American College of Clinical Engineering

GUIDELINES

FOR

MEDICAL EQUIPMENT DONATION

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American College of Clinical Engineering

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ACCE GUIDELINES FOR MEDICAL EQUIPMENT DONATION

1. INTRODUCTION

Used medical equipment has been donated from developed countries to less developed ones for decades. This recycling of goods accomplishes several important objectives. In developed countries it helps to reduce waste and landfills, as well as increase the rate of introduction of new technologies. In developing countries physicians gain quicker access to sophisticated technologies and, most important of all, less privileged patients gain wider access to better health care.

Unfortunately not all donations achieve their goals. Much donated equipment is not or cannot be used by the recipients. No reliable data is yet available, but it is believed that as much as one third of all donations do not achieve their eventual goals, wasting precious time and resources. Many factors contribute to this reality. Some donors are so anxious to get rid of their unwanted hardware, they pay little attention to the equipment's condition, availability of parts, documentation, supplies, and operator training in the recipient country. Some international relief organizations are forced to concentrate on volume rather than the quality of donated goods in order to gain publicity and please corporate donors. On the other side, many recipients do not screen carefully what they ask for nor invest enough time and resources to plan and support what they get. Sometimes they are spoiled by the notion that they can always ask for another one and discard what they do not want or failed to maintain. Finally, the lack of communication between the donor and recipients before the shipment of goods is probably the single most important reason many donations did not work out well.

In an attempt to address these problems, the American College of Clinical Engineering (ACCE) formed a committee to discuss and find means to improve the effectiveness of donations of medical equipment. The committee is composed of ACCE members that have had significant international experience. The present document, *Guidelines for Medical Equipment Donation,* summarizes the recommendations of that committee.

By adopting these *Guidelines* both donor and recipient organizations can expect to realize the following benefits:

- better match between need and availability
- improved pre-donation planning and preparation
- assurance of completeness and quality of donated goods
- high likelihood that received equipment will be installed and used
- assurance of maintainability of donated equipment
- continuous quality improvement through follow-up evaluations

These *Guidelines* are divided into five sections. The first section helps the potential donor to screen out equipment that should not be made available for donation. The second section is designed to assist the donor to find the right recipient, through a careful evaluation of the recipient's clinical need and its resources for operating and maintaining the donated equipment. The third section helps the donor and the recipient to plan and prepare for the donation. The fourth section provides reminders for assuring a successful transfer of goods, including assembly, packaging, shipping, documentation, customs clearance, unpacking, and installation. The fifth and final section is devoted to an evaluation of the each donation so both parties can learn how to avoid past mistakes and improve future transactions.

NOTE: These *Guidelines* are focused only on medical equipment and does not address other medical devices such as disposables, in-vitro diagnostic kits, and reusable accessories. As special precautions are needed in handling those devices, potential donors and recipients should seek expert advise from clinical staff or manufacturers.

2. SUITABILITY FOR DONATION

Prior to making a piece of equipment available for donation, it is crucial that the potential donor makes a critical evaluation of it. It is not only a waste of precious resources to move useless and unsafe equipment from one place to another, it also undermines the good will and trust that everyone is trying to build.

2.1. General Quality

The donor should ensure that donated medical equipment is fully operational at the system and subsystem level. All essential accessories and supplies should be available. The donor should follow a checklist to ensure that all subsystems, components, accessories, and supplies (for initial operations) are included, and should supply the recipient with such a checklist. (Checklists are often found in manufacturers' operating manuals and can be prepared by the former operators.) Documentation, especially operating and service manuals with part lists, is critical to the eventual usability of the donated equipment.

2.2. Safety, Specifications and Standards

All medical equipment should meet or exceed existing safety and performance specifications provided by the manufacturer. In addition, they should meet standards promulgated by ANSI, AAMI, NFPA, UL, CSA, or international bodies such as ISO and IEC. Equipment that has not been approved by the United States Food and Drug Administration Center for Devices and Radiological Health require special export licenses. Equipment subject of FDA or manufacturer recalls or hazard alerts should not be donated. Equipment that has nonfunctional subsystems can be donated provided that those subsystems are clearly identified and labeled.

2.3. Obsolescence

A minimum of two years of manufacturer's sales and technical support should be available. This support should include repair parts, accessories, either reusable or disposable, and troubleshooting, repair and maintenance assistance. Obsolete equipment or equipment for which replacement parts are unavailable should be shipped only if they are designated *for parts only*.

2.4. Appropriate Technology

In considering the provision of medical equipment to developing countries, potential donors should favor the following desirable characteristics in such equipment:

- simplicity of operation
- minimal number of accessories required
- availability of necessary operating supplies (particularly disposable) in the recipient country
- standardization with other equipment in the locale
- ease of maintenance
- tolerance to hostile environment (see Sections 4.1.1 and 4.1.4)

3. EVALUATION OF POTENTIAL RECIPIENTS

The most important prerequisite for a successful donation is that the potential recipient truly needs the equipment being requested and has the means to operate and provide maintenance for it. Although equipment supplied may be completely functional, it will be ineffective if not appropriate for the services provided at the recipient site and if not able to be financially supported through its remaining life cycle. Previous recipient experience with donations is a plus, but not essential for the success of the operation. Appendix A is a form and Appendix B, a checklist, to assist both potential donors and recipients in addressing the issues discussed below.

3.1. Clinical Need

To properly justify the need for the goods being requested, the donor should demand from the potential recipient(s) the following information: which and how many procedures will be performed using the requested equipment; why the resources presently available (attach a list with descriptions) are not satisfactory; and an analysis on how the requested equipment will help meet the expected clinical demand.

3.2. Readiness to Absorb the Technology

The recipient should be required to provide information showing that it is ready to use and maintain the equipment being requested. Such readiness includes trained operators, appropriate environment, ancillary equipment, maintenance capability, and financial viability. It is acceptable that the recipient demonstrates that it has plans and means to address any shortcomings.

3.2.1. Human Resources

The recipient must have properly trained physicians, nurses, and/or technicians that will be operating the requested equipment. If none are available currently, an explanation of how the training is going to be achieved is required.

3.2.2. Environment

The recipient should describe available facilities, such as physical space, electrical and pneumatic power, heating, ventilation, and air conditioning (HVAC), to install and operate the requested equipment. Particular care should be devoted to the availability of a stable electrical supply, air conditioning, and humidity control, which are vital to the performance of sophisticated medical equipment.

3.2.3. Material Resources

If the donated equipment is not accompanied by required ancillary equipment, the availability or means to acquire the latter should be described. The availability of supplies needed to operate the equipment locally must be researched and confirmed.

3.2.4. Maintenance Resources

The recipient should describe human, material, and financial resources available to service and maintain the requested equipment within its institution. Information about service available from local manufacturer representatives and independent service organizations should also be included.

3.2.5. Financial Feasibility

The recipient must demonstrate that it has the financial ability to install, operate, and maintain the requested equipment.

4. PRE-DONATION PLANNING

Assuming that the donor is reasonably convinced that the potential recipient really needs the equipment and can support it for the remainder of its useful life, the two parties should start planning for the donation. First, the donor needs to provide to the recipient detailed information regarding the installation, operation, and maintenance of the equipment. This information will enable the recipient to begin pre-installation tasks, including the training of personnel for operation and maintenance. In a few extreme cases, the recipient may cancel the donation after

realizing that it cannot support the equipment. After all requirements have been satisfied, the recipient will notify the donor to assemble and package the equipment for shipping.

4.1. INSTALLATION, OPERATION, AND MAINTENANCE REQUIREMENTS

4.1.1. Installation Requirements

The donor should specify the installation location, accessibility, floor loading capacity, space and power requirements (voltage, frequency, phase, and power consumption), and environmental conditions. Care should be taken to identify any unusual extremes of temperature, humidity, dust and power fluctuations that could adversely affect the equipment's operation. If available, the donor should ensure that detailed installation instructions are provided. Most, if not all, of this information is available in the equipment's operating or service manual.

4.1.2. Operation Requirement

The donor should inform the recipient of all the necessary subsystems, such as cables, reagents, filters, electrodes, and recording paper, that will be required to operate the equipment to be donated. Often test equipment and calibration standards are required to ensure performance and accuracy of the equipment. Availability of these items throughout the remaining useful life of the equipment should be ascertained. Again, required operator training should be stated clearly.

4.1.3. Maintenance Requirement

The donor should seek guidance from its own service personnel so it can provide detailed maintenance requirements, such as technician training, special tools, preventive maintenance frequency and materials, and test and calibration equipment needed.

4.1.4. Special requirements

Any special requirements should be identified and communicated to the recipient. These include but are not limited to air or water cooling, electrical power, water quality, mechanical, layout or radiation or acoustic shielding requirements. Sometimes specialized software may be required to install, operate, or maintain equipment.

4.2. PRE-DONATION RECIPIENT PREPARATIONS

After receiving the information listed above, the recipient should start preparing the site and personnel for receiving the equipment. When all the preparations are ready, the recipient will notify the donor.

If pre-installation work is required, the recipient should inform the donor when the work will be completed. It is advisable that the recipient supplies to the donor details such as floor plans, architectural drawings, and blueprints, enabling the donor, from experience, to identify problems and recommend solutions.

If the recipient has difficulty in securing training for operating and maintenance personnel, the donor should be prepared to suggest alternative training providers or, in some instances, offer training if the recipient can afford to send people to the donor's site. Such instruction should address operation, maintenance, and repair.

5. DONATION IMPLEMENTATION

5.1. Assembly, Packaging, and Shipment

Prior to packaging the equipment to be donated, the donor should ensure that it is safe and performing within manufacturer's specifications. This can be accomplished by performing an operational verification procedure found in most operating manuals. In addition, all accessories and supplies should also be checked. All software necessary for equipment operation should be included. Training aids such as slides, books, and videotapes should be supplied if available. The checklist mentioned in Section 2.1 should be used to verify that all subsystems, components, and accessories and supplies are included. This checklist will also be helpful in the preparation of the shipping documents.

Equipment that may contain patient material should be properly decontaminated prior to packaging and shipment. Radioactive sources should be removed and properly packaged in special shipment containers (with radioactive marking on outside). Fluids should be drained and fragile parts, packaged with great care. International shipments are often handled roughly by people without proper training and equipment and, therefore, subject to high probability of damage.

All equipment should be shipped with operation and service manuals. Software version numbers and significant hardware updates if applicable should be noted. The operation manual should contain detailed operating instructions and list all necessary subsystems, accessories, user replaceable parts, reagents, and other supplies such as chart paper, gases, coolants. and chemicals. The service manual should contain specifications, schematics, operating instructions, troubleshooting, repair and maintenance procedures, cleaning and/or sterilization recommendations, and replacement parts list. If available, procedures or recommendations for periodic inspection, maintenance and calibration to assure that the equipment is maintained in a safe and effective operating condition should be provided by the supplier. If the documentation is not available, the donor should consider purchasing it to unsure the eventual usability of the donated equipment.

Donated equipment should be packaged in accordance to the method of shipment to minimize damage in transit. For surface shipment, waterproof wrapping and wooden crates are a necessity. Air shipment requires less sturdy packaging, but limitations in size and weight are more severe.

Shipping documents should list everything inside the respective packages and clearly indicate that the shipment is a donation. Sample shipper's export declaration form and instructions can be obtained from the Department of Commerce through the Bureau of Census, Washington, DC 20233.

Donors not familiar with packaging, shipping, and documentation may consider seeking assistance of freight forwarders. companies specializing in assisting exporters in transferring goods to other countries.

5.2. Customs Clearance, Unpacking, Installation, and Maintenance

Customs clearance is the sole responsibility of the recipient. If special documentation is needed, the recipient should request it prior to the shipment.

The recipient should inspect all containers and contents for damage and should verify that the contents are intact and nothing is missing. Any irregularities should be reported immediately to the donor and to the shipping company for insurance claims. The manuals received with the equipment should be distributed to the appropriate personnel: operating manual to the operator and service manual to the clinical engineer or biomedical technician. If a centralized library exists, the manuals should be forwarded to that location.

Installation should be performed according to the instructions received from the donor. After the installation, verification of proper and safe operation must be performed prior to clinical use.

After verifying that the equipment received is working properly, the recipient should implement a program of periodic inspection, maintenance and calibration to assure that the equipment is maintained in a safe and effective operating condition for its remaining useful life. If an in-house maintenance department does not exist, the recipient should recommend such a department to the institution's administration.

6. FOLLOW-UP EVALUATION

After installation and operation, the donor and the recipient should assess the level of operational success or failure of the medical equipment donated. This assessment fosters communication between donor and recipient, encourages the continued support of the donor, and allows both parties to learn to improve from previous experience.

The recipient should not hesitate to identify mistakes made by the donor. Of equal importance, the donor should demand honest and timely response from the recipient. The success of future donations will be enhanced as a result of such assessments.

The ACCE would appreciate any comments and suggestions that donors and recipients have on these *Guidelines*. Please send all correspondence to: ACCE, c/o ECRI, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA.

APPENDIX A

MEDICAL EQUIPMENT DONATION REQUEST FORM

Note: Fill a form for each TYPE of equipment requested even when several units are needed.
Attach sheets with more additional information if there is not enough space on this form.

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1. REQUESTER IDENTIFICATION

- NAME OF THE INSTITUTION:

- NAME OF THE DEPARTMENT:

- STREET ADDRESS:

- CITY, STATE:

- COUNTRY, POSTAL CODE:

- PHONE & FAX NUMBERS:

- CONTACT PERSON & TITLE:

- DATE & SIGNATURE:

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2. EQUIPMENT IDENTIFICATION

- EQUIPMENT NAME:

- IMDC CODE (ECRI):

- CLINICAL APPLICATION(S):

- QUANTITY REQUESTED:

- SAMPLE BRANDS AND MODELS:

- ACCESSORIES NEEDED:

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3. REQUEST JUSTIFICATION

3.1 Procedure(s) that will be performed using the requested equipment, with estimated number per month:

3.2 Explain why the resources (equipment, methods, procedures, etc.) presently available are not satisfactory:

3.3 When equipment is being requested to complement or replace existing equipment or services, please describe the resources presently available:

3.4 Compare the expected demand and the production capacity of the equipment being requested:

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4. READINESS TO ABSORB THE TECHNOLOGY

4.1 Human resources available (indicate additional training if necessary)

4.2 Material resources (additional equipment and devices needed)

4.3 Space and special installation available or planned

4.4 Maintenance requirements (in-house service, external contracts, etc.)

4.5 Financial considerations (for installation, operation and maintenance)

APPENDIX B

MEDICAL EQUIPMENT DONATION ACTION CHECKLIST

	RESPONSIBILITY	
ACTION	**DONOR**	**RECIPIENT**
2. SUITABILITY FOR DONATION 2.1. General Quality 2.2. Safety, Specifications and Standards 2.3. Obsolescence 2.4. Appropriate Technology	evaluate unnecessary equipment prior to offering it for donation	
3. EVALUATION OF POTENTIAL RECIPIENTS 3.1. Clinical Need 3.2. Readiness to Absorb the Technology 3.2.1. Human Resources 3.2.2. Environment 3.2.3. Material Resources 3.2.4. Maintenance Resources 3.2.5. Financial Feasibility	request information from potential recipient and evaluate it to determine likelihood of success for donation	submit information to potential donor using request form (Appendix A)
4. PRE-DONATION PLANNING 4.1. INSTALLATION, OPERATION, AND MAINTENANCE REQUIREMENTS 4.1.1. Installation Requirements 4.1.2. Operation Requirement 4.1.3. Maintenance Requirement 4.1.4. Special requirements 4.2. PRE-DONATION RECIPIENT PREPARATIONS	provide data to recipient	use donor's data to prepare personnel and infrastructure
5. DONATION IMPLEMENTATION 5.1. Assembly, Packaging, and Shipment 5.2. Customs Clearance, Unpacking, Installation, and Maintenance	donor's responsibility	recipient's responsibility
6. FOLLOW-UP EVALUATION	analyze process and improve procedure	provide feedback to donor