

Health Technology Regulations

Will replace Group III products in the Hazardous Substances Act of 1973



Objective: Safety of medical devices

Safety for patient and operator:

- Manufacture
- Utilisation
- Maintenance

Not addressed in Hazardous Substances Act but implemented by Radiation Control

History

- Draft regulations of 1998
- Draft regulations by Mr Cheng (WHO)
- Relevant sections of Hazardous Substances Act
- Outcomes from workshops

Import or local manufacture of medical devices

- No person shall import or locally manufacture any medical device unless a licence in terms of the regulations has been granted
- The Minister may exempt any person from any provision of these regulations
- The Minister may determine that any provision of these regulations shall not apply to any medical device

Classification of medical devices

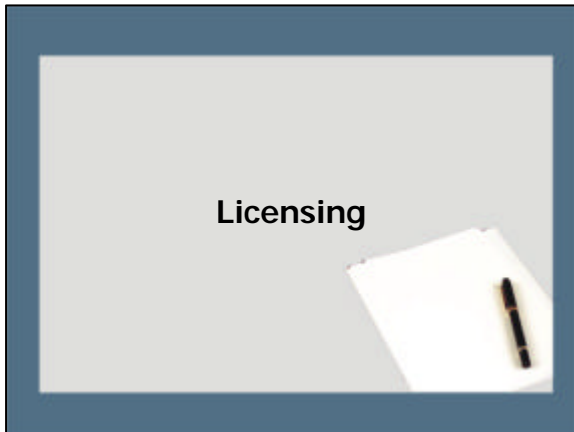
- Medical devices shall be classified into 4 classes, and the classification rules shall be applied, see [Appendix X pg **](#)

<u>CLASS</u>	<u>RISK LEVEL</u>
• I	Low Risk
• IIa	Low-moderate Risk
• IIb	Moderate-high Risk
• III	High Risk

Why not classes 1, 2, 3 and 4?

Delegation of power

- The Director-General may authorize any officer of the Department of Health, to exercise any power, duty or function conferred or imposed on the Director-General in terms of this Act.
- Radiation Control will continue to do this task



Licensing

The Director-General may issue a licence to import or manufacture any medical device:

- on application in the prescribed manner
- on payment of the prescribed fee
- subject to the conditions of the regulations

Licensing

- The D-G may require an applicant to furnish any further information
- The D-G may conduct any investigation in respect of the applicant
- The Director-General may cancel or vary any condition to which a licence is subject or impose any further conditions in respect of a licence

Application for a licence: Class 1

Class I devices to be registered but not licensed Declaration by the manufacturer that the device in question:

- Complies with the Essential Principles of Safety and performance (refer to GHTF)
- Complies with the Quality Standard SANS 13485/ISO 13485

Application for a licence: Class IIa and higher

- Colour brochure (including technical specs)
- A letter from the manufacturer in which the importer is appointed as an authorised representative (only for manufacturers not directly represented in SA)
- Certification that the medical device conforms to:
 - a) the Quality Standard SANS 13485/ISO13485
 - b) the Risk Management Standard ISO 14971

Application for a licence: Class IIa and higher (contd)

- Declaration by the manufacturer that the device in question complies with the applicable Essential Principles of Safety and Performance (GHTF)
- Results of clinical trials in the case of a Class IIb and higher medical device (Only for new technologies)

Licence application (contd)

- If the D-G refuses to license a medical device, the D-G shall in writing notify the importer or local manufacturer stating -
 - (a) the reason(s) for such refusal; and
 - (b) the deadline for submission of any further representations by the importer or local manufacturer


Advertising

The fact that a medical device has been licensed by the Department of Health may not be used in any way by the licence holder as the basis for any claim regarding the clinical efficacy of that medical device

Period of validity and renewal of licenses

A licence shall be valid for a period as indicated in the licence

Labeling & Other Regulations



Labeling

A waterproof, indelible, permanently affixed label, which displays the letters "NDOH" and the licence number must appear on each medical device and the container or packaging. If the label is too large to be fitted adequately to the device, it must be affixed to the container or packaging that contains the medical device. The label must be clearly visible on the medical device and/or its container and/or packaging at the port of entry

Labeling (contd)

Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to SANS ISO 15223:2005 or the international version of this standard ISO 15223:2000

Appeals to Minister against decisions of, and conditions imposed by, the D-G


Any person aggrieved by a decision of the D-G may submit objections and/or proposals to the D-G and may ultimately appeal to the Minister, who may in his/her discretion confirm, set aside, amend or replace such refusal or condition

Other regulations:

- Suspension and cancellation of licenses
- Embargo
- Seizure
- Health officers
- Duties of health officers
- Offences
- Disposal of goods seized

Post-market obligations

Obligations of the licence holder and vendor



Licence holder: records

Every licence holder shall for every Class IIa and higher medical device, keep a record of every sale, leasing or donation:

- Name, physical address, telephone number and e-mail of the purchaser;
- Name of the manufacturer, model, and serial number
- Accessories, upgrades and modifications
- Date of sale, leasing or donation and date of commissioning of the device

Licence holder records (contd)

The records shall -

- at all times be kept by the licence holder, in a place which is reasonably protected against fire and theft;
- at all reasonable times be made available for inspection at the request of a health officer;
- in the event of a change of ownership of the business concerned, be handed over to the new owner;

Licence holder records (contd)

The records shall -

- at the request of the D-G be delivered to an address specified by the D-G
- be disposed of only in such manner as may be approved by the D-G
- be retained for at least two years after the device has been decommissioned (or ten years after the device is no longer manufactured?)

Complaint handling

The licence holder shall keep a documented procedure to handle complaints. A telephone number, fax number and an e-mail address shall be provided to users for reporting comments and complaints

Implant registration

The licence holder must provide two implant registration cards to be completed by the healthcare facility or medical practitioner who performs the implant procedure and the licence holder must ensure that one completed card is returned within 5 working days after the device has been implanted. The healthcare facility or medical practitioner who performs the implant procedure must retain the other card. The cards must be stored in a place which is protected against fire and theft;

Recordkeeping of defects and adverse events

- If the licence holder becomes aware of a defect/adverse event that affects the safety, operation, use or maintenance of a device then the D-G and all users of the device must be informed of the steps to be taken to address the problem
- Defects/adverse events that require modification/recall of the device must be reported to the D-G as well as all the users of that device

Procedure after an adverse event

If an adverse event occurs (in South Africa) during the use of a licensed medical device and it is suspected that the device has played a role in the adverse event then the **user** shall isolate the device in question, maintaining all its accessories and settings and the device shall not be adjusted or used until inspected, tested and declared safe by an **independent competent person** who shall not have been involved in the maintenance, calibration and/or repair of the device

Procedure after an adverse event

- The user must report the adverse event, to both the licence holder and the D-G, within two days of the event
- This report shall comprise a brief description of the event and details of the medical devices involved

Procedure after an adverse event

NOTE: If no independent competent person can be found to do the inspection and testing then a person competent to do so may be used provided that an independent person, knowledgeable in the use and technical features of such devices, is present and witness that such inspection and testing is fair and unbiased. Such independent person must approve the report of the inspection and testing by signing every page and signing a declaration that declares the inspection and testing was fair and unbiased

Reporting the adverse event

The **licence holder** must report to the D-G every serious adverse event/defect in relation to a licensed medical device that the licence holder becomes aware of, within **X** calendar days. If a serious adverse event, which occurs in South Africa, is reported to the licence holder, the licence holder shall conduct an investigation into the adverse event and report to the D-G as soon as possible on the steps taken to address such serious adverse event/defect

Reporting the adverse event

The Director-General may:

- appoint a Commission of Enquiry, should the nature or extent of the risk so warrant, to investigate the adverse event and submit a report
- cause the publication or communication of any adverse event, situation of risk, serious malfunctioning or any hazard to the public in general and/or medical device stakeholders in particular.

Maintenance of medical devices

The licence holder must offer a maintenance and repair service for every device licensed and must guarantee that spares will be available for the lifetime of that device

Maintenance of medical devices

The licence holder must ensure that personnel who calibrate, maintain, service, repair or in any way work on the licensed device receive appropriate training from the original manufacturer, or a person approved by the original manufacturer. In the case where the licence holder outsources the maintenance etc to a third party then that third party must have received appropriate training from the original manufacturer or a person approved by the original manufacturer.

Maintenance of medical devices

The onus is on the licence holder to provide a document from the original manufacturer, **naming and certifying** the person(s) who have been adequately trained and also certifying that the maintenance and service facilities are acceptable

Maintenance of medical devices

The licence holder shall keep documents of the original manufacturer's specified procedures, work instructions, measurement procedures and reference materials, as necessary, for performing all servicing activities, and shall make these documents available to the third party where appropriate.

Maintenance of medical devices

Any person maintaining, servicing, repairing, calibrating or in any way working on medical equipment in Classes IIa, IIb or III must be competent to do so and must have received adequate training for the particular device in question or be supervised by a person trained and competent in such work

Maintenance of medical devices

Any person maintaining, servicing, repairing, calibrating or in any way working on medical equipment in Classes IIb or III must be competent to do so and must be registered (registerable?) with ECSA or supervised by a person registered with ECSA

Maintenance of medical devices

In the case of Class IIb and Class III medical devices such person must be in possession of written certification by a person approved by the manufacturer of the device that he or she is competent to work on that device and such certification shall state the level to which maintenance, service, repair, calibration may be performed

Maintenance of medical devices

Any institution, hospital, clinic or business acquiring and using medical devices must:

- maintain an up-to-date inventory of all licensed medical devices
- have and implement a preventive maintenance program for all medical devices according to manufacturer specs
- have an equipment management recording system in which repair and maintenance records are kept. A minimum set of data is required to be kept for every device

Maintenance of medical devices

Any institution, hospital, clinic or business acquiring and using medical devices which outsources the maintenance and/or repair of some or all of its medical devices shall:

ensure that the provider of the outsourced services employs competent technicians to do the maintenance or repairs, or

Maintenance of medical devices

- subcontracts competent technicians to do the maintenance or repairs and
- keeps adequate records of all maintenance and repairs done and will make these records available to the user whenever requested to do so
- provides written certification that only genuine spares from the original manufacturer will be used

Maintenance of medical devices

Any institution, using medical devices which outsources the maintenance and/or repair of its medical devices shall monitor the performance of the provider(s) of the outsourced service(s) in the following respects:

- The cost of maintenance/ repair for every item of medical equipment (jobcard for every device)
- The time taken to perform the maintenance and/or repair

Training of users of medical devices

- The licence holder must provide training to users in the correct operation and appropriate maintenance and calibration for every medical device sold.
- The licence holder must provide training, where appropriate and requested by the user, for the user's technical personnel in maintenance, service, repair and calibration for every medical device sold. Such training shall be at a level agreed to by the licence holder and the user.

Training of users of medical devices

- Any institution, hospital, clinic or business acquiring and using medical devices must ensure that any user of any device in that institution, etc has been adequately trained to use that device
- No person who has **not** been trained in the correct operation of a medical device in class IIa or higher may use that device

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