



Guidance Document

Guidance for Hospitals Donating Medical Devices

Introduction

The objective of this document is to provide Canadian hospitals with the information required to undertake medical device donations in a manner that provides the best possible value to recipients, is compliant with Canadian regulations and minimizes donor liability.

Background

The World Health Organization (WHO) has identified a critical and increasing need for donated medical equipment in low resource countries. WHO states that “in some countries, nearly 80% of health-care equipment is donated or funded by international donors or foreign governments” [1]. Thus there is a strong imperative for Canadian healthcare workers to assist their colleagues in low-resource countries wherever possible.

However, the process of sending decommissioned equipment to a low resource country has many pitfalls and risks. A CMBES study on medical equipment donations from Canada to low resource countries [2] confirmed what has been found in studies of donations from other wealthy countries – a high percentage of donated equipment from Canadian hospitals is never put into use by the recipients.

Additionally, some hospitals are hesitant to donate their used medical devices because the relevant Canadian regulations issues and potential liability surrounding donations are not well understood.

The objective of this document is to provide Canadian hospitals with the information required to undertake medical device donations in a manner that provides the best possible value to recipients, is compliant with Canadian regulations, and minimizes donor liability.

Collaborating with Recipient Organization

Before considering a donation, it is vital that the donor organization enter into a dialogue with the recipient organization to confirm that the devices to be donated will

meet the needs of the recipient and that the recipient has the resources to operate and maintain the equipment.

The reasons why a high percentage of donated equipment is never put to use are many, including a lack of spare parts and accessories, lack of training, lack of supporting manuals, poor communication between the donor and the recipient hospital, lack of clear equipment specifications, unneeded equipment, and poor donor planning. A simple but all too frequent example is Canadian medical equipment that operates on 110 Volts being sent to a country with a 220 Volt electrical supply.

However, by considering medical device donations in collaboration with the recipient organizations, many of these pitfalls can be avoided.

The availability of consumable parts (with regards to the donated device) in the region in which the destination healthcare facility is located must be evaluated. All available instruction manuals and guides pertaining to the donated medical device should be included with the device. If possible and available, useful consumable parts may be donated with the medical device.

Organizations that Facilitate Equipment Donations

The Ontario Surplus Hospital Equipment Network (OSHEN) is an initiative of the Clinical Engineering Society of Ontario (CESO) that provides a platform for healthcare facilities to connect with an appropriate recipient for their donated devices [6].

In the province of Quebec, an organization called Collaboration Santé International (www.csiquebec.org) has been accredited by the Quebec Ministry of Health and Social Services (MSSS) since 1996 to recover surplus materials from the Health Network for humanitarian aid purposes.

In British Columbia, Rotary World Help (<https://rotaryworldhelp.com>) is active in sending surplus medical equipment to low resource countries. As of 2022 they have shipped 430 containers of equipment to 61 different countries.



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ECRI [7] strongly recommends that hospitals partner with a medical surplus recovery organization (MSRO) to maximize the effectiveness of equipment donations and has created a list of questions that hospitals can use to help evaluate the capacity of an MSRO.

Relevant Canadian Regulations

In Canada, the sale of medical devices is regulated by Health Canada under the Canadian Medical Device Regulations (SOR/98-282) [3]. The regulations regard any donation of a medical device as a “sale without consideration” or a zero-dollar sale. Hospitals donating a used device should be aware of the regulations governing the sale of medical devices as they take on the role of a “*distributor*” of a device in the eyes of Health Canada. As a distributor, healthcare facilities must follow many of the regulations that apply to device manufacturers and importers.

Section 26 of SOR/98-282 stipulates the following: “Subject to section 37, no person shall import or *sell* a Class II, III or IV medical device unless the manufacturer of the device holds a license in respect of that device.” The “*sell*” qualifier above means that the donor of a class II, III, or IV device must ensure that a device is properly licensed. Up-to-date active and archived licenses can be found in the Medical Devices Active License Listing (MDALL) [4]. This license requirement does not apply to Class I devices or donations intended for animal use (i.e., any class of device can be unlicensed and donated for veterinary use).

As a distributor of a medical device, Health Canada requires that certain distribution records be kept as a part of sections 53, 55, and 56. Records must be kept for each donated device containing sufficient information to permit complete and rapid withdrawal of the medical device from service. Location of the device and contact information of the recipient should be kept for passing along alerts and recalls if received from the manufacturer. Distribution records must be available for timely retrieval. The distributor must retain the distribution record for the longer of:

- The projected useful life of the device, or
- Two years after the date the device is shipped.

As a distributor under section 57.1, records must also be maintained for the purpose of complaint handling. These records will document any reported problems relating to the performance or safety of the device and all actions taken by the distributor in response to complaints that are received. Under section 58, the distributor of a device must establish and implement documented procedures that will enable the distributor to carry out an investigation into any reported

problems or pursue an effective and timely recall of the device.

Minimizing Liability

The Healthcare Insurance Reciprocal of Canada (HIROC) is a not-for-profit healthcare safety advisor and the primary insurance provider for healthcare facilities across Canada. HIROC’s experience is that issues arising from the donation of devices are infrequent, and most donations are made to developing countries [5]. HIROC provides detailed guidelines for hospitals to minimize their liability when donating medical devices. HIROC recommends that a donor facility should develop a system that documents the following information for each device:

- Serial number, model, manufacturer, license, photographs of the system
- Inspections, tests, cleaning performed at the time of donation
- History of all PM, repairs, alerts and recalls, corrective action
- Condition of the device at the time of donation
- Recipient information

Devices should undergo thorough inspection by the Clinical/Biomedical Engineering department and Infection Prevention and Control before being released for donation.

Creating and updating these records, as well as performing reactionary measures to any reported problems is a responsibility best handled by the Clinical/Biomedical Engineering department, as they routinely maintain such information in their equipment management database.

HIROC also recommends that a liability waiver be created and signed by the donating and receiving parties to provide the donor with some protection to limit liability. A sample waiver document is included in Appendix 1 below.

CMBES Recommendations

The keys to successful donations of medical devices are effective communications between donors and recipients of donations. In addition, although policies may vary between healthcare facilities, consistent adherence to a carefully developed procedure is the best way to reduce risk when donating used devices. A CMBES produced video [8] summarizes best practices for donations.

Clinical/Biomedical Engineering departments should play a key role in deciding if a device is appropriate for donation. Clinical/Biomedical Engineering departments should ensure



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devices meet all regulatory requirements, safety guidelines and that the necessary accessories, spare parts, instruction manuals, service manuals are available to support the donation.

The attached Sample Waiver Document (Appendix 1) and the Donation Checklist (Appendix 2) or similar documents should be included in the organization's policy regarding equipment donations.

[7] "Make Your Device Donations Count-Use a Medical Surplus Recovery Organization," ECRI [Online]. Available: https://www.ecri.org/search-results/member-preview/hdjournal/pages/donating_medical_equipment, Retrieved April 29, 2023.

[8] Donations - Understanding Challenges & Best Practices, CMBES, October 6, 2015, <https://youtu.be/R27CPPAwL1Y>, Accessed October 19, 2022.

References:

- [1] "Medical device donations: considerations for solicitation and provision" World Health Organization, Geneva, Switzerland, iv, 21 p. (2011). [Online]. Available: <https://apps.who.int/iris/bitstream/handle/10665/44568/9789241501408-eng.pdf?sequence=1&isAllowed=y>, Retrieved February 28, 2022.
- [2] Adjabu, N, B. Bradley, B, Gentles, B; C. Mirzazadeh, C, "A Study of Medical Equipment Donations From Canada to Developing Countries: Progress and Challenges", Presented at Appropriate Healthcare Technologies for Low Resource Settings (AHT 2014), <https://digital-library.theiet.org/content/conferences/10.1049/cp.2014.0789>
- [3] "Medical Device Regulations," Health Canada, Ottawa, Ontario, Canada, SOR/98-282, June 23, 2021. [Online]. Available: <https://laws-lois.justice.gc.ca/PDF/SOR-98-282.pdf>, Retrieved February 28, 2022.
- [4] Government of Canada, H. C. (2022, January 6). *Medical Devices Active Licence listing (MDALL) - your reference tool for licensed medical devices in Canada*. Maintenance. Available: <https://health-products.canada.ca/mdall-limh/>, Retrieved February 28, 2022.
- [5] "Donating Used Medical Devices to Third Parties," HIROC, Toronto, Ontario, Canada. [Online]. Available: <https://www.hiroc.com/resources/risk-notes/donating-used-medical-devices-third-parties>, Retrieved February 28, 2022.
- [6] *Ontario Surplus Hospital Equipment Network (OSHEN)*. OSHEN. (n.d.). Available: <https://oshen.ca/index.php/login-page>, Retrieved February 28, 2022.



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Appendix 1. Sample Waiver Document

(NAME OF HEALTHCARE FACILITY)

Waiver of Liability for the Donation of Medical Equipment & Supplies

DISCLAIMER: This document will affect your legal rights and liabilities. Please read carefully.

(Healthcare facility name) offers the medical equipment/ products itemized on the attached pages for donation to the recipient identified at the bottom of this document.

(Healthcare facility name) shall assume no responsibility for damage or injury incurred during shipment, use by the recipient or recipient's assignee, or subsequent breakdown or malfunction. Reasonable attempts have been made to include operator and service manuals with the equipment, but it is the sole responsibility of the recipient to ensure that the equipment is appropriately maintained, and that the recipient's staff are competent and trained to use or responsibly donate or resell the equipment.

(Healthcare facility name) is not responsible for monitoring or communicating any alerts or recall notices from the device manufacturer to the recipient. The recipient acknowledges and agrees that the manufacturer's warranty may no longer apply once the equipment has been donated.

The recipient acknowledges that they accept the items in their current condition, on an 'as is' basis.

No warranty, expressed or implied, is given by (Healthcare facility name) for the usability, safety, reliability, efficacy or sterility of this equipment. These responsibilities rest solely with the recipient. The recipient expressly acknowledges and assumes full responsibility for any and all known, obvious and foreseeable physical risks associated with the equipment, including but not limited to the risk of serious bodily injury and death.

The signature of the recipient's agent at the bottom of this form constitutes full knowledge and acceptance of the terms of this waiver on behalf of the recipient organization and is irrevocable.

The recipient, on behalf of himself/herself/his/her organization, the respective heirs, successors and assigns, acknowledges and agrees not to make or continue any claim or proceeding against (Healthcare facility name), together with all parents, subsidiaries and affiliates and together with all respective directors, officers, employees, servants, agents, successors and assigns arising from or in any way related to the use and/or operation of the equipment.

The recipient acknowledges and agrees to indemnify and save (Healthcare facility name) harmless from all liability, all manner of actions, causes of action, suits, demands and costs, including but not limited to those brought by a third party arising from any actions or omissions related in any way to the use and/or operation of the equipment.



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Recipient Information and Signature

Recipient's Name (please print)	
Recipient Company Name ("company")	
Recipient's Address and Other Contact Information	

I, _____ (full name), hereby warrant and represent that I am the authorized agent and representative of the above-named company ("company") and I have been expressly authorized by the company to purchase/receive the equipment listed below. I have had an opportunity to ask questions about this waiver and my questions have been answered to my satisfaction. I agree to assume the known, obvious and foreseeable physical risks associated with the equipment as well as any injury/harm/loss arising from the organization's own negligence. I have read, understood, and am authorized to indicate my company's acceptance of the terms of this waiver. I have, by my signature below, bound the company to the terms and conditions of this Waiver.

Recipient or Agent Signature

Date

(Healthcare facility name) Representative Information & Signature

I, _____ (print name), hereby warrant and represent that I am the authorized agent and representative of (Healthcare facility name) and I have been expressly authorized by (Healthcare facility name) to donate the equipment listed below/attached page, and I have, by my signature below, bound (Healthcare facility name) to the terms and conditions of this Waiver.

(Healthcare facility name) Representative Signature

Date

List items being donated below or on a separate, attached sheet.

<i>Item Description</i>	<i>Serial Number</i>	<i>Model</i>	<i>Manufacturer</i>	<i>licence number</i>



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Appendix 2 – Donation Checklist

The following is a checklist with recommended points for healthcare facilities to be aware of before donating medical equipment:

- Before considering a donation, it is vital that the donor organization enter into a dialogue with the recipient organization to confirm that the devices to be donated will meet the needs of the recipient and that the recipient has the resources to operate and maintain the equipment.
- The medical/Biomedical Engineering department and infection prevention should do a thorough analysis to determine if the medical device is suitable for donation and will function for a reasonable amount of time in the destination country.
- The availability of consumable parts (with regards to the donated device) in the region in which the destination healthcare facility is located at must be evaluated.
- All available instruction manuals and guides pertaining to the donated medical device should be included with the device.
- If possible and available, useful consumable parts with regard to the donated device may be donated with the medical device.
- The medical/Biomedical Engineering department should verify that the manufacturer of the device holds an active Health Canada license in respect of the device.
- The medical/Biomedical Engineering department should keep distribution records for each donated device in case a recall of the medical device from service is issued or for the purpose of medical device alerts handling.
- The medical/Biomedical Engineering department should update the vendor regarding devices new owners so they can communicate any information such as a recall notice to the new owner.
- The medical/Biomedical Engineering department should document and keep a record of the following:
 - Serial number, model, manufacturer, license, photographs of the system
 - Inspections, tests, cleaning performed at the time of donation
 - History of all PM, repairs, alerts and recalls, corrective action
 - Condition of the device at the time of donation
 - Recipient information