

**Guide for
Medical Device Manufacturers on Auditing
by the Health Products Regulatory Authority
to the Medical Device Regulations**



1 SCOPE

This guidance document applies to all products that meet the definition of a medical device under the medical device Regulations.

2 INTRODUCTION

The purpose of this document is to provide guidance to manufacturers regarding post-market surveillance auditing of Irish based medical device manufacturers by the Health Products Regulatory Authority under the Irish medical device Regulations.

3 BACKGROUND

The Health Products Regulatory Authority (HPRA), previously the Irish Medicines Board, became the Competent Authority for general medical devices, active implantable medical devices and *in-vitro* diagnostic medical devices on 01 October 2001. The Department of Health and Children previously held this role. The Competent Authority is the body, which has the authority to act on behalf of the government of a Member State to ensure that the requirements of the Medical Devices Directives are carried out in that particular Member State. The directives and consequent national regulations determine the role of the Competent Authority, which is to ensure that all medical devices sold on the Irish market meet the essential requirements of the legislation and in doing so do not compromise the health and safety of patients, users and where appropriate, any other persons.

4 LEGISLATION

As the Competent Authority for medical devices in Ireland, the HPRA may conduct post-market surveillance in relation to products manufactured by Irish based manufacturers and those placed on the Irish market. This post-market surveillance activity forms part of the review of manufacturer's compliance to the EU Directives and related Irish legislation by the HPRA.

The legal basis is supported by the following:

- Active Implantable Medical Device Directive 90/385/EEC, as amended, Article 2 and S.I. No. 253 of 1994 European Communities (Active Implantable Medical Devices) Regulations 1994, Article 16 and 17.
- Medical Device Directive 93/42/EEC, as amended, Article 2 and S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations 1994, Article 22 and 23.

- *In-vitro* Diagnostic Medical Device Directive (IVD) 98/79/EC, Article 2 and S.I. No. 304 of 2001 European Communities (Medical Devices) Regulations 2001, Article 8 and 17.

The HPRA has an obligation to ensure that the medical device legislation in Ireland is complied with by the manufacturers of medical devices in Ireland and those medical devices placed on the Irish market. Where compliance with the legislation is an issue, appropriate action may be necessary with regard to the protection of public health.

The Irish legislation referred to above can be obtained from the Government Publications Sale Office, Molesworth Street, Dublin 2, or from the website of the Department of Health and Children.

5 DEFINITIONS

All relevant definitions may be found in 'Guidance Note 6: Glossary of Terms for Medical Devices', which can be downloaded from the 'Publications and Forms' section of www.hpra.ie.

6 POST-MARKET SURVEILLANCE

Post-market surveillance is carried out by either:

- a Proactive surveillance
- b 'For cause' audit

Proactive surveillance is carried out dependant on what the HPRA deems appropriate e.g. targeted audits in relation to a specific category. A 'for cause' audit is conducted as a result of a market issue, which requires market follow-up in the interest of public health.

Post-market surveillance audits can be initiated from a number of sources:

- Concerns raised in relation to vigilance issues
- Changes in legislation
- Complaints received about CE marked products
- Post-market surveillance sampling across a specific technology / sector
- Receipt of information from internal / external sources
- Requests from other Competent Authorities
- Any other source that may arise from time to time

This is not an exhaustive list but should serve to outline how post-market surveillance audits are chosen.

Post-market surveillance can take place by way of audit. The aim of the audit is to ensure that the medical device manufacturer is complying with the essential requirements and schedules of the medical device legislation and related statutory instruments.

An audit by the HPRA does not mean that there has been a breach of the legislation. It may be part of a proactive programme of surveillance deemed necessary by the HPRA.

7 AUTHORISED OFFICERS AND INFORMATION FOR INSPECTION

An authorised officer of the HPRA may visit the manufacturing premises to conduct a post-market surveillance audit. Other technical staff from the HPRA may attend in support of the authorised officer.

An authorised officer is defined within the Irish legislation, Article 23 of S.I. No. 252 of 1994, European Communities (Medical Devices) Regulations, 1994.

7.1 Article 23

- 1 The Minister may appoint such and so many persons as the Minister deems fit to be authorised officers for the purpose of these Regulations.
- 2 An authorised officer shall be furnished with a warrant of appointment as an authorised officer and, when exercising any power conferred on an authorised officer by these Regulations, shall, if requested by any person affected, produce the warrant to that person.
- 3 An authorised officer –
 - shall obtain access, on request, to the place of manufacture or storage of devices and available for inspection any documentation required under the relevant Schedule or Schedules of the legislation
 - shall obtain access on request to any ship or other vessel, aircraft, railway wagon or other vehicle in which he has reasonable grounds for believing that devices are being transported for sale in the State or export to Member State,and there or at any place make such examinations, tests, or inspections as he may consider appropriate for the purposes of these Regulations.
- 4 An authorised officer –
 - may ask the manufacturer of a device, his authorised representative or the person who places the device on the market or puts it into service, to supply the information provided for in article 22(1) within a period specified by the authorised officer,
 - may select a sample of the device and take it away for examination and testing, and

- shall take reasonable measures to guarantee confidentiality with regard to the forwarding of the copies relating to the EC type-examination.
- 5 An authorised officer may require, where the information required to be kept available under article 22 is not available, that the manufacturer or his authorised representative have a test performed at his own expense within the time specified by an approved body to verify compliance with the standard specification applicable to it and the essential safety requirements.

In addition to the authorised officer, specific reference is made to the availability of information for inspection under Article 22 of S. I. No. 252 of 1994.

7.2 Article 22

A manufacturer who has submitted an application for CE marking under the conformity assessment procedures set out in the schedules to these Regulations shall keep available for inspection any documentation required under the relevant schedule or schedules.

This is also detailed in Article 16 and 17 of S.I. No. 253 of 1994, European Communities (Active Implantable Medical Devices) Regulations, 1994 and Article 8 and 17 of S.I. No. 304 of 2001, European Communities (Medical Devices) Regulations, 2001.

It is important for manufacturers to understand that the HPRA are bound to observe confidentiality with regard to information obtained in carrying out its tasks under Article 20 of EU Directive 93/42/EEC, as amended, Article 19 of EU Directive 98/79/EC, and Article 15 of 90/385/EEC, as amended. Any information in relation to a post-market surveillance audit is kept confidential by staff of the HPRA.

8 BEFORE THE AUDIT

The HPRA will contact the medical device manufacturer to arrange the date, time and duration of the audit. In the case of a proactive audit, the manufacturer will be given at least four weeks notice prior to the audit.

A confirmation letter will be sent to the medical device manufacturer specifying the date and time agreed and a list of the areas the audit will cover.

The manufacturer may be requested to supply some information in advance of the audit, for example:

- A brief company profile
- A list of products manufactured
- The details of the Notified Body

- A high level manufacturing flow chart
- Relevant procedures

As 'for cause' audits generally arise from a public health issue, the HPRA is obliged to investigate an issue by whatever method is appropriate. A 'for cause' audit of a manufacturing site may be deemed to be necessary. In this case, a request to go onsite immediately may be made. The date of the visit will only be changed in exceptional circumstances.

9 DURING THE AUDIT

At the start of the audit, a brief opening meeting will take place to outline the audit, explain the requirements under the legislation and discuss the audit plan, the types of non-compliances, break times, etc.

During the audit, the HPRA authorised officer will take note of any areas of concern and discuss these when they arise with the manufacturer.

At the end of the audit, a close out meeting will be held where the findings of the audit will be presented and any non-compliance to the medical device regulations will be raised. At this meeting, the non-compliances will be documented and discussed and a timeframe for completion of a corrective action plan will be agreed with the medical device manufacturer.

Once satisfactory responses have been received, the HPRA will issue a letter to the medical device manufacturer to that effect.

Where satisfactory responses have not been received and/or where breaches of the regulations have taken place, further action may be taken which can in certain circumstances involve the use of the enforcement power by the HPRA as outlined in the legislation.

10 NON-COMPLIANCES

There are two types of non-compliances; major and minor non-compliances.

A major non-compliance is where the relevant essential requirements or any part of the Medical Device Directives or related Irish transpositions or related amendments have not been (appropriately) applied and/or which may result in a significant risk to public health. A major non-compliance will require a corrective action within a short agreed timeframe.

A minor non-compliance is where the relevant essential requirements or any part of the Medical Device Directives or related Irish transpositions or related amendments have not been (appropriately) applied. The severity of a risk of a minor non-compliance would be

significantly less than a major non-compliance. A minor non-compliance will require a corrective action within an agreed timeframe.

If it is the case that there are major non-compliances, the manufacturer will be given four weeks to respond to the non-compliances with corrective actions. A timeline will also be agreed for the correction of minor non-compliances. Evidence of completed corrective actions must be supplied to the HPRA.

In addition, there may be observations raised at an audit. An observation is a mechanism to prompt the manufacturer to improve future practice and does not require corrective action. However, observations will be discussed and where possible a process of implementation will be agreed.

11 WHO TO CONTACT AT THE HPRA

This guide and associated documents can be found in the 'Publications and Forms' section of www.hpra.ie.

Alternatively, they can be obtained from the HPRA directly as follows:

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