



Therapeutic Products Directorate  
Medical Devices Bureau  
Room 1605, Main Statistics Canada  
Building  
Tunney's Pasture, P.L. 0301H1  
Ottawa, Ontario  
K1A 0L2

June 19, 1998

**To: Medical Devices Stakeholders**

**Subject: Guidance for the Labelling of *In Vitro* Diagnostic Devices (Draft)**

The proposed *Medical Devices Regulations* set out the requirements governing the sale, importation and advertisement of medical devices. The goal of the Regulations is to ensure that medical devices distributed in Canada are safe, effective, and meet quality standards. It is the intention of the Therapeutic Products Programme to have these proposed Regulations published in Canada Gazette II in May 1998 and begin implementation on July 1, 1998.

This draft document, titled *Guidance for the Labelling of In Vitro Diagnostic Devices*, sets out the Programme's guidance for Industry on the subject. It is being provided now in a draft format so that interested stakeholders can comment and participate in its development.

This guidance document is intended to assist manufacturers in understanding and complying with the regulatory requirements for labelling *in vitro* diagnostic devices.

For more information on *in vitro* diagnostic devices please contact:

Maria Carballo

Head, In Vitro Diagnostic Devices Section, Device Evaluation Division

phone: (613)-954-9391

To comment on this document or to get more information on how to label an IVDD please contact by July 15, 1998:

Maria Carballo

Device Evaluation Division, Medical Devices Bureau

1605 Main Statistics Canada Building,

Postal Locator: 0301H1

Tunney's Pasture, Ottawa, Ontario K1A 0L2

phone: (613) 954-9391, fax: (613) 946-8798

e-mail: [Maria\\_Carballo@hc-sc.gc.ca](mailto:Maria_Carballo@hc-sc.gc.ca)

Thank you for providing your  
comments.

Beth Pieteron

A/Director

Medical Devices Bureau

Attachments





Health Canada Santé Canada



PROGRAMME DES PRODUITS THERAPEUTIQUES  
THERAPEUTIC PRODUCTS PROGRAMME

**Therapeutic Products Programme**

**Programme des produits thérapeutiques**

OUR MISSION: To ensure that the drugs, medical devices, and other therapeutic products available in Canada are safe, effective and of high quality.  
NOTRE MISSION: Faire en sorte que les médicaments, les matériels médicaux et les autres produits thérapeutiques disponibles au Canada soient sûrs, efficaces et de haute qualité.

**DRAFT**

Therapeutic Products Programme  
GUIDANCE DOCUMENT

**Guidance for the Labelling of *In Vitro* Diagnostic Devices**

Date Prepared / Draft Number	June 24, 1998 (file: labl_ivd.wpd)
Supersedes	March 24, 1998 intro1.dft
Date Approved by Responsible Authority	
Date Transmitted for External Consultation	
Document Number	GD012/RevDR-MDB

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## **1 Introduction**

### **1.1 Purpose**

This guideline is intended to assist manufacturers in the labelling of *in vitro* diagnostic devices (IVDDs) to meet current Canadian regulatory requirements.

### **1.2 Scope**

This guideline addresses the labelling requirements of Part 1, Sections 21, 22, and 23 of the *Medical Devices Regulations*, for all products deemed to be IVDDs under these Regulations. This may apply to IVDDs intended for research use if they are also labelled or otherwise represented by manufacturers for a specific diagnostic, investigational or therapeutic application. The guidance document "*Guidance for the Classification Rules For In Vitro Diagnostic Devices GD007/RevDR-MDB*" provides additional information on these topics.

Additional information regarding the labelling requirements for all medical devices can be found in the document "*Guideline for the Labelling of Medical Devices Sections 21 to 23 of the Medical Devices Regulations GD011/RevDR-MDB.*"

Although this guideline does not specifically address the labelling for IVDDs intended for near-patient use, the information for these products required by Sections 21 to 23 of the *Medical Devices Regulations* should be expressed and presented with the intended user of the device in mind. Directions for use should be clearly written in a step by step format and include illustrations and drawings where appropriate. The user should be clear as to what action is to be taken in the case of a particular result and on the possibility of a false positive or false negative result.

The Medical Devices Bureau reserves the right to ask for more labelling information than is indicated in this guideline if it is felt that such labelling will impact on the safe and effective use of this device.

### **1.3 Definitions**

- 1.3.1 LABEL: as defined in the *Food and Drugs Act* "...label" includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package... ."
- 1.3.2 *In vitro* diagnostic device: A medical device or a product subject to section 3.1 of the *Medical Devices Regulations* that is to be used *in vitro* for the examination of specimens derived from the human body.
- 1.3.3 DIRECTIONS FOR USE: defined in the *Medical Devices Regulations* as "...full information as to the procedures recommended for achieving the optimum performance of the device and includes cautions, warnings, contraindications and possible side effects."

- 1.3.4 CONTROL NUMBER: defined in the *Medical Devices Regulations* as "...a unique combination of letters or symbols that is assigned to a medical device by the manufacturer and from which a complete history of the manufacture, control, packaging and distribution of a production run or lot of the device can be determined."
- 1.3.5 TEST KIT: an IVDD that contains reagents or articles or both, manufactured, sold or represented for use in combination to conduct a specific test.

## 2 Labelling requirements for IVDDs

The labelling of all medical devices is governed by Part 1, Sections 21, 22, and 23 of the *Medical Devices Regulations*. The following sections of this guideline (Sections 3,4,5 and 6) indicate the regulation in italics followed by the requirements specific to IVDDs.

### 3 Labelling information for IVDDs as required by Section 21 Subsection (1) Paragraphs (a) to (j) of the *Medical Devices Regulations*

*Section 21 Subsection (1) Paragraphs (a) to (j): No person shall import or sell a medical device unless the device has a label that sets out the following information:*

- (a) *the name of the device;*
- (b) *the name and address of the manufacturer;*
- (c) *the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;*
- (d) *in the case of a Class III or IV device, the control number;*
- (e) *if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, which may include the size, net weight, length, volume or number of units of the device;*
- (f) *the words "Sterile" and "Stérile", if the manufacturer intends the device to be sold in a sterile condition;*
- (g) *the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;*
- (h) *unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented, including the performance specifications of the device if those specifications are necessary for proper use;*
- (i) *the directions for use, unless directions are not required for the device to be used safely and effectively; and*
- (j) *any special storage conditions applicable to the device.*

#### 3.1 Label

All IVDDs must have a LABEL which provides the information specified in Section 21

Subsection (1) Paragraphs (a) to (j) of the *Medical Devices Regulations*. The LABEL as defined in the *Food and Drugs Act* includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. Labelling for IVDDs includes, but is not limited to, the immediate device container label, the reagent/component label and package insert.

### **3.2 Labelling requirements for a package insert**

Package inserts are essential for most IVDDs. The requirements for a package insert indicated in this section of the guideline apply to the majority of TEST KITS for all classes of IVDDs. It is recognized that the extent of the information required in the package insert may depend upon the complexity and safety considerations of the test.

The information required for a package insert may be presented in a different format than that indicated in 3.2.1 to 3.2.10 of this guideline.

#### **3.2.1 Name of the IVDD [Section 21 Subsection (1) Paragraph (a)]**

The name of the IVDD on the label should enable the user to identify the device and distinguish it from other similar devices.

#### **3.2.2 Name and address of the manufacturer [Section 21 Subsection (1) Paragraph (b)]**

The name and mailing address of the manufacturer is required.

#### **3.2.3 Intended use [Section 21 Subsection (1) Paragraph (h)]**

The package insert should clearly indicate intended use(s) and indications for use of the IVDD. The following information should be included:

- Nature of the intended use (e.g. screening, monitoring, diagnostic, etc.). Class IV IVDDs not intended for donor screening must indicate “**Not for donor screening**” on the device container label and package insert.
- Technology of the IVDD (e.g. ELISA, chromatographic, etc.).
- Type of test: qualitative or quantitative.
- The specific disorder, condition, or risk factor of interest for which the test is intended, i.e. the analyte to be measured.
- Description of the patient population the IVDD is to be used in.
- Indicate if the device is for use in clinical laboratories, alternative care sites, or home use. Note: The Limitations section of the package insert should include any specific training required for test performance or use.
- Type of specimen(s) required (e.g. serum, plasma, etc.).
- Indicate if the IVDD must be used in combination with or installed with or connected to other medical devices or equipment.
- Specific contraindications for use, e.g. “Use of this device is contraindicated in recent influenza vaccine recipients...” when considerable cross-reactivity can be expected in recent influenza vaccine recipients, etc.

An example of an intended use statement is the following:

[Manufacturer's Name]'s [Assay Name] Enzyme Immunoassay (EIA) is used for the qualitative (or quantitative) detection of Antibody to Human Immunodeficiency Virus Types 1 and/or 2 (HIV-1 and HIV-2) in human serum or plasma, and is indicated as a screening test for serum or plasma (or "Not for donor screening") and as an aid in the diagnosis of infection with HIV-1 and/or HIV-2.

### **3.2.4 Summary and explanation [Section 21 Subsection (1) Paragraph (h)]**

Indicate a brief summary and explanation of the test and how it works, including the clinical benefits and limitations of the test with respect to intended use. Describe the technique(s) and reactions (biological, chemical, microbiological, immunochemical, etc.) used, citing literature references where appropriate. The summary should include descriptions of the types of antibodies and antigens used in the test, (e.g. synthetic peptide, monoclonal, recombinant, etc.), and purification methods.

### **3.2.5 DIRECTIONS FOR USE [Section 21 Subsection (1) Paragraph (i)]**

Section 21 Subsection (1) Paragraph (i) requests DIRECTIONS FOR USE unless directions are not required for the device to be used safely and effectively. Most IVDDs will require DIRECTIONS FOR USE. Directions for use are defined in the *Medical Devices Regulations* as the procedures recommended for achieving the optimum performance of the device, including warnings and precautions, contraindications, and possible side effects.

The required information may be presented in a package insert in a format different from that indicated in Section 3.2.5. For example, warnings and precautions may be indicated under a separate heading. Components of a TEST KIT may be indicated in a table format along with instructions for preparation and use, storage conditions, stability information, warnings and precautions, etc.

#### **3.2.5.1 Components (reagents, supplies, etc.)**

- a) The description of a component should include the following:
  - Name of the component.
  - Contents in terms of quantity (e.g. number of vials, if applicable), mass and/or volume or concentration. For reagents, indicate the following:
    - (a) Quantity, proportion, concentration or activity of each reactive ingredient. For biologicals, indicate the source and measure of activity.
    - (b) A statement indicating the presence of catalytic or non-reactive ingredients, such as buffers, preservatives or stabilizers, where this information is needed for the safe and effective use of the test.
  - Specify the maximum number of tests that can be performed with stated contents.

- Complete directions for preparation (reconstitution, mixing or dilution).
  - Storage instructions for both opened and unopened reagents. Note: This information can also be provided in a separate section of the package insert.
  - Information regarding possible deterioration of the reagent, i.e. indicators of reagent, calibrator or quality control material deterioration, where applicable.
  - Appropriate warnings and precautions. This information can also be provided in a separate section of the package insert.
- b) Indicate any essential components and/or special equipment or instruments not provided. Include details such as sizes, numbers, types, quality, etc. Examples are: incubators, precision pipettes, calibrated thermometers, appropriate disinfectants and disinfection procedures, appropriate reaction vessels (specify glass, polystyrene, polypropylene), etc. For instruments such as microplate readers, indicate required specifications such as wavelength, band width, absorbance, precision, filters, etc.
- c) Indicate any dedicated instruments/equipment/software. Include the following:
- Name of the instrument.
  - Model number(s)/version number(s).
  - Brief description of use or function, performance characteristics/specifications, warnings and precautions, limitations, etc.

### 3.2.5.2 Warnings and precautionary statements

Indicate appropriate warnings and precautionary statements for the safe and effective use of the IVDD. Warnings alert the user to potential serious adverse reactions and safety hazards that can occur in the proper use, or misuse, of an IVDD. Precautions alert the user to the special care or procedures necessary for the safe and effective use of the IVDD. The use of international symbols and signal words such as “warning” and “caution” are effective in alerting the user to a hazard.

For all classes of IVDDs, indicate the statement:

**For in vitro diagnostic use.**

Biological Hazards:

IVDDs containing material of human or animal origin are required to have a statement to the effect:

**CAUTION: the device contains material of human or animal origin and should be handled as a potential carrier and transmitter of disease.**

For IVDDs containing potentially infectious agents, indicate whether any antigens and/or control sera have been inactivated and provide a complete description of what tests have been performed on positive and negative controls, and results obtained, for HCV, HBV, HTLV and HIV. If the testing revealed the presence of an infectious agent, a hazard statement should be included to the effect:

**HAZARD: The device may transmit [infectious agent] and should be handled with extreme caution. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents.**

Section 21 Subsection (1) Paragraph (f) the *Medical Devices Regulations*, requires the word **Sterile**, if the manufacturer intends the device or components to be sold in a sterile condition.

Examples of appropriate warnings and precautions:

- Do not pipette by mouth.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Wear protective clothing and disposable gloves while handling the kit reagents.
- Wash hands thoroughly after performing the test.
- Use in ventilated area.
- Avoid contact with eyes; use safety glasses; in case of contact, flush with water immediately and contact a doctor.
- Avoid contact with skin; use gloves; in case of contact with skin, flush immediately and thoroughly with water.
- Handle DMSO containing reagents with care, since DMSO is readily absorbed through the skin.
- For acids, include appropriate warnings for spills such as “wipe up spills immediately and flush with water” and “should the reagent contact eyes or skin, flush with copious amounts of water and consult a physician”.
- For biological spills, indicate appropriate disinfectants and disinfection procedure.
- Dispose of all specimens and components of the kit as potentially infectious agents.
- Do not use the kit or any kit component past the indicated expiry date.
- Do not use any other reagents from different lots in this test, unless the reagent is designated to be used with other lots of the same kit.
- Do not use any reagent in other TEST KITS, unless the reagent is designated to be used with other kits.
- Avoid microbial contamination of reagents.
- Bring all reagents or components to room temperature before use.
- For manual pipetting of samples and controls, use individual pipette tips to eliminate carryover.

### 3.2.5.3 Specimen collection and handling

Indicate the following:

- Description of the specimen.
- Criteria for acceptance or rejection of samples.
- Patient preparation, precautions and procedure for specimen collection (e.g. removal of particulate matter by centrifugation, etc.).
- Additives and preservatives to be added to the specimen, to preserve the integrity of the specimen.
- Storage and handling requirements.
- Any known interferences.

#### **3.2.5.4 Test procedure**

a) For the test method:

Instructions for use must provide complete information relevant to the safe and effective use of the IVDD. The following information should be included:

- Description of the required amounts of reagents, samples, and controls; incubation schedules, temperature, wavelengths used for measurement, and other relevant environmental conditions under which the device is to be used.
- Sample selection and handling.
- Performance/ turnaround time.
- Calibration information: controls, reference samples, blanks, preparation of standard curve, indication of the maximum and minimum levels of detection, etc.
- Stability of the final reaction product.
- Quality control procedures and materials required. Indicate whether positive and negative controls are required and what are considered to be satisfactory limits of performance.

b) For the individual reagents:

- Complete instructions for preparing use-dilutions or mixing of individual reagents, unless provided in an alternate section of the package insert.
- Test volumes and DIRECTIONS FOR USE, unless provided in an alternate section of the package insert.

#### **3.2.5.5 Results**

Indicate the step by step procedure for calculating the value of the test sample, including appropriate formulae and a sample calculation.

#### **3.2.5.6 Interpretation of results**

Indicate the criteria for acceptance or rejection and whether further testing is required if a particular result is obtained. For example, requirements for duplicate tests if the initial test is

reactive.

Indicate the significance of the test results obtained, including information as to what degree a negative test does or does not exclude the possibility of exposure to, or infection with, the organism, etc. A positive or negative result must be clearly defined with cutoff levels where appropriate.

If the test is designed to provide qualitative results, provide an explanation of expected results.

If the test requires the interpretation of “visual” results, e.g. colorimetric reactions, include a high quality photograph or reproduction of results.

### **3.2.5.7 Limitations**

Indicate test limitations and all known contraindications, if not stated in a previous section of the package insert, with references if appropriate. This section may include qualifications of personnel performing the test and/or interpreting test results; an indication that results should only be used in conjunction with other clinical and laboratory data; various patient and clinical factors that may affect marker levels; and factors that should be considered when interpreting test results.

### **3.2.5.8 Expected values**

Indicate the range of expected values based on studies of test results from various populations.

Indicate how the range was established and clearly identify the population(s) which were used for the testing. Include literature references where appropriate.

### **3.2.5.9 Disposal**

Indicate appropriate decontamination and disposal procedures of used or expired kits and/or reagents. Disposal of all specimens and kit components must comply with all applicable waste disposal requirements.

Note: Decontamination and disposal information may also be provided in the “Warnings and precautions” section of the package insert.

### **3.2.6 Performance characteristics [Section 21 Subsection (1) Paragraph (h)]**

The Performance characteristics section must include a summary of data from clinical trials upon which the performance of the test is based. Performance characteristics such as sensitivity, specificity, predictive values, reproducibility, repeatability, stability, limits of detection and measurement range, earliest clinical detection in comparison with tests of reference, etc., are required. Indicate 95% confidence intervals where appropriate.

### **3.2.7 Storage instructions [Section 21 Subsection (1) Paragraph (j)]**

- a) Indicate the storage conditions necessary to ensure the stability of the product in the unopened state for both device and individual reagents. Recommended storage temperature intervals and other conditions for storage such as light, humidity, etc. should be stated. Examples of appropriate statements are: 2 °C to 8 °C, 2...8 °C, -

20 °C or below,  $\leq -20$  °C, protect from freezing, do not freeze, store in the dark, store desiccated, etc.

- b) Indicate storage conditions as outlined above for opened or reconstituted/mixed reagents.

### **3.2.8 Identifier [Section 21 Subsection (1) Paragraph (c)]**

The identifier or catalogue number should be indicated on the package insert.

### **3.2.9 Date of issue**

The date of issue of DIRECTIONS FOR USE or of any revision should be indicated.

### **3.2.10 Bibliography**

The Bibliography should include pertinent up-to date references for information cited in the text and any other references related to the subject matter.

## **3.3 Immediate container LABEL requirements**

The Manufacturer should refer to Section 3.2 of this guideline for a complete description of the abbreviated requirements indicated below.

### **3.3.1 Name of the IVDD [Section 21 Subsection (1) Paragraph (a)]**

### **3.3.2 Intended use [Section 21 Subsection (1) Paragraph (h)]**

An example of an appropriate statement for the immediate container LABEL is the following:

**[Assay name] for the detection of antibodies to Human Immunodeficiency Virus Types I and II (HIV-1/HIV-2) in human serum or plasma. Not for donor screening.**

Note: Class IV IVDDs not intended for donor screening must indicate “**Not for donor screening**” on the device immediate container LABEL and package insert.

### **3.3.3 Contents of kit [Section 21 Subsection (1) Paragraph (e)]**

List of kit contents, including quantities, descriptions, volumes, number of tests, etc. If more than a single determination may be performed using the product, any statement of the number of tests must be consistent with instructions for use and amount of material provided.

### **3.3.4 Warnings and precautions [Section 21 Subsection (1) Paragraph (i)]**

Warnings or precautions for users appropriate to the IVDD, including the statement “**For In Vitro Diagnostic Use**” for all IVDDs, and “**Sterile**”, if the manufacturer intends the kit to be sold in a sterile condition.

For IVDDs containing potentially infectious agents, whether inactivated or not, indicate a statement to the effect:

**Handle all the reagents as though capable of transmitting infection.**

### **3.3.5 Storage instructions [Section 21 Subsection (1) Paragraph (j)]**

Storage instructions, including any special storage conditions applicable to the IVDD.

### **3.3.6 Expiration date [Section 21 Subsection (1) Paragraph (g)]**

Expiration date based upon the component of the IVDD having the shortest projected useful life. Expiration dates are required for the unopened IVDD or its components (reagents, calibrators, quality control materials, etc.) and for the opened IVDD or its components if different from the unopened IVDD.

### **3.3.7 Name and address of the manufacturer [Section 21 Subsection (1) Paragraph (b)]**

### **3.3.8 CONTROL NUMBER [Section 21 Subsection (1) Paragraph (d)]**

A CONTROL NUMBER is required for Class III and IV IVDDs, in order to determine the complete manufacturing history of the product. It is standard convention for most IVDD kits or kit components to indicate a lot number.

If it is a multiple unit product, the CONTROL NUMBER should permit tracing the identity of the individual units.

### **3.3.9 Identifier [Section 21 Subsection (1) Paragraph (c)]**

The identifier or catalogue number of the IVDD is required.

### **3.3.10 Specific operating instructions**

Where applicable.

## **3.4 Reagent LABEL requirements**

The Manufacturer should refer to Section 3.2 of this guideline for a complete description of the abbreviated requirements indicated below.

### **3.4.1 Name of the IVDD and reagent [Section 21 Subsection (1) Paragraph (a)]**

For reagents to be used within a single kit, indicate the name of the reagent and the name of the IVDD. For multipurpose reagents which can be used with a number of kits, the name of the reagent should be sufficient.

### **3.4.2 Contents [Section 21 Subsection (1) Paragraph (i)]**

Quantity, proportion or concentration of each reactive ingredient; and for a reagent derived from a biological material, the source and a measure of its activity.

If more than a single determination may be performed using the product, any statement of the number of tests should be consistent with instructions for use and amount of material provided.

### **3.4.3 Warnings and precautions [Section 21 Subsection (1) Paragraph (i)]**

Indicate warnings and precautions appropriate to the reagent, including the statement “**For In**

**Vitro Diagnostic Use”** for all reagents, and **“Sterile”**, if the manufacturer intends the reagent to be sold in a sterile condition.

For reagents containing potentially infectious agents, whether inactivated or not, indicate a statement to the effect:

**Handle the reagent as though capable of transmitting infection.**

#### **3.4.4 Storage instructions [Section 21 Subsection (1) Paragraph (j)]**

Appropriate storage instructions adequate to ensure the stability of the product. Where applicable, include information such as conditions of temperature, light, humidity, and other pertinent factors.

For products requiring further manipulation, such as reconstitution and/or mixing before use and with storage in the original bottle, appropriate storage instructions should be provided for the reconstituted or mixed product.

#### **3.4.5 Expiration date [Section 21 Subsection (1) Paragraph (g)]**

Expiration date based on the stability of the individual reagent in both its unopened and opened state.

#### **3.4.6 Name and address of the manufacturer [Section 21 Subsection (1) Paragraph (b)]**

#### **3.4.7 CONTROL NUMBER [Section 21 Subsection (1) Paragraph (d)]**

A CONTROL NUMBER is required for Class III and IV reagents, in order to determine the complete manufacturing history of the product. It is standard convention for most IVDD reagents to indicate a lot number.

#### **3.4.8 Identifier [Section 21 Subsection (1) Paragraph (c)]**

The identifier or catalogue number of the reagent, where applicable.

### **4 Labelling information for IVDDs as required by Section 21 Subsection (2)**

*Subsection (2) Section 21: The information required pursuant to subsection (1) shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user.*

The information must be conspicuous and clear enough to read as well as intended to last for the life of the device. The label information must be presented in a format most likely to be understood by the expected user. Test marketing of the device labelling may be required in some cases.

### **5 Labelling information for IVDDs as required by Section 22**

*Subsection 22.(1) Subject to subsection (2), where a medical device is intended to be sold to the general public, the information required by subsection 22(1) shall*

(a) be set out on the outside of the package that contains the device; and  
(b) be visible under normal conditions of sale.

*Subsection 22.(2) Where a package that contains a medical device is too small to display all the information required by section 21, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale.*

The information must be visible for two reasons: to allow the intended user to make an informed choice and to easily permit the identification of the device for postmarket activities such as recall.

Under some circumstances, the package that contains the device may be too small to allow the DIRECTIONS FOR USE to be displayed. The DIRECTIONS FOR USE may then accompany the product as a package insert. In these circumstances, information on the outside of the package should refer the user to this further labelling.

## **6 Labelling information for IVDDs as required by Section 23**

*Subsection 23.(1) Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French.*

*Subsection 23.(2) Subject to subsection (3), where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchase.*

*Subsection 23.(3) The following information shall, as a minimum, be in both English and French:*

- (a) all warnings and contraindications; and*
- (b) the directions for use of a device that is sold at a self-service display.*

Section 23 reflects the need to accommodate the two official languages set out in the *Official Languages Act* and ensures that devices sold in Canada are labelled in both official languages where it is reasonable and prudent to do so.

As a minimum, the device must be labelled in either English or French in addition to which other languages are permitted. Section 23(2) recognizes that it may not be economically reasonable nor necessary to supply the DIRECTIONS FOR USE in both official languages at the time and point of sale for every device. It should be noted that the DIRECTIONS FOR USE must be readily available in the other official language at the request of the purchaser.

Devices sold to the general public at a self-service display are a special case. Self-service implies the absence of a “learned intermediary” such as a health care professional, to assist the user in the safe and effective use of the device. Self-service also implies sale in a variety of ways, for

example, by catalogue mail order and via the Internet. In such cases, the DIRECTIONS FOR USE must be supplied in both official languages at the time of purchase.

## **7 Labelling for IVDDs containing explosive materials or components**

In addition to the requirements referred to in Section 21, an IVDD containing explosive material or components is required to have the following information on the LABEL:

- The identity of the material or the components.
- The nature of the potential hazard.
- The precautions that should be taken during handling, storage or disposal of the device in order to avoid an explosion.

## **8 Bibliography**

- 8.1 BS EN 375:1992 Specification for Labelling of in vitro diagnostic reagents for professional use.
- 8.2 21 CFR Food and Drugs Parts 800 to 1299.
- 8.3 Guidance for the Labelling of Medical Devices: Sections 21 to 23 of the Medical Devices Regulations.
- 8.4 21 CFR Food and Drugs Part 660.