



Medtech Canada Guidance for Site Visits, Product Demonstrations and Evaluations

This Guidance is intended to supplement, and be read in conjunction with, the MedTech Canada Code of Conduct. Capitalized terms used herein are as defined in the MedTech Canada Code of Conduct.

1. SITE VISITS

A Site Visit is an event in which an HCP, HCI or GO travels to a Company's manufacturing or product demonstration site, or to a Company's customer site, to view, observe and/or evaluate the Company's manufacturing process or a demonstration of the Company's non-portable Medical Technology.

The following guidelines apply to Site Visits:

- **Legitimate need:** Site Visits should only occur where there are legitimate reasons to support the need for a Site Visit. Always consider whether the Medical Technology can be effectively demonstrated in a virtual matter or at the HCI's location, rather than necessitating a Site Visit.
- **Planning the Site Visit:** In order to allow for adequate time for Companies to organize Site Visits, HCI, HCPs and GOs requesting Site Visits (including without limitation as part of a Request for Proposals, Request for Information or other procurement process) should provide Companies with reasonable advance written notice for the Site Visit. It is also recommended that requested Site Visit dates be published as part of the RFX, as applicable, and that exact Site Visit dates and related information be confirmed upon publication of "short listed" suppliers. In the event that the Site Visit needs to be cancelled by either party, reasonable advance written notice should also be provided. This will allow MedTech Canada member Companies to best plan the Site Visit.
- **Number of Site Visits.** Save exceptional circumstances, only one Site Visit per project or procurement should occur. To the extent possible, HCIs and procuring organizations should utilize best efforts to ensure that their Site Visit attendees do not change throughout the project or procurement process, thereby reducing the need for multiple or repeat Site Visits.
- **Location:** To the extent possible and depending on the purpose for the Site Visit, every effort should be made to conduct the Site Visit in Canada and at the location closest to the HCI, HCP or GO's place of business. The Site Visit location should be selected based on objective criteria, not considering the visitors' personal travel preferences.
- **Number of HCI Attendees:** The number of visitors attending the Site Visit should be kept to a minimum, and only include those who have a legitimate need to view the Medical Technology being presented or observed at the Site Visit.

- **Duration of Site Visits:** The duration of the Site Visit shall be no longer than is necessary to view or evaluate the manufacturing process or Medical Technology, as applicable. Companies shall provide the attendees with an itinerary prior to the commencement of the Site Visit that clearly identifies the duration of the Site Visit and the Medical Technology or manufacturing process being observed.
- **Meals, Travel and Hospitality:** Companies may pay for the modest travel, hospitality, meals and refreshments for a reasonable number of HCI attendees to the Site Visit, as referenced above. Where the HCI requests additional attendees beyond that which is considered reasonable, then the HCI should be the one responsible to pay for all such additional attendees' meals, travel and accommodations. Any meals, travel or hospitality provided by the Company shall be in accordance with the MedTech Canada Code of Conduct and MedTech Canada Guidance on Meals and Travel. Without limiting the foregoing, it is not appropriate to pay for meals, refreshments, travel or lodging or other expenses of guests of HCI attendees or any other person who does not have a legitimate professional interest in the business information or Medical Technology being viewed at the Site Visit.

2. MEDICAL TECHNOLOGY DEMONSTRATIONS

Companies may invite HCI representatives to view a demonstration of their non-portable Medical Technology by arranging a Site Visit, in accordance with the guidelines above. Companies may also bring portable Medical Technology to an HCI location for demonstration purposes. The following guidelines apply for Medical Technology demonstrations:

- **Consider virtual:** Companies should consider whether a live demonstration is truly necessary and consider providing virtual demonstrations where practicable.
- **Planning the demonstration:** In order to optimize Medical Technology demonstrations:
 - HCIs should give Companies reasonable advance notice of a requested demonstration.
 - As applicable, it is recommended that requests for demonstrations be published in the Request for Proposals or Request for Information, with exact dates for the demonstration being confirmed upon publication of "short listed" suppliers. In the event that the demonstration needs to be cancelled by either party, reasonable advance written notice should be provided.
 - The parties should agree in advance as to Medical Technology or types of procedures which are to be demonstrated
 - The parties should identify the attendees for the demonstration, being those who have a legitimate interest in the Medical Technology being demonstrated
 - The parties should mutually agree on the date and time for the demonstration, allowing sufficient time for equipment set up and testing prior to the demonstration, time for questions and answers, etc.
 - The parties should advise each other in advance of any screening or other requirements in advance of the demonstration (e.g., security checks, immunizations, NDAs, etc.)
 - The parties should set up appropriate room and space for the demonstration (for example, a lead lined room is required for c-arms and mobile x-ray demonstrations)
 - The parties should arrange for a secure location for the equipment to be stored at the site before and after the demonstration, as necessary

- The Company should be the one to arrange for the delivery, installation and removal of the Medical Technology from the site
- HCI to provide the “ship to” address, and identify the dock available and opening and closing hours of the shipping and receiving department, to receive the relevant Medical Technology
- **Control:** The Medical Technology must remain in the control of the Company throughout the course of the demonstration. Upon conclusion of the demonstration, the Medical Technology should be removed from the HCI site. Alternatively, Medical Technology can be stored at the HCI location for a limited period of time before or after the demonstration, provided it is stored in a manner so that it cannot be utilized without the presence of the Company, acknowledging that consumables may have been depleted as part of the demonstration and therefore unable to be removed. No usable Medical Technology (consumables or otherwise) should be left at the HCI site at the end of a demonstration.
- **Documentation:** the parties should enter into a signed written arrangement documenting the Medical Technology being demonstrated, the purpose of the demonstration, its duration, and any other terms and conditions applicable to the demonstration.

3. MEDICAL TECHNOLOGY EVALUATIONS LOANS

Medical Technology evaluations loans are defined as situations where Companies provide HCI and HCPs with Medical Technology on loan free of charge, for their use in their own clinical environment, on a short-term basis for the purposes of evaluating the Medical Technology prior to a purchasing decision for new equipment. This is permitted provided:

- **Legitimate need:** the purpose of the Medical Technology loan is truly to provide the HCI or HCP with the opportunity to evaluate a Medical Technology for which the HCI or HCP does not have previous experience and/or requires a trial period to ensure that the Medical Technology meets the HCI or HCP’s needs. It is not appropriate to provide a free Medical Technology loan where the HCI or HCP does not have a legitimate need to trial the Medical Technology including, for example, where the HCI or HCP has already purchased or tested the same Medical Technology.
- **Limited duration:** the length of the evaluation loan must be defined at the outset and be limited to a reasonable evaluation period. Free equipment loans which continue beyond the reasonable amount of time to evaluate the Medical Technology are inappropriate.
- **Documentation:** the evaluation loan must be documented in a signed written agreement between the parties stating the Medical Technology being evaluated, the purpose of the evaluation, its duration, and any other applicable terms and conditions.

Under no circumstances should a Site Visit, demonstration or evaluation loan be undertaken with the intention to unlawfully, unduly or improperly influence the HCP, HCI or GO.