



MEDEC

CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

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MEDEC Code of Conduct

On Interactions with Healthcare Professionals and Government Officials



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The Goal Of The MEDEC Code

- 1.1 Canada's Medical Technology Companies ("MEDEC") is dedicated to advancing healthcare through innovative technologies, devices and diagnostics ("technologies"). MEDEC believes that access to high quality, cost-effective healthcare technology is paramount to the improvement of patient care. MEDEC represents companies that design, develop, manufacture and market medical technologies and related services used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.
- 1.2 Medical technologies are often highly dependent upon "hands on" Healthcare Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable medical technologies are often placed in the human body to replace or strengthen a body part. Surgical medical technologies often serve as extensions of a physician's hands. In other circumstances, medical technologies are non-invasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Healthcare Professionals. Some medical technologies work synergistically with other technologies, or are paired with other products that deploy technologies in the safest and most effective manner. Many medical technologies require technical support during and after deployment.
- 1.3 In pursuing this mission, MEDEC member companies ("Companies") recognize that adherence to ethical standards and compliance with applicable laws is critical to the Canadian medical technology industry's ability to continue its collaboration with Healthcare Professionals. MEDEC member companies comply with applicable regulatory requirements, including those pertaining to the Health Canada Medical Devices Special Access Programme. Further to the requirements of the Regulations, member companies are prohibited from promoting the sale of unlicensed devices. Where a physician has expressed their intent to submit a Special Access application, member companies can supply the information necessary to support the application in direct response to questions from the physician, but may not facilitate the application beyond the provision of information considered appropriate under the rules of the Program.
- 1.4 Companies encourage ethical business practices and socially responsible industry conduct related to their interactions with Healthcare Professionals and Government Officials.
- 1.5 Companies also respect the obligation of Healthcare Professionals to make independent decisions regarding Company products. MEDEC supports and respects the guidelines and policies established by professional societies or organizations that outline the obligations of the profession, while interacting with the Canadian medical technology industry.





- 1.6 MEDEC has revised and restated its 2005, 2010 and 2012 versions of this Code of Conduct. The 2015 version recognizes the changing business environment in Canada and globally. It also recognizes that healthcare regimes are governed by different laws, policies and practices. The 2015 MEDEC Code of Conduct represents a solid framework for the Canadian marketplace. This Code is intended for interactions with Healthcare Professionals and Government Officials and includes, but is not limited to, those individuals or entities that purchase, lease, recommend, use, train, arrange for the purchase or lease of, or prescribe Companies' medical technology products in Canada.¹

All terms in this Code of Conduct are defined in the Glossary, Appendix D.

2

Scope Of The MEDEC Code

- 2.1 There are many forms of interactions between Companies and Healthcare Professionals that advance medical science or improve patient care, including:
- 2.1.1. **Advancement of Medical Technology.** Developing cutting-edge medical technology and improving existing products are collaborative processes between Companies and Healthcare Professionals. Innovation and creativity are essential to the development and evolution of medical technologies, often occurring outside the laboratories of medical technology companies. Heart valves, orthopaedic implants, cardiac rhythm devices, surgical tools and infusion pumps are just a few examples of the array of complex medical technologies developed through research collaborations and consulting relationships between Healthcare Professionals and Companies.
 - 2.1.2. **Safe and Effective Use of Medical Technology.** The safe and effective use of sophisticated electronic, in vitro diagnostic, surgical or other medical technology often requires Companies to offer Healthcare Professionals appropriate instruction, education, training, service and technical support.
 - 2.1.3. **Research and Education.** Companies' support of *bona fide* medical research, education and enhancement of professional skills serves patient safety and increases access to new technology.
- 2.2 MEDEC recognizes that Companies may interact with Healthcare Professionals or Government Officials for many legitimate objectives other than selling, leasing, recommending, arranging for the sale or lease of, or prescribing products, and that some of these relationships are not addressed in this Code. Any interpretation of the provisions of this Code, as well as Companies' interactions with Healthcare Professionals or Government Officials not specifically addressed in this Code, should be made in light of the following principle: Companies shall ensure ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of their products.

3

Compliance with the MEDEC Code of Conduct

The MEDEC Code of Conduct applies to all MEDEC member companies. Non-member companies may use the MEDEC Code as guidance in their Company's interaction with Healthcare Professionals or Government Officials.

All Companies are strongly encouraged to adopt this Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code

¹ The MEDEC Code of Conduct will be a "living" document, reviewed by the MEDEC Code of Conduct Committee annually to ensure the Code is aligned with the business environment.

with respect to their interactions with Healthcare Professionals or Government Officials related to medical technologies. The main intent of a compliance program is to ensure that there is not any “undue influence” on a sale or transaction with a Healthcare Professional or Government Official.

Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Company, namely:

1. implementing written policies and procedures;
2. designating a compliance officer and compliance committee;
3. conducting effective training and education;
4. developing effective lines of communication (including an anonymous reporting function);
5. conducting internal monitoring and auditing;
6. enforcing standards through well-publicized disciplinary guidelines; and
7. responding promptly to detected problems and undertaking corrective action.

Companies are encouraged to include an assessment of Code compliance in their internal monitoring and auditing process.

3.1 Certification

MEDEC will publish the names of those Companies who adopt the Code and become “Code Certified”. To obtain certification, Companies will need to either complete training available through MEDEC or provide evidence of their own equivalent internal compliance training programs. In addition, each Company will need to certify in writing that they agree to follow the Code and have delivered Code compliance training to all of their commercial personnel. This certification must be signed off at the executive level within each Company and reissued on an annual basis to maintain certification.

Companies who are “Code Certified” will be allowed to use the MEDEC Code of Conduct logo when responding to customer procurement requests. MEDEC will encourage Group Purchasing Organizations, hospitals and other customers generally to look for the MEDEC certification when reviewing procurement response submissions.

3.2 Inter-Company Disputes

Any MEDEC member disputes outside the scope of sections 3 to 16 of the Code of Conduct, including but not limited to compliance with any legislation or directive which is not within the jurisdiction of the Violations Review Committee, should be resolved between the MEDEC members themselves through dialogue. The MEDEC CEO can be asked to deal with these complaints with a view to resolving them between MEDEC members.

Companies are encouraged to report potential violations of the Code of Conduct to the MEDEC CEO for resolution as provided in this Section 3 of the Code of conduct. Failing that, such potential violations will be reported to the Violations Review Committee. The primary role of the Violations Review Committee is to eliminate confusion with respect to Code interpretation and ensure a level playing field among Companies. The Violations Review Committee’s jurisdiction applies to complaints of violation of Section 3 to 16 of the Code of Conduct.

4

Company-Conducted Product Training and Education

MEDEC recognizes the essential commitment that Companies make to provide Healthcare Professionals or Government Officials with appropriate product education and training. Historically, both industry and Healthcare Professionals or Government Officials have worked collaboratively in providing education and training on medical technologies and therapies in order to improve the health of patients. Companies have a responsibility to make product education and training



available to Healthcare Professionals, a practice that is strongly encouraged. However, Companies also recognize the need for Healthcare Professionals to preserve the freedom of the medical profession and maintain independence in ongoing education and assessment of Companies' products and services.

4.1 When providing these programs and activities, Companies should adhere to the following:

- Companies should ensure that the primary purpose of the program is to address the educational/training needs of the Healthcare Professionals. If meals and refreshments are provided, they should be modest in value. Activities primarily promotional in nature should not be considered as educational/training programs.
- Programs and events should be conducted in clinical, laboratory, educational, conference or other appropriate settings including the Company's own facilities or commercially available meeting facilities that are conducive to effective transmission of knowledge. Where possible, programs requiring "hands-on" training in medical procedures should be held at training facilities, medical institutions, laboratories or other appropriate facilities. The training staff should have the proper qualifications and expertise to conduct such training.
- Companies may pay for reasonable travel, lodging (should an overnight stay be required), meals and refreshment costs incurred by attending Healthcare Professionals.
- Companies are not permitted to facilitate or pay for the meals, refreshments, travel, lodging or other expenses of guests of Healthcare Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

5 Third-Party Educational Conferences

Bona fide independent, educational, scientific or policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences sponsored by national, regional or specialty medical associations or societies, conferences organized by accredited continuing medical education providers. All third-party education conference decisions should be made based on objective criteria that does not take into account the value or volume of purchases made by, or anticipated from, the recipient. Companies may support these conferences in various ways:

5.1 Conference Sponsorships. Companies may provide conference sponsorships when the event is primarily dedicated to promoting objective scientific and educational activities and discourse. Such sponsorships may either be (a) provided to the conference sponsor to reduce the overall conference costs; or, (b) provided to institutions or relevant organizations to allow attendance by Healthcare Professionals to support professional development, in which case the institution, organization or the conference sponsor selects the attending Healthcare Professionals. Such sponsorships should be paid only to organizations with a genuine educational purpose or function and may be used only to reimburse the legitimate expenses for *bona fide* educational activities. Such sponsorships also should be consistent with relevant guidelines established by professional societies or organizations. The conference sponsor should be responsible for, and control the selection of, program content, faculty, educational methods and materials.

5.2 Direct Support of HCPs. Companies may not provide direct financial support to Healthcare Professionals for professional development at third-party educational conferences.

5.3 Meals and Refreshments. Companies may provide funding to the conference organizer to support the conference's meals and refreshments. Also, Companies themselves may

provide meals and refreshments for all Healthcare Professional attendees, but only if it is provided in a manner that is also consistent with the sponsor's guidelines. Any meals and refreshments should be modest in value.

- 5.4 Faculty Expenses.** Companies may make grants directly to conference organizer for reasonable honoraria, travel, lodging and modest meals for Healthcare Professionals who are *bona fide* conference faculty members.
- 5.5 Satellite Symposiums.** Companies may sponsor satellite symposiums at third party conferences and provide presentations on subjects that are consistent with the overall content of the conference, provided that all information presented is fair, balanced and scientifically rigorous. Companies may determine the content of these events and be responsible for faculty selection. Company support for such events must be disclosed in all materials relating to the satellite event.
- 5.6 Advertisements and Demonstration.** Companies may purchase advertisements and lease booth space for Company displays at conferences. Any games of chance such as sweepstakes or draws need to comply with applicable local laws and the MEDEC Code of Conduct (see Gifts Section 8). Any benefit must not exceed the limits noted in the Gifts Section 8.

6

Sales, Promotional and Business Meetings

It is appropriate for Companies to conduct sales, promotional and other business meetings with Healthcare Professionals or Government Officials to discuss, for example, product features, contract negotiations and sales terms, insofar as the relationship does not impede on the Healthcare Professional's or Government Official's ability to maintain professional autonomy and independence. Such meetings should occur at or close to the Healthcare Professional's or Government Official's place of business. It is appropriate for Companies to pay for occasional modest meals and refreshments for Healthcare Professional or Government Official attendees in an environment that is conducive to the exchange of information. Where plant tours or demonstrations of non-portable equipment are necessary, it is appropriate to pay for reasonable travel costs of attendees. However, it is not appropriate to facilitate or pay for meals, refreshments, travel, lodging or other expenses of guests of Healthcare Professionals or Government Officials or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

7

Arrangements with Consultants

Many Healthcare Professionals and Government Officials serve as consultants to Companies providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at Company-sponsored training and product collaboration. It is appropriate to provide Healthcare Professionals and Government Officials with reasonable compensation for performing these services. The following factors support the existence of a *bona fide* consulting arrangement between Companies and Healthcare Professionals or Government Officials:

- All consultancy agreements should have full transparency and HCPs should notify their employer.
- Company consulting arrangements should be written, signed by the parties and specify all services to be provided.
- Compensation paid to consultants should be consistent with fair market value for the services provided.
- Consulting agreements should be entered into only where a documented legitimate need and purpose for the services is identified in advance.
- Selection of consultants should be on the basis of the consultant's qualifications and expertise



to address the identified purpose and should not be related to the volume or value of business generated by the consultant.

- Company-sponsored meals, refreshments and meeting venues that occur in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- Companies may pay for reasonable and actual expenses incurred by consultants in carrying out the subject of the consulting arrangement, including reasonable and actual travel, modest meals and lodging costs incurred by consultants attending meetings with, or on behalf of, Companies.
- When a Company contracts with a consultant for research services, there should be a written research protocol.
- Government officials may be brought in as consultants and their employer should be notified.

8

Gifts

- 8.1** Except in very few well defined situations below, Companies must not provide gifts to Healthcare Professionals or Government Officials. The only acceptable gifts that can be provided must be occasional and relate to the Healthcare Professional's practice, benefit patients or serve a genuine educational function, and must not be of a personal nature. Some examples of gifts allowed are medical textbooks or surgical and anatomical models, and any such gifts from a company may not exceed a fair market value of \$100 CDN for any one instance.
- 8.2** Companies may occasionally give Healthcare Professionals or Government Officials items of minimal value (having a fair market value of \$10.00 CDN or less) as long as such are within the permitted categories above. Some examples are pens and notepads in the course of a business presentation or training. Gifts must not be given in the form of cash or cash equivalents (ie., gift cards or gift certificates); must be recorded accurately; and must be provided in connection with a normal business relationship, without the expectation of reciprocity.
- 8.3** It is not considered appropriate to give gifts to a Healthcare Professional or Government Official for their significant life events such as a marriage, birth or birthday. However, in the case of a death, each Company may make its own determination as to the appropriateness of sending flowers or making a donation subject to the maximum fair market value limit of \$100 CDN or less.

9

Grants and Charitable Donations

Companies may make educational and research grants and charitable donations for philanthropic purposes. It is not appropriate for Companies to provide grants and donations for the purpose of unlawfully inducing Healthcare Professionals or Government Officials to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of Companies' products. It is not allowable to provide a grant or donation directly to an individual Healthcare Professional or Government Official except where allowable in Section 5. All grants and donations must be provided directly to the Requesting Organization. All grant and donation decisions should be made based on objective criteria that does not take into account the value or volume of purchases made by, or anticipated from, the recipient. Companies should implement appropriate measures to ensure that such grants or donations are not employed as an unlawful inducement. In addition, grant and donation decisions should be made without the control or influence of the sales organization and be appropriately documented. This section does not apply to Education and Research Funding provided as a Contract Value Add. These are covered in Section 10.

9.1 Educational Grants

Educational Grants in accordance with Section 5, may be provided to educational institutions, professional organizations, and public healthcare institutions in support of *bona fide* continuing medical education programs, grand rounds, patient education and public education as long as all requirements of this Section are met. The Requesting Organization is responsible for controlling content, materials, budget, and selection of faculty. Educational Grants cannot be provided to Healthcare Professionals, medical practices or private healthcare institutions and cannot be used for recreation or entertainment or for programs in which the majority of content is not educational. Educational Grants can be monetary or medical technology, however, medical technology that is intended to be multi-use can only be provided as a loaned grant specifically for the requested program.

9.2 Research Grants

Research Grants may be provided to research institutions for purposes such as supporting genuine independent medical research for the advancement of medical science, or the improvement of healthcare delivery and increased patient access to healthcare technology. Research Grants must have scientific merit, well-defined objectives and milestones as well as reporting obligations to the donor organization to confirm appropriate grant use as per the applicable objectives and milestones. Research grants may not be unrestricted and may not be linked, directly or indirectly, to the purchase of medical technology from the granting organization.

9.3 Charitable Donations

Companies may make monetary or Medical Technology donations for charitable purposes such as supporting patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be made only to organizations. Such organizations may include hospital foundations but do not include Healthcare facilities. Donations of Medical Technology intended for clinical use are not allowable except where the donation is intended to support a humanitarian mission/disaster relief effort organized through a charitable organization. Charitable donations should not be made in response to a request by a Healthcare Professional or Government Official unless the Healthcare Professional or Government Official is an officer or employee of the organization and submits a written request on behalf of the organization.

10 Request for Proposals (RFP) and Tenders

10.1 Industry will follow all applicable conduct requirements in an RFP.

10.2 It is not unlawful for healthcare facilities to request “value added” items, grants or donations from Companies in conjunction with an RFP or tender process. Therefore “value added” requests are not unlawful inducements. However, MEDEC does not consider all “value added” requests as procurement best practice, unless the “value add” relates to the product and services requested in the RFP and are clearly defined (documented) within the RFP document. More detailed information can be found in Appendix A, MEDEC Value Add Position Paper dated May 2016.

11 Entertainment and Recreation

It is not appropriate for Companies to provide or pay for “Entertainment” for Healthcare Professionals or Government Officials regardless of whether the Healthcare Professional or Government Official is a consultant, speaker or otherwise.

12 Meals and Travel

Modest and reasonable meals and travel may be provided to Healthcare Professionals or Government Officials as an occasional business courtesy when part of a *bona fide* exchange of scientific,



educational or business information. The time, duration of meals, and the venue in which they are provided should always be subordinate to the business purpose. Modest travel expenses are generally defined as economy class with exceptions permissible for legitimate reasons. It is not appropriate to provide meals or travel to spouses or guests of Healthcare Professionals or Government Officials or for any other person without a *bona fide* professional interest in the event.

This similarly applies to meals and travel in the following sections: 4. Company Conducted Product Training and Education, 5. Third-Party Educational Conferences, 6. Sales, Promotional and Business Meetings and 7. Arrangements with Consultants.

13 Product Evaluations

Product evaluations are defined as situations where Companies leave products and services for use for a limited time by Healthcare organizations free of charge.

In accordance with procurement policies or guidelines of the Healthcare Professional's organization, companies may provide products to Healthcare Professionals, at no charge, as part of the sales and customer evaluation processes.

- Product evaluation purposes in the interests of a potential customer in order to ensure that the potential customer's requirements are satisfied;

The following are required to be in place at the start of the evaluation period:

- The length of the loan must be known and limited to a reasonable evaluation period.
- The arrangement must be documented between the institution and the Company stating the duration and subject of the evaluation, as well as its purpose.

Under no circumstances should a product evaluation be undertaken with the intention to unlawfully influence an RFP.

14 On-Site Product Demonstrations

On-site demonstrations are situations where Healthcare organizations utilize or observe equipment in their own clinical environment on a trial basis in the presence of a Company as part of the equipment selection process. The equipment remains in the possession of the Company over the course of the demonstration. The Company must assess if providing an on-site demonstration is appropriate in each circumstance.

Prior to the start of the on-site demonstration, the arrangement must be documented between the Healthcare organization and the Company which will contain the details and purpose of the demonstration, including the duration of the demonstration, the equipment and the scope of the on-site demonstration.

Upon the conclusion of the demonstration, the equipment should be removed by the Company, or stored at the Healthcare organization's location in a manner so that it cannot be utilized without the presence of the Company. Please reference the MEDEC Medical Imaging On-Site Product Demonstrations Guidance Document, Appendix B.

15 Site Visits

Where site visits to clinical or manufacturing sites are necessary in order to evaluate products, Companies may fund reasonable expenses which are in line with this code and the member orga-

nization's travel policies for the visit under the following conditions:

- Whenever possible site visits should occur in Canada. Companies should fund expenses only for attendees with a *bona fide* professional interest in the equipment.

Please reference the MEDEC Medical Imaging Staging an Effective Site Visit Guidance Document, Appendix C.

16 Third Party Intermediaries

In many instances Medical Device & Technology companies engage third party intermediaries (TPI) for the commercialization, distribution or sale of products and services to Healthcare Professional (HCP). Such entities may fall under the description of distributors, agents, subagents, wholesalers, brokers or independent sales agents. [See glossary for definition.]

Companies are liable for actions and activities of such third party intermediaries. Therefore, special attention should be given to ensure that TPIs undergo a full due diligence prior to retaining such third parties. Due diligence needs to be updated on a regular basis (at least every 3 years). More frequent updates are necessary whenever major changes occur with the TPI such as ownership changes, mergers, acquisitions, changes in executive leadership.

MEDEC emphasizes that it is the responsibility of each Company to train TPIs on the various foreign and local anti-bribery and health care compliance policies including training on the Company's own internal compliance program.

MEDEC provides further guidance through the "Joint Guidance for Medical Device Diagnostics Companies on Ethical Third Party Sales and Marketing Intermediary (SMI)". In addition, training tools and other Due Diligence Resources are accessible through the MEDEC website.

Note: This 2017 MEDEC Code of Conduct supersedes and replaces all previous MEDEC Codes of



Conduct. Companies will communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ascertain that their interactions with Healthcare Professionals comply with all applicable laws and regulations. This Code of Conduct is intended to facilitate ethical behaviour, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations.

Value-Adds in Competitive Tendering


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What is a Value-Add?

A value-add is a product, service, or funding of any nature that is solicited in an RFX or offered by a supplier company as part of an RFX response at no additional charge or on concessionary terms.

IN GENERAL

Healthcare systems in Canada use tendering processes for the procurement of medical devices and diagnostics technologies. These tendering processes are becoming increasingly complex with growing requests for value-adds and are requiring a significant allocation of resources. The medical device industry is concerned about the direction of requests for these value-adds and the “uneven playing field” that may result due to them.

This paper outlines MEDEC’s position regarding the definition of appropriate value-adds¹ in a fair and transparent sourcing process.

MEDEC POSITION

It is MEDEC’s position that medical technology companies and their customers (i.e., Canadian hospitals) should not be expected to buy business through value-add or in any other form of transactional relationship. There should be no unlawful inducement through unrelated or indirect grants or donations.

Non-RFX² Value-add Requests

In the event a university, hospital or other institution would like to request a grant or donation, or other grant or donation not related to a specific product or service sourcing need, MEDEC recommends that these requests follow a transparent process completed outside of an RFX process, one that respects all stakeholders’ business protocol guidelines as well as MEDEC’s Code of Conduct.

RFX Value-Add Requests

All RFX proponents should be bound by the same guidelines.

Acceptable Sourcing Protocol:

- Any request for a value-add must relate to the product(s) or service(s) requested in the RFX.
- The value-add request should be clearly defined and documented within the RFX document.
- An example of a directly related value-add would be supplier support to optimize patient outcomes for the proposed product(s) and/or service(s), such as training and education.
- Value-adds should not be a mandatory requirement of the RFX.
- When a proposal contains a separate price envelope, the values-adds should be presented exclusively in this price envelope or form their own envelope so that it does not influence the quality evaluation of the product. Furthermore, objective and strict evaluation grids should be used to counter balance the influence of the value-adds in the final overall evaluation.

MEDEC POSITION

Medical technology companies and their customers (i.e., Canadian hospitals) should not be expected to buy business through value-add or in any other form of transactional relationship.

ABOUT MEDEC

MEDEC is the national association representing the medical technology industry in Canada. Our members are committed to providing safe and innovative medical technologies that enhance patient care and advance patient outcomes. The medical technology industry in Canada employs over 35,000 Canadians in close to 1,500 corporate facilities, and has sales of nearly \$7 billion per annum. We are committed to ensuring that Canada has a strong and vibrant medical technology industry.

Acceptable Supplier Protocol:

- Value-adds offered by a supplier should be clearly documented as part of the RFX response.
- The value-add should be limited to product(s) or service(s) provided for a related purpose and be reasonably necessary or useful for proper installation, use, or servicing of the product. It should contribute to more effective patient care.
- Value-adds should adhere to the MEDEC Code of Conduct, Canada's anti-bribery and anti-corruption laws, and each company's own code of conduct and ethics. Value-Adds should not promote an anticompetitive environment in any manner.

Unacceptable Value-Adds:

- Unrestricted value-adds, and value-adds that include items such as: cash payments to individuals or institutions, unrelated capital equipment, direct benefits to specific individuals, and/or donations or grants which do not relate to the medical device industry or the products or services in the RFX are not appropriate.
- Value-adds linked to, or in any way connected with, the purchase of products not requested on the RFX are not appropriate.
- An RFX requesting specific value-adds unrelated to the products or services being sourced are not appropriate.
- Mandatory value-adds are not appropriate for fair business practice.

Glossary

For the purposes of this position paper a Value-Add is defined as follows:

A value-add is a product, service, or funding of any nature that is solicited in an RFX or offered by a supplier company as part of an RFX response at no additional charge or on concessionary terms. The value-add provides additional benefit(s) to the contracting body or its affiliations over and above the specific product or service requested in the RFX.

The term "RFX" (Request For <business opportunity>) is used to represent any type of formal procurement process, such as Request for Information (RFI), Request for Proposal (RFP), Request for Quote (RFQ), or Request for Tender (RFT) from a Canadian healthcare institution, system or governing body.



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Diagnostic Imaging – Updated March 2016

GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT DEMONSTRATION & EVALUATION

This document has been developed by MEDEC in consultation with healthcare organizations to provide guidance to Membership and to prospective purchasers on how to prepare for and conduct effective on-site product demonstrations and evaluations.

The objectives of this document are to: i) promote consistent, fair and transparent processes within the vendor community, ii) encourage accountability for public funding and optimal allocation of resources and iii) ensure that all stakeholders (hospitals, independent healthcare facilities, purchasing organizations, and vendors) maximize the benefits afforded by on-site product demonstrations and evaluations through a consistent understanding of the key requirements.

A “Checklist” has also been included in the Appendix to assist the Demonstration Co-ordinator in preparing for and documenting key elements of a successful demonstration process.

Definition:

On-site product demonstrations & evaluations are situations where healthcare organizations evaluate equipment in their own clinical environment on a short term basis in the presence of the vendor company as part of the equipment selection process. The equipment remains the property of the company over the course of the evaluation. The company in consultation with the healthcare facility shall determine if providing an on-site demonstration/evaluation is appropriate in each circumstance.

For equipment where the care, custody and control does not remain with the vendor, policies and documentation related to “loaning equipment” will apply.

Stage One: Pre-Demonstration & Evaluation Requirements

1. Notice of Demonstration

Upon short list notification and a request to provide product demonstrations, MEDEC members will use best efforts to arrange such demonstrations as soon as they are able. Based on the availability of the appropriate equipment and resources, this planning and co-ordination could take up to 4 weeks.

In the event that the demonstration or evaluation needs to be cancelled by either party, a minimum of 5 business days written notice will be provided.





GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT DEMONSTRATION & EVALUATION *(cont'd)*

2. Demonstration & Evaluation Agreement

Any required Demonstration Agreement should be communicated well in advance of the demonstration date and signed by both parties prior to commencement of the demonstration.

3. Key Information and Requirements prior to Demonstration & Evaluation

In order to optimize the demonstration, the following information should be shared and agreed to by all parties prior to the demonstration or evaluation:

- Identify and book accordingly the types of procedures that wish to be evaluated so that the demonstration equipment can be appropriately configured
- Where appropriate, consider reducing the number of patient bookings during the demonstration period to allow for a better evaluation by staff
- Identify evaluation criteria, key stakeholders & clinical specialties to participate in demo
- Each organization (hospital & vendor) to identify a key contact to facilitate communications between the parties (name, title, phone number & email address)
- Mutually agree to the dates of the demonstration, allowing sufficient time for equipment set up and testing prior to clinical demonstrations, time for staff training, days for the demonstration and time for equipment to be packed up and removed from the facility. Times required may vary based on the type of equipment being evaluated.
- Site to communicate to vendor any requirements for screening for entry into OR Suites or Specialty areas (ie. proof of insurance, NDAs, security checks, immunizations...) in advance of the demonstration
- Site to provide appropriate room/space for set-up & testing of demonstration equipment (a lead lined room is required for c-arms and mobile x-ray machines) as well as a secure location should the equipment be required to stay at the site outside of the demonstration hours
- Site to identify a key contact person for networking information and set up and to provide required networking information, such as: IP Addresses, IP Subnet, IP Gateway, DICOM Modality Worklist information & other information as requested by vendor
- Shipping & Receiving: Site to provide the correct "Ship To" address, identify the type of dock available and the opening & closing hours of the Shipping/Receiving Department
- Site to provide a no-charge Purchase Order for the demonstration equipment unless mutually agreed that this is not required

GUIDANCE FOR CONDUCTING AN EFFECTIVE ON-SITE PRODUCT DEMONSTRATION (*cont'd*)

- Vendor guarantees that all medical devices provided for demonstration have been properly licensed by Health Canada, and that the product being demonstrated fits the exact specifications of that quoted by the vendor.
- With the co-operation of the healthcare facility, vendor is responsible for the delivery, installation and removal of the equipment

4. Duration of Product Demonstrations & Evaluations

The following are **suggested** guidelines for the duration of the demonstration and evaluation period, depending on the type of equipment:

| | |
|----------------------------|----------------|
| Ultrasound | 3 days maximum |
| C-arms, Mobile Radiography | 1 week maximum |

Each demonstration will identify in advance a mutually agreed upon delivery date, installation/set up period, training period and a removal date.

Note: For mobile radiography, the first day (typically a Monday) will be used for product delivery, set up & staff training with clinical demonstrations to begin on day two.

5. Escalation of Member Issues about an On-Site Product Demonstration

Should any concerns related to On-Site Product Demonstration requests arise amongst MEDEC Members, the member organization will contact MEDEC, who will in turn, address these concerns with the purchasing organization, explaining why/how their request does not fit with MEDEC's on-Site Product Demonstration Guidance.



Appendix: Diagnostic Imaging On-Site Product Demonstration & Evaluation Checklist

| Stage One: Pre-Demonstration | Most Responsible Person | Date | Completed |
|---|-------------------------|---------------------|-----------|
| Written notice of Dates available to Vendor | Manager | Up to 4 weeks prior | |
| Return Signed Demo Agreement to Vendor (if required) | Stakeholders | Up to 4 weeks prior | |
| Communicate to vendor any requirements for screening for entry into OR Suites or Specialty areas | Manager | Up to 4 weeks prior | |
| Provide no charge PO for shipping and tracking the demo equipment | Purchasing | Up to 4 weeks prior | |
| Provide complete shipping and delivery instruction | Manager | Up to 4 weeks prior | |
| Identify the type of dock and Hours that is available at the Shipping/Receiving Department - notify Vendor | Purchasing | Up to 4 weeks prior | |
| Identify key stakeholders that will be participating / evaluating during the product demonstration - communicate to Vendor & staff | Stakeholders | Up to 4 weeks prior | |
| Book down the regular patient work load on the system being evaluated | Manager | Up to 4 weeks prior | |
| Provide Vendor with evaluation schedule - start times, rooms etc. | Senior or Charge Tech | Up to 2 weeks prior | |
| Book room for testing & setup of demo equipment (a lead lined room is required for c-arms & mobile x-ray machine setup), and confirm a secure location for the equipment if required to remain on-site outside of demonstration hours | Manager | Up to 2 weeks prior | |

| Stage Two: Clinical Demonstration & Evaluation Day | Most Responsible Person | Date | Completed |
|--|--------------------------------|------------------|-----------|
| Vendor rep(s) to register/sign-in according to facility policy | | | |
| Vendor rep(s) to observe facility policy pertaining to infection control | Senior or Charge Tech | Day before start | |
| Confirm Bookings reduced to accommodate Demo | | | |
| Move system from biomed to final evaluation room | BIOMED / Vendor | Day before start | |
| Allow vendor access to system 1 hour prior to start time | Senior or Charge Tech | | |
| One Hour system training and overview prior to first case | Stakeholders / Vendor | | |
| At the end of each day or as pre-determined by the customer and vendor, review to ensure required cases have been completed | Stakeholders / Vendor | | |
| At end of the demo, the customer ensures (with support of the vendor) that all patient data is removed and the equipment is cleaned according to vendor provided recommendations | Senior or Charge Tech / Vendor | | |





Updated: March 2016

GUIDANCE FOR STAGING AN EFFECTIVE SITE VISIT

PURPOSE OF DOCUMENT

This document has been developed by MEDEC to provide guidance to its Membership in responding to site visit requests by prospective purchasers. The objectives of this document are to: i) promote consistent, fair and transparent processes within the vendor community, ii) encourage accountability for public funding and optimal allocation of resources and iii) provide guidelines for effective and efficient Site Visits for all involved parties (ie. vendors, purchasing organizations, and hospitals).

For the purpose of this document, a “purchasing organization” is defined as an organization with an official interest and participation in the decision making process, including hospitals, clinics, purchasing groups, local or regional health boards, etc. A modality is considered to be product areas such as Angiography, CT, MR, Computed Radiography, Digital Radiography, PACS, etc.

MEDEC Members understand the occasional need for prospective purchasers (“purchasing organizations”) to evaluate products at clinical and/or manufacturing sites, as an important part of the equipment selection process. Ensuring quality site visits and an optimal experience is of paramount importance to the MEDEC members as well as to the purchasing organizations. If deemed appropriate by members, they may agree to fund such evaluations and visits in accordance with the following limitations and directions:

1. Site Visit Planning

In order to allow adequate time to organize site visits and effectively meet the purchasing organization’s objectives, a minimum of (4) four weeks written notice is requested for all site visits. It is also recommended that specific site visit dates be published as part of each tender, and that site visit dates and participants (along with the participants information – contact info, travel documents, etc required for travel if applicable) be confirmed upon publication of “short listed” vendors. This will allow MEDEC members to co-ordinate travel to best accommodate the purchasing organization.

Site visit plans may be shared by vendors in order to improve efficiency of scheduling for all participants involved but may not be used to increase the recommended number of attendees.



GUIDANCE FOR STAGING AN EFFECTIVE SITE VISIT *(cont'd)*

2. Site Visit Location

Every effort will be made to conduct site visits locally where local sites best represent the Member's product of focus for procurement. For multi-modality purchases, the site visit may include one location per single modality.

3. Number of Purchasing Organization Representatives Permitted on Site Visits

Purchasing organization representatives should be employees or team members with clinical privileges at the purchasing organization or relevant hospital. As visits are for the sole purpose of clinical evaluation of products, site visits should only include clinical personnel such as physicians, technologists, administrative directors, physicists and bio-medical engineers. For PACS or RIS-related Visits, Clinical IT, IT Admin and/or IT Consultants are encouraged to participate.

It is also recognized that in some instances, a non-clinical representative from the purchasing organization may be required to attend the site visit to ensure fairness and integrity of the process. To respect patient privacy during the site visit, only clinicians can be present in patient treatment areas; all non-clinical attendees are requested to stay outside of rooms where patients are undergoing treatment (eg. angiography suites).

All of the guests listed above will be included in the total number of Purchasing Organization attendees whose travel and expenses can be covered by the members as outlined below:

- a) **Single modality projects cannot exceed a total of 3 purchasing organization representatives.**
- b) **Multi-modality projects cannot exceed a total of 5 purchasing organization representatives.**
- c) **Bulk buy/multi-site projects cannot exceed 7 purchasing organization representatives.**

Note: Multi-site organizations are considered a single purchasing organization for the same modality regardless of the number of sites represented.

Should the purchasing organization request additional representatives, that is allowable however the purchasing organization will be responsible for paying all associated travel and other expenses for such representatives.

There may be some consideration for the addition of a maximum of one more representative to the above limits if there is a need for multiple sub-speciality representation. The additional representative will represent the combined interests of the multiple sub-specialties and will be mutually agreed upon by all members.

GUIDANCE FOR STAGING AN EFFECTIVE SITE VISIT *(cont'd)*

4. Number of Visits

Only one (1) visit per single modality project should be made. Members should request that the representatives required for equipment selection be identified at the time of the site visit request and that all travel information be provided to ensure timely booking of any travel arrangements that may be required. To support fairness, the purchasing organizations must utilize their best efforts to ensure that the identified representatives do not change throughout the equipment selection process.

5. Duration of Site Visits

The duration of site visits shall be no longer than is necessary to evaluate the products and their clinical and technical capabilities. MEDEC Members shall provide the purchasing organization with an itinerary prior to the commencement of the site visit that clearly identifies the equipment and model that is being demonstrated.

The MEDEC Code of Conduct applies, and will be followed regarding any activities and interaction on site visits.

6. Screening Policies for Entry into OR Suites or Other Specialty Areas

Any requirements for screening at host sites (ie. proof of insurance, NDAs, security checks, immunizations...) must be communicated by the Vendor, to the Evaluation Team well in advance of the Site Visit.

7. Travel Expenses and Meals

MEDEC Members will offer the same travel arrangements to Purchasing Organizations as are offered to their own employees. Business Class or First Class travel is not permitted nor is it reimbursable by MEDEC members.

Meals may be provided as an occasional business courtesy when part of a *bona fide* exchange of scientific, educational or business information. The time, duration of meals, and the venue in which they are provided should always be subordinate to the business purpose, and fall within each Company's compliance policies. Should the purchasing organization have a more restrictive policy than MEDEC's, it is the purchasing organization's policy which will be applied.

This MEDEC Site Visit Guidance shall apply to all site visits whether the customer or vendor is paying for the travel.

GUIDANCE FOR STAGING AN EFFECTIVE SITE VISIT *(cont'd)*

8. Escalation of Member Issues about a Site Visit

Should any concerns related to Site Visit requests arise amongst MEDEC Members, the member organization will contact MEDEC, who will in turn, address these concerns with the purchasing organization, explaining why/how their request does not fit with MEDEC's Site Visit Guidance.



Appendix D – Glossary

MEDEC Code of Conduct Glossary

Advertisement Includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the medical technology

Bona Fide In good faith, without fraud or deceit

Charitable Donation The making of a financial or medical technology gift to a registered charitable organization with no expectation of benefit

Charitable Organization Organizations that are recognized as a registered charity, have received a registration number from the Canada Revenue Agency and are exempt from paying tax on their revenue and are operated exclusively for charitable purposes (i.e., the relief of poverty, the advancement of education or other purposes that benefit the community in a way the courts have said are charitable) and devotes its resources to charitable activities.

Company / Companies MEDEC Member company / companies

Consultant A Healthcare Professional who is engaged by a Company under a consulting agreement

Consulting Arrangement Any relationship in which services are provided to a Company by a Healthcare Professional in exchange for remuneration

Continuing Medical Education (CME) A specific form of continuing education that helps those in the medical field maintain competence and learn about new and developing areas of their field. These activities may take place as live events, written publications, online programs, audio, video, or other electronic media.

Education Communicating information directly concerning or associated with the use of Companies' medical technologies, e.g., information about disease states and the benefits of medical technologies to certain patient populations

Educational Grant A financial or medical technology contribution made to an organization in exchange for support of an educational activity.

Entertainment Includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events and other leisure arrangements.

Evaluation Products Capital or disposable medical technology products provided by Companies at no charge to Healthcare Professionals for a limited amount of time in order for the product to be evaluated for its ability to meet certain functional requirements and its ease of use.

Faculty Member a Healthcare Professional who is a genuine speaker at a Third Party Educational Conference including as a participant in a panel of speakers

Gift Something voluntarily transferred by one person to another without compensation

Government Official (GO) Includes any official or employee of a government agency or other governmental unit, political party, party official or candidate, or public international organization. Also includes officers and employees of government-owned companies, or companies substantially controlled by such governments.

Grant A financial or medical technology contribution made to an organization in exchange for support of an educational or research activity. Generally includes an expectation that something of value will be received in return for the ability of the Grantor to withhold payment or request a return of funds if the performance does not occur.

Health Care Institution Any institution, corporation, government body, agency or committee and any other organization involved in; the purchase or other acquisition, supply or distribution, assessment, funding or recommendation of Medical Technologies (other than the Company's contracted Third Party Intermediaries), the administration of Medical Technology.

Healthcare Professionals (HCP) Individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' medical technology products in Canada. This includes both clinical and non-clinical people who make product-related decisions of the sort listed. This is a broad definition, intended to encompass anyone with material influence over purchasing decisions. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

MEDEC Canada's Medical Technology Companies

Medical Technology Medical products, technologies and related services and therapies use to diagnose, treat, monitor, manage and alleviate health conditions and disabilities

Reasonable Related to meals, travel, and accommodations, means in accordance with the Company's corporate travel policies and the policies of the Healthcare Professional's organization

Research Grant A financial or medical technology contribution made to an organization in exchange for support of a research activity. A research grant is usually given with the expectation that the data or manuscript will be made available to the Grantor.

Research Institution Any institution, corporation, government body, agency or committee and any other organization involved in; investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in light of new facts, or practical application of such new or revised theories or laws whose studies are reviewed and approved by an accredited Ethics Review Board.

Requesting Organization Organization responsible for soliciting support from Companies. Can include Educational Institutions, Charitable, Research, or Professional Organizations

Satellite Symposiums scientific/clinical programs that offer educational content through faculty presentations, lectures, posters, etc. including CME and non-CME accredited activities

Site Visit An event during the sales process in which a Healthcare Professional travels to a Company's location to participate in activities that cannot be provided at the Healthcare Professional's home location, such as: demonstration of non-portable equipment and observing the manufacturing process.

Special Access A program run through Health Canada that allows Healthcare Professionals to gain access to medical devices that have not yet been approved for sale in Canada. Special Access is requested in emergency use cases or when conventional therapies have failed, are unavailable or are unsuitable to treat a patient.

Sponsor A person or organization that pays the cost of an activity or event in return for the right to advertise and promote during the activity or event (Merriam-Webster).

Sponsorship The right to advertise during an event or activity purchased by a person or organization.

Training Training on the safe and effective use of medical technologies.

Third Party Educational Conference A conference or meeting conducted by or on behalf of national, regional, or specialty medical professional associations, accredited CME providers, or training organizations with a genuine educational purpose or function that is: a) independent and b) of an educational, scientific, or policymaking nature and for the genuine purpose of promoting scientific knowledge, medical advancement, or the delivery of effective healthcare.

Third Party Intermediary Any third party that sells, or resells, or assists in selling or reselling any products manufactured or distributed by a Company, and receives a fee, commission, discount or other compensation for such services. Terms typically used to describe such third parties include broker, agent, principal agent, dealer, reseller, distributor, consultant, intermediaries, business partner or any representative acting on behalf of the Company in a sales capacity

Value Add Free-of-Charge product or financial payment provided as a part of an executed sales contract. Value Adds must be clearly indicated as such in the contract or tender response. Examples include: medical technology, warranty upgrades, service, training, and/or funding for education, fellowships, or research.