltage, frequency, phase, and dissipation), needed water volume and pressure (and drainage), and environmental conditions.
- If pre-installation work is required, the recipient should state when the work will be completed.

Note: All healthcare facilities have to request the approval of the MoH before starting any negotiation related to healthcare equipment donation.



Donor Specific Responsibilities

The following are donor specific responsibilities, depending on the context of the healthcare equipment and at the discretion of the Ministry of Health:

- When the donation process is initiated by the donor, a letter of intent must be submitted to the MoH to ensure healthcare equipment specifications conform with the MoH equipment guidelines.
- When the donation process is initiated by the recipient, the donor must receive the official request for the donation from the MoH.
- Conduct assessment visit to the recipient facility prior to the donation.
- Ensure the healthcare equipment is fully operational at the system and sub-system levels. Used equipment should be fully rebuilt or reconditioned.
- Ensure that the healthcare equipment complies with the technical specifications provided by the recipient.
- Ensure availability of a full set of technical and manual documents (installation, operation, maintenance and repair manuals) in at least one of the official languages.
- Provide a list of and supply sufficient consumables and spare parts to last one year at a minimum.
- Provide details for manufacturers or authorized dealers to source spare parts and consumables.
- Ensure commitment from manufacturer to provide technical support to the recipient, including troubleshooting, repair and maintenance assistance.
- Specify when the healthcare equipment was originally purchased, at what cost, its expected life span and for how long it has been in operation.
- Provide all shipping documents in advance (packing list, a clear statement that the equipment is being donated, certificate of decontamination from qualified staff, quality assurance test details, etc.).
- Provide a document of warranty (guarantee) for the replacement or repair of faulty equipment, if new.
- Ensure proper packaging of the equipment to minimize damage during transportation.
- Specify the following requirements for proper use of the equipment: installation location, installation, operation, maintenance, safety requirements (such as shielding), accessibility, floor loading capacity, space and electrical power (voltage, frequency, phase, and dissipation), water volume and pressure (and drainage) needed and environmental conditions.
- Provide competent and qualified engineer to install and commission equipment.
- Define staff and training requirements for users and technicians.
- Support needed maintenance of the healthcare equipment for at least one year.
- Conduct evaluation visit to the recipient facility after the donation depending on the context of the healthcare equipment.

Responsibilities are subject to change based on agreement from both the donor and the recipient.

2. Planning the donation

When the donor and recipient are confident that they have the resources required to meet the above requirements, they can begin to plan the donation together.



At this stage,

- The recipient should have completed the needs assessment and developed the technical specifications of the needed healthcare equipment.
- The recipient and donor should have had a clear and honest discussion about what they are able to contribute. All communications between the donor and recipient should be recorded during this process.
- The donor and the recipient must develop a clear agreement that outlines the terms of the donation, including the costs and risks incurred by both stakeholders. If the partnership has an active agreement in place, the recommended content for the new donation could also be prepared as an addendum to the agreement, particularly if the agreement already covers some aspects of healthcare equipment donation.
- The signed agreement must clarify and include a project plan including activities and tasks, required resources, outputs, responsible stakeholders, conditions, timelines and how the healthcare equipment will be supplied, including involving local vendors where applicable.

Why should local vendors should be involved when possible?

- When local markets for healthcare equipment are ignored or bypassed, it is likely that the required after-sales support for service, parts, and consumables may not be adequately available.
- Consulting and involving local vendors will help to establish beneficial and sustainable relationships between the users and the vendors of equipment and build the local technical capacity.
- Purchasing locally will help boost the Rwandan economy.

3. Packing and shipping the healthcare equipment

The donor should ensure the proper packaging of the healthcare equipment, as the equipment is likely to be in long periods of transit. Therefore, the packaging must be strong and sturdy to withstand rough handling and to minimize damage during transportation. The equipment packaging should include:

- A clear packing list identifying all components, indicating the contents of each numbered carton by quantity, serial number, weight, and any special storage conditions.
- All essential shipping documents (should be sent by express, insured mail and if possible, faxed or emailed in advance).
- Installation, operation, maintenance and repair manuals, if available.
- Procedures or recommendations for periodic inspection, maintenance, and calibration to ensure that the equipment is maintained in a safe and effective operating condition.

Further, special care in packaging should be taken for the following cases:

- Healthcare equipment that may contaminate should be properly packaged, shipped, and accompanied by the certificate of decontamination.
- Radioactive sources should be removed and properly packaged in special shipment containers (with radioactive marking on outside).
- Fragile healthcare equipment should be packaged with great care and with markings on outer packaging.



- For surface shipments, appropriate packaging is necessary to protect equipment from exposure.

4. *Receiving the equipment*

Depending on the agreement, the recipient should support the donor to clear the healthcare equipment through customs.

When the recipient receives the equipment, either at customs or recipient premises, the recipient should conduct the following inspections:

- *Customs inspection:* at customs, the reception team should inspect all containers and contents for damage and should verify that the contents are intact and nothing is missing. Any irregularity should be communicated immediately to the donor and shipment company.
- *Health facility inspection:* upon arrival at the health facility, the reception team checks if all the required documents to receive the healthcare equipment are supplied and ensure that the equipment meets all the technical specifications agreed on in advance. If the equipment is technically complex, the recipient should ensure that the unpacking and verification are done by a technically competent and knowledgeable person to reduce the risk of damage.

If the healthcare equipment does not pass the inspection stages, the recipient should inform the donor of the issue for resolution. If the donor cannot find a solution, the recipient has the right to reject the donation, and the donor will bear all the costs related to the return or disposal within an agreed timeline based on the agreement.

The transportation cost of the equipment within the country will be covered either by the donor or recipient depending on the agreement.

5. *Installing and commissioning the donated healthcare equipment*

The donation agreement signed between the two parties should state the responsibilities of each party, including installation and commissioning of the healthcare equipment. This work should be done by a competent and qualified engineer according to the instructions from the manufacturer. Commissioning includes verification of proper and safe operation, which must be performed prior to clinical use.

Once the equipment is installed, the recipient should implement a program of periodic inspection, maintenance, and calibration to ensure that the equipment is maintained in a safe and effective operating condition for its remaining life span.

To ensure the equipment is used in the most effective way, the donor is required to train the end users and engineers on how the equipment should be properly used and maintained according to manufacturer instructions and based on the terms of agreement.

Final acceptance should be confirmed by the recipient to the donor once the equipment is installed and fully functioning.



6. Follow-up Evaluation

The mere supply of equipment does not guarantee a positive impact on healthcare delivery and health outcomes. Following the installation and commissioning of the equipment, the donor and the recipient should assess the level of operational success or failure of the equipment donated. This assessment fosters communication between the donor and recipient, encourages the continued support of the donor, and encourages both parties to learn and improve from previous experience.

The following success indicators for the follow up evaluation should be defined in the agreement between the donor and the recipient and based on the context of the equipment:

- Functionality of equipment
- Ability of end users to properly operate equipment
- Ability of engineers or technicians to properly maintain and fix equipment
- Availability of spare parts and consumables

Further, it is critical for the timing of the follow up evaluation to be defined in the agreement between the donor and the recipient.

Amendment of these guidelines

These guidelines may be amended from time to time in whole or in part where deemed necessary.

Commencement of the guidelines

These guidelines come into force on the day of Signature.

Done at Kigali **14 JUL 2017**/2017


Dr. Diane GASHUMBA

Minister of Health

