

A GUIDE FOR THE DEVELOPMENT OF MEDICAL DEVICE REGULATIONS



ESSENTIAL DRUGS AND TECHNOLOGY PROGRAM
DIVISION OF HEALTH SYSTEMS AND SERVICES DEVELOPMENT

PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
WORLD HEALTH ORGANIZATION

in cooperation with
MEDICAL DEVICES BUREAU
THERAPEUTIC PRODUCTS DIRECTORATE
HEALTH PRODUCTS AND FOODS BRANCH
HEALTH CANADA

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FOREWORD

The fast development of healthcare technology, the increased complexity in medical devices and their impact in the delivery of health services are central issues addressed by the health sector reform processes currently under way in nearly all countries of the Region of the Americas. It is the responsibility of the states to protect the health of the population. This publication has been prepared to guide the regulatory authorities in ensuring the safety, efficacy and quality of medical devices.

The guideline is based in the documents of the Canadian Medical Devices Regulation and documents of the Study Groups of the Global Harmonization Task Force (GHTF) in the field of international harmonization of regulatory requirements. It also presents an overview of the United States and European Union regulations.

The main author, with the contribution of experts of the Medical Devices Bureau, Health Canada, originally prepared the guide. During the past two years this document has undergone a revision and update process performed by the author and Medical Devices Bureau experts. The revision has taken in account comments provided by a group of experts from PAHO's Member States during the Consultation Meeting on Medical Devices held in Washington D.C., in October 1999, and documents produced by the Study Groups of the GHTF.

*Dr. Daniel López-Acuña, Director
Division of Health Systems and Services Development
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World Health Organization*

INTRODUCTION

The purpose of this paper is to provide a guideline for the Pan American Health Organization (PAHO) Member States seeking to develop a program to ensure the safety and effectiveness of medical devices. This guideline will be used by staffs of the Medical Device Bureau (Health Canada) and PAHO, as well as non-technical readers, during information and training sessions.

This work is mainly based on existing documentation such as the Canadian Medical Device Regulations and its accompanying Regulatory Impact Analysis Statement, the Canadian Treasury Board publications on general regulatory policies and procedures, and the Global Harmonization Task Force documents. Input has also been obtained from staff members of the Therapeutic Products Programme of Health Canada.

This guideline provides an overview of the regulatory methods in Canada, the United States and the European Union. These regulatory methods are illustrated by two “anchors” (learning and memory aids): first, a **life span diagram** (Figure 1) showing the different phases of a medical device from conception to disposal, and second, a table classifying the **tools of regulation** (Table 1) for the stages of control relating to the life span of medical devices. Table 1 is further developed to provide a structural view of the Canadian Medical Devices Regulations (Table 4). This structure is similar to those of the European Union and the United States systems. This approach hopefully makes the format of the Regulations easier to understand.

A summary of the key recommendations for establishing an affordable program to manage medical devices is illustrated in Figure 9, Mind Map of Key Points.

Section 1 describes the nature of medical device safety as a risk management process that must be continued throughout the life span of medical devices from conception to disposal. The safety and effectiveness of medical devices demands co-operation among the people who actively manage the different phases in the life span of medical devices. The responsibilities must be shared among the stakeholders.

Section 2 considers the role of the government. The stages of pre-market, on-market and post-market control are described with their commonly used regulatory tools. An example on the use of these tools in the Canadian Medical Devices Regulations is given.

Section 3 introduces the work of the Global Harmonization Task Force (GHTF) which has a mission to harmonize standards and procedures for medical

device regulation, as well as address other issues related to medical devices in different countries.

Section 4 provides suggestions for governments seeking to establish an affordable program for ensuring the safety and effectiveness of medical devices. Such a program requires that the government increases its knowledge of the medical device sector, and shares this understanding among the stakeholders. This will lead to the establishment of a clear policy on medical device management on which legislation and enforcement can be brought in when necessary and, as resources are available. Governments are urged to take advantage of the current development of the GHTF and the worldwide Quality Movement to reduce the local regulatory burden for the program.

Section 5 describes the different intentions of existing "export certificates" from Canada and the United States. Member States are urged to exercise caution when interpreting these certificates.

1. The Nature Of Medical Device Safety

The optimum assurance of medical device safety has several essential elements:

- It is a risk management issue
- It is closely tied with device effectiveness/performance
- It must be considered throughout the life span of the device
- It requires shared responsibility among the stakeholders

We shall discuss each of these features.

1.1 MEDICAL DEVICE SAFETY AND RISK MANAGEMENT

Safety can only be considered in relative terms. All devices carry a certain degree of risk that could cause problems in specific circumstances. Many medical device problems cannot be known until extensive market experience is gained. For example, an implantable device may fail in a manner that was not predictable at the time of implantation; the failure could be caused by conditions unique to certain patients. For non-implant devices, component failure can also happen in an unpredictable random manner. The best approach to device safety is to estimate the potential of a device becoming a hazard that could cause safety problems. This approach is often referred to as the **risk assessment** of devices.

Hazard is an object or a condition that could jeopardize safety, a source of potential danger. **Risk** is a measure of the incidence, likelihood, and severity of a hazard. In general, risk assessment is based on experience, evidence, computation, or simply guesswork. Risk assessment is a complex field of endeavour; it is largely influenced by personal perception and other factors such as cultural background, economic, and political climates. This field of knowledge is still developing.

In practice, the risk assessment of medical devices is based on experience of healthcare professionals. In the United States, the

government risk assessment of medical devices is mainly performed by members of the designated 16 panels of medical specialties (devices are categorized into three classes). In the European Union and Canada, the classification schemes for medical devices¹ are predominantly rule based. These categorize medical devices according to their potential hazard factors. Canada assigns four classes of devices. The European Union assigns four classes with class II divided into IIa and IIb.

In Europe and Canada, potential areas of hazard that need to be considered include the degree of invasiveness, duration of contact, body system affected, and local versus systemic effects. Therefore, an invasive device has higher potential hazard than a non-invasive device. Similarly, devices that have longer duration of contact; devices affecting vital organs such as the heart or the great arteries, and devices with systemic effects are assigned higher potentials of hazard. The degree of regulation imposed on any device is proportional to its potential hazard. This approach is known as **risk management**. The following quotations from the Canadian Medical Device Regulations (May 1998) illustrate such an approach. The first two safety and effectiveness requirements state that:

- “a medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to:
 - (a) identify the risks inherent in the device
 - (b) if the risks can be eliminated, eliminate them
 - (c) if the risks cannot be eliminated
 - (i) reduce the risks to the extent possible
 - (ii) provide for protection appropriate to those risks, including the provision of alarms
 - (iii) provide, with the device, information relative to the risks that remain
 - (d) minimize the hazard from potential failures during the projected useful life of the device

- a medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes **an acceptable risk** when weighed against the **benefits to the patient** and the risk is compatible with a high level of protection of health and safety.”

¹“Guidance for the risk based classification systems,” www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html.

This last clause highlights the risk/benefit nature of medical devices. The goal then is to maximize benefit and minimize risk.

1.2 EFFECTIVENESS/PERFORMANCE² OF MEDICAL DEVICES

Every device has a designed purpose, be it to diagnose a disease or to treat a clinical ailment (see Section 4.3.2). A device is **clinically effective** when it produces the effect intended by the manufacturer relative to the medical conditions. For example, if a device were intended for pain relief, one would expect the device to actually relieve pain and would expect the manufacturer to possess objective evidence, such as clinical test results, that the device does in fact relieve pain. Effectiveness in that sense might be termed **direct effectiveness** (i.e. it considers only the device itself and the effect the device has on the patient).

Relative effectiveness is the comparison of the direct effectiveness of a device with the effectiveness of other similar devices. The relative effectiveness of a device will be raised as an issue when it constitutes a safety concern. For example, consider an HIV test kit that is represented as being 80% accurate and indeed achieves 80% accuracy, while others on the market achieve 99% accuracy. In view of the health concerns related to HIV, the 80% accurate kit could be considered to pose a safety concern. Thus, effectiveness is closely linked to safety.

Safety and effectiveness examinations for medical devices are normally considered together by device attribute requirements, as stated in the 11 requirements in the Canadian Regulations (see Section 2.3). To further illustrate, a blood collection syringe with a blunt needle will be ineffective for collecting blood; it could also inflict bodily injury. An ineffective patient monitor could pose serious clinical safety problems to the patient.

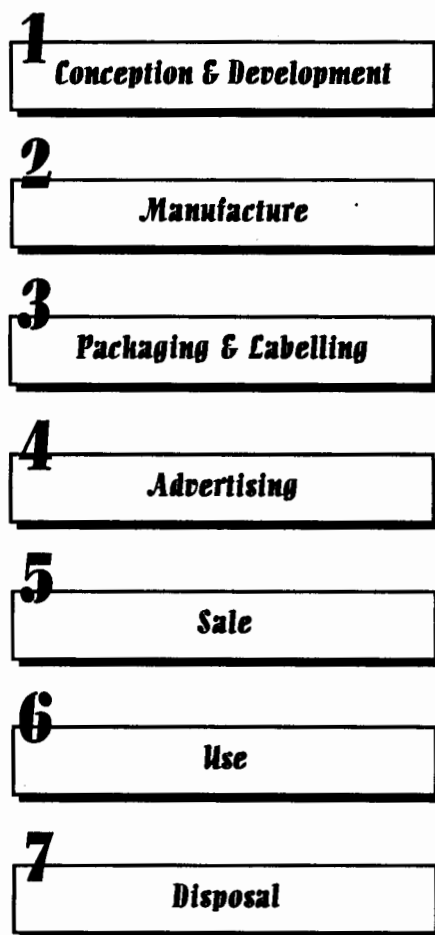
²Three terms: "performance," "effectiveness" and "efficacy" are commonly used in association with medical devices. For the purpose of this guideline, effectiveness means clinical effectiveness as described above. Performance means technical performance including clinical effectiveness. Efficacy, not used here, generally means effectiveness under an **ideal** controlled setting.

The above discussion mainly highlights the problems of inherent risk in medical devices. We shall now expand to illustrate how other aspects in the life span of medical devices can affect their safety and effectiveness.

1.3 PHASES IN THE LIFE SPAN OF MEDICAL DEVICES

The following diagram shows the major phases in the life span of a medical device from conception and development to disposal of devices.

FIGURE 1. MAJOR PHASES IN THE LIFE SPAN OF A MEDICAL DEVICE



It is important to recognize that any of these phases in the life span can affect the safety and effectiveness of a medical device. Some illustrations of how each can create health hazards are describe below:

1. CONCEPTION AND DEVELOPMENT

The scientific principles under which the device is based is fundamental to its safety and effectiveness. For example, a cardiac pacemaker should deliver a minute electrical impulse of certain size and shape that simulates natural functioning of the heart. Significant deviation from this could cause safety and effectiveness problems.

Soundness of concepts and adequacy of design, construction, testing (including clinical trials) require the scrutiny of an expert scientific staff to ensure that design parameters and performance characteristics do not impose unwarranted risks.

2. MANUFACTURE

In many traditional manufacturing processes **only the end products are subjected to inspection** for quality control, and frequently inspections are performed by sampling (i.e. not every finished product is inspected). The result is that a consistent quality of product cannot be ensured, and non-conforming products can get through the production line to the market.

3. PACKAGING AND LABELLING

Inadequately packaged devices pose risks to individuals handling them, especially if the device contains bio-hazardous material. Moreover, inadequate packaging may not provide sufficient protection to delicate devices, and subtle damage can result during transportation and handling. Well-sealed packaging is essential for devices that must be maintained sterilized.

Labelling is important in identifying the type of device. Similar to the situation for drugs, mis-labelling can result in serious problems. Hazard warnings and clear instructions for use are equally important to medical devices.

4. ADVERTISING

Advertisement can create desires and powerfully influence the mind's understanding. While misleading or fraudulent advertisement on medical devices may increase the chance of a sale, to the buyer, however, the purchase of the wrong device is not only a waste of money but also it deprives the buyer of appropriate treatment.

5. SALE

Medical devices are made available to the users through sales by the Vendor. This is a **critical stage** that leads to the device being put into actual use. If there are no controls on sales, the public may be exposed to a higher degree of risk of low quality or ineffective devices than if there were sales controls.

6. USE

Users of medical devices can have a profound effect on their safety and effective performance. Unfamiliarity with a certain technology or operating procedure, and the use of the product for clinical indication outside the scope of those specified in the labelling are examples of why devices fail despite the absence of any inherent design or manufacturing defects.

There seems to be a consensus in the clinical engineering community that user error underlies **at least half** of all medical device related injuries and deaths.

Re-using disposable devices without taking precautions to minimize associated risks can be lethal.

The lack of, or inappropriate calibration and maintenance is another factor that can seriously jeopardize safety and effectiveness of devices. These subtle issues are often overlooked or downplayed.

7. DISPOSAL

Disposal of certain types of devices should follow specific safety rules. For example, devices that are contaminated after use or devices that contain toxic chemicals can become a hazard to people or the environment and must be disposed of properly. A syringe is a common item that requires safe disposal.

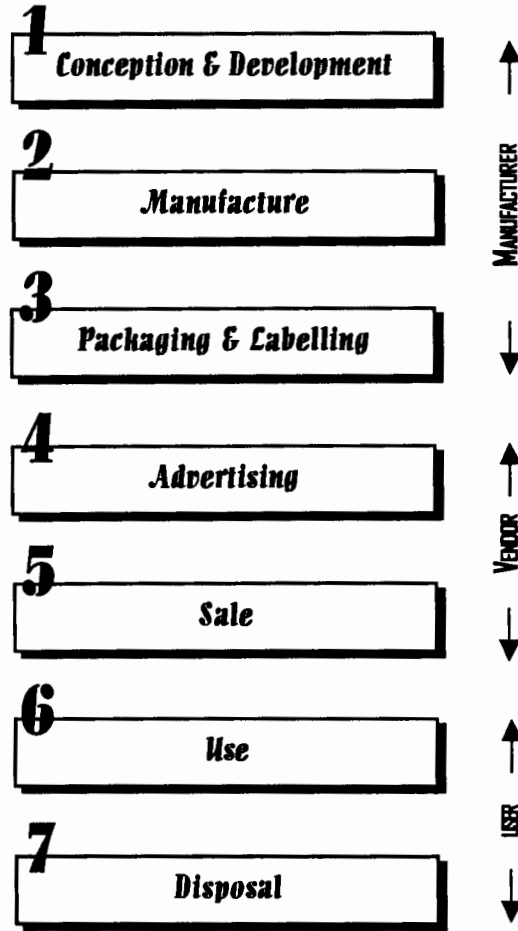
It is people who manage each of these phases in the life span of medical devices. To be able to ensure safety in all of the above phases, we need to identify the people who are directly involved with the activities in each phase. They should be called on to participate in ensuring the safety of each medical device.

1.4 PARTICIPANTS IN ENSURING THE SAFETY OF MEDICAL DEVICES

As shown in Figure 2, the Manufacturer manages the first three phases of the medical device's life span: the design and development, the manufacture, and the packaging and labelling of the product. The Vendor includes importers,

distributors, retailers and manufacturers who sell medical equipment. The User is usually a professional in a healthcare facility.

FIGURE 2. PERSONS WHO DIRECTLY MANAGE THE PHASES OF MEDICAL DEVICES



In addition to these three persons who are directly involved with the different phases of medical devices, there are the **Public** and the **Government**. The **Public** is the ultimate beneficiary of devices. In the case of over-the-counter (home-use) medical devices, the user is also the beneficiary. The government has the overall responsibility of overseeing that medical devices sold in the country are safe and effective. Together, the **Manufacturer**, the **Vendor**, the **User**, the **Public** and the **Government** are the **stakeholders**. All five play critical roles to ensure the safety of devices.

The most important factor that influences the willingness of all these stakeholders to co-operate is an informed and common understanding of the issues. Shared understanding is achieved through **communication** and mutual **education** among the stakeholders. An effective way to achieve this is by

having all stakeholders **participate** in establishing the process that ensures safety. This increases the likelihood that all parties concerned will see their roles more clearly and accept the reality in **sharing the responsibilities** that ensure the safety and effectiveness of medical devices.

1.5 THE ROLE OF EACH PARTICIPANT/ STAKEHOLDER

The manufacturer is the creator of the device and should ensure that it is manufactured to meet or exceed the required standards of safety and effectiveness. This includes the three phases (design/development/testing, manufacturing, packaging and labelling) that lead to a product being ready for the market.

The vendor is the interface between the product and the user. He/she should ensure that the products being sold comply with established standards. In this age of proliferation of technological devices and competitive markets, vendors should not make misleading or fraudulent claims about their products.

Vendors should not furnish false compliance certificates. Used or refurbished devices (Appendix 6) should be clearly labelled as such.

Vendors should provide after-sale services. Medical devices require specialized training from the manufacturer for proper use and services; therefore, the vendor should make such training a condition to the manufacturer or importer in accepting to sell the device. In turn, vendors should take the responsibility to support or train their customers.

Post-market surveillance is critical for ensuring device safety and effectiveness. The vendor must fulfill these obligations specified by the regulatory authority. For example, the vendor must make arrangements for processing reports relating to device safety and effectiveness.

In the case of home-use medical devices, the vendor should recognize the fact that the device being sold may now be in the hands of a layperson who may need special instructions for the proper use and maintenance of the device. Therefore effort must be made to educate and help the customer. A reference on this subject is given in an article by Michael Cheng.³

The users should make sure that they have qualifications and training in the proper use of the device. He/she should become familiar with the

³"Leadership in Health Services," Canadian Healthcare Association, Jan/Feb 1995, Vol. 4 No.1, pp14-18.

indications, contra-indications and operating procedures recommended by the manufacturer. It is crucial that experience gained with medical devices be shared with other users, the vendor and manufacturer to prevent future problems. This can be done by reporting any device problems to a co-ordinating center where warnings can be issued to other users.

When using medical devices, users should always bear in mind that the safety and health of the patients are in their hands. The user also has the responsibility to ensure proper maintenance of devices during active use and safe disposal of retired medical devices.

The public is the ultimate beneficiary from medical devices. They should be fully aware that all devices carry a certain risk and that they can help to promote safety and effectiveness through self education and by putting "customer pressure" (see Section 4.4) on vendors to comply with standards.

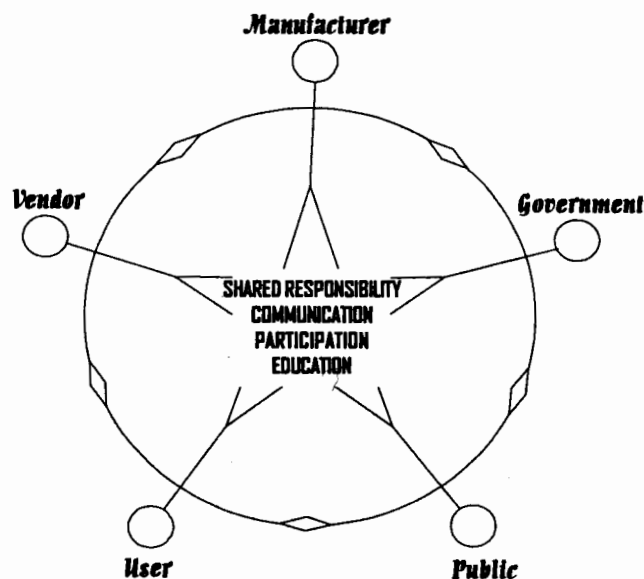
Medical devices are increasingly becoming available for home use, and the Public is becoming the direct user. Therefore, those who buy home-use medical devices should be aware of associated risks and take the responsibility to become educated in the functions and correct operating procedures for the devices they intend to use.

The government has the responsibility to oversee the efforts of the manufacturers and vendors to ensure that the medical devices they sell in the country are safe and effective. They should consult with all the stakeholders in establishing policies and regulations; **make policies and regulations fair and clear to all stakeholders**. Policies and regulations should be reviewed periodically to respond to changes in technologies by appropriate amendments. The government is the catalyst to create a healthy co-operation among the stakeholders.

1.6 SHARED RESPONSIBILITY FOR MEDICAL DEVICE SAFETY AND EFFECTIVENESS

In conclusion, the **ideal conditions** that will ensure the safety and effectiveness of medical devices require a shared responsibility by all stakeholders. This need for co-operation is illustrated in Figure 3.

FIGURE 3. IDEAL CONDITIONS FOR ENSURING THE SAFETY AND EFFECTIVENESS OF MEDICAL DEVICES



Note: The circle formed by the stakeholders illustrates the shared responsibility. The handshake ($\langle \rangle$) symbolizes cooperation and two-way communication (2-way arrow). The star highlights how the fundamental elements for co-operation function best when all stakeholders communicate with each other. *(It should be emphasized that the partnerships are balanced only if all stakeholder would play their proper roles).*

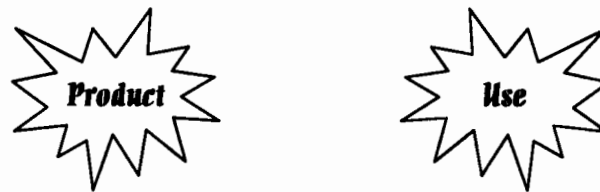
2. Government Regulations On Medical Devices

The previous section has demonstrated that medical device safety requires that all stakeholders co-operate and share the responsibilities. The roles of each party have been described. Now we shall concentrate on how the government can use regulations to fulfill part of its duties.

2.1 STAGES OF CONTROL

The safety and effectiveness of medical devices depend on two critical factors:

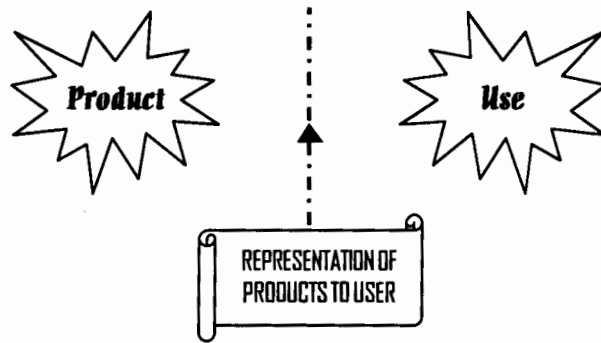
FIGURE 4. PRODUCT AND USE: TWO CRITICAL FACTORS



Pre-market review contributes to the control of the product, and **post-market surveillance** ensures that medical devices in use continue to be safe and effective.

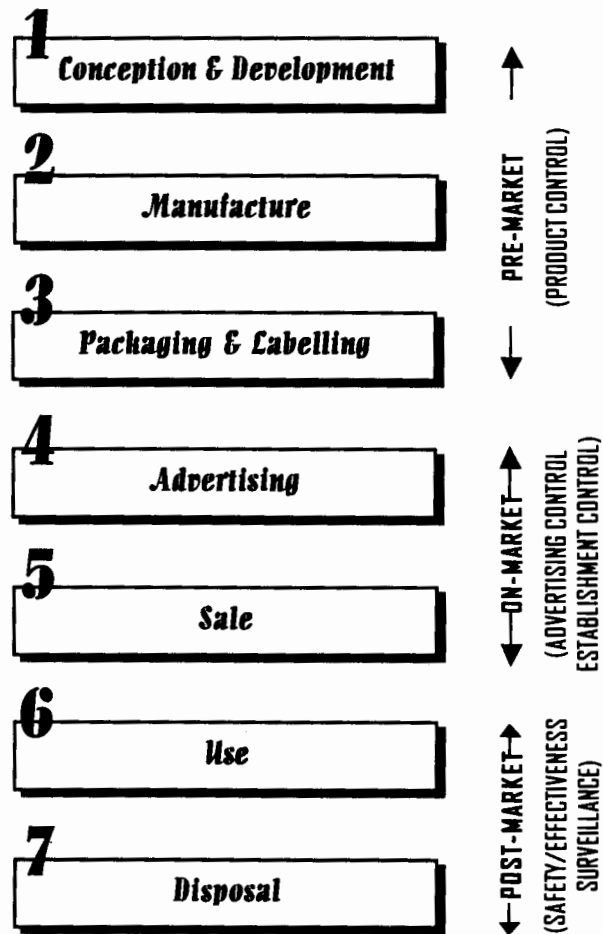
There is an important third element, which is the representation of the product to the user. This is controlled through labelling (during the pre-market stage) and advertisement during the **on-market** stage. A powerful component of product representation, however, is through verbal presentation by the vendors, over which the government has little control. Here, user/public education is key to guard against mis-representation.

FIGURE 5. PRODUCT REPRESENTATION



We can identify these three stages of regulatory control by relating them to the now familiar Life Span diagram shown below.

FIGURE 6. COMMON STAGES OF GOVERNMENT CONTROL



Pre-market control is performed on the device to ensure that the product being sold complies with accepted safety and performance standards.

Advertising control is maintained to prevent misleading or fraudulent claims by uninformed or unethical merchants.

Establishment (company) control, in effect, imposes on the vendor the obligations of post-market surveillance and provides the government with records for tracking purposes.

Post-market surveillance includes the maintenance of official and systematic procedures and records for device safety and performance throughout its useful life.

The tools used in each of these three stages of regulatory control are summarized in Table 1. Note the different terms used by the different governing bodies. Their functions, however, are actually quite similar.

2.2 TOOLS OF REGULATIONS

TABLE 1. COMMON TOOLS OF REGULATIONS

COUNTRY	PRE-MARKET	ON-MARKET		POST-MARKET EXAMPLES OF REQUIREMENTS
		ADVERTISING CONTROL	VENDOR ESTABLISHMENT CONTROL	
Canada	- Device license	- Generally, prohibition of misleading or fraudulent advertisement - In Canada, Classes II, III, IV require device license to advertise. See Table 5 in Appendix I.	- Establishment license	- Mandatory problem reporting - Distribution records - Complaint handling - Recall procedure - Implant registration - Possibly, qualification of the user, or mandatory user education
European Union	- Compliance label (the CE mark)		- Responsible person registration	
United States	- Marketing Clearance Letter		- Establishment registration	
Others	- Export certificate - Manufacturer's certificate		- Sales notification*	

Note: *Sales notification can be given after-sale (see description on next page)

It is important to keep in mind that different countries have different systems of **pre-market review**. For example, in Canada, devices of classes III and IV are subject to in-depth scrutiny, while class II devices require only manufacture's declaration of safety and efficacy submission before sale. Class I devices are exempted from any pre-market submission (but they must still satisfy the safety and effectiveness requirements, see Table 4 in Appendix 1). In the United States, Class III and new devices that cannot be found to be substantially equivalent to a legally marketed product that does not require an approved pre-market approval (PMA) application,

require clearance through the PMA or Product Development Protocol (PDP) process.

Different countries acknowledge satisfactory pre-market review in different ways. In Canada, it is the **Device License** given by the Therapeutic Products Directorate (TPD). In the European Union (EU), a device is given a compliance label, the **CE mark** issued by a notified body (an authorized government or **private agent** as determined by the member state, currently there are more than 25 authorized agents in the EU). In the United States, the manufacturer of the device receives a **Marketing Clearance Letter** from the Food and Drug Administration (FDA).

Export Certificate or Manufacturer's Certificate: For device-importing countries, a convenient tool to ensure product conformance to certain standards or regulations is to request that the device exporter obtain a certificate of compliance issued by their national regulatory agency. For example, countries like Canada are now providing device Manufacturer's Certificates to exporters certifying that the device being exported meets Canadian regulatory requirements. An application by exporters can be made to Health Canada, and the compliance office will verify whether or not the device has complied with Canadian regulations. Other countries can be requested to do the same. However, at present there is no international standard for issuing this kind of certification, and caution must be exercised in interpreting such certificates (see Section 5).

Advertising control is an important tool to ensure that the public is protected from misleading and fraudulent claims put forth by unethical or uninformed merchants. This requirement should be universal (see Section 4.2.1).

Vendor establishment (or company) control allows the government to track vendors of medical devices in the country. In Canada, the establishment (or individual wishing to sell medical devices) applying for permission to sell medical devices is given an establishment license. In the United States, the establishment (Manufacturers, Initial Importer, Specifications Developer, Contract Sterilizer, Re-packer and/or Re-labeler) must be registered with the FDA. The European Union requires that a responsible person of the vendor establishment be registered. The licensing or registration process also imposes an obligation on the vendor for post-market surveillance duties.

Sales notifications have less stringent requirements. Where establishment licence or registration are not needed before selling any medical devices, the government can use these options. As an on-market tool, the government would require the vendor to serve a notice of intention to sell certain medical devices. As a post market tool, the government would require the vendor to notify the government within a certain time period after the first sale of a device in a country. In both cases, the

government can use the notifications to track vendors and impose post-market obligations.

Post-market surveillance: The continued assessment of safety and effectiveness of medical devices in use is as important as pre-market scrutiny. The proof of a medical device is in how it stands up to the conditions of use. No amount of rigor in any pre-marketing review process can predict all possible device failures or problems arising from device misuse. It is through actual use that unforeseen problems related to safety and effectiveness can occur.

Post-market surveillance generally includes a system for registering and investigating adverse incidents relating to the use of a device, and for requiring the manufacturer to recall or modify a defective device. Canada now has a mandatory requirement for vendors and manufacturers to report all device-related incidents which have resulted or could result in serious injury or death.

It is important that a post-market surveillance program include a system for informing other users and the public of hazards and issues relating to medical devices.

As described in Section 1, the user plays a critical role in the safety and effectiveness of medical devices. Thus, **user competence** for certain devices should be considered for control. In Canada and the United States, user qualifications are governed by the user's professional association.

Next, we shall use the Canadian Medical Devices Regulations to illustrate how some of the above tools are used in a comprehensive regulatory program.

2.3 AN EXAMPLE OF THE USE OF REGULATORY TOOLS

The Table 2 illustrates how the regulatory tools are used in the Canadian Medical Devices Regulations. It relates the stages and focus of controls, the persons directly involved and the regulatory tools used.

Only the major functions are listed in the last column of this Table 2. Actual requirements vary with different classes of devices. Please refer to Table 4 in Appendix 1 for further details and reference number for the regulatory clauses in the actual Regulations.

Canada imports most of its medical devices. The Vendor is represented by importers and distributors. The importer must make sure that imported devices from foreign manufacturers have Canadian licenses. Furthermore, the other two stakeholders, namely, the User and the Public are not

regulated under these regulations. This increases the importance of education of the user and the public so that they are informed and can participate effectively in the process of ensuring the safety and effectiveness of medical devices.

TABLE 2. AN EXAMPLE OF THE USE OF REGULATORY TOOLS

STAGE	CONTROL	PERSON	REG. TOOL	ITEMS OR ACTIVITIES REGULATED	MAJOR FUNCTION
PRE-MARKET	PRODUCT	MANUFACTURER	DEVICE LICENSE	Device attributes	- Safety and effectiveness requirements - Device characteristics review
				Device manufacturing	- All devices (except class I) require a quality system for manufacturing
				Device labeling	- Accurate description of product - Instruction for use
ON-MARKET	SALE			Advertising	- Prohibits misleading or fraudulent advertisement
				Establishing license (Sales license)	- Allows government to be informed which establishment is selling what devices - Requires vendor to fulfill after sale obligations
POST-MARKET	AFTER-SALE	VENDOR	AFTER-SALE OBLIGATIONS	Distribution record	- Permits complete and rapid removal of devices in case of problems
				Complaint handling	- Procedures and records of reported problems relating to safety or performance
				Problem reporting	- Mandatory reporting of any serious device incident
				Recall procedure	- In case of device recall, the procedure is in place and can be utilized
				Implant registration	- Facilitates notifying the patient of pertinent post-implant information

2.3.1 SAFETY AND EFFECTIVENESS REQUIREMENTS

The examination of the **Device Attributes** is the principle task of pre-market review. Factors examined include intended use, design, material, construction, packaging, labelling, accessories, software and performance. The Canadian Medical Device Regulations (May 1998) has 11 requirements relating to the safety and effectiveness of medical devices.⁴ These

⁴Document SGI N020R5 from www.GHTF.org.

requirements are condensed from the “essential principles of safety and performance of medical devices” (document SGI N020R5 from www.GHTF.org) recommended by the Global Harmonization Task Force (see Section 3). The Canadian requirements are quoted below from regulatory clauses 10 to 20.

10. A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to:
 - (a) identify the risks inherent in the device;
 - (b) if the risks can be eliminated, eliminate them;
 - (c) if the risks cannot be eliminated,
 - (i) *reduce the risks to the extent possible*
 - (ii) *provide for protection appropriate to those risks, including the provision of alarms*
 - (iii) *provide, with the device, information relative to the risks that remain*
 - (d) minimize the hazard from potential failures during the projected useful life of the device.
11. A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.
12. A medical device shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.
13. During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.
14. The characteristics and performance of a medical device shall not be adversely affected by transport or conditions of storage, taking into account the manufacturer’s instructions and information for transport and storage.
15. Reasonable measures shall be taken to ensure that every material used in the manufacture of a medical device shall be compatible with every other material with which it interacts and with material that may come into contact with it in normal use, and shall not pose any undue risk to a patient, user or other person.

16. The design, manufacture and packaging of a medical device shall minimize any risk to a patient, user or other person from reasonably foreseeable hazards, including
 - (a) flammability or explosion;
 - (b) presence of a contaminant or chemical or microbial residue;
 - (c) radiation;
 - (d) electrical, mechanical or thermal hazards; and
 - (e) fluid leaking from or entering into the device.
17. A medical device that is to be sold in a sterile condition shall be manufactured and sterilized under appropriately controlled conditions, and the sterilization method used shall be validated.
18. A medical device that is part of a system shall be compatible with every other component or part of the system with which it interacts and shall not adversely affect the performance of that system.
19. A medical device that performs a measuring function shall be designed to perform that function within tolerance limits that are appropriate for the medical conditions, purposes and uses for which the device is manufactured, sold or represented.
20. If a medical device consists of or contains software, the software shall be designed to perform as intended by the manufacturer, and the performance of the software shall be validated.

2.3.2 *QUALITY SYSTEM REQUIREMENTS*

Quality systems for manufacturing are a new requirement in the Canadian Medical Devices Regulations. Studies have shown that many recalls and serious problems associated with devices are caused by poor design and the lack of manufacturing controls. Implementing an effective quality system will reduce the likelihood of this occurrence and will provide greater assurance that safe and effective medical devices are manufactured.

A quality system is defined as the organizational structure, responsibilities, procedures, processes and resources needed to implement quality management. A closely related term is "Good Manufacturing Practice (GMP)".

A commonly known quality system standard is the ISO9000 family of standards from the International Organization for Standardization. The ISO9001 and ISO9002 standards are for general application for products

or services. The ISO13485 and ISO13488 standards are for the medical device industry. ISO13485 includes all the elements of ISO9001 plus a **minimum set** of supplementary requirements for the **quality assurance** of medical device manufacturing (see Appendix 2). The same relationship exists for ISO13488 and ISO9002. ISO13488 is equivalent to ISO13485 but without the design control requirements.

Quality system requirements impose strict quality controls on every aspect of the manufacturing activities listed on the table in Appendix 2. There are twenty categories of requirements. The result is a tightly controlled manufacturing system which greatly reduces the chance of non-conforming products. Furthermore, a quality system has the feature of continuous improvement: all the elements of the system are periodically subject to system audits, management review, and corrective or preventive actions to maintain or improve the quality of the product.

All major medical device manufacturing countries have quality system requirements for their manufacturers. The following table shows the standards used.

TABLE 3. QUALITY SYSTEM STANDARDS USED BY DIFFERENT COUNTRIES

COUNTRY	ON-MARKET
European Union	EN46001, EN46002
United States	QS (21 CFR part 820)
Japan	GMP (QS Standard for medical devices #1128)
Canada	ISO13485, ISO13488 (see Appendix 1 table)

With the rapid growth in the global market for medical devices, there is a need to harmonize national standards in order to minimize regulatory barriers and to facilitate trade. Harmonization also reduces the cost of local industry and government regulations.

In the next section, we shall describe the role of the Global Harmonization Task Force in finding common elements and ways to unify the different national standards for assuring the safety and effectiveness of medical devices.

3. Global Harmonization Task Force (GHTF)

The Task Force was established in 1992, and its work is on-going. The main objective of the Task Force is to seek a common approach for assuring the production of safe, effective and high quality devices, as well as an efficient vigilance and post market surveillance system to monitor the safety and effectiveness of devices in use. The founding members are Australia, Canada, Japan, the European Union, and the United States.

There are four Study Groups: their objectives are as follows:

Group 1: identification of features of regulatory systems, which present opportunities for harmonization amongst participating members. In June 1999, the GHTF adopted a guide on “essential principles of safety and performance of medical devices” drafted by this group. (See footnote reference on Section 2.3.1).

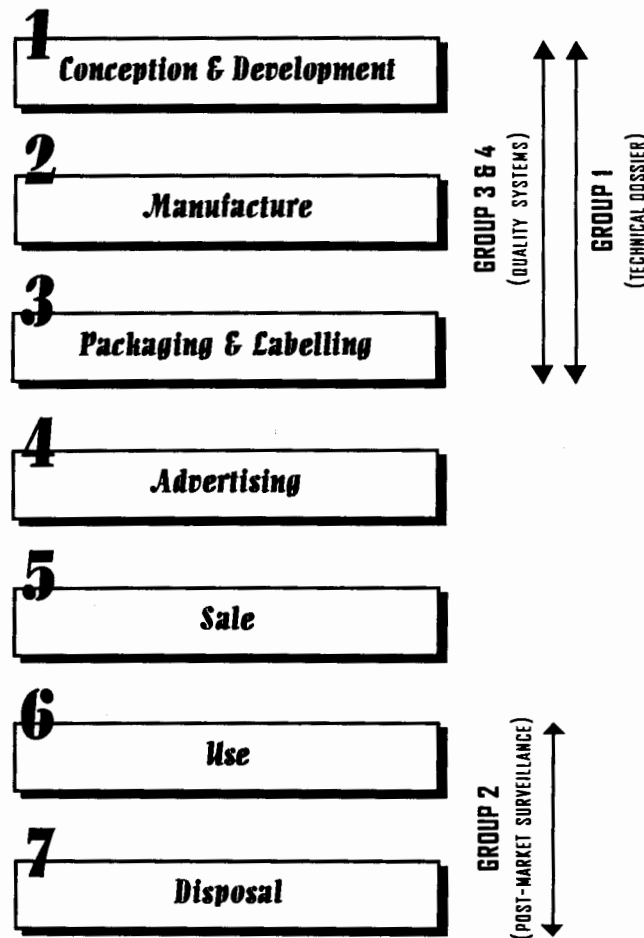
Group 2: development of a vigilance and postmarket surveillance system to improve the protection of the health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This is to be achieved by the evaluation of reported incidents, and where appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such repetitions.

Group 3: development of guidance for the application of quality system standards for the medical devices sector.

Group 4: examination of quality system auditing practices and the development of guidance documents, which will assist in the harmonization of the auditing process.

It is helpful to relate the work of these four group to the life span aspects of medical devices that we are now familiar with (see Figure 7).

FIGURE 7. SCOPES OF WORK OF THE STUDY GROUPS OF THE GHTF



We see that other than the commercial aspect of advertising and sales, which give freedom to local variations, the Study Groups involve all other aspects that have direct impact on the safety and effectiveness of medical devices. Therefore, recommendations from the Task Force can provide excellent reference or guidance for countries that are establishing medical devices regulation programs. The benefits of following recommendations from the Task Force include the following:

- 1) Countries can ensure that their regulating controls are not in significant conflict with actual harmonizing rules and guidelines.
- 2) Critical issues such as safety and effectiveness requirements; quality manufacturing; standards and procedures of post-market surveillance are studied in-depth by experts of different countries to reach a consensus of recommendations.

- 3) Global harmonization and cooperation in post-market surveillance can result in an international data bank on devices that allows rapid access of device information or alerts and recalls globally. This can greatly promote safety and effectiveness of medical devices.
- 4) A country program that is harmonized with other countries will create opportunities for mutual recognition agreements and other arrangements. Such agreements would reduce regulatory burdens and costs of local government and industry, as well as promoting regulatory co-operations, commerce and trade.
- 5) Other emerging issues of international significance could be proposed to the Task Force for a common solution.
- 6) GHTF provides countries an opportunity to participate and observe regulatory developments that they could adopt. At the June 1999 GHTF meeting, medical device regulators of the Americas launched a regional GHTF group.

4. Optimizing The Use Of Regulatory Resources

Implementing a full regulatory program can be very expensive and resource demanding. The global harmonization of standards is, in effect, tackling this problem by steering manufacturers in different countries more and more toward producing medical devices with uniform standards. The methods and procedures of government regulations are also becoming more similar. These developments create opportunities for countries to establish low cost programs that promote the safety and effectiveness of medical devices by taking full advantage of what others have done in this field.

A good approach in setting a clear direction for all stakeholders is to establish a comprehensive national policy or guideline on medical device management. Then the government can bring in legislation and enforcement to suit the country's conditions and needs. Five principal activities are identified:

- Increasing knowledge of the medical device sector
- Establishing basic programs
- Drafting a comprehensive policy/guideline
- Promoting compliance and cooperation
- Setting priorities for monitoring and enforcement activities

4.1 INCREASING KNOWLEDGE OF THE MEDICAL DEVICE SECTOR

Several key activities are suggested:

- 1) Tap into the INTERNET for a great deal of relevant information that is freely available. A list of web site addresses is given in Appendix 3.
- 2) Become a member of the Global Harmonization Task Force (GHTF) in order to benefit from the experience of experts from other countries. Knowledge will grow quickly by active participation in the projects of the Task Force.

- 3) Form a partnership with a country that is already a member of the GHTF and has a functioning regulatory program on medical devices
- 4) Make connections with local and international medical device problem co-ordinating centers (Appendix 3).

4.2 ESTABLISHING BASIC PROGRAMS

As discussed in the first section of this guideline, medical device safety and effectiveness is multi-phased and requires co-operation among the stakeholders. It is essential to identify the stakeholders in each country by creating a list of manufacturers, importers, distributors, retailer, institutional users (both public and private healthcare facilities), lay users (estimated from the number of home-use medical device vendors), and concerned citizen groups.

The program should also include other important activities: holding education/consultation sessions with the stakeholders to discuss the issues; creating an atmosphere conducive to mutual trust and open discussions; and, inviting input from the stakeholders. The government should not under-estimate the willingness of stakeholders to help suggest solutions to problems that affect them. The results of these sessions will help to share understanding of issues affecting the safety and effectiveness of medical devices, and should lead to the development of a policy/guideline that sets a direction for everyone (see Section 4.3). Apart from the rich source of practical suggestions that stakeholders can offer, they are more likely to comply with any requirements that they have participated in making. A guideline on how to conduct Public Consultation is given in Appendix 5.

If there are a significant number of medical devices being sold or used in the country, then two basic programs should be set up as soon as possible: (1) Basic legislation; (2) Problem sharing.

4.2.1 BASIC LEGISLATION

If the government has not already passed legislation, this should be done:

- (a) to prohibit misleading or fraudulent advertising of medical devices,

Advertising has a powerful influence on people. A prohibition on the misleading or fraudulent advertisement of health devices should be an essential legislation. This is particularly important since home-use medical devices are rapidly increasing as people are becoming more health conscious.

Advertising control does not have to be resource demanding. For example, in Canada, even though the prohibition of misleading or fraudulent advertising is legislated, the Government does not routinely screen device advertising. The Government, however, will respond to inquiries or complaints made by the public or health care professionals. If the advertiser cannot convincingly prove their claims, the government can take action to prohibit the advertisement.

- (b) to empower the government to stop the sale of a device or initiate recall under urgent hazardous conditions. Again, this is essential legislation in case the manufacturer or the vendor has not taken adequate action to ensure the safety of their product.

4.2.2 *PROBLEM REPORTS SHARING*

The government should establish a problem co-ordinating center where any device problem that occurs can be reported. This information can then be shared with other users in the country and in other countries.

If the government has no funding to set up such a center, encourage the users and the vendors to form a network. There is a good chance that they will support such a program since it is in their self interest. Also, hospitals and universities are institutions that are likely to have the resources and willingness to co-ordinate such activities. The scientific testing laboratories in these institutions would be very helpful for problem investigations. For example, they could be used to confirm bacterial contamination, or to investigate possible electrical hazards.

4.3 DRAFTING A COMPREHENSIVE POLICY OR GUIDELINE ON MEDICAL DEVICE MANAGEMENT

A policy or guideline on medical device management should be established irrespective of whether there are resources available to administer the legislation and implementation. Going through the exercise of drafting up a policy or guideline will clarify the minds of both the government and the other stakeholders on what the problems are and how to address them. The resulting policy/guideline will set a direction for how to manage potential problems. It will also provide a foundation for shared understanding and shared responsibility of all the concerned parties (as illustrated in Figure 8 in Section 4.5).

4.3.1 ADVANTAGES OF A NATIONAL POLICY

While a national policy generally does not need a legislative base, it serves as a framework of rules for decision making and guidance. In some countries, a national policy may automatically have legal recognition. Some of the advantages of a national policy are as follows:

- 1) it is written in non-legal terms, hence easier for lay people to understand;
- 2) it can provide more explanatory information than a regulatory document;
- 3) a guideline can be written as a policy supplement to include even more detailed information on means and procedures to achieve policy objectives;
- 4) policies and guidelines do not require a legal process to modify. In a rapidly changing environment, it may be necessary to change a policy or guideline quickly.

The policy on medical device management can also include instructions for the role of each stakeholder (see Section 1.5). For example, the role of the user can be broadened to include issues such as the care and maintenance of devices (Appendix 6), thus introducing an integrated approach to medical device management.

Depending on the culture and legal system, a country may find it more effective to legislate all key requirements of the policy. In such a case, the Canadian Medical Device Regulations described in Appendix 1 can serve as a reference. Countries that have decided to accept devices that are approved by other countries can simplify the pre-market control regulations (Sections 4.3.3).

Some countries may prefer to legislate the items gradually as the need is demonstrated and as resources for monitoring and enforcement become available (see Section 4.5).

4.3.2 DEFINITION OF MEDICAL DEVICES

The term "medical devices" includes everything from highly sophisticated computerized medical equipment to simple wooden tongue depressors. It is not an easy task to arrive at a definition that would describe the characteristics of thousands of medical devices already available on the market. Furthermore, any definition will likely be inadequate to cover new medical devices that are continually being invented. For references, the Canadian definition of medical devices can be found in Appendix 1; those of the United States and the European Union are given in Appendix 7.

A practical approach to this problem would be to describe medical devices in general terms, and then include a guidance document to provide supplementary information. The guidance document can then be amended as necessary. The following general description of medical device is modeled after the Canadian definition.

“An article, instrument, apparatus, machine or contrivance whose use is for the diagnosis, treatment, mitigation or prevention of a disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.”

A country can draft its own definition and supplementary guidance document from this statement and other references given in the appendices.

4.3.3 PRE-MARKET APPROVAL

Pre-market approval is one of the most important aspects of any comprehensive policy. The difficulties of establishing a local pre-market review team is not just financial but also whether specialized scientific and clinical expertise is available in the country. However, with the work of the Global Harmonization Task Force (GHTF) and the ability to look to approval decisions in other countries, it is now feasible for many countries to avoid the expense of a local pre-market review team.

If we look at the global statistics (Appendix 4) on medical device manufacturers, they reveal that the United States, the European Union, Japan and Canada manufacture over 90% of the medical devices in the world. All these countries are members of the GHTF. They have comprehensive regulatory systems and are committed to produce medical devices that follow the “Essential Principles of Safety and Performance of Medical Devices” which are recommended by the Task Force.

Therefore, as an alternative to a local pre-market review team, a government can adopt the policy accepting devices that are manufactured in compliance with the standards of another country. The alternatives include, for example, devices with a “CE” mark, devices with a Canadian or Japanese License, or devices that have been granted marketing clearance by the US-FDA. This way the citizens of the importing country can be assured of the same device risk exposure as the citizens of the exporting countries. Since it may be necessary to verify the authenticity of such compliance, device suppliers can be asked to obtain a Manufacturer’s Certificate or Export Certificate, without cost to the local government. However, since existing “export certificates” differ in purpose and format, it is important to be cautious in their interpretation (Section 5 discusses this issue).

A similar approach can be used for **local medical device manufacturers**. The government can require that local manufacturers make submissions for compliance acceptance, to an accepted country that has a pre-market review team. In fact, this is what the manufacturers have to do anyway if they want to sell internationally. If a country has competent private organizations, the government can authorize such organizations to perform the pre-market assessment, as the European Union is now doing (see section 5).

The **Quality System** certification of local manufacturing facilities is usually delegated to authorized third party agents. In the case of the United States, U.S. FDA, following completion of an inspection, will issue a letter to the firm denoting their compliance status. Currently the cost of inspection is borne by U.S. FDA, and is performed, almost without exception, by U.S. FDA employees.

The avoidance of a local pre-market review team will greatly reduce the regulatory burden on the government. On the other hand, some countries may have a sufficient number of local manufacturers to warrant a limited local pre-market review team.

For medical device importing countries, it is of the utmost importance that medical device authorities have a close co-operation with the customs department. In fact, customs officers should be well informed of the government policy and the basic criteria of approved devices.

4.3.4 VENDOR ESTABLISHMENT CONTROL

The vendor establishment control allows the government to be informed of which establishment is selling what devices. Its main purpose is to place the responsibility of after-sale obligations on the vendor.

As listed on Table 1 in Section 2.2, there are two general ways to accomplish this: (1) sales notification, and (2) establishment licence or registration.

Sales notification generally is a less effective method. Vendors automatically are permitted to sell medical devices as long as they notify regulatory authority, either before or after the sale as required by the authority.

Establishment Licence or Registration, on the other hand, requires that the vendor either obtains a licence or be registered before the vendor is allowed to sell medical devices. This method has several advantages.

- It ensures that the government has records of the vendors.
- It enables the government to place emphasis on after-sale obligations.

- It provides a means for the government to enforce requirements; for example, by suspending the licence if the vendor does not fulfill after-sale responsibilities.
- It allows the government to require an annual renewal of the licence or registration in order to keep updated information on the vendors.

Since the latter method places considerable demand on the government, the government can impose a fee on the licensing or registration process. This fee will help to defray the cost of administration. The fee may also help to strengthen the vendor's efforts to fulfill their obligations to avoid losing the licence that they have paid for.

Experience from Canada reveals that Establishment Licence is a more effective means than Sales Notification in keeping records of the vendors. The Canadian guidance documents on Establishment Licensing is available on the INTERNET: www.hc-sc-gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html. A sample establishment registration form can be found in "Filename mc_elap_e" www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/forms.html.

The Control Of Home-Use, Used, Refurbished, Donated Devices

A recent development in the medical device market is the rapid increase in the number and variety of **home-use medical devices**. This results in a shift from institution based professional users of medical devices to lay users. Here education of the consumer is key to safety and effectiveness. Some suggestions are given in an article by Michael Cheng.⁵

Two other issues for consideration are: (1) **used and refurbished devices** re-packaged for sale. Vendors should be required to report the history of the device and clearly label any relevant information; (2) **donated devices or equipment**. WHO has issued a draft guideline providing recommendations for both the donor and the recipient. Reference material on these two issues are given in Appendix 6.

4.3.5 POST-MARKET SURVEILLANCE

Post-market surveillance has a critical role in ensuring the safety and effectiveness of medical devices. In addition to the problem-sharing center described in Section 4.2.1, a full program of post-market surveillance should be described in the policy/guideline. These should include the major components of after-sale obligations for the vendor: distribution record,

⁵"Leadership in Health Services," Canadian Healthcare Association, Jan/Feb 1995. Vol. 4 No. 1, pp14-18.

complaint handling, mandatory problem reporting, recall procedure and implant registration. The Canadian guidance documents on these requirements can be obtained from the INTERNET: www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html. For the United States FDA guidance, see point 1 below. The GHTF is working on more standardized formats for post-market surveillance (INTERNET www.ghf.org).

If a country can support the administrative personnel and data storage/retrieval system, a full post-market program should be enforced. In case of budget restrictions, the setting of priorities is described in Section 4.5.

It is important to note the following points:

- 1) For some devices, post-market surveillance serves to complement pre-market data. The United States FDA has issued the following statement:

“Pre-market testing cannot address all devices-related concerns. While post-market surveillance will not be used in lieu of adequate pre-market testing, post-market surveillance can serve to complement pre-market data. Certain issues that arise during pre-market evaluation of a device may be more appropriately addressed through data collection in the post-market period rather than prior to approval/clearance for marketing. FDA will consider the potential to collect post-market surveillance data to allow more rapid progress to market.”

This is quoted from FDA's “Criteria and Approaches for Post-market Surveillance” which is available on the INTERNET: www.fda.gov/cdrh.

- 2) The chance of discovering device problems increases with the number of devices in use. Therefore, it is important to be connected to the database of other countries. A global connection will maximize the effectiveness of the system.
- 3) The quality of problem reports improves with some technical knowledge of devices. Both clinical engineers and biomedical equipment technicians in healthcare facilities can be very helpful in this task. If the problem report is to be added to the problem databank for trend or other statistical analyses, the report must follow certain standards for it to be useful. A sample problem reporting form is given “Filename: mdrptfrm_e” www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/forms.html. Each government should adopt recommended formats and procedures from the Global Harmonization Task Force (Study Group 2) when they become available.

- 4) Truly effective post-market surveillance programs rely heavily on the co-operation of all the stakeholders, especially the user and the vendor. Most of the obligatory surveillance activities rest with the vendor, but the user is the ultimate monitor of device performance and reporter of problems encountered. The surveillance program should be promoted and developed to encourage co-operation. Section 4.4 suggests an opportunity to accomplish this.
- 5) Finally, if user errors are frequent, then a **user qualification** program that is controlled through a professional association can also be a useful tool that will not make undue demands on government resources. Similarly, as a proactive measure, this tool can be used for devices of high-risk classes

4.3.6 RECOGNITION AND USE OF ESTABLISHED NATIONAL OR INTERNATIONAL STANDARDS

Regulatory agencies increasingly recognize the compliance with consensus national or international standards as a partial fulfillment of regulatory requirements. This practice can reduce cost and simplify the regulatory process.

A regulatory agency will need to specify the list of standards that is recognized by the agency and make the policy of recognition clear to the stakeholders. Examples of such policies and lists of standards can be obtained from the following INTERNET web-sites:

- United States: www.fda.gov/cdrh/modact/fr0225ap.pdf
- Canada: www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/policy.html

4.4 PROMOTING COMPLIANCE AND COOPERATION

Promotional activity is a powerful tool that encourages compliance, and reduces the burden of enforcement. Often, bad practices are the results of not knowing better alternatives. If the policy or regulatory program is well disseminated to the stakeholders and properly understood, the regulating agency has already made the most important step toward the harmonized compliance of all the parties concerned. **User/public education is crucial in guarding against mis-use and mis-representation of medical devices.**

Finally, we should remind ourselves that medical device users, patients and the public are people for whom medical devices are designed (the

customers). They are the people who have the most concern for device safety and effectiveness; they can readily become great allies to the government in applying “customer pressure” for compliance. Governments should appeal to their self-interests to play their proper roles. On the other hand, with the worldwide Quality Movement, manufacturers and vendors nowadays are embarking on customer focussed missions: they would like to provide quality products and quality services to customers. **These are positive developments.** Governments can capitalize on such developments by encouraging their voluntary co-operation. This will result in a low cost program that ensures the safety and effectiveness of medical devices. The stakeholders can be regarded as tripartite: the provider (manufacturer, vendor), the consumer (user, the public) and the government. Co-operation will create a win-win-win situation!

4.5 SETTING PRIORITIES FOR MONITORING AND ENFORCEMENT ACTIVITIES

“Reference to the Compliance and Enforcement Strategy related to medical devices in Canada can be found in the website www.hc-sc.gc.ca/therapeut/htmleng/strategy.html, filename: *tpcompliance_enforc_e*.

In countries where resources are limited, setting priorities for the monitoring and enforcement efforts can follow the ladder as suggested in Figure 8 - Priorities for Monitoring and Enforcement.

Preventing sub-standard devices from appearing in the market place is the first priority for every government. For most countries, this will mean an effective import control to ensure that acceptance criteria specified in the policy are strictly enforced. As pointed out earlier, it is of the **utmost importance that medical device authorities have a close co-operation with the customs department. Effective and efficient customs procedure is critical to import control. Here, customs enforcement officers need a clear policy, education and training.** They should be well informed of the medical device acceptance criteria.

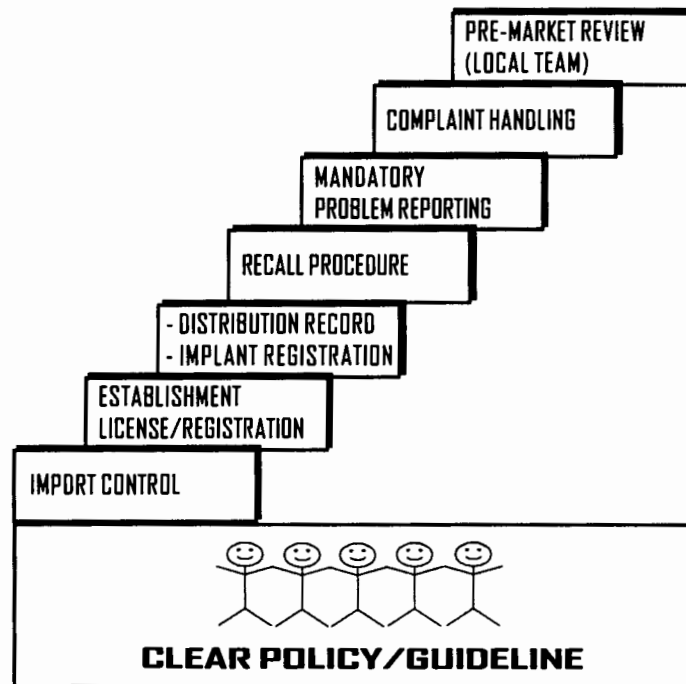
In case of a medical Device Alert or recall, the information on where all such devices are being used is essential for an alert to be issued. The distribution record is key to this identification. Since it is the vendor's responsibility to keep distribution records, it should be a government priority to control the vendor establishments. The government can also make use of the advantages described in Section 4.3.4. For example, this activity can be self-financing.

The recall of a device generally indicates a high potential for serious problems. Inspection of recall procedure would ensure that an effective and efficient procedure is in place in case of recalls. Random monitoring of the operation in an actual recall incident can verify the true efficiency and effectiveness of the procedure and ensure that the vendor is responsible.

Mandatory problem reporting will increase the probability that serious problems are reported and relayed to other users. However, the government will need considerable data storage/retrieval capacities and the personnel for data administration. At the same time, connecting with large international database is important for information exchange.

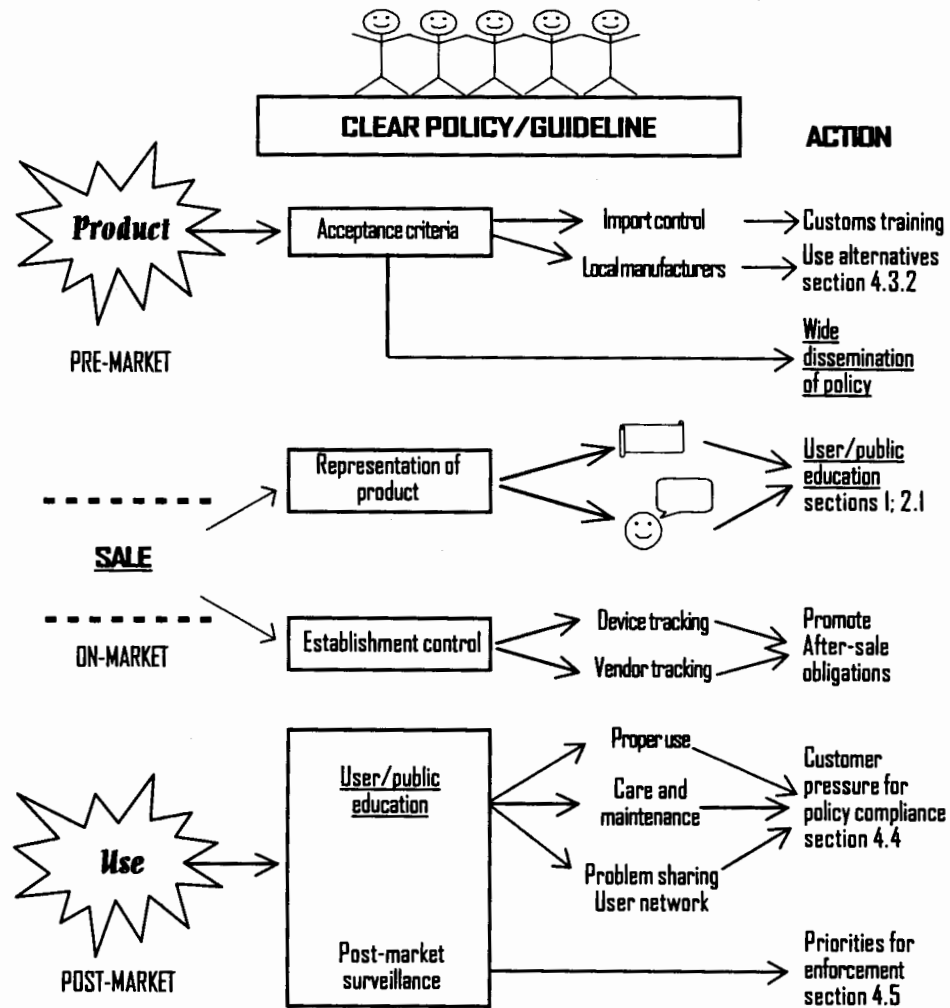
Complaint handling is more of an investigative nature. Therefore, this can take a lower priority relative to the urgency of recall and serious problem reporting. Furthermore, interpreting the degree of the urgency of a complaint may demand considerable technical knowledge and experience.

FIGURE 8. PRIORITIES FOR MONITORING AND ENFORCEMENT



4.6 SUMMARIZING THE KEY POINTS

FIGURE 9. MIND MAP OF KEY POINTS



5. Cautions For Interpreting Medical Device “Export Certificates”

Importers should be well aware of the fact that there are different kinds of certificates testifying the characteristics of medical devices being exported. For example, Canada currently has two kinds of certificates applicable to medical devices. The United States has four. These are briefly described below:

CANADA

- 1) **The Canadian Export Certificate for Medical Devices.** This certificate allows vendors to export medical devices that are not manufactured for sale or for consumption in Canada. This certificate has legal status (Section 37 of the Food and Drug Act and Section 89 of the Medical Devices Regulations). (The United States issues analogous certificates under section 801 and 802 of the Federal Food, Drug and Cosmetic Act, see below).
- 2) **The Canadian Manufacturer's Certificate for Medical Devices** (Appendix 8). This certificate requires the manufacturers to make the following declaration before a Commissioner or a Notary:
 - (a) each device is manufactured, produced and sold in Canada in accordance with the requirements of Canada's Food and Drug Act and Regulations thereunder; and
 - (b) tests have been conducted in respect of each device and that the tests indicate that the nature of the benefits claimed to be obtainable through the use of each device and the performance characteristics of each device are justified.

This declaration is submitted to Health Canada for verification and counter-signature for compliance.

The United States (the writer wishes to thank the FDA team for providing the following descriptions).

- 1) **The United States “Export Certificate” Section 801(e)(2)** grants permission for the export of unapproved medical devices which are not equivalent to devices cleared for marketing, in the U.S., after the firm has submitted to the FDA proof of safety of the device and obtained a letter from the foreign government granting permission to import the device.

- 2) The United States “Certificate of Exportability” Section 801(e)(1) certifies the export of unapproved devices not in U.S. distribution which would be considered adulterated or misbranded under U.S. law because of a lack of obtaining marketing permission, non U.S. labeling , and /or not being manufactured under QS Regulation. These devices must be equivalent in design and intended use to class I and II medical devices already granted marketing permission by FDA, labeled for export, and must be in compliance with the specification of the purchaser and the laws of the foreign country.
- 3) The United States “Certificate of Exportability” Section 802 certifies the export of unapproved devices which are manufactured in compliance with the requirements of the QS Regulation or equivalent FDA recognized international standard and which are authorized for marketing in a “tier one” country. Tier one countries included those in the EU, EEA, Australia, Canada, Israel, Japan, New Zealand and South Africa.
- 4) The United States “Certificate to Foreign Government” is issued for devices that are legally marketed in the U.S. and in compliance with the Food, Drug & Cosmetic Act.

THE WORLD HEALTH ORGANIZATION

The widely used **WHO Export Certificate** at present applies only to pharmaceutical products.

Comments

The Canadian Export Certificate and the United States certificates all impose the condition that the exported device does not contravene any known requirement of the laws of the importing country. However, this does not provide protections for countries that do not have regulations or a national policy on medical device acceptance.

Clearly, there is a need to establish a uniform format for different countries to certify that the medical device being exported complies with their domestic regulatory requirements.

APPENDIX 1: THE CANADIAN MEDICAL DEVICES
REGULATIONS (a brief guide with excerpts from the
Regulatory Impact Analysis Statement)

DEFINITION OF MEDICAL DEVICE

The Canadian Food and Drug Act defines medical device as follows: an article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in man or animal,
- (b) restoring, correcting or modifying a body function or the body structure of man or animal,
- (c) the diagnosis of pregnancy in humans or animals, or
- (d) the care of humans or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.

Purpose of Regulation: To ensure that medical devices distributed in Canada are both safe and effective and of high quality.

PRINCIPLES FOR IMPLEMENTATION

- 1) the level of scrutiny afforded a device should be dependent upon the risk that the device presents, and
- 2) the safety and effectiveness of medical devices can best be assessed through a balance of quality systems requirements, pre-market scrutiny and post-market surveillance.

Scope of Regulation: The regulations govern the manufacturers, importers and distributors on the importation, advertisement and sale of medical devices as well as after-sale obligations.

A Structural View of the Canadian Medical Devices Regulations. This table is not official. It has been constructed by the author to help understanding the legal document.

TABLE 4. A STRUCTURAL VIEW OF THE CANADIAN MEDICAL DEVICES REGULATIONS

STAGE	CONTROL	PERSON	ITEMS OR ACTIVITIES REGULATED	CLASS OF DEVICE	REQUIREMENTS	REGULATIONS
PRE-MARKET	PRODUCT	MANUFACTURER	Device attributes	all	Safety and effectiveness II requirements	r10-20
			Device manufacturing	I	No quality system requirement	
				II	ISDI3488-98 quality system	r32(1) and (2)
				II, IV	ISDI3488-98 quality system	r32
			Device labeling	all	Specific requirements	r21-23
Device license	II, III, IV	Successful pre-market review	r26, r28-43			
ON-MARKET	SALE	VENDOR (IMPORTER, DISTRIBUTOR, MANUFACTURER)	Advertising	all	Prohibits misleading advertisement	Act, section 20
				II, III, IV	Requires device license	r27
				Contraceptive	Restricts sample distributions	r24
			Establishing license (Sales license)	all	Distributors and importers must hold an establishment license	r25, r26, r44-51
I	Manufacturers must hold an establishment license if they sell directly to users	r25, r44(d)				
POST-MARKET	AFTER-SALE	VENDOR (IMPORTER, DISTRIBUTOR, MANUFACTURER)	Distribution record	all	Record	r52-56
			Complaint handling	all	Procedure and record	r57-58
			Problem reporting	all	Mandatory reporting of serious accidents	r59-62
			Recall procedure	all	Mandatory reporting of recalls	r63-65
			Implant registration	all	Record	r66-68

Notes: For detailed legal descriptions, please refer to references given by the last column.
r = regulation clause number, Act = Canada Food and Drug Act.

CLASSIFICATION RULES FOR MEDICAL DEVICES

The *Regulations* set out a system for classifying medical devices into one of four classes; class I representing the lowest risk devices and class IV representing the highest risk devices. See Appendix 1.1.

DEVICE ATTRIBUTES

Devices sold in Canada must meet eleven fundamental safety and effectiveness requirements. Manufacturers must possess evidence that their devices meet those requirements. Further, manufacturers must provide assurance to the TPD that the requirements have been met. Even if data

are not submitted, the manufacturer is required to have evidence on site, if and when requested.

DEVICE MANUFACTURING

Manufacturers must provide an attestation that the devices they sell in Canada are produced in accordance with a certified quality system. Class I devices are exempt from device licensing and exempt from quality system requirements. However, they must comply with safety and effectiveness requirements.

DEVICE LABELLING

All medical devices must be labelled in accordance with specified labelling requirements for information disclosure.

DEVICE LICENCE

Device manufacturers must hold a medical device licence to manufacture Class II, III or IV medical devices for sale in Canada. Medical device licensing involves submission of information to the TPD. The degree of information which must be submitted to provide assurance to the TPD that the requirements have been met is proportional to the class of the device. For example, Class IV devices require more information to be submitted than class III devices; class III devices require more information than class II devices.

Annual renewal of licences for Class II, III and IV devices will be required before the first of November each year. This validation will consist of a statement by the licensee confirming that all the information previously submitted with respect to the device is still correct. The annual renewal process will start in November, 1999.

There is a provision for manufacturers who propose to make one or more changes to their licensed device to submit an application for a licence amendment. The amendments will include changes that are significant or administrative. A significant change is defined as a change that could reasonably be expected to affect the safety or effectiveness of a medical device. An administrative change would be a change that would not affect the safety or effectiveness of a medical device. A significant change requires the submission of data to support the proposed change.

The same licence application may include; a system, a test kit, a group of devices which can include a procedure pack or tray, an administrative family of devices and a group family consisting of a collection of groups of devices.

If an application for the licensing of a device is preceded by an application for authorization for an investigational testing, then certain data components will not be required with the licence application. The TPD believes that this approach ensures that the data will not be reviewed twice and also will encourage research and development of new technologies in Canada.

The TPD may issue a conditional licence for a medical device for those devices where specified tests, which may include post-marketing confirmatory studies, are needed to demonstrate that the device continues to meet the safety and effectiveness requirements and for *in-vitro* diagnostic devices where testing of the protocols and the results of the test lots are needed to demonstrate that the device is safe and effective.

ADVERTISING

It is prohibited to make fraudulent claims in advertising any medical device. For a Class II, III or IV medical device, it is prohibited to advertise the device for the purpose of sale unless the manufacturer of the device holds a license in respect of that device, or unless the advertisement is in a catalogue that includes a clear and visible warning that the devices may not be licensed.

ESTABLISHMENT LICENSING

Importers and distributors of Class I, II, III and IV medical devices, as well as manufacturers of Class I medical devices who do not import or distribute through distributors holding an establishment licence, must hold an establishment licence in order to sell medical devices in Canada. An establishment may have one or more sites.

The licence is valid for one year and will expire on December 31st of each calendar year. The establishment licensing scheme involves submission of information to the TPD.

The TPD will accept one or more sites under one application for an establishment licence. The applicant is responsible for providing all required information and attestations for all the sites in the application.

POST-MARKET SURVEILLANCE

The post-market surveillance aspect of the *Regulations* requires manufacturers, importers and distributors to keep distribution records and to have written procedures to (a) handle complaints and investigate them, and (b) to recall defective devices from the market.

Manufacturers and importers must report (mandatory) to the TPD serious problems which have occurred with the use of devices following sale.

IMPLANT REGISTRATION

There are provisions to facilitate the tracking of certain implanted devices so that recipients of those implants may be notified of pertinent post-implant information. Devices which are subject to this requirement are listed in Schedule II of the *Regulations*.

APPENDIX 1.1

CLASSIFICATION OF MEDICAL DEVICES IN CANADA (MOSTLY FROM THE GUIDANCE DOCUMENT)

In Canada, medical devices are classified into one of Classes I to IV by means of the classification rules set out in the guidance document (see Appendix 3), where Class I represents the lowest risk and Class IV represents the highest risk. If a medical device can be classified into more than one class, the class representing the higher risk applies.

The classification rules were designed to be straight forward and user friendly and the following indicators of risk were used to create the rules: degree of invasiveness, duration of contact, body system affected, and local versus systemic effects. It is acknowledged that any rule system has limitations and cannot accommodate all devices. There may be cases where either a device cannot be classified because of an unusual characteristic or where the resulting classification is not optimum given known hazards associated with the use of the device. In these cases the device may be listed on the table to Rule 16 of the *Medical Devices Regulations*. The Canadian device classification rules were developed so that they were harmonized as much as possible with the European Union's device classification rules and the device classifications of the United States.

The degree of regulation imposed on any device is proportional to its risk. The following Table summarizes the submission requirements for pre-market review for the different classes of medical devices.

TABLE 5. CANADIAN REQUIREMENTS FOR PRE-MARKET REVIEW SUBMISSIONS

CLASS	II	III	IV
Safety and Effectiveness	Attestation of compliance	Summary of studies	Detailed information - pre-clinical and clinical studies - process validation studies - software validation studies - literature studies Risk assessment and risk reduction measures
Manufacturing	- ISO13488 quality system - list of standards used	- ISO13485 quality system Descriptions - material in mfg and pkg - method of sterilization - list of standards used	- ISO13485 quality system Submit - quality plan - material specifications - mfg and sterilization processes - list of standards used
Labelling	- attestation of compliance - labelled indication for use	- a copy of the device label	- a copy of the device label
Foreign market experience		- summary of devices sold - problem reports and recalls	- summary of devices sold - problem reports and recalls

APPENDIX 2: QUALITY SYSTEM REQUIREMENTS WITH ISO9001 AND ISO13485 RELATIONSHIP

Quality System requirements are specified in the standard ISO9001 for the twenty main elements (4.1 to 4.20) listed under the ISO9001 column. Additional requirements for medical devices are listed under the ISO13485 column.

TABLE 6. ISO 9001 AND ISO 13485 RELATIONSHIP (MAIN SECTIONS ONLY)*

#	GUIDANCE DOCUMENT TITLES	DOCUMENT CONTROL		WEB FILE NAME & DATE OF DOCUMENT
		Guide No.	Status	
1	Guidance for the Interpretation of Significant Change	G0001	Final V2	signchn2 Nov 9/98
2	Guidance for the Interpretation of Sections 28 to 31: License Application Type	G0002	Final	apptype Jan 12/99
3	Guidance for Medical Device Complaint Handling and Recall	G0003	Draft V2	recall2 Sep14/98
4	How to Apply for Authorization to Obtain Custom-Made or Special Access Devices	G0004	Draft	special Mar25/98
5	Guidance for Mandatory and Voluntary Problem Reporting	G0005	Draft V2	manrpt2 Sep14/98
6	Guidance for the Risk Based Classification System	G0006	Draft	risk5 May4/98
7	Guidance for the Risk Based Classification System of In Vitro Diagnostic Devices	G0007	Draft	ivdd_rsk Apr24/98
8	Preparation of a Premarket Review - Document for Class III and IV - Devices License Application	G0008	Final V2	prmk2 Oct23/98
9	Preparation of an Application for Investigational Testing (Devices)	G0009	Final	test_md3 Oct23/98
10	Preparation of an Application for Investigational Testing (Devices)	G0010	Final	test_iv2 Oct23/98
11	Guidance for the Labelling of Medical Devices. Section 21 to 23 of the Medical Devices Regulations	G0011	Draft	lbl_dv9 Jan11/99
12	Guidance for the Labelling of In Vitro Diagnostic Devices	G0012	Draft	lbl_ivd Jun19/98

Continues on the next page

Continues from previous page

#	GUIDANCE DOCUMENT TITLES	DOCUMENT CONTROL		WEB FILE NAME & DATE OF DOCUMENT
		Guide No.	Status	
13	Guidance on How to Complete the Application for a New Device License	GDD13	Final V4	lcn_nw4 Jan6/99
	Application form		V5	md_interpret Oct14/98
14	Guidance for the Interpretation of the Medical Devices Regulations as They Apply to Medical Device Establishment Licensing	N/A	N/A	lcn_nw4 Jan6/99
	Application form		N/A	md_interpret Oct14/98
15	Guidance on How to Complete the Application for an Amended Device License	GDD15	N/A	N/A
	Application form		V2	lic_amm2 July29/98

**Note: quoted from "the iso9000 and 13485 essentials" 2nd Edition, Canadian Standards Association.*

APPENDIX 3: WEB-SITES AND ADDRESSES
FOR MEDICAL DEVICE INFORMATION

WEB-SITES

CANADA

The main Health Canada site is www.hc-sc.gc.ca.

All medical devices guidance documents and medical device related information can be obtained from www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/guidmd.html.

THE UNITED STATES OF AMERICA

The main FDA site is www.fda.gov/default.html.

The corresponding medical device related information site is (this site also offer "Device Advice", a self-service site for medical device and radiation product information) www.fda.gov/cdrh/general.html.

The FDA enforcement report site is (this site would offer information also useful for import control) www.fda.gov/opacom/Enforce.html.

THE EUROPEAN UNION

The main site (multi-lingual) is (it is necessary to search for medical device documents) www.Europa.eu.int/.

THE UNITED KINGDOM

The main site is www.Medical-devices.gov.uk. It also offers a link to other countries www.Medical-devices.gov.uk/site.htm.

THE GLOBAL HARMONIZATION TASK FORCE

The main site is www.ghf.org. It provides update information about the Task Force and reports from the study groups. It also offers an extensive list web sites of Ministry of Health of countries around the world.

ECRI

The site www.ecri.org serves as a collaborating center for health technology for WHO and PAHO.

The site www.mdsr.ecri.org provides information on medical device hazards.

An informative commercial site is www.devicelink.com.

ADDRESSES TO OBTAIN MEDICAL DEVICE INCIDENT REPORTS

UNITED KINGDOM

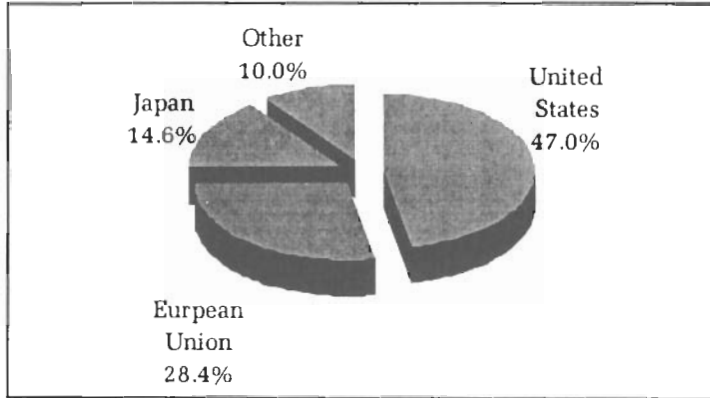
Medical Device Agency,
Hannibal House,
Elephant & Castle,
London SE1 6TQ, UK
Fax: 0171 9728109
E-mail: aic@medcial-devices.gov.uk

AUSTRALIA

The Australian Recalls Co-ordinator
Recalls Unit, Therapeutic Goods Administration
PO Box 100, Woden ACT 2606
Australia

APPENDIX 4: GLOBAL STATISTICS ON MEDICAL DEVICE PRODUCTION (1996)

FIGURE 10: GLOBAL STATISTICS ON MEDICAL DEVICE PRODUCTION (1996)*



Note: *data obtained verbally from Strategis, Industry Canada, March 1999.

APPENDIX 5: PRINCIPLES OF PUBLIC CONSULTATION

Except from "Consultation Guidelines For Managers In The Federal Public Services," Treasury Board of Canada

- 1) To be effective, consultation must be based on openness, trust, integrity, mutual respect for the legitimacy and point of view of all participants, and transparency of purpose and process.
- 2) The outcome of consultation should not be predetermined. Consultation should not be used to communicate decisions already taken.
- 3) The initiative to consult may come from inside government or outside - each should respond as constructively as it can.
- 4) Whenever possible, consultation should involve all parties who can contribute to or are affected by the outcome of consultation.
- 5) Participants in a consultation should have clear mandates. Participants should have influence over the outcome and a stake in implementing any action agreed upon.
- 6) Some participants may not have the resources or expertise required to participate. Thus, financial assistance or other support may be needed for their representation to be assured.
- 7) Effective consultation is about partnership. It implies shared responsibility and commitment: a clear, mutual understanding of the issues, objectives, purpose, and expectations of all parties is essential; the agenda and process should be negotiable; any constraints should be established from the outset.
- 8) Participants should have a realistic idea of how much time a consultation is likely to take and plan for this in designing the process.
- 9) All participants must have timely access to relevant and easily understandable information and commit themselves to sharing information.
- 10) Effective consultation will not always lead to agreement; however, it should lead to a better understanding of each other's positions.
- 11) Where consultation does lead to agreement, whenever possible, participants should hold themselves accountable for implementing the resulting recommendations.
- 12) Effective consultation requires follow-through. Participants are entitled to know what use is made of the views and information they provide; they should also be made aware of the impact their ideas and involvement ultimately have on government decision-making.

APPENDIX 6: REFERENCES: RE-USE, REFURBISHED,
DONATED, CARE AND MAINTENANCE
OF MEDICAL DEVICES

RE-USE AND REFURBISHED MEDICAL DEVICES

- 1) Re-Use of Single Use Devices 1999 Conference Proceedings and Tapes: Association for the Advancement of Medical Instrumentation (USA).
- 2) The Reuse of Single-Use Medical Devices -Guidelines for Health Care Facilities: Canadian Healthcare Association:
- 3) Compliance Policy Guides on: Reconditioners/Rebuilders of Medical Devices; Contamination of Devices Labeled As Sterile; and Reuse of Medical Disposable Devices: Food and Drug Administration (USA)
- 4) The Reuse of Medical Devices Supplied for Single-Use Only: Medical Devices Agency (UK).

DONATED MEDICAL DEVICES/EQUIPMENT

- 1) Guidelines for Health Care Equipment Donation, 4th Draft: World Health Organization, WHO/ARA/97.3.
- 2) Guidelines for Medical Equipment Donation: American College of Clinical Engineering, 1995.

CARE AND MAINTENANCE OF MEDICAL DEVICES/EQUIPMENT

- 1) Chapter on Management of Medical Equipment. District Health Facilities: guidelines for operation and development. World Health Organization, Western Pacific Series No.22.
- 2) El mantenimiento del material medico esencial: una prioridad insoslayable. Foro Mundial de la Salud, volumen 15, 1994.

APPENDIX 7: DEFINITIONS OF A MEDICAL DEVICE

THE EUROPEAN MEDICAL DEVICE DIRECTIVE

A medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and

which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

THE UNITED STATES FOOD AND DRUG ADMINISTRATION (FROM THE FEDERAL FOOD, DRUG AND COSMETIC ACT, US CODE OF FEDERAL REGULATIONS TITLE 21, P2)

The term "device" (except when used in paragraph (n) of this section and in sections 301(I), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –

- 1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- 2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- 3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is

not dependent upon being metabolized for the achievement of any of its principal intended purposes.

The **Canadian** definition is given in Appendix 1.

APPENDIX 8: SAMPLE MANUFACTURER'S CERTIFICATE

**MANUFACTURER'S CERTIFICATE
TO COVER EXPORTS OF
MEDICAL DEVICES**

**CERTIFICAT DU FABRICANT
RELATIF À L'EXPORTATION
DES INSTRUMENTS MÉDICAUX**

We, the undersigned, manufacturer of the following devices,

Nous soussignés, fabricants des instruments

DEVICES - INSTRUMENTS:

do hereby certify that

- (a) each device is manufactured, produced and sold in Canada in accordance with the requirements of Canadas Food and Drug Act and Regulations thereunder; and
- (b) tests have been conducted in respect of each device and that the tests indicate that the nature of the benefits claimed to be obtainable through the use of each device and the performance characteristics of each device are justified.

déclarons

- (a) que chaque instrument est fabriqué, produit et vendu au Canada en conformité de la Loi sur les aliments et drogues du Canada et du règlement qui en découle;
- (b) que des essais ont été effectués pour chacun des instruments et que ces essais démontrent que les déclarations faites au sujet des avantages de l'utilisation des instruments en question et au sujet de leurs caractéristiques de performance sont justifiées.

NAME OF MANUFACTURER - NOM DU FABRICANT:

DATE

TITLE AND SIGNATURE OF AUTHORIZED PERSON
TITRE ET SIGNATURE DE LA PERSONNE AUTORISÉE

Declared before me at _____

this _____ day of _____ 20____

A Commissioner, Notary, etc.



Health and Welfare Canada
Health Protection Branch

It is hereby certified that

- (a) devices manufactured, produced and sold in the manner above described would not, by reason of the method of manufacture thereof, be in violation of the Food and Drugs Act of Canada and the Regulations thereunder; and
- (b) devices manufactured and sold in compliance with said Act and Regulations may be exported without restriction.

DATE

SIGNATURE

Drug and Environmental Health
Inspection Division
Health Protection Branch
Burnaby, B.C.

Déclaration fait en ma présence à _____

ce _____ jour de _____ 20____

Un commissaire, notaire, etc.



Santé et Bien-être social Canada
Direction générale de la protection de la santé

Il est attesté

- (a) que les instruments fabriqués, produits et vendus selon les modalités susmentionnées ne contreviennent pas, du fait de leur méthode de fabrication, à la Loi sur les aliments et drogues du Canada et au règlement qui en découle;
- (b) que les instruments fabriqués et vendus en conformité de ladite Loi et du dit règlement peuvent être exportés sans restriction.

DATE

SIGNATURE

Division de l'inspection drogue et
de l'hygiène du milieu
Direction de la protection générale de la santé
Burnaby, C.B.

GLOSSARY

Note: Terms in regulations are legally binding and therefore have restricted meanings. For example, manufacturer, distributor, vendors, retailers all have precise definitions in regulations, and their definitions vary in regulations of different countries. A regulation normally has an accompanying list of definitions of terms used.

The main text of this guideline, however, is written to promote a general understanding of medical devices and their regulations; therefore, the words used are non-binding and carry general meanings. A few terms pointed out by reviewers of this guideline for clarification are defined below;

Manufacturer: any person who makes medical devices.

Distributor: any person who distributes medical devices.

Vendor: any person who sells medical devices. This person could be a manufacturer, an importer, a distributor, a whole seller, or a retailer.

Person: includes an establishment (in that case, person-in-charge or person responsible).

Effectiveness: a device is clinically effective when it produces the effect intended by the manufacturer relative to the medical conditions. For example, if a device were intended for pain relief, one would expect the device to actually relieve pain and would expect the manufacturer to possess objective evidence, such as clinical test results, that the device does in fact relieve pain. Effectiveness can be thought of as efficacy in the real world clinical environment.

Efficacy: not used in this guideline, generally means effectiveness under an ideal controlled setting.

Performance: technical performance including effectiveness.

The following glossary applies to Appendices 1, 2, and 8 of this guideline, which describe the Canadian Medical Devices Regulations.

Act: the *Food and Drugs Act*.

Active Device: a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or

from a patient without substantially altering the energy or the substance is not an active device.

Active Diagnostic Device: an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity.

Active Therapeutic Device: an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury.

Bar Code: a unique bar code in the symbology of the Universal Product Code (UPC), the Health Industry Business Communications Council (HIBCC) or the European Article Number (EAN), assigned to a medical device by the manufacturer.

Body Orifice: a natural opening or a permanent artificial opening in the body, such as a stoma.

Central Cardiovascular System: the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries.

Central Nervous System: the brain, meninges, spinal cord and cerebrospinal fluid.

Closed-loop System: in respect of a medical device, means a system that enables the device to sense, interpret and treat a medical condition without human intervention.

Control Number: a unique series of letters, numbers or symbols, or any combination of these, that is assigned to a medical device by the manufacturer and from which a history of the manufacture, packaging, labelling and distribution of a unit, lot or batch of the device can be determined.

Custom-made Device: a medical device, other than a mass-produced medical device, that:

- (a) is manufactured in accordance with a health care professional's written direction giving its design characteristics;

- (b) differs from medical devices generally available for sale or from a dispenser; and
- (c) is
 - (i) for the sole use of a particular patient of that professional, or
 - (ii) for use by that professional to meet special needs arising in the course of his or her practice.

Dental Material: a medical device that is intended to be inserted into the pulp cavity of a tooth or attached only to the enamel or dentin of a tooth. It does not include a surgical or dental instrument.

Directions For Use: in respect of a medical device, means full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contraindications and possible adverse effects.

Dispenser: a person who is a member of a professional governing body and who is entitled, by virtue of their membership in that body, to manufacture or adapt a medical device in accordance with a health care professional's written directions in order to meet the specific requirements of a patient.

Genetic Testing: the analysis of DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis.

Health Care Facility: a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities.

Health Care Professional: a person who is entitled under the laws of a province to provide health services in the province.

Identifier: a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices.

Implant: a medical device that is listed in Schedule 2.

Invasive Device: a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface.

In Vitro Diagnostic Device or IVDD: a medical device that is intended to be used *in vitro* for the examination of specimens taken from the body.

Manufacturer: a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Medical Device: a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.

Medical Device Family: a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use.

Medical Device Group: a medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name.

Medical Device Group Family: a collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group.

Name Of The Device: in respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices.

Near Patient In Vitro Diagnostic Device or Near Patient IVDD: an *in vitro* diagnostic device that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or the bedside.

Objective Evidence: information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out in the definition "objective evidence" in section 2.19 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time.

Person: includes a partnership and an association.

Qualified Investigator: a person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care in the province and who is designated, by the ethics

committee of the health care facility at which investigational testing is to be conducted, as the person to conduct the testing.

Recall: in respect of a medical device that has been sold, means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device

- (a) may be hazardous to health;
- (b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or
- (c) may not meet the requirements of the Act or these Regulations.

Safety and Effectiveness Requirements: the safety and effectiveness requirements set out in sections 10 to 20.

Significant Change: a change that could reasonably be expected to affect the safety or effectiveness of a medical device. It includes a change to any of the following:

- (a) the manufacturing process, facility or equipment;
- (b) the manufacturing quality control procedures, including the methods, tests or procedures used to control the quality, purity and sterility of the device or of the materials used in its manufacture;
- (c) the design of the device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories; and
- (d) the intended use of the device, including any new or extended use, any addition or deletion of a contra-indication for the device and any change to the period used to establish its expiry date.

Surgical or Dental Instrument: a reusable medical device that is intended for surgical or dental use, including cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping, without connection to an active device.

Surgically Invasive Device: an invasive device that is intended to enter the body through an artificially created opening that provides access to body structures and fluids.

System: a medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name.

Test Kit: an *in vitro* diagnostic device that consists of reagents or articles,

or any combination of these, and that is intended to be used to conduct a specific test.

Validation: confirmation by examination and the provision of objective evidence that the requirements for a specific intended use have been fulfilled, as set out in the definition “validation” in section 2.18 of International Organization for Standardization standard ISO 8402:1994, *Quality management and quality assurance - Vocabulary*, as amended from time to time.