

WORLD TRADE ORGANIZATION

G/TBT/N/CAN/47
16 October 2002

(02-5610)

Committee on Technical Barriers to Trade

Original: English/
French

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>CANADA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Department of Health Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Canadian Enquiry Point, 200-270 Albert Street, Ottawa, Ontario, Canada, K1P 6N7 Tel.: +1 613 238 3222, Fax.: +1 613 569 7808, E-mail: info@scc.ca
3.	Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [X], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Medical devices (ICS: 03.120.01, 11.040.01)
5.	Title, number of pages and language(s) of the notified document: Proposed Amendments to the Medical Devices Regulations (1293 - Quality systems) (English and French, pages 3021-3028)
6.	Description of content: The <i>Medical Devices Regulations</i> were promulgated in July 1998. Because of the complexity and magnitude of the work that needed to be done to implement some of the requirements of the Regulations, Part 5 of the <i>Medical Devices Regulations</i> contained transitional provisions and delayed the coming into force dates of certain requirements including quality systems requirements which were delayed to July 1, 2001. As July 1, 2001, approached, Health Canada decided that more time was needed to prepare for the implementation of the quality system requirements and requested an amendment to delay the coming into force date of the requirements to January 1, 2003. Health Canada anticipated that the 18-month period between July 1, 2001, and January 1, 2003, would serve as a transition phase whereby manufacturers of Class II, III and IV devices would have an opportunity to increase their ability to comply with the <i>Medical Devices Regulations</i> by January 1, 2003. Health Canada also saw the 18-month period as an opportunity for manufacturers of Class II, III and IV devices to voluntarily submit valid ISO 13485 or ISO 13488 quality management system certificates to Health Canada before such certificates become mandatory under the Regulations on January 1, 2003. The proposed amendments pertain to the quality system requirements contained in sections 32 and 43 of the <i>Medical Devices Regulations</i> .

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These proposed amendments require that:

- the organization that performs the audit of the manufacturer's quality system be a quality system registrar, who is recognized by the Minister of Health as having the necessary training, experience and technical knowledge in the design and manufacture of medical devices and in the effective implementation of quality systems to determine whether a quality system satisfies the applicable standards referred to above, and conducts quality system audits in accordance with the applicable guidelines and practices established by the International Organization for Standardization (ISO);
- the registrar, upon completing a satisfactory quality system audit, issues, to the manufacturer, a quality system certificate, which will be valid for a maximum of three years;
- the manufacturer, when applying for a medical device licence, submit a copy of its quality system certificate to the Minister, to demonstrate that its device is in compliance with the above-stated standards;
- the manufacturer submit a copy of a new quality system certificate before the three-year expiry date of the certificate previously submitted to the Minister;
- the manufacturer submit a copy of a new or modified quality-system certificate within 30 days of its issuance, when one is issued before the expiration date of the one previously submitted to the Minister, for example, addition of a manufacturing site to the original facility scope;
- if a quality system certificate is suspended or cancelled for whatever reason by the registrar who issued it, the registrar notify Health Canada within 15 days of the suspension or cancellation;
- manufacturers who already have medical devices licences on January 1, 2003, submit a quality system certificate for their licenced medical devices before November 2003, as part of their annual update to the documents and information that they supplied with respect to their devices as required under section 43 of the *Medical Devices Regulations*, entitled the "Obligation to Inform" section.

7. Objective and rationale, including the nature of urgent problems where applicable:
Protection of human safety

8. Relevant documents: Canada Gazette, Part I, 5 October 2002

9. Proposed date of adoption: not stated
Proposed date of entry into force: 1 January 2003

10. Final date for comments: 19 December 2002

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:

The electronic version of the regulatory text can be downloaded at:

<http://canada.gc.ca/gazette/part1/pdf/g1-13640.pdf>