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MEDICAL DEVICES BULLETIN

Health Canada's mission is to help the people of Canada maintain and improve their health.

Welcome...

It is my pleasure to welcome readers to the inaugural issue of the *Medical Devices Bulletin*. The field of medical devices in Canada is now undergoing major, rapid changes in technology, regulations, health policy and funding.

Communication with our clients is an important part of the Health Protection Branch's policy, as outlined in *A Policy Framework (1994)*. We want to make our decisions, and the rationale for them, publicly accessible in a timely manner. We want to inform medical device users about the risks and benefits to help them make intelligent decisions regarding device purchase and use. And we want to share new and existing knowledge on health-related issues. This newsletter will play an important role in accomplishing these aims for the Medical Devices Program.

Another important policy issue for the Branch is cost recovery. For the Medical Devices Program, cost recovery is tentatively scheduled to start in September of 1995. A great deal of dialogue is necessary to make sure that Branch needs are met while any negative impact on industry or consumers is minimized.

This promises to be a challenging year for the Medical Devices Program and its clients. Please let us have your feedback on ways we can improve communications with you.

Kent Foster
Assistant Deputy Minister
Health Protection Branch

Challenges in 1995

As part of the review of federal regulatory programs, the Minister of National Health and Welfare established a Medical Devices Review Committee (known as the Hearn Committee) to make recommendations on the regulation of medical devices. The Committee's report, *Direction for Change*, was released in August 1992. The Minister accepted the Committee's recommendations in principle. Subsequently, The Health Protection Branch (HPB) developed a strategic implementation plan titled "*Development Plan for an Improved Medical Devices Regulatory Program*", which was endorsed by the Hearn Committee in April 1993.

The Hearn Committee's recommendations led to the creation of a separate Medical Devices Bureau in September 1993. In order to improve service delivery to its clients, the Medical Devices Program was further consolidated by

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functionally linking medical devices staff in the five HPB Regional Offices to the Bureau. An overview of the Program's new structure is given in a following article.

During the year that I have been Director of the Bureau, key management and staff positions have been filled, standard operating procedures and tracking mechanisms have been improved; the backlog of premarket review of Part V devices has been reduced; a risk-based classification system and proposals for major changes in the regulation of medical devices in Canada have been developed.

Our main challenges in 1995 include the transition to cost recovery and the consultation process that will lead to the development of new regulations based on risk. Dialogue with clients on these regulatory proposals began in March 1995 and will continue during the year. The following common vision for these regulations was established by industry and the Medical Devices Program in a consultative meeting held on January 9, 1995:

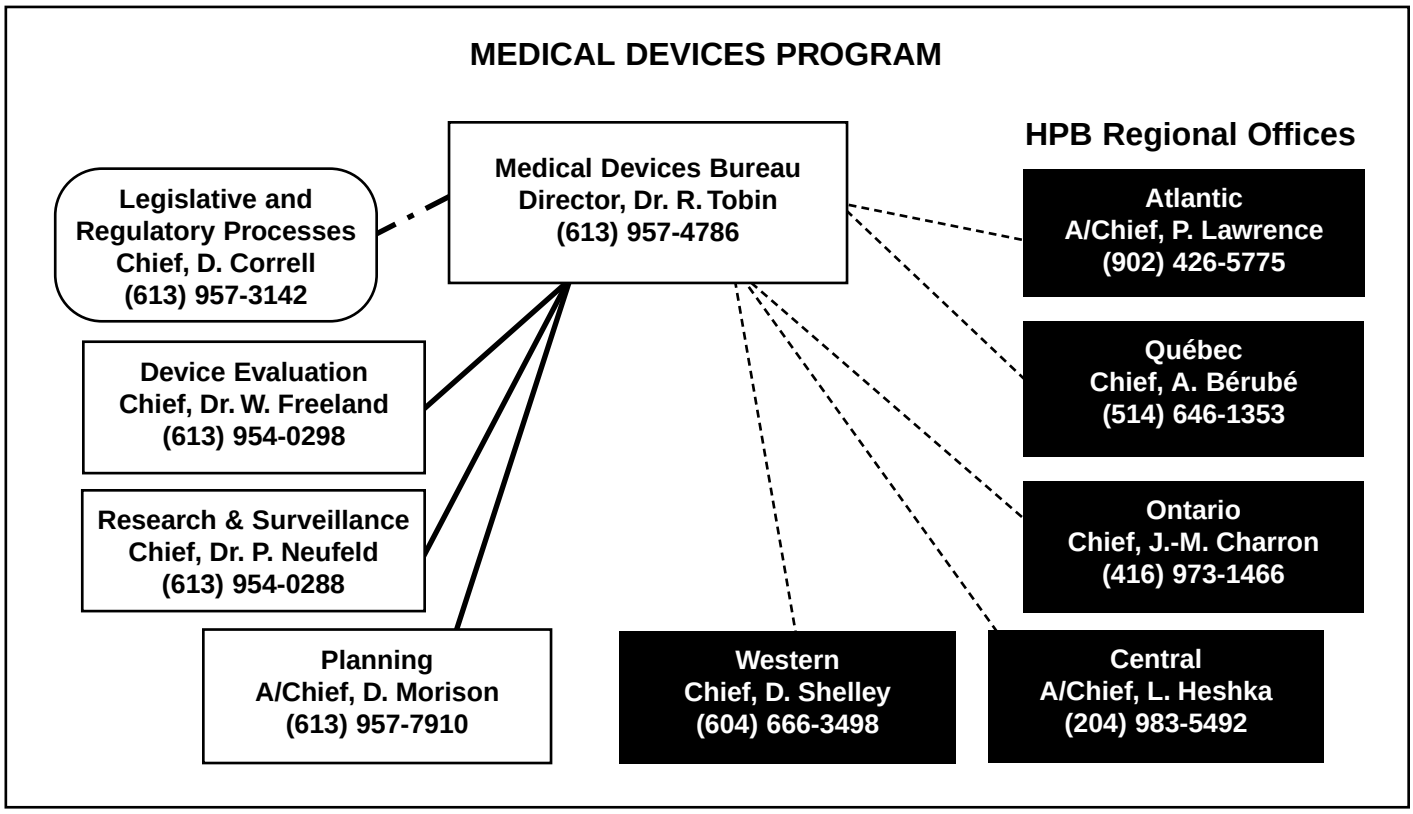
"To apply to medical devices available on the Canadian market a level of scrutiny appropriate to the level of risk they represent. The scrutiny will be achieved by a balance of the key elements – quality systems, premarket review and post market surveillance. Without compromising the health and safety of the Canadian public, minimize the regulatory burden on industry by recognizing (harmonizing) the regulatory requirements of Canada's major trade partners."

In support of this vision, efforts continue in the areas of global harmonization, development of international standards, and establishment of mutual recognition agreements and third-party certification systems.

I sincerely hope that the *Medical Devices Bulletin* will serve as a good communication medium to inform you of issues as they arise.

R.S. Tobin, Ph.D.
Director,
Medical Devices Bureau

The organization chart will help you identify the person or area most relevant to your questions.



MEDICAL DEVICES PROGRAM – AN OVERVIEW

Under the restructured Medical Devices Program the three organisations – **Medical Devices Bureau, Legislative and Regulatory Processes** and the **HPB Regional Offices** – work together to provide service to the Program's clients.

The Program, in partnership with health care professionals, the public, manufacturers and other domestic and foreign government agencies, is in the business of ensuring that medical devices in Canada are safe and effective when used properly. The Bureau's mandate is to apply risk management principles to:

- Conduct premarket and post-market assessment of the safety and effectiveness of medical devices and, where necessary, take action to ensure manufacturers' compliance with the *Medical Devices Regulations*;
- Provide scientific and technical expertise and leadership in the development of and compliance with Canadian and internationally equivalent laws and regulations; and,
- Acquire and provide scientific and technical information as well as expert advice, and initiate information-sharing among clients to promote the safe and effective use of medical devices.

The Bureau has three Divisions: **Planning, Device Evaluation** and **Research and Surveillance**.

The **Planning Division's** major responsibilities stem from the *Development Plan for an Improved Medical Devices Program*. Current activities include:

- Developing a Risk-Based Classification System (RBCS) for devices. The RBCS has been accepted by an external Advisory Committee as a "framework to develop regulations and conformity assessment procedures with the objective of international harmonization";
- Developing regulatory requirements (in consultation with clients) to complement the RBCS;
- Ongoing negotiations for Mutual Recognition Agreements (see the article "European Negotiations" on p. 6);
- Implementing the Cost Recovery Initiative (see article on p. 5 for a profile of this major initiative);
- Representation on international standards committees and the Global Harmonization Task Force;
- Managing the Notification Database which holds current information on all notified devices and suppliers/manufacturers of devices; and,
- Tracking submissions of devices regulated under *Part V* of the *Medical Devices Regulations*.

The Division is also responsible for developing, maintaining and improving other Bureau databases and related systems, such as the Problem Reporting Database which contains information on problems reported by medical device users, and the Medical Devices Bulletin Board Service (BBS). For more information on the BBS and how to access it, please see page 7.

The **Device Evaluation Division** is responsible for premarket review of devices that are regulated under *Part V* of the *Medical Devices Regulations,* and that require a Notice of Compliance before they can be offered for sale. The majority of such devices are those designed to be implanted in the human body for more than 30 days. The Division is also responsible for recommending the release of certain devices on compassionate grounds. Recently, the Division has been assigned the responsibility of reviewing medical device advertisements to be aired on radio or television.

For years, the premarket review process had lengthy delays which were criticized by industry, health care professionals and the Canadian public. A special effort has been made to eliminate the backlog. An overall improvement in service has been achieved by implementing new management approaches and principles of risk management, adopting standard operating procedures, dedicating staff to special device categories, recruiting additional staff and improved partnership with industry.

Risk management principles clearly indicate the next priorities: the need for improved regulation of high-hazard, non-implantable devices; and improvements in the regulation of *in vitro* diagnostic devices used in the screening of blood, blood products and human tissues.

The **Research and Surveillance Division** conducts research into hazards associated with new or existing technologies, develops standards, evaluates the post-market experience of device usage, and provides scientific and technical information to users and manufacturers.

The Research Section will be conducting research on several high-risk, trouble-prone medical devices, including angioplasty catheters, lithotripters and anaesthesia valves. A departmental policy will be completed (with client input) for dental amalgams, based on a hazard assessment conducted during 1994-95.

The Post Market Surveillance Section collects information on device failures and concerns from users, manufacturers, Branch laboratories and international sources. Staff investigate and then initiate voluntary corrective or regulatory compliance action, as necessary, to ensure that faulty devices are either corrected or removed from the market place. It also operates a toll-free **Medical Devices Hot-Line (1-800-267-9675)** to receive device incident reports or concerns, respond to inquiries and provide information on issues of public concern.

The Section also maintains a database of device problem reports, interacts with foreign device agencies on device recalls and concerns, and produces publications such as *Medical Devices Alerts, Information Letters* and *It's Your Health (*formerly *Issues)*.

Legislative and Regulatory Processes (LRP) provides assistance to the Medical Devices Program in developing legislative amendments and regulations, and in establishing compliance policies and guidelines. It also provides advice respecting the interpretation and application of the *Food and Drugs Act* and *Medical Devices Regulations,* and collaborates with the program in negotiating or conforming with international regulatory activities and agreements. LRP coordinates the preparation and distribution of *Information Letters* and *Medical Devices Alerts*.

HPB's five **Regional Offices** across Canada contribute significantly to the Medical Devices Program. The Bureau and HPB Regional Offices work together to investigate problem reports and to ensure that regulatory actions are taken, particularly compliance for *Part V* devices. HPB inspectors visit hospitals or other health care providers, sample and analyze products, and inspect manufacturing operations. The inspectors also investigate problems with the use of medical devices. Analysts conduct laboratory tests of specimens against guidelines or standards.

When hazards to health or regulatory violations are identified, the inspectors promote voluntary compliance by industry, such as product recalls, or they initiate regulatory enforcement measures to ensure appropriate corrective actions are taken by importers, distributors and manufacturers.

Problem Reporting Process

Consumers, industry, hospitals and health professionals can report problems experienced with medical devices by completing a **Problem Reporting Form**. To obtain the form, call the **Medical Devices Hot-Line: 1-800-267-9675**, or one of the HPB Regional Offices identified in the chart. The Problem Reporting Form will also be available on the Medical Devices Bulletin Board Service.

PUBLICATIONS

The Program uses a variety of publications to inform the public, industry, health professionals and hospitals on various topics and issues.

Information Letters are published to inform industry, hospitals and health professionals of proposed regulatory amendments and to obtain their comments on the suggested changes.

Medical Devices Alerts quickly advise users of hazards associated with the use of a specific medical device or device class. Alert 106 , "Contamination of Laparoscopic Insufflators with Patient Fluids", was published on February 3, 1995.

Dear Doctor Letters inform practitioners on issues that are of concern to them.

It's Your Health, formerly ***Issues,*** are articles intended for the public, the media and special interest groups. They cover a wide variety of subjects. Two recent *Issues* on medical devices are available. "**Electromagnetic Devices**" helps consumers protect themselves from the misleading promotion of such devices. "**Sunglasses**" gives consumers comparisons of different types of sunglasses and what amounts of UV they block.

Copies of these publications are available from any of the Regional Offices (see organization chart for phone numbers) or from the Research and Surveillance Division: **Tel. (613) 954-0287 or FAX (613) 993-0281**.

COST RECOVERY INITIATIVE

One of the recommendations of the Medical Devices Review Committee (the Hearn Committee) was "the development, through appropriate consultations with clients, of a cost recovery system applied selectively to defray, in part, the cost of operating an improved medical devices regulatory program."

Although the tight fiscal environment has been a motivating force in the search for new sources of revenue, fairness to taxpayers and efficient operations are the most important factors in implementing client fees for a particular activity. If demands on the Medical Devices Program are to be met, and if the the Program is to continue to maintain and improve services to meet the needs and expectations of clients, it is necessary to look at cost recovery for adequate funding. Expected benefits include:

1. Continued program services based on stable, long-term funding;
2. Continued timely availability of safe and effective medical devices to health care providers and the Canadian public; and,
3. Continued international competitiveness through timely information processing and issuance of compliance documents, resulting in improved service to industry.

Information Letter 811 invited responses from industry on cost recovery. Some were in support of charging fees. Others had concerns about the potential impact fees may have on small businesses, as well as on the quality of the Canadian health care system. The Branch does not want to compromise the viability of any business or to compromise the quality of the health care system.

In early stages of the initiative, a proposed fee schedule for services delivered and rights or privileges granted in *Part V* of the *Medical Devices Regulations* will be implemented. These services include premarket evaluation of new and supplementary submissions, and issuance of Notice of Compliance and Supplementary Notice of Compliance documents.

The fee schedule for *Part V* is tentatively scheduled to start in September 1995. Submissions awaiting review at the time these regulations come into force will not be exempt from fees.

The entire initiative will be phased in over three years to allow for ongoing consultations with industry to address client needs, to alleviate concerns during the implementation period and to improve internal processes.

EUROPEAN NEGOTIATIONS

In June 1994, Health Canada formally entered into negotiations with the European Union (EU) for a Mutual Recognition Agreement (MRA) in the medical devices sector. A MRA, as now envisioned, would allow products destined for export to be assessed locally for conformity to the regulatory requirements of the other party. The work would be carried out on the basis of operating principles and procedures as set by the other party. The proposed agreement would thus:

- enable Canadian manufacturers to meet EU regulatory requirements in Canada on a cost-effective basis;
- end repeated testing of the same product regardless of its final European destination;
- simplify the process for Canadian exporters to get needed EU approval based on mutual recognition of testing and certification procedures. Canadian exports could reach their final destination more rapidly.

At the December 1994 negotiation session, a two-phased approach to developing an MRA was discussed. In the short term, given that the European regulatory system is based almost entirely on premarket evaluation, the scope of an agreement would necessarily be limited to the two premarket activities occurring in Canada, namely, implantable devices subject to *Part V* requirements of federal regulations, and provincial requirements for electrical safety. In the long term, provided that the new regulatory schemes in both jurisdictions evolve as anticipated, the scope of an agreement could be expanded to include additional items, such as quality systems certifications, etc.

Both parties are interested in pursuing a mechanism by which medical devices manufactured in either the EU or Canada could flow more freely into each other's jurisdiction, provided that devices meet basic principles of safety and efficacy. Canada will continue to negotiate with the Europeans to ease market access for Canadian products into Europe, and *vice versa*, at the next round of negotiations scheduled for June 1995.

LATEX ALLERGY PROJECT

A small percentage of the population is sensitive to natural rubber latex (NRL), a favoured material for many medical devices and household goods. Over the past four to five years latex allergy has been recognized as a significant, potentially life-threatening problem for some patients and health care workers. Symptoms can range from minor skin irritation to anaphylactic shock.

The percentage of health care workers sensitive to NRL is higher than that in the general population. The rising incidence of latex sensitization has paralleled the increased use of latex gloves. NRL can often be avoided by using gloves made of synthetic elastomers. However, alternative materials may cost more and some may be less effective than their NRL counterparts.

The Bureau is working to reduce the health risk and economic impact of latex sensitivity by collaborating with professional medical associations to encourage awareness of NRL sensitivity as a possible cause of skin irritation, respiratory symptoms and systemic reactions, to help in finding ways to accommodate the allergic health care worker and to lessen the development of latex sensitivity in susceptible individuals. To this end, Bureau staff are contributing time to the following initiatives:

- Patient Guideline and Assistance: A guideline for people already diagnosed as latex allergic is available.
- Hospital Guideline: A hospital guideline assessing occupational health and patient care risks is planned. A compendium of non-latex gloves has already been produced. Test results on glove protein levels are available.
- Glove Labelling: Ensure that medical gloves are labelled with material of manufacture.

- Rubber Chemicals: Evaluate the safety of rubber-containing medical devices through investigations of mercaptobenzothiazole (MBT) and other allergenic compounds released during use of the device.

For additional information on latex allergy, contact Andrew Douglas, Research and Surveillance, **Tel (613) 954-0738; FAX (613) 993-0281; Internet: adouglas@hpb.hwc.ca**

ROUND TABLE ON EMI

Electromagnetic interference (EMI) problems are becoming more common in hospitals as microelectronic parts are used in more critical care devices, such as cardiac monitors, ventilators, infusion pumps and infant incubators. This interference comes from the increasing number of electronic devices and consumer products that emit EMI, especially portable radio frequency transmitters such as cellular phones and two-way radios. Several hospitals in Canada have banned the use of portable radio frequency transmitters in certain, or entire areas of hospitals, or restricted their use within a given distance of medical devices.

The Round Table on Electromagnetic Compatibility in Health Care held in Ottawa September 22-23, 1994 gathered North American electromagnetic interference experts, medical device manufacturers and telecommunications industry representatives. Participants agreed that the total banning of radio frequency transmitters from hospitals as a general policy was not justified. They favoured rational management of wireless telecommunication devices used in various areas of a hospital.

They also agreed to establish a Task Force on Electromagnetic Compatibility in Health Care made up of users, regulators, manufacturers and researchers. The Task Force will coordinate electromagnetic interference testing, promote the sharing of test results and other information, and develop guidelines on the management of electromagnetic interference in hospital and home care environments.

The Proceedings of the Round Table were published in April 1995. For details contact Dr. Kok-Swang Tan, Research and Surveillance, **Tel (613) 954-0287, 954-0380; FAX (613) 993-0281**.

ELECTRONIC BULLETIN BOARD SERVICE

The Medical Devices Electronic Bulletin Board Service (BBS) has been developed for the health care community and the medical devices industry. The BBS is part of the Health Protection Branch's "Health Information Net" (HINet) that encourages two-way communication between the Department and the public. Available throughout the world on Internet, the BBS is both very easy and very inexpensive to use.

You can access:

- Notification Database System
- Notices of Compliance Listings
- Recall data from Health Canada and the U.S. Food and Drug Administration
- Problem Reporting Form (now under development)
- Recent *Alerts, Information Letters, Dear Doctor Letters, Urgent Messages* and the *Medical Devices Bulletin*
- Lists of available departmental publications
- *Medical Devices Regulations* in full
- and more

How to access the BBS:

Step 1 - Access the HINet server.

Dialup: (613) 941-0979 or (613) 941-1139 and 941-0810

Internet: hpb1.hwc.ca via Telnet.

Step 2 - Log in by typing “hpbnet” in lower case letters at the Login prompt.

Step 3 - Sign on. Follow the instructions on the screen to register as a new user (read the About HIN entries and the Welcome Mail message).

For more information contact:

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Tel (613) 941-0436; FAX (613) 957-7318

HINet Email: medevadm

Internet: swinthro@hpb.hwc.ca

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The *Medical Devices Bulletin* is intended to improve communications with Program clients. In future we will inform you of current Program activities such as the status of regulatory changes and mutual recognition agreements with other nations, as well as serious device problems reported to the Program. This publication is intended to serve you, so please let us know what you would like to see in future issues.

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