Capital Health

CDHA Biomedical Engineering

Requirements for Implementing Technology in the Clinical Research Setting

Preamble:

Biomedical Engineering is responsible for ensuring that medical devices, equipment and technology entering CDHA facilities are in compliance with standards and regulations established by the federal and provincial governments as well as with CDHA policies and procedures (e.g., RS 03-003, CH 90-010, CH60-010 & CH 90-005). This document provides researchers with guidelines detailing these requirements to help ensure they do not delay study initiation. Please contact Biomedical Engineering at the **earliest convenience** should there be any questions regarding compliance or licensing.

It is important to note that any medical device, equipment and/or technology being used at CDHA, regardless of cost, must be acquired through CDHA's Procurement Department. Procurement will ensure the vendor/provider is aware of our requirements and Biomedical Engineering will confirm that these requirements have been met upon completing an incoming inspection.

The following services/testing/certifications may be subject to additional fees and must be covered by the study budget/sponsor. As these costs are variable, it is best to contact Biomedical Engineering for an estimate.

(1) Canadian Standards Association (CSA) Certification: In general, equipment used in CDHA facilities must be CSA approved or possess an equivalent certification from an accredited organization. In the absence of one of these forms of certification, a special inspection will be required for each individual device. This inspection requirement will apply to all equipment, even for those of the same design and regardless of previous use. If the applicability of the certification requirement is in question, please contact Biomedical Engineering for clarification.

(2) Medical Device License: All medical devices (Class II and above) sold in Canada must have a medical device license. The use of the term "sold" is applicable to technology transferred from one institution to another and does not necessarily involve monetary consideration. For example, a medical device fabricated at Dalhousie University and provided to CDHA at no cost constitutes a sale of a medical device. Even if proof of exemption is provided by the study sponsor, Biomedical Engineering may conduct its own evaluation of license requirements. Consult Biomedical Engineering early in the process to help ensure regulatory issues do not delay the study.

(3) Device Development: Complete documentation is required for devices developed for research applications in the clinical setting. This documentation is to include theory of operation, electrical/electronic schematics and diagrams of any mechanical components and a parts list. Optimally, the Professional Engineer responsible for the design will have stamped and signed the accompanying documentation.

(4) **Third Party Equipment Providers:** Third party study sponsors that provide study equipment should be made aware of CDHA's certification and licensing requirements. As studies are more frequently involving collaborators in a number of countries, the requirements of the individual facilities/countries may not always be considered. Acquiring these medical equipment/devices through CDHA's Procurement Department will help ensure these requirements are addressed. Please note that equipment provided by sponsors or developed by researchers must include appropriate service documentation that details inspection and maintenance requirements.

(5) Modifications to Existing Devices: In most cases, existing equipment that has been modified to meet research requirements will not retain its original certification or medical device licensing. In such cases CSA certification or, more likely, a special inspection will be required for each individual device. Medical device licensing, investigational or otherwise, may also have to be revisited.

(6) **Incoming Inspection:** Medical equipment and medical devices used in the clinical research setting must receive an incoming inspection by Biomedical Engineering. In addition to verifying compliance to the guidelines detailed above, electrical safety and functional testing will be carried out in accordance with CDHA's Biomedical Engineering policies.

(7) Software Development/Applications: Health Canada considers software developed for use or application in the clinical environment to be a medical device. Accordingly, such software is subject to the licensing requirements of the Medical Device Regulations.

(8) **Ongoing Maintenance and Service:** CDHA requires that all medical equipment and devices that are used in the clinical research setting be subject to the preventative maintenance (PM) requirements established by the original equipment manufacturer. In the case where a sponsor maintains the equipment, documentation of any service activities (i.e., repairs, PMs and upgrades) must be provided to Biomedical Engineering in order to maintain a service history on the technology in question. Medical equipment/devices and other technology used in a previous research study must be resubmitted for inspection if the device is to be used in a subsequent research application. Researchers are to ensure that equipment is submitted to Biomedical Engineering for preventative maintenance/inspection at the prescribed intervals.

(9) **Use of CDHA Equipment in Research Applications:** It is important that researchers track and record control numbers (i.e., BME#) of CDHA equipment used in their studies. This will make it much easier for Biomedical Engineering to provide service records for these devices as is normally required by the study sponsor. These records may also be required if the study is inspected by Health Canada. Researchers should verify that any CDHA equipment used in the study is serviced by Biomedical Engineering at the prescribed intervals.

(10) **Hardware and Software Modifications during the course of the Study:** Any changes implemented in either the hardware or software components of the equipment being used in the study must be approved by Biomedical Engineering before being implemented. Such changes may require revisiting the certification and device licencing requirements.

Other Resources – Links and Contact Information:

CDHA Biomedical Engineering	Contact
VG Office - Rm 1025 Dickson	**(902)-473-5427**
HI Office – Rm 6342 Halifax Infirmary	**(902)-473-3113**
CDHA Procurement	**Contact**
Bethune Building	**(902)-473-5796**
Health Canada Links	**Link**
Medical Device Regulations	http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/
Drugs and Health Products - Medical Devices	http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/index-eng.php
Establishment License (Active Listing)	http://webprod5.hc-sc.gc.ca/el-le/
Medical Device License (Active Listing)	http://webprod5.hc-sc.gc.ca/mdll-limh/index-eng.jsp
Health Canada Forms	**Link**
Application Forms (All)	http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/index-eng.php
Application (Investigational Testing)	http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/itapp_demee_form-eng.php
Health Canada Guidance Documents	**Link**
Investigational Testing Agreement.	http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/invagr_entche-eng.php
Investigational Testing Guidance Document.	http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_ita_im_ld_aee-eng.php
Health Canada Contacts	**Contact**
Dr. Fred Lapner – Head of Investigational Testing – Medical Devices	Fred.Lapner@hc-sc.gc.ca (613)-954-4598
Medical Device Licensing Division	MDB_Enquiries@hc-sc.gc.ca (613)-957-1909
Other	**Contact and Links**
Canadian Standards Association	www.csa.ca
QPS Evaluation Service	www.qps.ca
Phil Weedon (QPS – Local Representative)	(902)-860-1619 pweedon@qps.ca