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Health Canada Santé Canada

Spring 1996

MEDICAL DEVICES BULLETIN

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

EDITORS' MESSAGE

In these demanding times, the renewed promise of spring provides an excellent opportunity to review the previous year's accomplishments, while forging ahead with new activities for the coming year. As the Medical Devices Bureau enters its third year of operation, the Medical Devices Program, whose members include the Bureau and five Regions, is now well integrated. The Program's accomplishments, which have resulted from the efforts of this dedicated team, have set the stage for another year full of challenges. The staff of the Medical Devices Program join us in wishing you a pleasant and productive year.

The Editors

RECENT HIGHLIGHTS

On October 30 and 31, 1995, the Medical Devices Program (MDP) participated in the first trilateral health meeting, hosted by the Health Protection Branch (HPB). Three participating countries, represented by the U.S. Food and Drug Administration (FDA), the Health Ministry of Mexico, and HPB signed a historic *Memorandum of Cooperation*. The *Memorandum* addresses initiatives such as sharing technical and scientific information; exchanging scientists; communicating evaluations of foods, drugs and medical devices; and pre- and post-market activities. This agreement marks a significant step toward the goal of international harmonization in today's global environment. The MDP is looking forward to participating in joint reviews of selected medical devices with these countries.

Drafting of the proposed new regulatory requirements, for publication in *Canada Gazette*, *Part I*, was initiated (see feature on page 6). We could not have accomplished the revision of the proposed regulations without the assistance and expert advice from MDP stakeholders and partners. Our sincere thanks to all who provided their input to this endeavour.

Cost recovery, which has been in place for Part V medical devices since January 1, 1996, has become a reality, and will help the MDP to provide much more efficient service to our clients.

In This Issue

Canada

ERRATUM

In the Fall 1995 issue of the *Medical Devices Bulletin*, an incorrect telephone number was given for the Canadian Standards Association (CSA) in our article entitled *ISO 9000 Handbook Now Available to Medical Devices Industry*. The correct telephone number is 1-800-463-6727.

DENTAL AMALGAM UPDATE

In the Fall 1995 issue of the *Bulletin*, the formation of the MDP's stakeholder committee on the safety of dental amalgam was announced. The committee consists of representatives from the dental profession, the Canadian Dental Association, dental material manufacturers, university researchers, citizen advocacy groups and provincial health ministries.

The first committee meeting was held in Toronto on November 27, 1995. At the meeting, the MDP's internal report, *Assessment of Mercury Exposure and Risks from Dental Amalgam*, prepared by Dr. Mark Richardson, was made public. Since then, over 300 copies of the report have been distributed to interested individuals.

The committee met again on February 16 and 17 to discuss Dr. Richardson's report in detail, make presentations on the issue of amalgam safety, and consider options for a departmental position on the safety of amalgam. A summary of the February meeting with the committee's recommendations is now available. Although the recommendations of the committee are not binding on the Department, they will be a major factor in the development of a departmental position statement on amalgam scheduled for release later this year.

Copies of Dr. Richardson's report and the summary of the February meeting and recommendations can be obtained from Kathy Bird at (613) 954-0288 (tel.) or (613) 993-0281 (fax).

UPDATE ON ELECTRO-MAGNETIC INTERFERENCE WITH MEDICAL DEVICES

Electromagnetic interference (EMI) with medical devices continues to attract public attention through the news media. In the Spring 1995 issue of the *Medical Devices Bulletin*, we reported on the MDP's Round Table on EMI in Hospitals, held in September 1994. Shortly thereafter, the CBS television newsmagazine *Eye to Eye* featured a story on electric wheelchairs that went out of control because of EMI. Although there have been no similar reports in Canada, CBC's *Marketplace* broadcast a segment on the problem. In June 1995, an *Issues* entitled *Electromagnetic Interference with Powered Wheelchairs* discussed the potential hazards of EMI and ways to reduce the risks.

Some powered wheelchairs, including the two brands made in Canada, already have an EMI immunity level that provides a reasonable degree of protection against the more common sources of EMI. In addition, all powered wheelchair manufacturers in Canada and the United States have agreed to include labelling information on the EMI immunity level of the wheelchair.

A more recent EMI concern, the possibility that digital cellular phones can interfere with some types of pacemakers, has been reported from the Mayo Clinic in Rochester, Minnesota and the Mount Sinai Medical Center in Miami Beach, Florida. In these clinical studies, interference occurred only when the phones were placed in very close proximity to the pacemakers. HPB has not received reports of any incidents of cellular phone interference with pacemakers in Canada. However, digital cellular phones have only recently been introduced here, and their number is expected to grow rapidly. As a result, the MDP has conducted laboratory tests to assess the hazard from digital cellular phones and has confirmed that while EMI can occur, the risk of a life-threatening malfunction is low. No interference was

observed from analog cellular phones. As a result of this work, HPB issued *Medical Devices Alert No.108, Digital Cellular Phone Interference with Cardiac Pacemakers*, November 6, 1995.

MDP researchers are collaborating with scientists at McGill University and the Center for the Study of Wireless Electromagnetic Compatibility at the University of Oklahoma to conduct further studies into the effects of digital cellular phones on cardiac pacemakers and other medical devices.

Copies of Health Canada publications mentioned in this article may be obtained from Dr. K.S. Tan at (613) 954-0380 (tel.) or (613) 993-0281 (fax).

COST RECOVERY INITIATIVE UPDATE

New Fees Regulations Status and Implementation Date

Following comprehensive discussions with industry, the fee schedule was significantly revised from that which was published in *Canada Gazette, Part I* on June 10, 1995. The changes to the fee schedule were approved by Treasury Board and the Special Committee of Council of Parliament. *The Medical Devices Fees Regulations* were published in *Canada Gazette*, *Part II* on December 27, 1995, and enacted on January 1, 1996.

Fee Application Package

A fee application package is now available. The package contains the fee application form, fee payment procedure, a document entitled *Guideline for the Interpretation of a New Device under Part V of the Medical Devices Regulations,* and the service standards applicable to Part V. It is available electronically on the Health Information Net BBS (see Electronic Communications with MDP), and in hard copy from the Medical Devices Bureau, regional offices, and some industry associations.

Basic Interpretation of New Device

Further to Section 2 of the *Regulations,* the definition of a "new device" is provided in greater detail in the *Guideline for the Interpretation of a New Device under Part V of the Medical Devices Regulations.* The following guidelines may also assist manufacturers with their applications under the new *Medical Devices Fees Regulations:*

- The submission of a single component device for which one or more uses is identified requires one review and, therefore, one charge. Additional uses identified at a later date, in a separate submission, will incur an additional charge.
- The submission of a multi-component device system, where all principal components must be used together and cannot be sold and used separately, will be assessed as one review. If any component can be sold and used separately with another system, an additional charge will be incurred.
- Each change in labelling or in the manufacturing process must be tied to one or more devices affected by that change. When a manufacturer who has received a notice of compliance proposes to make a change in the label of a device or in the method of production of a device, the manufacturer will be charged a single fee irrespective of the number of devices affected by the change.

Fee Schedule and Summarized Payment Procedures

Changes to the fee schedule and payment procedures include those described in the table below.

Item	Procedure	Cost
Screening fee per device	The fee must be attached to the device submission. A cheque or money order in Canadian dollars should be made payable to the Receiver General for Canada.	• $500
Evaluation • Evaluation of a new device submission and issuance of a Notice of Compliance • Evaluation of a supplementary device submission and issuance of a supplementary Notice of Compliance	Following screening, the manufacturer will be invoiced for the balance of the payment. Payment is due upon receipt of the invoice.	• $10,500 • $5,500
Reduction of Fee Provisions • *Estimated gross sales less than $60,000 over two years* of marketing the product, verified by audited sales records following the fee verification period • *Estimated gross sales less than $200,000 over two years* of marketing the product, verified by audited sales records following the fee verification period	The manufacturer must provide sufficient evidence to support a claim for fee reduction. If the application for fee reduction is approved, the manufacturer will be invoiced for the appropriate amount. If necessary, the fee will be adjusted following the two-year verification period. The manufacturer will be required to pay the difference if the actual sales exceed the estimated sales. In the case where estimated sales exceed actual sales, a refund will be issued.	• $1,000 • 5% of gross sales
Manufacturer Name Change Replacement or Duplicate Copy of a Notice of Compliance or Supplementary Notice of Compliance	The manufacturer should submit a request for a name change or duplicate copy of a Notice by completing the fee application form and submitting a cheque or money order, in Canadian dollars, with the application.	• $500 • $150 per copy

For further information about the MDP cost recovery initiative, contact Linda Bierbrier at (613) 957-1594 (tel.) and (613) 957-7318 (fax).

ELECTRONIC COMMUNICATIONS WITH MDP

Health Information Net BBS

The Health Information Net electronic bulletin board service (BBS) can be accessed by direct dial-up or by Internet using Telnet, Gopher, or World Wide Web (WWW).

Direct Dial-up

For dial-up access, the numbers are (613) 941-0979, 941-1139, 941-0810, 952-9597 or 954-6151. Once a connection is made, login using **hpbnet** (lowercase). Follow the instructions on the screen to register as a new user. A login name and password will be assigned.

Internet Access

The address for Telnet or Gopher is **hpb1.hwc.ca.** For Telnet access, login using the same instructions outlined above for modem access. For Gopher access, select the HPB BBS Information topic once the menu is displayed. The address for the WWW site is **http://hpb1.hwc.ca:8300.** No login is necessary for WWW access as you are automatically logged in as an anonymous user.

Environmental Health Directorate WWW Site

The Environmental Health Directorate (EHD) WWW site offers access to information for program areas under its auspices, including the Medical Devices Program. The address for the site is **http://www.hwc.ca/dataehd.**

GUIDE TO MEDICAL DEVICE RECALL REPORTING IN CANADA

A medical device recall is defined in Section 2, page 2 of the *Medical Devices Regulations* and includes any action taken in respect of a device marketed by a manufacturer or importer after becoming aware that the device:

- is or may be hazardous to health;
- fails or may fail to conform with any claims made relating to the effectiveness, performance characteristics, or safety of the device; or
- does not comply with the *Food and Drugs Act or Medical Devices Regulations.*

A recall may include the physical retrieval of the device from actual users, as well as any form of retrofit or correction made at user institutions, including labelling or instructional changes and user advisories.

How A Recall Is Initiated

A medical device recall is initiated voluntarily by the manufacturer, legal agent, or importer of the device, as part of fulfilling their responsibility to protect the health and well-being of Canadians by removing from the market, or correcting, defective devices or those in violation of the *Regulations*. The manufacturer may also initiate a recall at the request of the MDP, following an inspection of the manufacturing facility or the importer's establishment by a Medical Devices Inspector, or as a result of an investigation by MDP scientific and clinical staff into a reported problem with a medical device.

The regulatory requirements for recalls are essentially reporting requirements. Part IV of the *Regulations,* Sections 30 and 31, requires the manufacturer and importer to notify the Health Protection Branch of its intent to do so on or before initiating a recall. Each recall requires at least two pieces of correspondence:

1) the initial notice, including as much information required by Section 30 as is available at the time, and

2) the results, confirming completion, providing any missing information and stating the final disposition of the product as required by Section 31.

In order to facilitate recall reporting and monitoring by the MDP, the following information is usually requested:

- the accession/notification number assigned to the device by the MDP, and, if applicable, a Notice of Compliance Submission Number;
- the device name, model/catalogue number(s), serial or lot number(s) and any other means of identification;
- names and addresses of manufacturers and importers, where applicable;
- reason(s) for initiating the recall action and the consequences of using the device in its affected state;
- total number of the device manufactured in, or imported into Canada, and dates of manufacture or importation;
- total number of affected products distributed in Canada and total number remaining in inventory at manufacturer/importer;
- names and addresses of all Canadian distributors;
- names and addresses of all direct accounts, including amounts distributed to each and dates of distribution;
- methods of recall (recall strategy), including copies of communication to users and distributors, response forms sent to all accounts, and instructions for return, modification, or disposal of the affected product, as applicable;
- date the action was initiated in Canada;

- information summarizing the effectiveness of the recall action, including verification of receipt of information by users, amounts of defective product recovered (if applicable), and final disposition of product; and
- the proposed plan of action to prevent recurrence of the problem.

Recall Procedures

The HPB recommends that manufacturers/importers prepare written recall procedures to reflect these requirements and incorporate them into their standard operating procedures (SOPs), based on their status as a firm that manufactures and/or distributes medical devices in Canada.

Enforcement by MDP

Compliance with the recall aspects of the *Regulations* is enforced by Medical Device Inspectors in the five regional offices. Advisories concerning recall actions should be sent to the regional office for the area in which the manufacturer/importer is located. Manufacturers located outside Canada should contact the MDP to determine where to send recall notices.

For information on medical device recalls, contact Jim Moore at (613) 954-8186 (tel.) or (613) 954-0941 (fax).

DIALOGUE CONTINUES ON PROPOSED REGULATORY CHANGES

Since the publication of the last issue of the *Bulletin,* an *Ad Hoc Stakeholder Group* composed of representatives from industry and non-industry stakeholders convened five times with a working group representing the MDP. The stakeholder group was established last summer to provide feedback on revisions to regulatory proposals. Over the course of the five meetings, the group provided further comments and assisted in reviewing the proposal released in December 1995. Appropriate consideration was given to the many comments received from a variety of stakeholders.

In January 1996, the MDP presented the revised proposals at four workshops held in Vancouver, Montreal, Toronto and Washington. The comments received from these workshops will be reviewed by the MDP and taken into account in preparing for the initial publication of the regulations in *Canada Gazette, Part I*, scheduled for the first quarter of fiscal year 1996-97.

An appropriate comment period will be provided following the *Canada Gazette, Part I* publication, during which time comments from interested stakeholders will be encouraged. The MDP will consider the comments received when preparing for publication of the final regulations in *Canada Gazette, Part II,* scheduled for March 1997.

Copies of the December 1995 version of the regulatory proposals may be obtained from Linda MacDonald at (613) 957-7285 (tel.) or (613) 957-7318 (fax).

DOS AND DON'TS OF ELECTRIC HEATING PADS

Electric heating pads are commonly used for the treatment of sore muscles and joints in homes, nursing and long-term care treatment facilities, and in some hospital applications. If improperly used, however, electric heating pads can present the potential for serious injury or death.

Patients at risk of tragic consequences from using electric heating pads include those with decreased temperature sensation, diabetes, spinal cord injuries, and a history of stroke. Patients on medication for pain or sleeplessness, or those who have been drinking alcohol, are also at risk. Infants are at particular risk because a heating pad can cover a large area of their small bodies. They may also be unable to move when burned.

The Medical Devices Program has reviewed an advisory on electric heating pads from the U.S.

Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC). The advisory indicates that the CPSC receives an average of eight death reports per year associated with the use of electric heating pads. Most of these deaths are caused by heating pad fires and involve persons over the age of 65. In addition, there are approximately 1,600 annual heating pad burn injuries that are direct thermal burns not caused by fire; approximately 45 percent of those injuries involve persons over the age of 65.

To minimize the potential for injury when using an electric heating pad, the MDP recommends that users of electric heating pads:

DO

- Read and follow all manufacturer's instructions.
- Inspect the heating pad before each use to ensure that it is in proper working order. Electric heating pads should be discarded if they look worn or cracked, if the electrical cord is frayed, or if the controls do not select all of the optional heat settings, including "OFF".
- Keep a removable cover over the pad during use.
- Place the heating pad on top of, rather than underneath, the body part in need of heat. The temperature of a heating pad can increase if heat is trapped when the pad is placed under a body part.
- Unplug the heating pad when not in use.

DON'T

- Use a pad on an infant.
- Use a pad on a person who is paralyzed or has skin that is not sensitive to temperature changes.
- Use a pad on a sleeping or unconscious person.
- Use a pad in an oxygen-enriched atmosphere or near equipment that stores or emits oxygen.
- Crush or fold a heating pad during use or storage.
- Unplug a heating pad by pulling its connecting cord.
- Use pins or other metallic fasteners to hold the pad in place.

For information on electric heating pads, contact Bill Wallace at (613) 954-0736 (tel.) or (613) 954-0941 (fax).

HAVING TROUBLE WITH YOUR NOTIFICATION?

The Medical Devices Program is pleased to announce that the publication

"Guide to the Preparation of a Notification Pursuant to Part II of the Medical Devices Regulations"

is now available. In an effort to standardize the presentation of the information required to complete your Notification, a revised form has been included in the Guide. You can receive a copy by

calling (613)957-1909,
or faxing (613)954-7666

Alternatively, it is accessible on the BBS.

We hope that you find this document to be user-friendly and that it will eliminate the problems encountered in the past.

The Program is looking forward to receiving feedback on the usefulness of this document.

NEW SUBMITTER'S GUIDE FOR IMPLANTABLE DEVICES

The 1996 version of the *"Submitter's Guide for Compliance with Part V of the Medical Devices Regulations"* is now available to Program clients for comments. Copies are available on the Health Information Net, BBS or by contacting Thomas Henter at (613) 954-0172 (tel) or (613) 941-4726 (fax).

NEW INFECTION CONTROL GUIDELINES DUE THIS SPRING

HPB's Laboratory Centre for Disease Control (LCDC) is preparing a draft guideline entitled *Infection Control Guidelines — Preventing the Transmission of Bloodborne Pathogen Infections in Health Care and Public Service Settings.* The guideline will consider infection control implications from an occupational health perspective. The draft guideline is scheduled to be posted on the Health Information Net BBS early this April.

Questions and comments regarding this and other Infection Control Guidelines should be directed to the Division of Nosocomial and Occupational Infections, LCDC, at (613) 952-9875 (tel.) or (613) 952-6668 (fax).

HOW TO CONTACT THE MEDICAL DEVICES PROGRAM

Medical Devices Bureau Hotline 1-800-267-9675

REGIONAL OFFICES

Western 1-604-666-3845 Central 1-204-983-5451

Ontario 1-416-973-1596 Quebec 1-800-561-3350

Atlantic 1-902-426-5575

You can also contact us via the Internet at:

"..."@isdtcp3.hwc.ca Replace the "..." with the name of the person you wish to contact i.e. kamlesh_gupta@isdtcp3.hwc.ca

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The *Medical Devices Bulletin* is intended to serve clients, staff, partners and stakeholders of the Medical Devices Program. Please let us know what you would like to see in upcoming issues.

For information contact:
Bill Wallace (613) 954-0736 or Kamlesh Gupta (613) 957-4986.

For comments and recommendations, or to change/correct an address, please check the appropriate box and return to:

Medical Devices Bureau, Health Protection Branch,
Postal Locator 0301H1, Tunney's Pasture, Ottawa, Ontario K1A 0L2
FAX (613) 954-0941

❑ Address Correction/Change ❑ New Address

Name/Title:_____ Company Name:_____

Old Address:_____

New Address:_____

Comments/Recommendations:_____

_____