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Letter from the Editor

Welcome to the second edition of the medical devices newsletter of 2008.

Welcome to the second edition of the medical devices newsletter of 2008. In this edition we provide an overview on the 'Guidelines for Safe and Effective Management and Use of Point of Care Testing' which was launched in April 2008 by the Minister for Health and Children, Ms Mary Harney. This article highlights the key recommendations for safe and effective use of point of care tests in a hospital environment. The document is the result of work carried out following collaboration between the Association of Clinical Biochemists in Ireland, Academy of Medical Laboratory Science, Royal College of Physicians and the Irish Medicines Board.

In this issue we also provide an outline of our recent safety notice on the 'Safe and effective use of bench-top steam sterilisers'. A series of recommendations are presented for consideration. The safety notice is available for download from the IMB website at **www.imb.ie**.

As always readers are encouraged to provide feedback particularly in relation to articles that may be of interest by contacting us at **medicaldevices@imb.ie**

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Point of Care Testing, A Co-operative Movement

The Irish Medicines Board in association with chemical pathologists, clinical biochemists and medical scientists has produced 'Guidelines for Safe and Effective management and Use of Point of Care Testing (POCT) within the hospital environment[1]'. POCT is unique in that it requires a co-operative approach as it involves not only regulatory and laboratory professionals but also many of the allied medical professionals, especially nurses, senior managers and most importantly the patient or customer. The draft guidelines were distributed to other professional groups for comment prior to publication.

Ms Mary Harney, Minister for Health and Children in April 2008 affirmed the importance of POCT issues. The emphasis on quality, for the individual carrying out, acting upon and receiving, results from POCT through clinical governance is paramount. Dr Tracey Cooper, Chief Executive of the Health Information and Quality Authority recommends in the Foreword to the Guidelines that "all individuals, both clinicians and managers, with a responsibility for delivering and providing point of care testing services, and as an extended multi-disciplinary team, should undertake a baseline of their service against these good practice guidelines and, where gaps exist, move towards implementing the necessary changes". The document is a practical guide to those using or considering the use of POCT devices. The aim is to provide guidance for safe and effective management and use of POCT, using *in-vitro* diagnostic kits (IVDs) that are fit for their intended purpose and used by a competent individual, on the correct patient, giving quality results, which ultimately form part of the patient's medical record. It identifies the regulatory requirements and gives guidance on how to implement a POCT service. Whilst it was developed for a hospital environment, it can also be applicable to the use of POCT in non-hospital settings.

Ms Mary Harney (Minister for Health and Children)

What is Point of Care Testing?

A POCT service may be defined as a quality-assured pathology service using analytical devices (including test kits and analysers), provided near to the patient rather than in the traditional environment of a clinical laboratory.

What is a POCT device?

A POCT device is a test kit, strip, or analyser used to generate a diagnostic result that will be used for patient diagnosis, treatment or investigation. The majority of analytical devices that are used for POCT fulfil the definition of an *in-vitro* diagnostic medical device (IVD). Broadly, an IVD is a device intended by a manufacturer for the *in-vitro* examination of specimens derived from the human body to provide information regarding a physiological, pathological or therapeutic state.

What are POCT devices typically used for?

POCT devices can produce a rapid test result in a timely manner in the immediate vicinity of the patient such as in the Emergency Medicine Department, the Intensive Care Unit and other designated areas of the hospital. POCT improves turnaround time and can be advantageous in remote areas where access to a laboratory is limited. POCT may offer an easier access to an instant service but in many cases the broader range of tests provided by the central laboratory is required.

Specific POCT devices are or can be routinely used in the following locations.

Secondary care setting (in hospital):
- Emergency Medicine departments
- Intensive Care Unit
- Operating theatres
- Coagulation clinics
- Renal units
- Liver units
- Diabetic clinics
- Hospital wards
- Out-patient departments
- Occupational health departments

Primary care setting:
- GP surgeries
- Community clinics
- Health centres
- Industrial medical centres
- Community pharmacies
- Anticoagulation clinics
- Ambulance service

Regulatory Control of POCT Devices

The majority of POCT devices fulfil the definition of an *in-vitro* diagnostic medical device (IVD), and are regulated by the *In-vitro* Diagnostic Medical Devices Directive 98/79/EC. The Irish Medicines Board (IMB) is the Competent Authority for *in-vitro* diagnostic medical devices in Ireland. Its role is to ensure that all IVDs available on the Irish market comply with the IVD Directive. There is a statutory obligation on manufacturers to notify the IMB of all adverse incidents involving IVDs. Direct user reporting, although not mandatory, is strongly encouraged and there is a requirement to report to risk management groups in

1 Guidelines for Safe and Effective Management and Use of Point of Care Testing. Approved by the Academy of Medical Laboratory Science, Association of Clinical Biochemists in Ireland, Irish Medicines Board and RCPI Faculty of Pathology. November 2007

From left to right: *Dr. Jan Guerin (IMB), Ms. Ann O'Connor (IMB), Dr. Gerard Boran (RCPI Faculty of Pathology), Dr. Helen Grimes O'Cearbhaill (ACBI), Mr. Tadhg Hurley (AMLS) and Dr. Nuala McCarroll (ACBI)*

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accordance with local hospital policy.

Why the need for guidelines?

Testing was traditionally carried out in clinical laboratories by trained professionals, but with advancement in technology e.g. miniaturisation and simplification of devices, some testing has moved outside the laboratory and nearer to the patient. These type of near patient tests can be used by non laboratory professionals such as clinical professionals, patient carers or by the patient in special circumstances, such as a blood glucose tests for diabetes. The apparent ease of use can make individuals forget that all devices have to be used according to the manufacturer's recommendations, with an awareness of the limitations or contraindications for use. The major risks arise from poor operator competency; lack of proper supervision, governance or accreditation of the POCT service; failure to use quality assurance schemes; inappropriate testing and uncertainty on how to act on test results. However, users must realise that at present, POCT is not a replacement for the conventional laboratory service, but rather a supplement to it. In situations where critical clinical decisions are made on POCT results, verification by the central laboratory may be required by the local POCT policy.

The movement of testing away from the central clinical laboratory nearer the patient must be to the benefit of the patient, and the extra resources required to do this must be justifiable. The evidence of benefits for the patients is currently limited, apart from the fact that results can be produced in a shorter time frame with the potential to facilitate speedier therapeutic intervention. However, except in specific areas for specific tests (e.g. blood gases in Intensive Care Units or Emergency Medicine Departments), availability of the test result may not be the limiting factor in speedier throughput of patients or therapeutic intervention. The Hospital Services Executive (HSE) have stated that policy decisions will be evidence based, but evidence in the literature upon which to base conclusions or make recommendations for a major move to POCT is limited. The most comprehensive review to date on evidence based practice for POCT was carried out by groups of American expert physicians, laboratorians and diagnostic manufacturers and was published in 2006 by the American Association for Clinical Chemistry[2]. This review acknowledges the popularity of POCT, the ability to produce speedier results and a shorter time frame to therapeutic intervention, but highlights that POCT when over utilised or incorrectly performed presents a patient risk, and leads to increased cost of care. A recommendation for well designed randomised control trials is made so as to ascertain the value of POCT.

Key Recommendations of the Guidelines[1] for the implementation and management of safe and effective POCT.

There are fifteen key recommendations in the POCT guidance which are considered necessary for the implementation and management of safe and effective POCT.

It is recommended that every hospital in Ireland should have a POCT policy consistent with these guidelines.

1. Clinical governance is an essential part of any POCT service and is best

2 Nichols JH, Christenson RH, Clarke W, Gronowski A, Hammett-Stabler CA, Jacobs E, Kasmierczak S, Lewandrowski K, Price C, Sacks D, Sautter RL, Shipp G, Sokoll L, Watson I, Winter W, Zucker M, National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Evidence Based Practice for Point of Care Testing. AACC Press:2006

From left to right: Dr. Jan Guerin (IMB), Mr. Wilf Higgins (HSE), Ms. Mary Harney (Minister for Health and Children), Mr. Pat O'Mahony (IMB) and Ms. Ann O'Connor (IMB)

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delivered through a multidisciplinary POCT Steering Group. Representatives from the appropriate laboratory disciplines play a vital role in this group.

2. The POCT Steering group should develop an organisation-wide policy to ensure that all POCT is carried out according to:
   (i) Relevant European and National legislation
   (ii) Laboratory and hospital accreditation standards
   (iii) Hospital or HSE requirements e.g. data protection, medical records
   (iv) Risk management requirements
3. POCT requests should be evaluated by the POCT Steering Group to ensure that clinical need and effectiveness are defined before a POCT service is introduced and that quality objectives are defined and subsequently evaluated.
4. POCT should not be considered when the laboratory can provide a result in a timely manner appropriate to the clinical condition.
5. Only IVDs that are approved by the POCT Steering Group should be used for POCT. This requirement should apply to all IVDs irrespective of whether they have been purchased, loaned, gifted or leased to the organisation.
6. POCT Operational Team(s) with relevant personnel should be appointed to oversee the day-to-day operation of POCT. Each Operational Team must be adequately resourced to enable them to implement, monitor and audit the day-to-day POCT policy.
7. The clinical laboratory has an essential role in the leadership and co-ordination of POCT.
8. Standard operating procedures should be developed and implemented for POCT, in compliance with manufacturers' instructions and relevant standards.
9. Only trained fully competent staff may undertake POCT.
10. POCT IVDs should be password-protected and only accessible by certified users.
11. Quality assurance, both internal and external, is key to assuring the accuracy and reliability of a POCT service.
12. Connectivity allows the central control and management of POCT analysers and facilitates the exchange of information from a remote site to the hospital information system and the patient permanent record. Connectivity should be resourced to a level which avails of the latest technology including electronic healthcare record and unique patient ID.
13. All adverse incidents that occur with POCT IVDs should be reported to the designated hospital committee, the manufacturer and the Irish Medicines Board as appropriate.
14. The POCT Steering Group should review and monitor quality objectives as required.
15. The POCT Steering Group has authority to withdraw and/or suspend service in the event of a safety-related or performance issue or lack of clinical effectiveness.

The implementation of these guidelines should facilitate a well-managed and properly governed system for the provision of POCT services, which in turn will deliver considerable benefits to the Irish health service and to patients."

Why do the guidelines not apply outside the hospital environment?

Assessment of instrumentation and methodology as to its accuracy, reproducibility, interference factors, external and internal quality performance and running costs, has been an integral part of laboratory medicine. The need to apply the same evaluation to POCT devices was not appreciated by non laboratorians until relatively recently. Performance claims and internal "quality" checks incorporated into the devices by the manufacturer were often accepted as adequate quality assessment. The advances in manufacturing technologies including the advancement of information technology and the ability to network and transmit data to a central point has greatly facilitated such monitoring within the hospital environment. Evaluating instruments, formulating internal quality control schemes and participation in external quality assurance schemes can be time consuming and expensive, and beyond the expertise of the individual POCT device user. Local guidelines for the implementation and management of safe and effective POCT in any environment need to be formulated and adhered to, if decisions regarding the care of individual patients are to be based on results from such devices.

The future for POCT?

The movement of testing away from the central laboratory to nearer the patient is being promoted as more convenient or accessible for the patient, and allowing "individual responsibility". However, the current system where the local doctors practice or health centre takes a blood sample or other biological sample from the patient, and has it transported to a clinical laboratory for detailed testing can also be both convenient and accessible. POCT appears to be considered by some as an answer to "patient choice and empowerment" and a way to reduce laboratory costs. This may be fuelled by clever marketing, and the new culture of self diagnosis. It is hoped that this popularity will not remove the need to apply an evidence based approach incorporating clinical governance, value for money and identification of the effect of POCT on important patient parameters such as morbidity, mortality and disease prevention. Some POCT has a role to play in specific situations, but it must be used appropriately, correctly performed, and resourced. The best way forward is a co-operative partnership between all parties involved, so that the collective expertise of laboratorians, allied health professionals, clinicians, regulators and health managers can be drawn upon to give the end user, the individual patient/customer the best outcome.

From left to right: *Dr. Gerard Boran (RCPI Faculty of Pathology), Ms. Mary Harney (Minister for Health and Children) and Dr. Nuala McCarroll (ACBI)*

Proactive compliance activity in relation to system procedure packs

It is the policy of the Medical Devices Department of the IMB to ensure the uniform application of legislation in relation to medical devices placed on the Irish market. Systems and procedure packs were identified as focus areas for the Medical Devices Department's post market surveillance programme for 2006 to 2007.

Under the medical devices legislation, there are two different ways in which medical devices may be placed or packaged together in order to place them on the market, as a procedure pack or as a system.

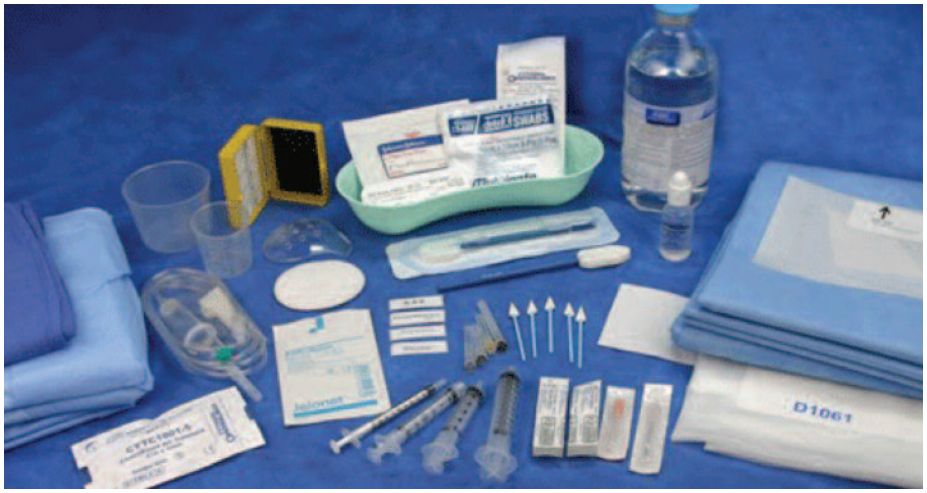
A procedure pack comprises of medical devices that are packaged together and placed on the market with the purpose of being used for medical treatment or surgical procedures. The components of the procedure pack may not necessarily be used in combination or at the same time.

A medical device system is similar to a procedure pack in that it contains a collection of medical devices packaged together. The difference is that the component parts of a system are intended to be used in combination as a unit. A joint replacement system such as a knee system may include a tibial component, a femoral component and a patella designed to be used together for a total knee replacement surgical procedure. Another example is a prosthetic system which may include knee, foot and ankle components intended to be used together.

Medical devices bearing the CE marking may be put together (within their intended purpose and within the limits of use specified by their manufacturers) in order to place them on the market as a medical device pack or a medical device system. The person legally responsible for placing such packs on the market must make a declaration that mutual compatibility has been verified, relevant information and instructions have been provided and that the activity is appropriately controlled and subject to inspection.

However, a pack or a system shall be treated as a device in its own right, requiring CE marking, where it incorporates any device which does not bear a CE marking or the chosen combination of devices is intended to be put to a different use to any intended by the manufacturer of each device.

The practice of assembling / manufacturing systems or procedure packs brings the assembler / manufacturer of such a system or procedure pack within the scope of the medical devices legislation as a system or procedure pack manufacturer. The specific obligations placed on such a manufacturer under Article 11 of the Medical Devices Regulations, S.I. no. 252 of 1994, include the requirement to register with the medical devices department of the Irish Medicines Board and



to draw up specified declarations and documentation including

- Declaration of mutual compatibility
- Technical documentation
- Traceability and vigilance system
- Registration

In addition, the information to be supplied with the system includes the following:

- Labelling requirements as outlined in Schedule 1, Point 13.3 of the Regulations.
- Instructions for use as outlined in Schedule 1, Point 13.6 of the Regulations.

These requirements were discussed in the medical devices newsletter issue 16 May 2006. IMB Guideline 25 – Guide for manufacturers of systems and procedure packs regarding legislative requirements was also issued at the end of 2006. These documents can be accessed on the IMB website **www.imb.ie**.

The IMB's compliance activity focused on manufacturers of systems and procedure packs, both registered

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and unregistered, and included compliance visits to identified manufacturers. The aim was to ensure that systems and procedure packs on the Irish market are in compliance with the relevant legislation, and to take action to bring non-compliant manufacturers into compliance.
The main findings following the compliance visits included

- **lack of knowledge of legislative requirements**
- **inadequate documentation and labelling.**
- **lack of traceability systems and post market surveillance / vigilance systems**
- **classification issues**
- **own brand labelling issues**
- **medicinal products in procedure packs**

Accurate and accessible records are a key factor in effective medical device management and are required by the medical device legislation. Any manufacturer of a system or procedure pack is obliged to ensure that they keep good records of the manufacturing of the pack and have the ability to trace the system if a recall of other activity is necessary.

It was noted that many systems manufacturers in Ireland appear to fall also within the definition of custom made medical device manufacturers and should be aware of the requirements in the legislation specific to custom made medical devices, in particular the requirements of Schedule 8 regarding the statement concerning devices for special purposes. Further information on custom made medical devices may be found in Guidance Note 14: Guidance Note for Custom-Made Medical Device Manufacturers.

Any of the non-compliances raised were followed up with each manufacturer and corrective actions agreed. It was noted on completion of the market surveillance activity, that it proved effective in raising awareness among system and procedure pack manufacturers of their obligations under the legislation and increasing compliance with the regulations.

Regulatory Update

In early May, the European Commission published a document for public consultation on their website 'Recast of the Medical Devices Directives'. The document poses questions on specific aspects of medical device regulation and how they might be changed. The Commission has indicated that this document does not represent a series of definitive proposals but rather questions to provoke discussion and debate. It is recommended that all interested medical device stakeholders should review the recast document.

The Medical Device Expert Group meetings took place in May. The main topics discussed included the impact of the New Approach regulation and the public consultation relating to the 'Recast of the Medical Devices legislation'. An update was also provided in relation to the national transpositions of Directive 2007/47/EC and the pilot project being run by the EU Commission to improve harmonisation on transpositions. At the meeting, the Commission advised that the inter services consultation in relation to the revisions to the Common Technical Specifications for annex II list A *in-vitro* diagnostic medical devices is also underway. Other issues discussed including better co-ordination of EU working groups, global harmonisation task force topics and the applicability of the traceability standard GS1 for tracking and tracing of products. With regard to the latter the standard has been submitted to CEN for consideration.

The 22nd Competent Authority (CA) Meeting for Medical Devices under French Presidency of the Council took place in Paris on 3rd and 4th of July. Representatives from the CAs of Member States and the European Commission attended. This CA Meeting provided an opportunity to discuss the 'Recast of the Medical Devices directives' document. The public consultation looks at the challenges and proposes different scenarios in relation to innovation, market surveillance and control of Notified Bodies. The CAs discussed the future of the regulatory framework for medical devices and considered options to strengthen the current regulatory framework. Areas discussed included the designation and monitoring of Notified Bodies, classification of 'quasi-medical' devices and the option of a centralised committee for medical devices. The impact of the New Approach Regulation was also considered particularly in the area of market surveillance and notified bodies. Reactivation of the Software Working Group was also discussed with several CAs proposing that the EC should consider this.

A two day Medical Device Expert Group (MDEG) Vigilance meeting was held in May. During the meeting manufacturers provided feedback on implementation and use the revised MEDDEV relating to the Vigilance System. An update was also provided in relation to GHTF Study Group 2.

The EU Compliance and Enforcement working Group (COEN) met in May. The meeting was attended by eighteen Member States where the main item discussed included the impact of the New Approach legislation on market surveillance. Other topics discussed included the development of a template protocol for co-ordinated action, determination of specific co-ordinated projects and guidance on legal tools in market surveillance.

The working group which steers the development of the European Database of medical devices (EUDAMED) took place in April. The result of software testing that was conducted on the system, development of a module for clinical investigation notifications and proposed future developments of the sys-

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tem were the main topics discussed. The Global Medical Device Nomenclature (GMDN) Agency also gave details on the translation process for GMDN codes into different languages which has recently begun. In addition, potential funding mechanisms for the GMDN system were discussed.

A subgroup of the Clinical Evaluation Task Force, of which Ireland is an active participant, met to discuss the development of the clinical module of the EUDAMED system which is one of the requirements of the revised Medical Device Directive. The clinical module is proposed to contain data relating to clinical investigations involving medical devices undertaken in Europe and to facilitate the exchange of information between Competent Authorities on clinical investigation reviews e.g. notification between CAs if objections are raised to an investigation or if an investigation is suspended.

The main topic discussed at the IVD Technical Group meeting in June was the proposed revisions to Common Technical Specifications (CTS), including addition of vCJD to Annex II List A. The Commission has requested that relevant stakeholders review the draft proposal and provide feedback in August. A small sub-group will meet in September to review and discuss the comments received. Stakeholders include European Medicines Agency (EMEA), National Institute for Biological Standards and Control (NIBSC), European competent authorities and manufacturers. The Global Harmonisation Task Force (GHTF) guidance documents 'Principles of *in-vitro* diagnostic (IVD) medical devices classification' (GHTF SG1 NO45) and 'Principles of conformity assessment of *in-vitro* diagnostic (IVD) medical devices' (GHTF SG1 NO46) were also discussed. This GHTF guidance document on the classification of IVD's is a risk based approach unlike the current European approach using positive lists i.e. Annex II of Directive 98/79/EC. The GHTF document on principles of conformity assessment that apply to each class of IVD medical devices is based on the principle that the regulatory demands are proportional to the risk class of the IVD Medical Device.

A Notified Bodies Operations Group (NBOG) meeting took place in Brussels during June. The major topic discussed related to the implications for Notified Bodies arising from the Revision to the Directive (2007/47/EC) with particular regard to conformity assessment requirements for different classes of medical devices (e.g. IIa and IIb). In addition, discussions took place relating to the guidance required for notified bodies relating to the interpretative document published by the EC earlier this year relating to Own Brand Labellers (OBL). Other topics discussed included notified bodies vigilance requirements, the peer-review system for NB surveillance audits and the proposed 'Recast of the Medical Devices Directives'.

In early May, the Classification and Borderline Working Group met in Brussels. This group's objective is to determine and harmonise classification of products that are either not readily classified using existing guidance or alternatively fall on the borderline between several different Directives (e.g. Medicinal Products Directive). All consensus positions achieved by this Working Group are published in the 'Manual on Borderline and Classification' which on the European Commission website at **http://ec.europa.eu/enterprise/medical_devices/borderline_classification_en.htm**. This document serves as a useful reference in addition to the existing guidance documents on classification.

Staff Update Staff Update Staff Update Staff Update Staff Update Staff Update Staff Update Staff Update

The Medical Devices Department is delighted to announce that *Dr. Judith Martin*, *Ms Fionnuala Boyle* and *Ms. Nicola Boland* have joined the medical devices team in recent months.

Fionnuala Boyle takes up the position of administrator for the class I / IIa product group within the post market evaluation section.

Nicola Boland takes up the position of administrator for the pre-market evaluation and audit sections.

Judith Martin takes up the position of IVD product manager in the post market evaluation section. Her primary responsibilities will be to manage the performance of the IVD Group and to ensure that post market issues that arise in relation to IVD products are managed effectively and efficiently. Judith's academic qualifications include a degree in Biotechnology from N.U.I. Galway and a Ph.D. in Biotechnology/Molecular Biology from N.U.I. Maynooth. Prior to joining the IMB, Judith worked in the medical device industry and has extensive experience in *in-vitro* diagnostic medical devices.

Safe and Effective Use of Bench-top Steam Sterilisers- SAFETY NOTICE

A new safety notice has been published on the IMB's website, to promote the safe and effective use of bench-top steam sterilisers to sterilise Reusable Invasive Medical Devices (RIMDs)

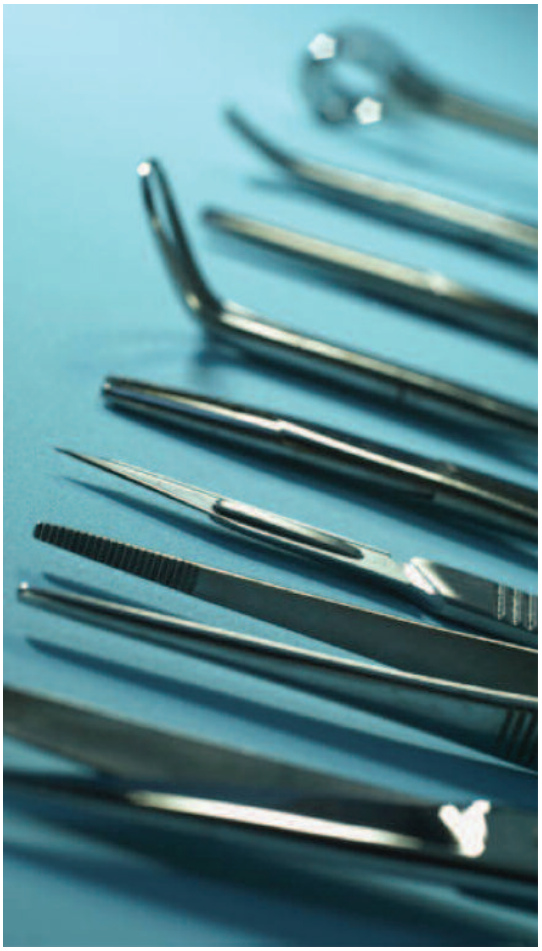
The safety notice is specifically aimed at healthcare professionals e.g. risk managers, medical and dental staff and is also provided for information for certain non-healthcare workers such as tattooists, body piercers, acupuncturists and cosmetic practitioners.

When bench-top steam sterilisers are used to sterilise RIMDs, they are considered to be medical devices. Such sterilisers must be CE-marked according to the Medical Devices Directive (93/42/EEC). Bench-top steam sterilisation is used to sterilise RIMDs that penetrate skin, mucous membranes or a body orifice. Examples of common RIMDs include scalpels, scissors, clamps, saws, dental hand pieces or drill bits.

The aim of steam sterilisation is to eliminate microbial growth, thereby preventing the transmission of infection to patients and healthcare workers from RIMDs. Sterilisation is achieved through direct contact of the device with steam at the required temperature, pressure and duration.

The notice gives examples of situations which may compromise sterilisation. These include the use of steriliser types which are unsuitable for the specific instruments to be sterilised, overloaded or inappropriately loaded steriliser chamber trays, and instruments that are not pre-cleaned and dried prior to sterilisation. The critical factors affecting the optimal performance of bench-top steam sterilisers are covered, including:

- **Steriliser Selection**
  The choice of bench-top steriliser should be based on the suitability of the steriliser for the type of devices to be sterilised e.g. wrapped / unwrapped/solid/hollow/devices with lumen, and also should have adequate capacity to sterilise the required number of devices at the required frequency.
- **Installation**
  Purchasers of sterilisation units should check what installation, commissioning and validation is required before the steriliser is put into service. This installation should be undertaken by a appropriately qualified individual.
- **Validation**
  The steriliser should be validated on a regular basis. Ongoing validation should be documented.
- **Loading of RIMDs**
  The bench-top steriliser must be loaded according to the manufacturer's instructions, the relevant code of practice and the capacity of the device. Devices should be appropriately cleaned and dried prior to loading.
- **Sterilisation Cycles**
  The sterilisation cycles should be validated for use with particular RIMDs, as per the manufacturer's recommendations and should define the critical cycle parameters such as sterilisation temperature, pressure and duration.
- **Storage of RIMDs**
  Unwrapped instruments are for immediate use only and should not be stored. Wrapped instruments may be stored prior to use.
- **Steriliser Water Quality**
  A contaminated water supply or a water supply with impurities can have negative effects on the success of sterilisation.
- **Maintenance**
  Routine maintenance should be carried out, as per the manufacturer's instructions, to monitor and ensure consistent steriliser performance. Routine maintenance should be documented.
- **Servicing**
  Bench-top sterilisers should be serviced by a suitably qualified service technician, in accordance with the manufacturer's instructions and industry standards.



In addition, the safety notice provides a useful list of reference documents, including relevant standards, codes of practice and guidance.

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