

DEFENSE
BULLETIN



*Adverse Incident
Reports 2000*

*DB (NI) 2001/01
MARCH 2001*



The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

The Medical Devices Agency is an Executive Agency of the Department of Health



The key aim of the Northern Ireland Adverse Incident Centre (NIAIC), part of Health Estates, is to record and investigate reported adverse incidents involving Medical Devices and equipment used in Health and Personal Social Services in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient or user injury. NIAIC has direct links with MDA who co-ordinate across the adverse incident centres in England, Scotland, Wales and Northern Ireland. NIAIC also disseminates safety information in Northern Ireland, including information provided by MDA.

Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety.

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1. EXECUTIVE SUMMARY

1.1 Developments in adverse incident reporting

The year 2000 was eventful for adverse incident reporting. The Northern Ireland Adverse Incident Centre (NIAIC) received 158 reports of adverse incidents during the year, a 31% rise on last year. The Medical Devices Agency (MDA) received 7249 reports of adverse incidents involving medical devices during the year, a 10% rise on last year. All incidents reported to NIAIC were investigated. MDA assessed the risk of all the incidents reported to them and 4466 of them required active investigation. The rest were either linked to an ongoing investigation or used to improve the quality of our ongoing trend analysis.

Our promotion of Liaison Officers reached its goal and a Liaison Officer who is responsible for adverse incident reporting and distribution of NIAIC warning notices and other guidance documents is now in place in every HSS Trust, Board and Agency.

Because of the importance in open reporting of adverse incidents, part of our work is encouraging a shift to a “safety culture” in the HPSS, where open reporting and balanced analysis are encouraged in principle and by example. This is in contrast to a “blame culture”, which encourages people to cover up errors for fear of retribution and act against the identification of the true causes of failure, because they focus heavily on individual actions and largely ignore the role of the underlying systems. With the introduction of effective clinical governance, this means that there is a shared goal between the individual and the organisation to minimise hazards related to the use of medical devices and to ensure that everyone who needs to, is able to use medical devices safely and effectively.

The issue of patient confidentiality had to be reconsidered carefully as well, in the light of revised General Medical Council guidelines for general practitioners (GPs). If GPs need to send adverse incident reports to NIAIC containing personal details of patients they should first obtain the patient’s consent; for the majority of incidents such details are not requested by NIAIC.

NIAIC’s adverse incident reporting system operates in a National and increasingly in a global context; we co-operate with our European partners in vigilance exchange and also with other worldwide partners via the Global Harmonisation Task Force through the MDA.

1.2 overview of adverse incidents reported to MDA in 2000

Of the 7249 reports received by MDA:

- 92 reports involved a fatality;
- 732 reports involved serious injury;
- MDA launched 1608 in-depth investigations;
- 2858 incidents were investigated by manufacturers under MDA supervision;
- 1270 reports did not need immediate MDA action, but were entered on the MDA database to enable the monitoring of trends and detect patterns;
- 369 of the reports received were investigated by other organisations and their conclusions made available to MDA.

Actions taken as a result of investigations include:

- publishing 49 warning notices;
- informing the authorities in EU member states in 32 cases;
- supervising or active involvement in 117 product recalls or field corrections and monitoring of a further 102;
- providing advice on safer device use or improved staff training in 158 cases.

In 915 cases manufacturers undertook to improve their designs or manufacturing systems.

This Device Bulletin includes: a review of the year's activities; information on how to report adverse incidents; a digest of the year's statistics; and a current list of warning notices issued.

2. INTRODUCTION

2.1 Device Technology and Product Areas

Table 1 lists the six areas of device technology with examples of product areas.

Table 1 –Device Technology Area and Product Areas

Section	Product area
Sterile, surgical and in vitro diagnostic devices	Contraceptives, dental devices, endoscopes, in vitro diagnostic devices (IVDs) including those for near patient testing, urinary catheters, ostomy and incontinence products, single-use sterile surgical devices, gloves and medical textiles. Methods and equipment for reprocessing devices. Pressure care equipment, contact lenses and care products.
Rehabilitation and transfer equipment	External prostheses (upper and lower artificial limbs), orthoses (upper and lower limb and body supports), walking aids, patient hoists and lifting devices, ambulance stretcher trolleys, patient/drug/theatre trolleys, hospital beds (powered and non-powered), physiotherapy equipment (treadmills, UV therapy).
Wheeled mobility and supportive seating/cushioning	Wheelchairs (powered and non-powered), scooters, buggies for younger disabled people, supportive seating and cushioning. Wheelchair transportation equipment. Wheelchair accessories.
Devices for diagnostic imaging, therapy, measurement, electro-surgery and disability	Equipment for daily living, audiology; urology; diathermy, physiological measurement (temperature, lung function), diagnostic imaging (X-ray, ultrasound, CT, MR, nuclear medicine), operating tables and lamps, radiotherapy equipment; surgical power tools.

Section	Product area
Critical care devices	Anaesthetic equipment, cannulae, cardio-pulmonary bypass, external pacemakers and defibrillators, dialysis, endotracheal tubes, enteral feeding, incubators, infusion pumps and sets, monitors (ECG, blood pressure), nebulisers, resuscitators, ventilators, neonatal phototherapy.
Implants and materials	Active implants (pacemakers, defibrillators, neurostimulators) and non-active implants, (heart valves, orthopaedic implants, ocular implants, plastic surgery implants), device materials.

2.2 Adverse incidents

Adverse incidents are events that produce, or have the potential to produce, unexpected or unwanted outcomes that affect the safety of patients, clients, staff and other people. For example:

- a patient, user, carer or professional is injured as a result of a medical device failure or its misuse;
- a patient's treatment is interrupted or compromised by a medical device failure;
- misdiagnosis due to medical device failure leads to inappropriate treatment;
- a patient's health deteriorates due to a medical device failure.

Incidents may identify the potential for harm even though actual harm is averted due to the timely actions of staff or fortuitous circumstances. We ask users to report incidents to NIAIC irrespective of whether harm is caused or not.

There is also a distinction between direct and indirect harm. Indirect harm can be caused by a device which does not normally come into contact with patients. For example a malfunctioning in vitro medical device (IVD) such as an automated analyser may lead to delayed or inappropriate treatment of a patient and therefore cause indirect harm. Incidents of this nature should also be reported to NIAIC. Details of how to do this are given in Appendix 2.

Adverse incidents can be caused by:

- defective design of the device;
- poor quality control during manufacture;
- damage in transit;

- inadequate reprocessing, repair or maintenance;
- inadequate instructions;
- inadequate user training;
- degradation of the device due to prolonged use or inappropriate storage;
- user error.

2.3 Challenging a blame culture

NIAIC aims to help prevent incidents happening and does not look to assign blame. No device will ever be 100% safe and constant effort is needed to reduce the rate at which incidents occur and, should they occur, the severity of the outcome.

The culture of blame continues to exist in many organisations and this does not help to resolve incidents. NIAIC aims to investigate incidents carefully and objectively and in an open manner. Our experience is that in many cases user error may contribute to an adverse incident but that there are often underlying causes for these errors. Many of the issues relate to device management and training of users of devices. NIAIC has been focusing increasingly on such areas during 2000 and this trend will continue.

We welcome reports of incidents that raise device-related issues even if user error has been identified as a likely cause. A one-off incident in one HPSS organisation when combined with several others may point to a need to deliver focused awareness training or amend manufacturer's instructions for use.

2.4 Why report adverse incidents to NIAIC?

By reporting adverse incidents to NIAIC, you are providing us with information that may enable us to prevent similar incidents happening again.

The information provided to NIAIC by users enables us to build up a national picture of what is happening with medical devices in Northern Ireland. This information is supplemented by reports from around the world. We review this information to identify trends and, where appropriate, take early action on specific problems.

Although many issues are resolved locally, often by a manufacturer repairing or replacing defective equipment, by reporting these incidents to NIAIC we may be able to prevent 'local' problems occurring elsewhere.

'This should not be allowed to occur again' is a common reaction to an adverse incident. Reporting incidents to NIAIC enables us to:

- take enforcement measures and monitor action taken by manufacturers to make devices safe or remove them from the market through co-operation with MDA;

2.5 What happens when you report an incident

- issue national warnings and recommendations for action to health and social care professionals;
- inform the relevant authorities through the MDA in other EU member states so that they can consider the need for national action.

Adverse Incident Database

All adverse incident reports received by NIAIC are entered onto our database and their receipt is acknowledged. A summary of the process is provided in Appendix 2. In some cases, databasing and acknowledgement is the only immediate action that we take because, either these cases had already been resolved, either locally or by the manufacturer and were categorised as “information only”; or these reports could be linked to ongoing investigations and were categorised as “known”.

The information from these last two report categories helps us to maintain up-to-date knowledge, via our database, about the various device types and failure modes. This can help to identify significant patterns or trends when reviewing the incident data.

Incident investigation

All other reports received by NIAIC are investigated. The method of investigation depends on the risk associated with the incident.

Incidents where there has been a death or serious deterioration in health (or the potential for such) are subjected to an in-depth investigation by our investigation officers. Such investigations may involve contact with the device user and manufacturer, a visit to the site of the incident and testing of the device involved (either by the manufacturer, or an independent test house). It is these investigations which typically result in NIAIC issuing safety advice.

Incidents where there has been a minor injury or no injury, and the potential for a more serious incident is low, are generally most effectively investigated by the device manufacturer. Details of the incident report is forwarded to the manufacturer and NIAIC monitors the progress of the investigation. The manufacturer’s final conclusions are passed to the reporter for information or comment.

At all stages of an investigation, the information available is subject to review in order to enable us to reassess the level of investigation and to determine what, if any, action we need to take. During the reviews we involve all investigation team members, including our Clinical and Nursing Professionals to advise on clinical or nursing aspects of the incident and the way the device had been used.

NIAIC Warning Notices

NIAIC issues warning notices to HPSS organisations and other users of medical devices about particular problems and risks and recommends appropriate actions to minimise such problems and risks. These notices are distributed to HSS Trusts, HSS Boards and Agencies for direct action and for onward transmission to relevant healthcare professionals. Where devices are used in primary care, NIAIC arranges for distribution to GPs, Dentists and other primary care professionals .

We have used the term ‘Hazard’ for the most immediate communication of safety information to the health service for many years. However, we have concluded that this is no longer always appropriate given the fact that the actions to be taken by recipients of our notices may have to be developed in conjunction with the medical device manufacturer on the basis of incomplete information. Therefore, from 1 January 2000, we introduced an additional series of safety warnings titled ‘Advice Notice. The criteria for the various safety warning categories are, in broad terms, as follows:

Hazard Notices are issued:

- in cases of death or serious injury, or where death or serious injury would have occurred but for fortuitous circumstances or the timely intervention of healthcare personnel (or a carer); and
- where the medical device is clearly implicated; and
- where immediate action is necessary to prevent recurrence.

Advice Notices are issued:

- in cases where there is the potential for death or serious injury, or there may be implications arising from the long term use of the medical device;
- where the medical device is likely to be implicated;
- where the recipient is expected to take immediate action on the advice.

Safety Notices are used to recommend or inform:

- where action by the recipient will improve safety;
- where it is necessary to repeat warnings on long standing problems;
- to support or follow up manufacturer’s field modifications.

3. HOW TO REPORT ADVERSE INCIDENTS

3.1 SN (NI) 2001/01

Details of how you should report an adverse incident are in Appendix 2, which contains the text of Safety Notice SN (NI) 2001/01 “ Reporting Adverse Incidents and Disseminating Warning Notices relating to Medical Devices, Non-Medical Equipment, Buildings and Plant “. This contains both practical details about how to contact us, and background information about the circumstances in which a report is necessary.

If in doubt, report the incident to us. We will be able to make a decision on the appropriate action to take based on the information you supply together with that available on our database.

If you require advice or further information contact the NIAIC on 028 9052 3704 or contact us by email at: NIAIC@dhsspsni.gov.uk

All HSS Trusts, HSS Boards and Agencies have nominated Liaison Officers who co-ordinate the reporting of adverse incidents and the dissemination of NIAIC warnings Notices (see SN (NI) 2001/01 and Appendix 3). Your Liaison Officer will be able to provide details of local adverse incident reporting procedures.

3.2 Returning medical devices for examination

About 10% of the adverse incident reports that we receive are accompanied by the devices involved, generally smaller single-use items or components of larger devices. Devices sent to NIAIC by post, courier or any other method should be decontaminated prior to despatch. **It is illegal to send contaminated items through the post or courier services.** Further information on decontamination of devices and how to send them to NIAIC is given in Appendix 2 (Annex D).

Users and reporters are reminded to include information on the contamination status of all devices sent to NIAIC.

4. 2000 IN THE DEVICE TECHNICAL AREAS

4.1 Sterile surgical and in vitro diagnostic devices

Many of the incidents investigated in this area involve devices that can be regarded as 'high volume/low risk' items, for example incontinence, injection, and drainage devices. Failures of these devices do not often result in serious injury to patients or users and therefore the most effective way of managing issues involving these devices is by monitoring trends in incident reporting.

Incontinence products

A review of data on the NIAIC and MDA databases confirmed that the level of reporting for these devices is low, especially from manufacturers. MDA held meetings with one of the larger UK manufacturers of these products and they have agreed to provide MDA, on a regular monthly basis, with details of all complaints received involving their products. Although the information provided relates only to one manufacturer's devices, it does provide MDA and NIAIC with additional information on the types of problems experienced with these products and their likely prevalence. MDA intend to extend this approach to other devices.

Publications

- In this device area, the following publications were issued:
- Device Bulletin DB2000/04 (NI): Single-use Medical Devices: Implications and Consequences of Reuse;
- Device Bulletin DB2000/05 (NI): Guidance on the Purchase, Operation and Maintenance of Benchtop Steam Sterilizers;
- Device Bulletin DB2000/02 (NI): Medical Devices and Equipment Management: Repair and Maintenance Provision,

Other guidance issued included the final section of the Microbiology Advisory Committee manual on Decontamination and Disability Equipment Assessment reports; a further four reports were published in 2000.

SN(NI)2000/31 Handling of Surgical Instruments on Loan from Another Organisation.

A lack of awareness of the need to control loaned surgical instruments has led to delayed or cancelled patient treatment. This Safety Notice highlights the importance of, amongst other issues, ensuring that appropriate procedures are put in place and followed; that all loan instrumentation is decontaminated both before and after use; and that systems are in place to allow instrumentation to be tracked through the decontamination processes.

4.2 Rehabilitation and transfer equipment

The majority of rehabilitation devices have to support the user's weight so when a failure occurs they are often injured. The number of adverse incident reports involving orthotics, hospital beds/cotsides, patient trolleys, walking aids and physiotherapy equipment has gone up considerably, with smaller increases for patient hoists and transfer equipment. In the case of artificial limb incidents there has been a reduction in the high volume of incidents received.

Cotsides

NIAIC issued Hazard Notice HN (NI) 2000/17 because of the risk of death from entrapment and asphyxiation from beds fitted with incompatible bedside rails (cotsides). Over the past three to four years NIAIC with MDA have taken a series of actions although the incidents continue to occur. We have:

- published two Hazard Notices and one Safety Notice;
- MDA has written to all suppliers of cotsides recommending they consider the design of the device with regard to patient entrapment, provide clear user instructions and that they affix permanent labels to the devices;
- MDA published an article on the safe use of cotsides in Professional Nurse (January 2000);
- MDA requested an evaluation of cotsides and their user instructions, which is in progress as part of the Disability Equipment Evaluation programme;
- MDA has drafted a Device Bulletin on the safe use of cotsides, which we intend to issue in 2001.

Although some incidents occur in hospitals, the major problem appears to be with use in the community. We plan to heighten awareness and target those responsible for cotside use in private dwellings and residential/nursing homes, making sure they have satisfactory safeguard procedures in place and are aware that incidents continue to occur.

Orthotics

The big increase in numbers of adverse incident reports involving orthotic devices follows many years of under-reporting. MDA have introduced a quarterly newsletter (on MDA website) providing feedback on MDA's incident work, a new incident report form specifically for orthotic incidents and generally promoted reporting at conferences and seminars. Requests for the newsletter has enabled MDA to increase their prosthetic and orthotic contact database thereby increasing the awareness of MDA's and NIAIC's role in safeguarding public health.

Artificial limbs

Two recalls were instigated because of fatigue failures of artificial limb components, and NIAIC issued two Safety Notices, SAN (NI) 2000/29 and SAN (NI) 2000/30. The limb manufacturers have re-designed the

defective components. The investigation highlighted the importance of correctly assessing the structural test results and building in a factor of safety.

Physiotherapy equipment

We received a report of a variable height couch that had cracked at the welded joints of its base. 20 other couches of the same model were inspected in the same organisation and all had begun to exhibit weld failure. The manufacturers attributed the problem to inappropriate use i.e. using the couches as a patient transfer system, outside their intended purpose. The manufacturer issued a Service Bulletin to advise users about the need to examine the couch bases and NIAIC published Hazard Notice HN (NI) 2000/22.

4.3 Wheeled mobility and supportive seating/cushioning

In-house testing

MDA in-house testing facilities and procedures for wheelchairs and artificial limbs are accredited by the United Kingdom Accreditation Service (UKAS) and are independently audited against their strict laboratory standards. This ensures that tests carried out for industry or as part of adverse incident investigations are in line with the appropriate standards.

Changes in reporting trends

There has been an overall increase in the numbers of incidents reported this year compared with 1999. Improved reporting has also been achieved on wheelchair accessories, but we need to improve on the number of reports connected with supportive seating and cushioning.

Some adverse incident reports received are still concentrating on the fault or damage to the equipment itself rather than how or where the incident occurred. This lack of information can make risk analysis difficult and may lead to delays in the investigation.

Transportation of wheeled mobility equipment

Transportation continues to be a major topic of discussion. A draft guidance bulletin is in preparation on the “Safe Transportation of Wheelchair Users Seated in their Wheelchairs”.

Improved liaison with reporters/users

Previous delays in investigations are now being further reduced and particular emphasis is being placed on keeping reporters of adverse incidents up to date as the investigation progresses. Controlled planning of in-house testing processes and close liaison with manufacturers also shortens the time that equipment is needed to be away from the user during investigations.

4.4 Devices for diagnostic imaging, therapy, powered surgical devices, physiological measurement and equipment for daily living

Diagnostic Imaging

Poor maintenance of X-ray equipment and the roles, responsibilities and training of service engineers continue to cause concern. In a recent incident a ceiling-mounted X-ray tube fell without warning onto the couch below because worn parts had not been detected and replaced during regular maintenance. A check of other sites found further units similarly affected and so Hazard Notice HN (NI) 2000/02 was issued.

Medical lasers

Medical lasers are used in many types of clinical procedure and are now increasingly being used for cosmetic purposes such as hair removal and skin resurfacing. These are often carried out in beauty salons and the knowledge and training of the users can be insufficient to ensure safety. Intense pulsed light sources are also used for these procedures and these devices pose similar risks to lasers. MDA gives technical advice for the control and regulation of these devices.

Electrosurgery (surgical diathermy)

The use of radio-frequency currents for cutting and coagulation of tissue is well established. However, some particular problems do recur. Contact between the patient and conductive materials, such as a metal equipment trolley, can lead to burns at the point of contact. Neglecting to clean or shave the skin at the point where the neutral return electrode is attached can result in burns in this area. Another problem is ignition of spirit-based cleaning materials by sparks at the active electrode.

Surgical stimulators

Surgical stimulators are used to detect the presence of motor nerves so that they can be avoided during surgery. A low-level electric current is used to stimulate the nerve and cause associated muscles to move. If the stimulator is faulty and fails to stimulate the nerve, the lack of movement may be taken as evidence that no nerves are present. This can lead to nerves being cut. We issued Hazard Notice HN (NI) 2000/15 after a manufacturer notified the MDA that they had withdrawn a motor nerve stimulator because of intermittent operation.

Physiological measurement

This product area covers a wide range of devices, from simple, mechanical items such as mercury-in-glass thermometers to electronic equipment such as electrocardiographs. Incorrect reading can lead to wrong diagnosis and ignoring the manufacturer's instructions can result in a variety of problems, including cross-infection.

Publications

Device Bulletin DB2000/03 (NI): Blood Pressure Measurement Devices – Mercury and Non-Mercury was issued.

Equipment for daily living

Disability devices and aids for daily living generate quite a number of adverse incident reports. Generally these are minor incidents but we did investigate a case in which a young child died after becoming trapped in a powered reclining chair. The child was lying underneath the leg rest and became trapped between the moving and fixed horizontal bars at the front to the chair as it descended. As a consequence NIAIC published Safety Notice SAN (NI) 2000/33 Electrically Operated Lift and Recliner Chairs.

4.5 Critical care devices

Defibrillation

During the year MDA received over 80 reports of problems associated with defibrillation. The most common issues were battery failure, failure to discharge, burns to the patient and internal circuit board problems. The start of the year also saw the introduction of between 600 and 700 automatic external defibrillator (AED) units into public locations such as sports centres, shopping centres and railway stations. The current trend is for defibrillators to be more complex, with multi-function options. A small number of the reported incidents have been attributed to the wrong choice of defibrillator for the specific application, for example an AED was used instead of a standard manual unit in a hospital where specialist staff were unable to adjust the settings of the AED to their requirements.

Anaesthetic & respiratory devices

The number of incident reports continues to rise, as does the number of requests from the police and coroners to investigate incidents. As more anaesthetic workstations and ventilators become computer-controlled and more electronically complex, we are seeing an increase in the number of software failures as well as user training issues.

The number of domiciliary patients on respiratory therapy is greatly increasing. The reporting of incidents and the dissemination of safety information to these device users will be one of the main targets in the coming year.

The publication of SAN (NI) 2000/43 on continuous positive airway pressure ventilation highlighted the importance of user training and the need to follow the manufacturer's instructions. NIAIC and MDA will continue to work with user organisations to promote training and adherence to manufacturer's instructions and to HSS Trusts' protocols.

Intravascular and enteral catheters

Following reported incidents of premature failure of implantable ports, MDA undertook a survey of implantation frequency in England. MDA found that relatively few port implantations were carried out each year compared with the rest of Europe. Cost could be a factor that influences the reduced use of this device, along with the relative complexity of implantation compared with long-term intravenous catheters.

The issue of neonatal parenteral feeding was raised in the media, following the release of an inquest report. MDA are currently liaising with manufacturers to review the instructions for use accompanying

4.6 Implants and materials

paediatric and neonatal central venous catheters, and are gathering literature on the current clinical practice associated with neonatal nutrition.

Safety Notice SN (NI) 2000/47 has been issued, giving advice on enteral feeding. Further work will be carried out in the coming year to look at issues surrounding administration of feed in the community care setting, as well as the hospital environment.

Infusion pumps

This year has seen NIAIC receive and investigate an increasing number of incidents of over-infusions involving infusion pumps. Fortunately, in Northern Ireland, none of these cases has resulted in fatalities.

NIAIC aim to issue an updated Device Bulletin on infusion systems in 2001.

Orthopaedic implants

The numbers of reports relating to knee implants increased, in line with the increased numbers of knees being implanted in the UK. MDA have adopted a policy of trend review for aseptic loosening failures, as a means to monitoring this more frequent type of report.

MDA continued to work closely with the British Orthopaedic Association (BOA), culminating in the formation of the MDA Orthopaedic Advisory Committee, drawing on representatives of BOA's specialist societies and biomechanics academics.

Non-active cardiovascular implants

Coronary stents continued to be high priority with numerous new designs receiving market approval, some with pharmaceutical or other biological coatings. The selection of coronary stents as one of the first areas for the National Institute for Clinical Excellence (NICE) to review this year was a reflection of this concern.

The use of endovascular stent grafts to repair abdominal aortic aneurysms is a comparatively new treatment option. NIAIC issued two Advice Notices relating to problems with long-term implantation of these devices and MDA continued to work with the UK EVAR trials to monitor performance of the range of models being implanted in this country.

Information was given to UK coroners on the importance of seeking NIAIC/MDA advice in the case of the unexpected death of a patient with a critical implant. A talk on the principles and benefits of incident investigation was also given to UK Interventional Radiologists at their annual meeting in November.

Unregulated products

Currently there are no unified regulatory controls across Europe for medical devices that use materials (viable or non-viable) of human origin or for

those that contain viable cells or tissues of animal origin. Any opinion on regulatory status from the European Commission or a National Authority for medical devices or medicinal products always comes with the caveat that an independent legal opinion should be sought.

The recent European initiative on human tissues in medical devices will require considerable technical contributions to negotiations in working groups, Council meetings and Commission meetings. The development of a standards framework for tissue engineering will require more input from MDA.

Non-vascular stent products

Issues relating to non-vascular stents have continued to be reported at a low but steady rate. They have displayed the problems typically seen with stents i.e. those of delivery and migration. Serious problems occur when these devices perforate tissue, for example the oesophagus, but we are not observing any trends relating to a particular product.

Active implantable devices

Pacemakers and defibrillators continue to account for the majority of incident reports received in this device area.. Advances in technology coupled with the need to reduce size and further enhance therapy capabilities are clearly presenting a challenge to industry. During the year we monitored a number of potential problem areas e.g. premature battery depletion. We also issued four MDA Pacemaker Technical Notes (PTN) to the cardiac pacing community, supporting manufacturer's advisory actions or providing focused information.

MDA continued their investigation into the potential adverse effects on pacemakers and defibrillators of magnets used as fasteners in clothing. Liaison with the clothing industry identified a need for appropriate warnings on such garments for pacemaker patients.

Plastic surgery implants

After further testing by manufacturers of soya bean oil filled breast implants, NIAIC issued Hazard Notice HN (NI) 2000/10 in June. This notice recommended the removal of Trilucent™ breast implants and followed on from the manufacturer's voluntary recall in 1999 (NIAIC Advice Notice AN (NI) 99/01).

December 2000 saw the publication of two Advice Notices, AN (NI) 2000/08 and AN (NI) 2000/09 due to the voluntary recall by two manufacturers of hydrogel-filled breast implants. These recalls followed a review by MDA of biological safety data relating to these products.

Publications

MDA produced two documents aimed at manufacturers: Guidance on Vigilance Reporting for Coronary Stents and Guidance on the Recall of Medical Devices.

5. STATISTICS FOR 2000

5.1 NIAIC Statistics

Figure 1 – Trend in adverse incident reports to NIAIC

The steady increase in incident reports received annually since 1996 is shown in Figure 1. This year saw a rise in incidents of 31% compared with last year's total. If this trend continues, the number of incident reports for 2001, the projected increase will be 44%. Compared with the number of incident reports received by MDA in 2000 for England and Wales, the level of incident reporting in Northern Ireland is below what would be expected.

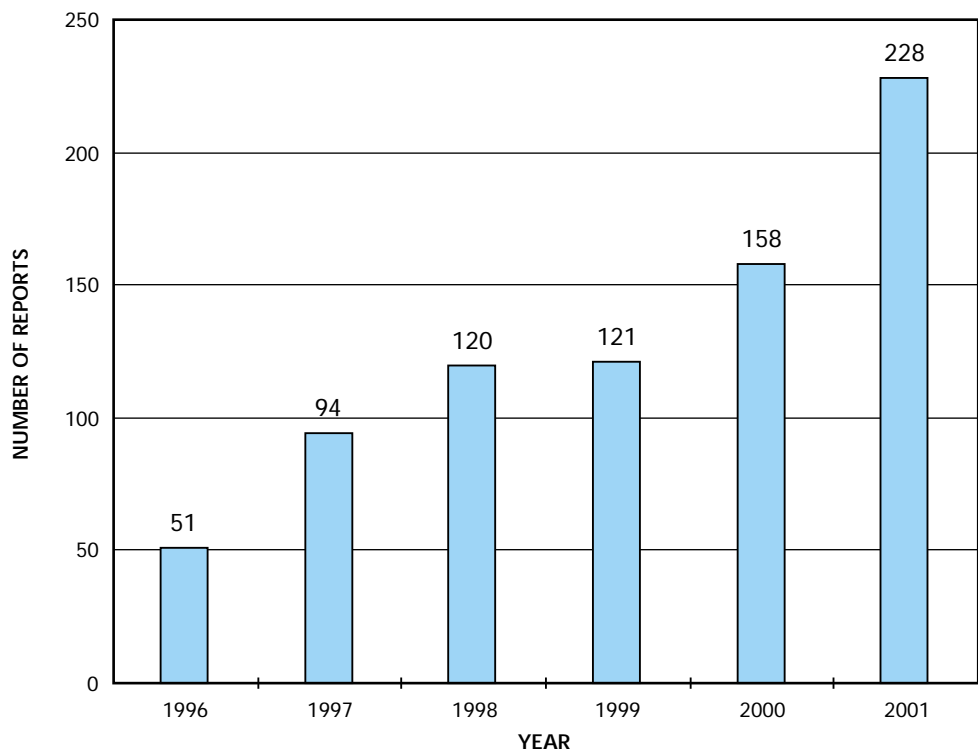


Figure 2 –Adverse Incident reporting by HSS Health Board Area

Figure 2 shows the reports received from HSS Board areas for the last three years. A degree of variation is accepted as this reflects the differences in HPSS structure in each area . As each HPSS organisation now has a Liaison Officer in place, the implementation of good Health & Safety Management practice and the focus on clinical governance issues, this will give us an opportunity to address the variation in reporting patterns. We have observed that those organisations that have implemented robust Health & Safety Management policies and procedures have shown a corresponding increase in the level of incidents being reported to us.

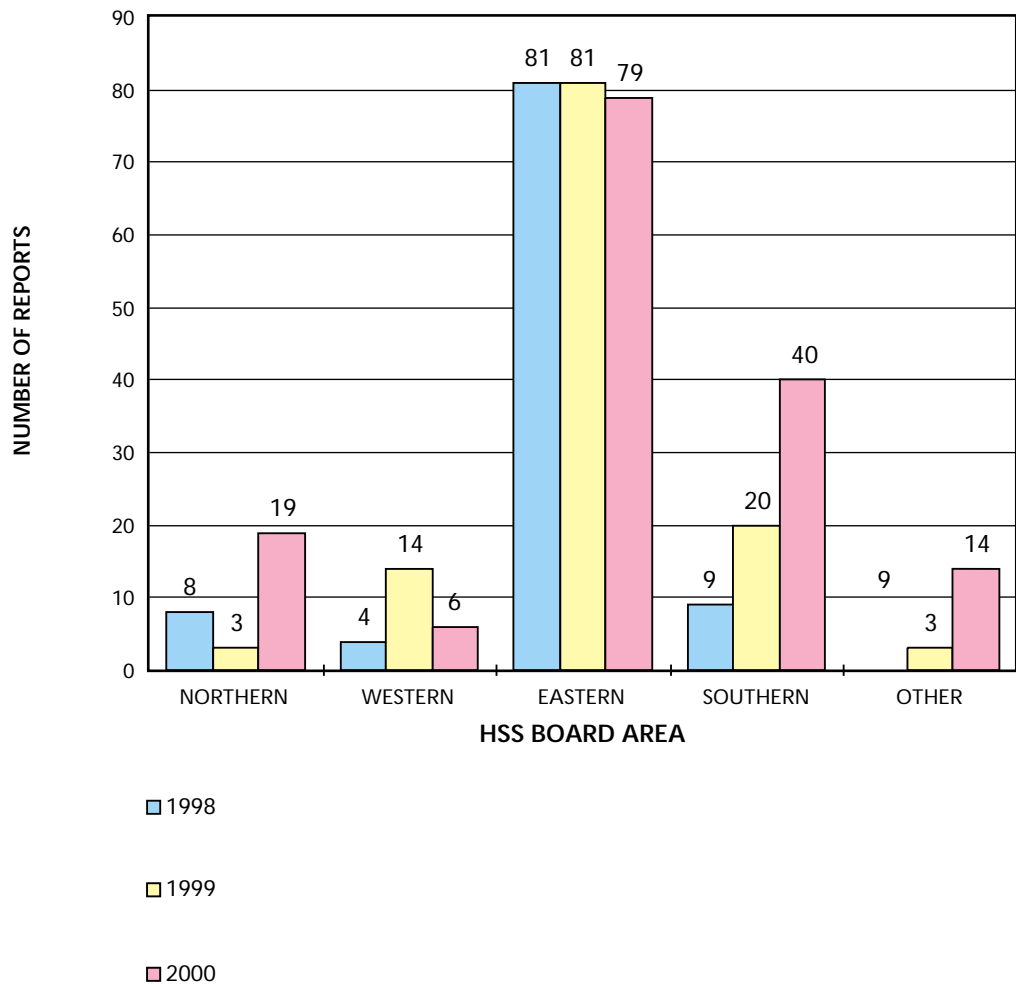


Figure 3 – Causes of adverse incidents

Figure 3 shows the causes of adverse incident investigations resolved during 2000 by NIAIC. The causes can be identified as faults resulting from problems before delivery (design, manufacture, quality control and packaging) and after delivery (performance or maintenance failures, device degradation). We also identified incidents where the main cause was believed to be user error. The category 'no established link to device' includes cases where either the device was subsequently found to work as intended (these incidents may be due to an intermittent fault, tampering or user error) or it was not available for inspection.

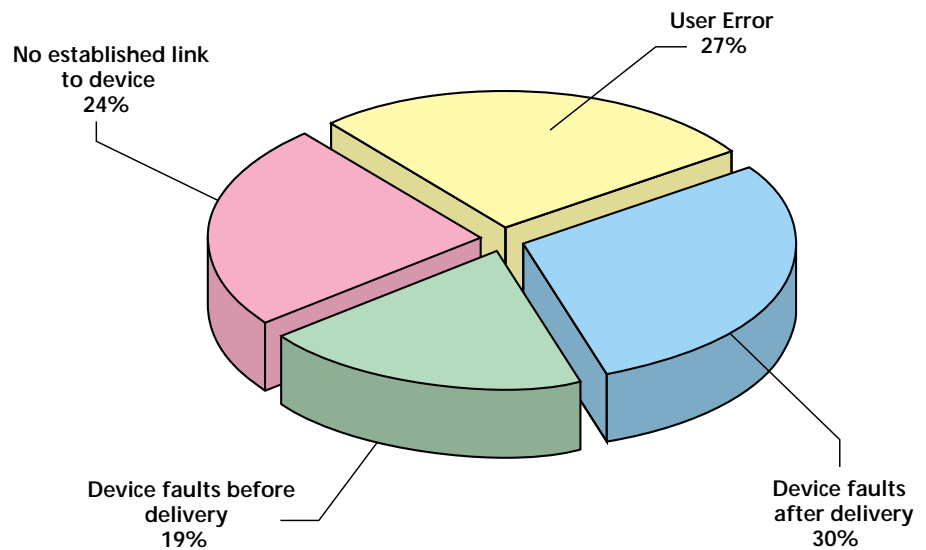


Figure 4 – Outcomes of investigations

Figure 4 shows the outcomes of the incident investigations resolved during 2000. Each category is not mutually exclusive and the percentage is of the total number of outcomes during the year. The ‘single faulty device’ category includes those cases where a single product item required replacement or repair but there was no evidence to justify a device recall or field correction action by the manufacturer.

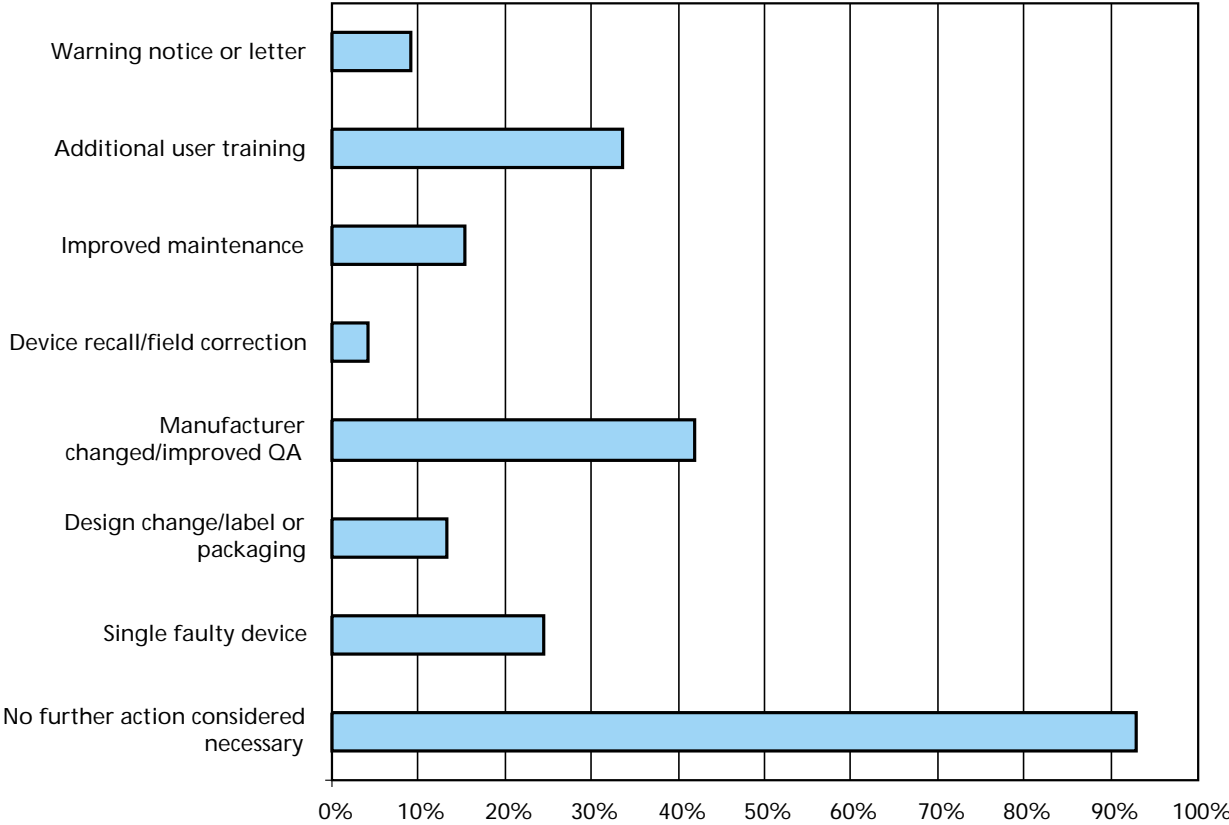
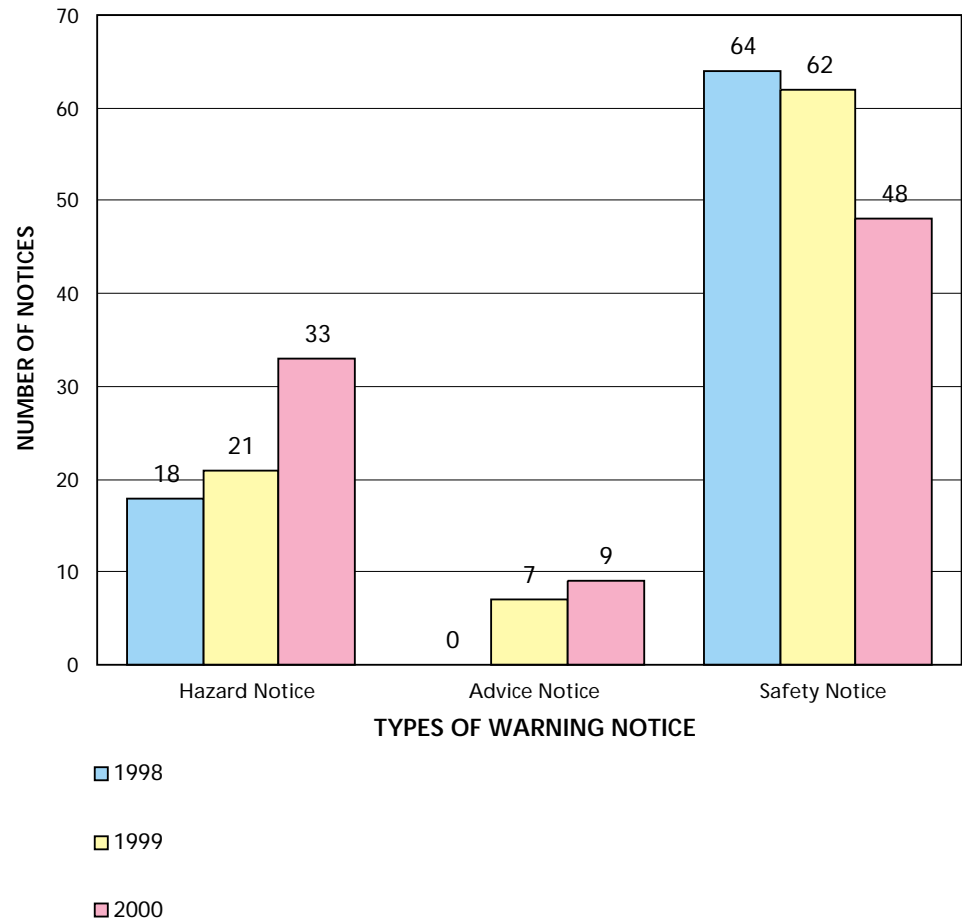


Figure 5 – NIAIC Warning Notices issued in 2000

Figure 5 shows the number of each of the main types of warning notice issued by NIAIC during 2000 as a result of adverse incident investigations. Advice Notices, Hazard Notices, Safety Notices were issued to the HPSS.



5.2 MDA Statistics

Figure 1 – Trend in adverse incident reports to MDA

The steady increase in incident reports received annually is shown in Figure 1. It also shows that the proportion of our incidents involving medical devices with CE marking is growing, as the number in use increases. This year saw a rise in incidents of over 10% compared with last year's total, which is in line with an underlying trend of around 11% per year.

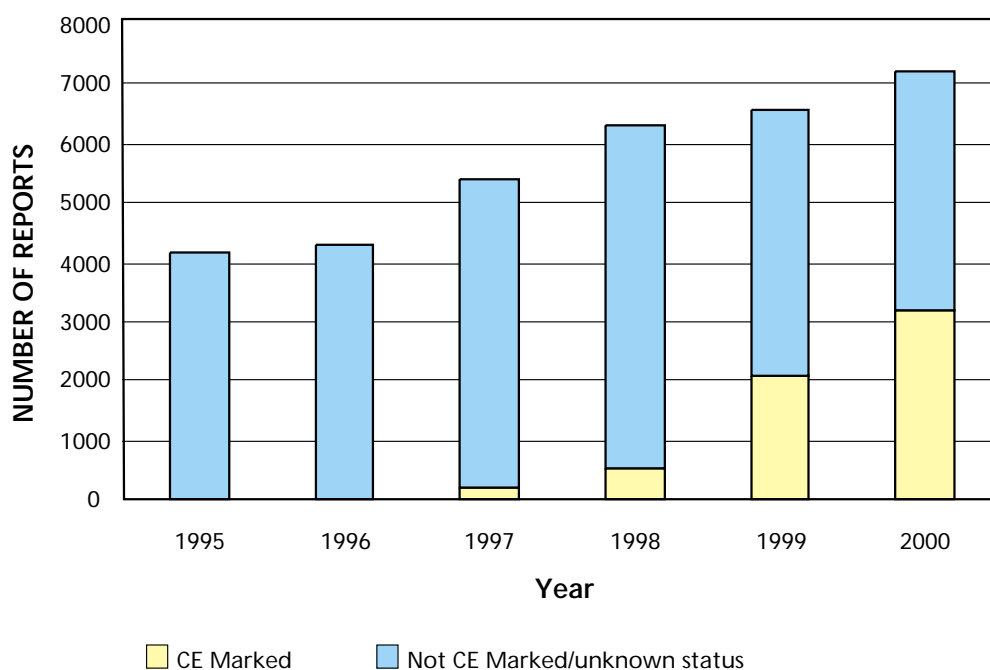


Figure 2 – Vigilance cases

The medical devices Regulations place a burden of mandatory reporting of incidents upon manufacturers, the so-called ‘Vigilance’ system. For the majority of devices this came fully into force in June 1998. Figure 2 illustrates both the number of adverse incidents received which we have classified as “Vigilance” cases and the number of incidents reported by manufacturers concerning CE marked devices, as currently registered on our database. We suggested last year that the drop-off in the growth of Vigilance cases, such that it now appears to have plateaued at around 500 per year, was probably due to a better understanding of the regulations by manufacturers.

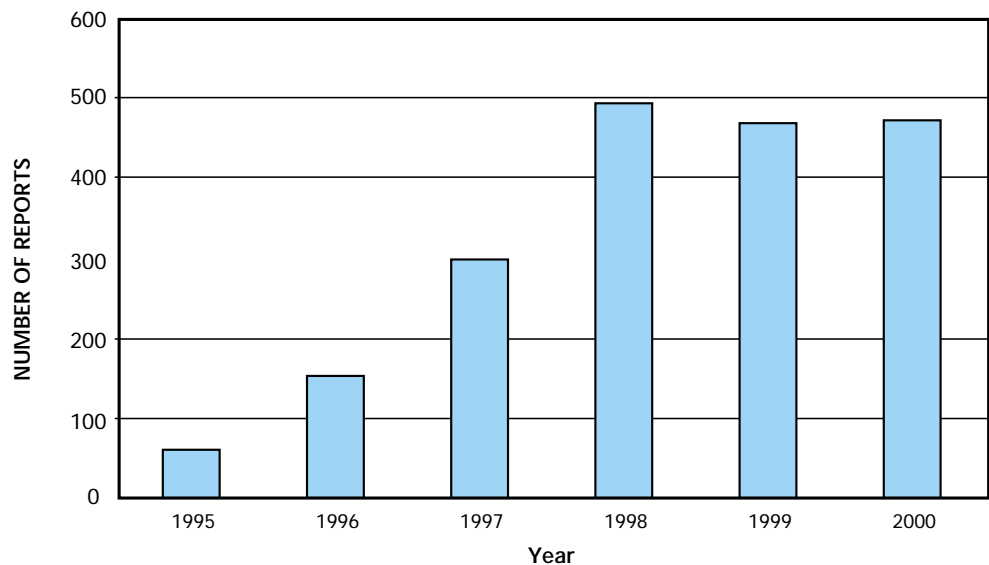


Figure 3 – Trends in reporting organisations

Figure 3 reveals the trends in the percentage of reports received by MDA from a range of organisations. The most significant trend is the increasing percentage of reports received from manufacturers since 1997. This general trend is not surprising but in view of the introduction of the Vigilance system it serves to reinforce the message of steadily increasing co-operation between MDA and industry.

The majority of MDA reports are still received from the NHS. Nevertheless the percentage of all reports received from the NHS has dropped from 72% in 1997 to 61% in 2000. The actual number of reports during the same period has risen from around 3800 to 4400.

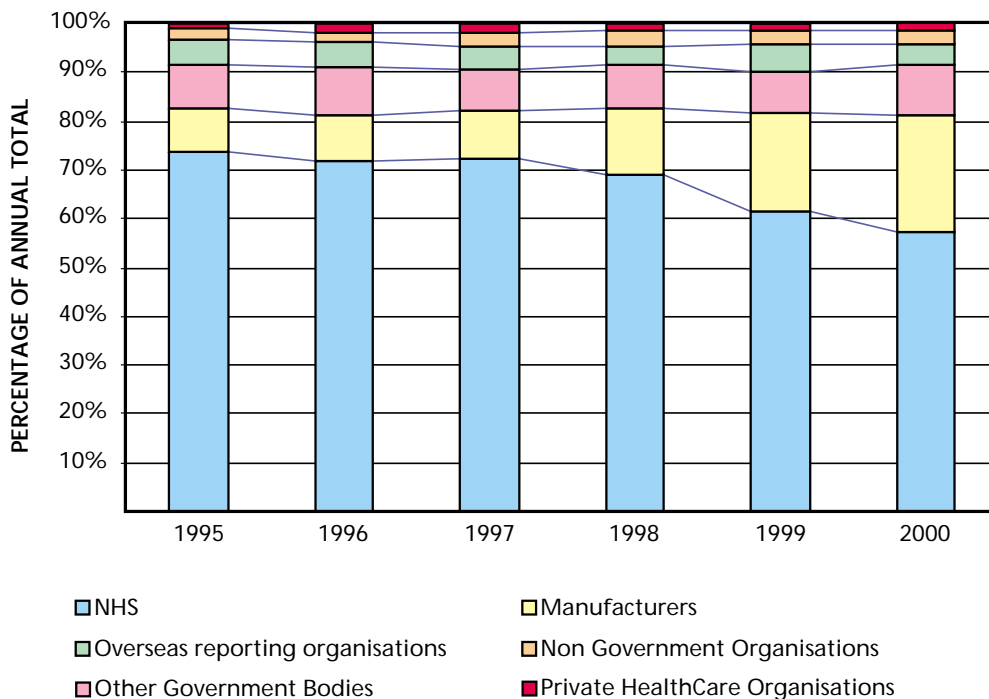


Figure 4 – Incident reports by NHS regions

Figure 4 shows the changes in reports received from NHS regions over the last three years. The total numbers reported by the English NHS Regions continues to increase year on year. 1999 to 2000 saw an increase of over 13%, due mostly to the success of the Liaison Officer network. As mentioned before, towards the end of 2000 MDA achieved its target of obtaining MDA Liaison Officers in 100% of Trusts, Health Authorities and Social Services Departments.



Key to regions:

NY – North Yorkshire; T – Trent; E – Eastern; L – London; SE – Southeast; SW – South West; WM – West Midlands; NW – Northwest.

Table 4 and Figure 5– Incident reports by device group

The device groups chosen for Table 4 and Figure 5 are broad categories covering similar types of device. The total number of reports received for each group is strongly influenced by the number of devices in use as well as the level of reporting for that type of device. Therefore a large number of reports does not necessarily mean that a particular device group has a high risk of causing problems.

Device	1999	2000	2000 trend	% change from trend
Wheeled mobility equipment	1104	1301	1336	-2.7
Active and non-active implants	917	964	1038	-7.6
Artificial limbs	850	600	789	-31.5
Infusion/transfusion/dialysis	705	665	1086	-63.3
Surgical equipment	556	652	596	8.6
Life support/incubators/monitors	485	426	518	-21.6
Others	407	612	404	34.0
Surgical consumables	280	331	318	3.9
IVDs	270	243	270	-11.1
Diagnostic imaging	188	229	193	15.6
Injection devices	178	410	180	56.1
Aids for daily living	127	193	148	23.6
Hoists	117	117	115	2.0
Drainage/suction	120	180	135	24.7
Beds/mattresses	81	108	89	17.4
Disinfection/sterilization/disposal	66	77	54	30.4
Walking aids	44	53	53	0.2
Orthoses	30	53	33	37.5
Physiotherapy equipment	28	35	31	12.6
Total reports	6553	7249		

Table 4 lists: the finalised incident numbers for 1999 and 2000; a predicted 2000 level for each device category based on a linear extrapolation of the incident numbers over the last 5 years; and a percentage change from the predicted level. The two most notable points are:

- the apparent large decrease in the expected numbers of incidents involving infusion, transfusion and dialysis equipment. This is because during 1998 and some of 1999 we entered National Blood Authority incident reports onto our database which is no longer the practice. The actual underlying difference in the figures is much lower at 12.5 %.
- the dramatic rise in the number of incidents involving injection devices is mainly due to a problem with a specific type of insulin pen injector.

Last year's large rise in incidents concerning IVDs has not been repeated and the increase in implant incidents is showing signs of slowing down.

Figure 5

Figure 5 gives the trend in adverse incident reports over the last 3 years for all device categories in Table 4 where the annual number of reported incidents is above or near 200.

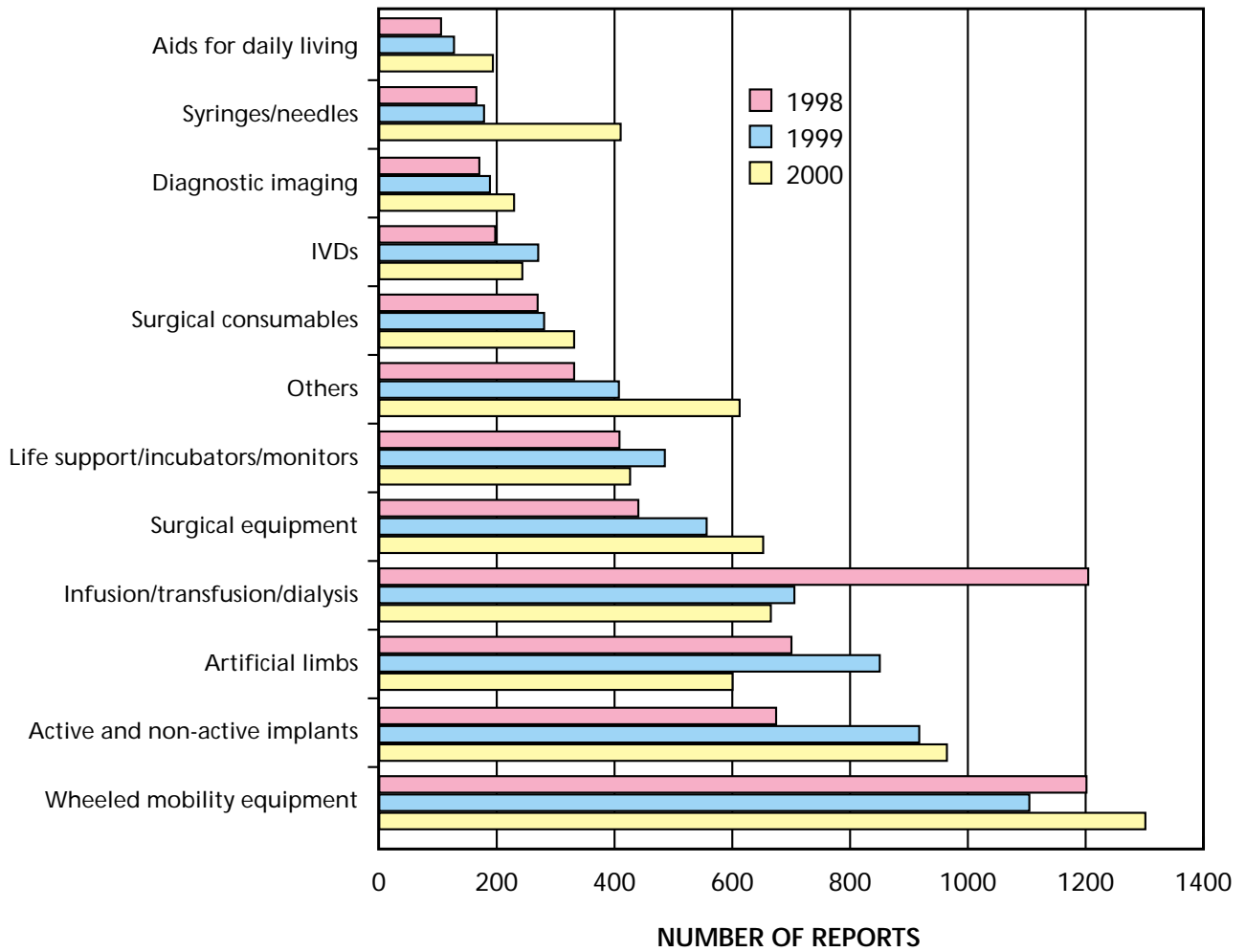


Figure 6 – Causes of adverse incidents

Figure 6 shows the causes of adverse incident investigations resolved during 2000. The causes can be identified as faults resulting from problems before delivery (design, manufacture, quality control and packaging) and after delivery (performance or maintenance failures, device degradation). We also identified incidents where the main cause was believed to be user error. The category 'no established link to device' includes cases where either the device was subsequently found to work as intended (these incidents may be due to an intermittent fault, tampering or user error) or it was not available for inspection. The proportions of incidents in each category are similar to those in previous years.

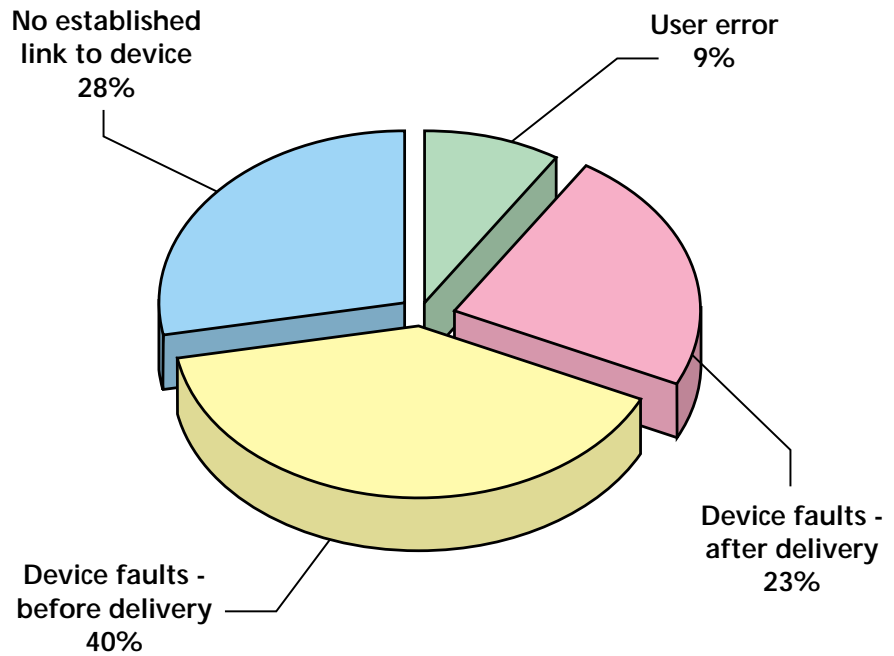


Figure 7 – Outcomes of investigations

Figure 7 shows the outcomes of the incident investigations resolved during 1999 and 2000. Each category is not mutually exclusive and the percentage is of the total number of outcomes during each year. The ‘single faulty device’ category includes those cases where a single product item required replacement or repair but there was no evidence to justify a device recall or field correction action by the manufacturer.

Categories of outcomes that showed an increase from 1999 to 2000 are:

- improved maintenance;
- manufacture changed/improved quality assurance
- no further action considered necessary

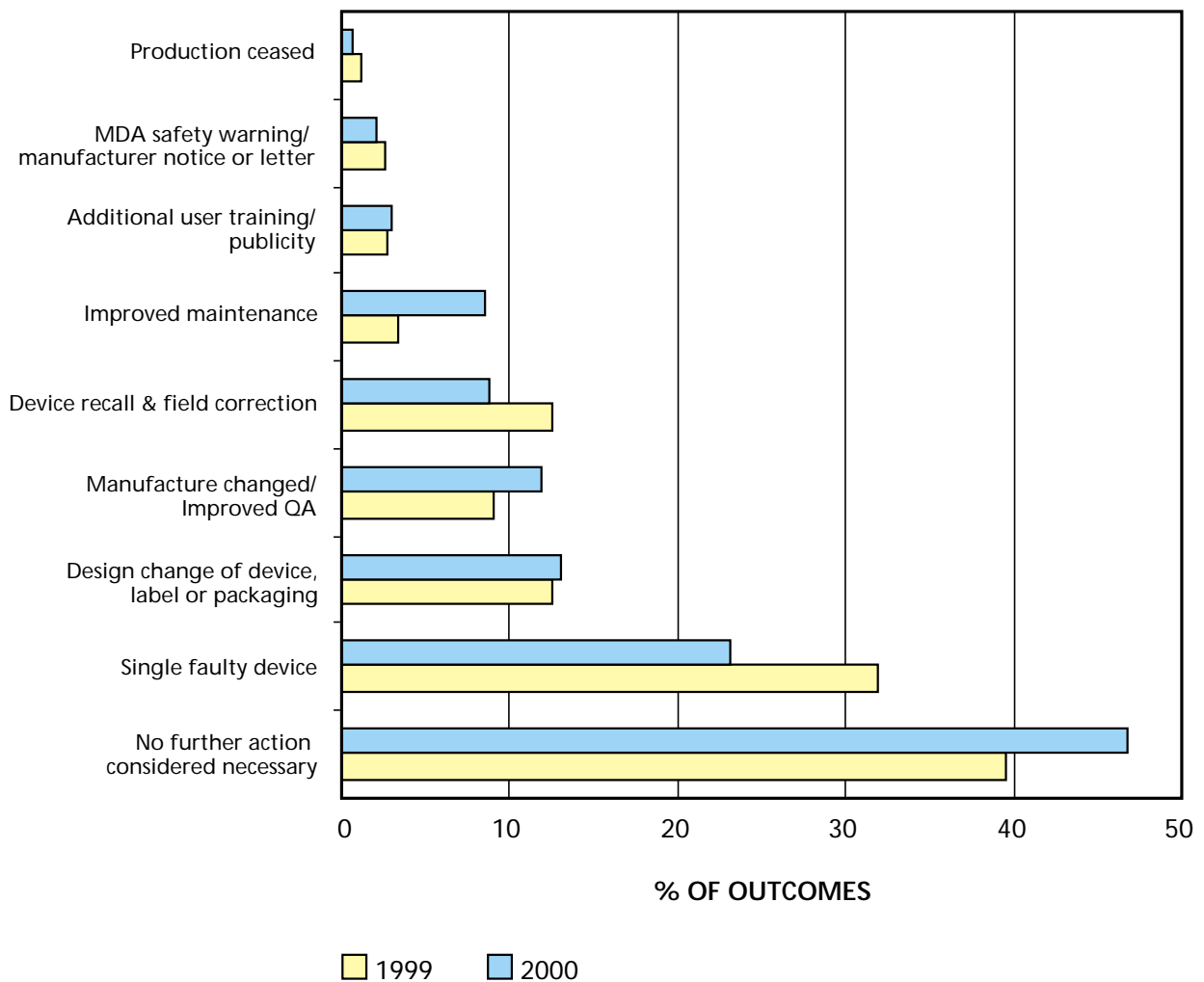
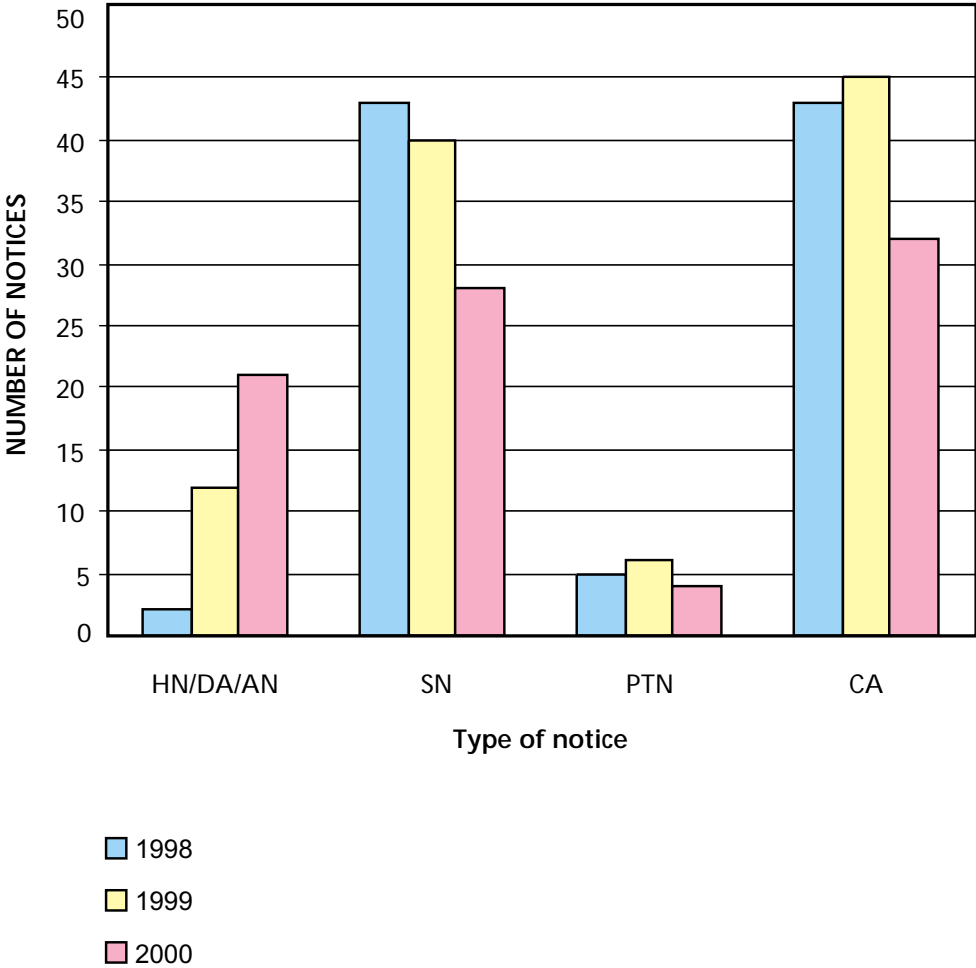


Figure 8 – MDA Notices issued in 2000

Figure 8 shows the number of each of the main types of safety advice issued by MDA during 2000 as a result of adverse incident investigations. Advice Notices, Device Alerts, Hazard Notices, Safety Notices and Pacemaker Technical Notes (AN, DA, HN, SN, PTN respectively) were issued to the UK health service. Competent Authority Notifications (CA) were issued by MDA to the other European Member states under the medical devices regulations.

NOTE: Advice Notices were introduced in January 1999 and were replaced by Device Alerts in January 2000.



APPENDIX 1. PUBLICATIONS

The lists below cover the last 3 years only.

HAZARD NOTICES

HN(NI)2000/33	GEC VMX (11kV) VACUUM CIRCUIT BREAKER Fracture Of Spider Bracket
HN(NI)2000/32	SOUTH WALES C4X OCB (11kV) SWITCHGEAR Contact manufacturer
HN(NI)2000/31	CMP BATTERIES LTD & 12V (6A) BATTERY CHARGERS BRANDED AS CPM 2000 TYPE 24V(4A,6A&7A) AND 12V, 6A FOR USE WITH POWERED WHEELCHAIRS Potential to overheat due to a failure on the internal circuit board - withdraw from use
HN(NI)2000/30	ALARIS P SERIES SYRINGE PUMPS P1000, P2000, P3000 SYRINGE PUMPS SOFTWARE V2 AND V4 ANOMALIES RELATING TO VOLUME LIMIT AND BOLUS FEATURES VOLUME LIMIT/BOLUS KEY ANOMALY
HN(NI)2000/29	AEI BVRP 17 OCB OCB slow closed following spring recharge
HN(NI)2000/28	ALL MANUFACTURERS 11KV OIL FILLED SWITCHGEAR Suspension of operational practice
HN(NI)2000/27	LUCY FRMU Disruptive failure
HN(NI)2000/26	LONG & CRAWFORD J4 SWITCH Blue phase contact fault
HN(NI)2000/25	SOUTH WALES SWITCHGEAR TYPE C4X (HV) OIL CIRCUIT BREAKER Update to HN(NI) 2000/19
HN(NI)2000/24	LUCY FRMU & FRMU MK1 Suspension of operational practice
HN(NI)2000/23	LONG&CRAWFORD(HV) HEATSHRINK CABLE TERMINATION T4GF3 RMU Overheating
HN(NI)2000/22	HOSKINS HEALTHCARE RONDO VARIABLE HEIGHT COUCH Risk of collapse

HN(NI)2000/21	REYROLLE LMI RMU CABLE DIVIDING BOX Disruptive failure
HN(NI)2000/20	REYROLLE ROKSS/CC RING END CABLE BOX Explosion
HN(NI)2000/19	SOUTH WALES SWITCHGEAR C4X (11KV) Contact manufacturer
HN(NI)2000/18	REYROLLE LMT2 (HV) TRANSFORMER Update On HN(NI)2000/06
HN(NI)2000/17	BEDSIDE RAILS (COTSIDES) RISK OF ENTRAPMENT AND ASPHYXIATION
HN(NI)2000/16	DRAEGAR 600W RADIANT HEATER TROLLEYS INCLUDING RADIANT HEATERS FOUND IN BABY THERM RESUSCITATION UNITS
HN(NI)2000/15	XOMED PULSATRON NERVE STIMULATOR PART NO 82- 62015 LOT CODES ALL Withdrawal from use
HN(NI)2000/14	ANGENIEUX AX CB OPERATING LIGHT INSTALLED PRIOR TO 1988
HN(NI)2000/13	DRAEGER 8000 INCUBATORS Skin temperature sensor failed
HN(NI)2000/12	REYROLLE SWITCHGEAR 'C' TYPE OIL CIRCUIT BREAKERS Suspension of operational practice
HN(NI)2000/11	UNINTERRUPTIBLE POWER SUPPLY (UPS) Failure in service
HN(NI)2000/10	TRILUCENT BREAST IMPLANTS Recommendation to remove
HN(NI)2000/09	ACRYFLEX SC60B-00V & SC600-2 AND ORION IFP3D6 INTRAOCULAR LENSES Recall due to increased rate of lens clouding
HN(NI)2000/08	LUCY (HV) FRMU Disruptive failure
HN(NI)2000/07	LONG & CRAWFORD (HV) T4G F3 RMU Disruptive failure
HN(NI)2000/06	REYROLLE LMT2 (HV) VOLTAGE TRANSFORMER Blue phase fuse blown

HN(NI)2000/05	MEDITECK LTD PRODUCTS Withdraw from use
HN(NI)2000/04	REYROLLE (HV) 'C' GEAR BUSBAR CHAMBER Contact manufacturer
HN(NI)2000/03	ONE TOUCH BLOOD GLUCOSE TEST STRIPS LOT NO 25722a Recall
HN(NI)2000/02	GEC APOLLO CTM MARK ONE CEILING MOUNTED SUSPENSION X-RAY TUBES Tube support dropped
HN(NI)2000/01	FERGUSON PALIN BVRPS + EEAEI BVRP17 OIL CIRCUIT BREAKERS Suspension of operational practice
HN(NI)99/22	POWER TRANSFORMER Dc resistance testing procedures
HN(NI)99/21	MIELE VENTED TUMBLE DRIERS MODELS T490, T640, T689 Fault in temperature control programme
HN(NI)99/20	BOOTS MICROWARMER: Fatal incident: withdrawn from use
HN(NI)99/19	LONG AND CRAWFORD J4 OIL SWITCH Electrical failure in band joint
HN(NI)99/18	ALSTHORN VMX FORM C CB Catastrophic failure
HN(NI)99/17	LONG AND CRAWFORD T4 GF3 (HV) RMU- Disruptive failure
HN(NI)99/16	GEC BVP17(HV) SWITCHGEAR Update on HN(NI)99/10
HN(NI)99/15	SHILEY ADULT DUAL CANNULA TRACHEOSTOMY TUBES Manufacturer's recall
HN(NI)99/14	HEWLETT-PACKARD CODEMASTER Defibrillator/monitors
HN(NI)99/13	FERNO-WASHINGTON AMBULANCE TROLLEYS Withdrawal of HN(NI)99/11
HN(NI)99/12	NEWTON BADGER LIFESTYLE CUB AND SERIES 800 ROYALE ELECTRICALLY POWERED INDOOR WHEELCHAIRS(EPICS)

HN(NI)99/11	PHOENIX FERNO-WASHINGTON AMBULANCE TROLLEYS Possible failure in use
HN(NI)99/10	GEC BVP17 (11KV) SWITCHGEAR Catastrophic failure
HN(NI)99/09	LONG & CRAWFORD (11KV) J3 OIL SWITCH Damage to switchgear
HN(NI)99/08	VICKERS RESUSCITAIRE NON-RETURN VALVE
HN(NI)99/07	LONG & CRAWFORD (11KV) T3GF3 RMU Contact manufacturer
HN(NI)99/06	LABOTECH AND PERSONALLAB AUTOMATED MICROPLATE ANALYSERS Intermittent sampling failures
HN(NI)99/05	GEC (HV) CIRCUIT BREAKERS TYPES VMX FORMS B&C, OX36 AND HMX36
HN(NI)99/04	MERLIN GERIN HV METERING UNIT Operational restriction
HN(NI)99/03	REYROLLE CAROLE END OF OIL SWITCH
HN(NI)99/02	LONG&CRAWFORD T3GF3/T4GF 3 (HV) SWITCHGEAR Update on HN (NI) 98/17 operational restriction lifted
HN(NI)99/01	No Hazard Notice issued under this reference number.
HN(NI)98/18	HOT SACK IV FLUID WARMER Overheating
HN(NI)98/17	LONG & CRAWFORD T3GF3/T4GF3 (HV)SWITCHGEAR Update on HN(NI)98/12
HN(NI)98/16	LMT2/RMS (HV)VOLTAGE TRANSFORMER Update on HN(NI)98/11
HN(NI)98/15	MERLIN GERIN ST CONTROL UNITS FITTED TO MASTERPACT & COMPACT CIRCUIT BREAKERS Potential loss of tripping characteristics
HN(NI)98/14	SOUTH WALES SWITCHGEARC4X 11KV 400A DOUBLE BUSBAR
HN(NI)98/13	LUCY, LONG & CRAWFORD, REYROLLE FRMU 11A 11FV 400 amp
HN(NI)98/12	LONG & CRAWFORD Update on HN(NI)98/10

HN(NI)98/11	REYROLLE BUSHING CO TRANSFORMER Suspension of operational practice
HN(NI)98/10	LONG & CRAWFORD SWITCHGEAR Suspension of operational practice
HN(NI)98/09	URIBARRI SINGLE & DOUBLE ADJUSTABLE CRUTCH
HN(NI)98/08	REYROLLE LMT23HV CIRCUIT BREAKERS Suspension of operational practice
HN(NI)98/07	REYROLLE SWITCHBOARD Suspension of operational practice
HN(NI)98/06	GEC ALSTHORM TYPE VMX (HV) CIRCUIT BREAKERS Suspension of operational practice
HN(NI)98/05	REYROLLE TYPES RO & RM HV SWITCHGEAR ACCESS COVER FIXING BOLT - Operational restrictions
HN(NI)98/04	GEC ALSTHOM TYPE VMX, MX AND BVP17 HV SWITCHGEAR Suspension of operational practice
HN(NI)98/03	PROTECTION AT STAIRS, BALCONIES ETC
HN(NI)98/02	3M CAPITAL HIP SYSTEM Poor short term performance of the femoral component
HN(NI)98/01	ELECTROLUX DRUGS REFRIGERATOR Ammonia leakage

ADVICE NOTICES

AN(NI) 2000/09	BREAST IMPLANTS NOVAGOLD NOVAMEDICAL/SOMATECH MEDICAL LTD Recall
AN(NI) 2000/08	BREAST IMPLANTS PIP HYDROGEL POLY IMPLANT PROTHESIS(PIP)/CLOVER LEAF PRODUCTS LTD Voluntary recall of pip hydrogel breast implants
AN(NI) 2000/07	ANEUREX STENT GRAFT SYSTEM MEDTRONIC AVE Nitinol frame fracture after implantation
AN(NI) 2000/06	USE OF TRANSPORT MEDIA DURING CHORIONIC VILLUS SAMPLING Inappropriate use

AN(NI) 2000/05	POWERED WHEELCHAIRS SCANDINAVIAN MOBILITY Overheating of battery charger
AN(NI) 2000/04	ANEUREX STENT GRAFT SYSTEM MEDTRONIC AVE Risk of aneurysm rupture
AN(NI) 2000/03	ACCORD (JOHNSON-ELLOY) TOTAL KNEE REPLACEMENT Do not implant this device
AN(NI) 2000/02	SHARPSAFE SHARPS BOXES 11 LITER AND 24 LITRE SIZES FRONTIER MEDICAL PRODUCTS All staff should be instructed in procedures for use
AN(NI) 2000/01	MECHANICAL HEART VALVES ST JUDE MEDICAL INC Recall of prosthetic heart valves
AN(NI) 99/07	ABBOTT IN-VITRO DIAGNOSTIC PRODUCTS: Additional precautions
AN(NI) 99/06	THROMBOEMBOLIC COMPLICATIONS INVOLVING SILZONE MECHANICAL HEART VALVES ST JUDE MEDICAL INC
AN(NI) 99/05	SINGLE PATIENT OF OPHTHALMIC MEDICAL DEVICES: Implications for clinical practice
AN(NI) 99/04	SINGLE PATIENT USE OF CONTACT LENSES: Implications for clinical practice various implications for clinical practice
AN(NI) 99/03	GLUTERALDAHYDE
AN(NI) 99/02	USE OF TRIAL CONTACT LENSES ON MULTIPLE PATIENTS
AN(NI) 99/01	TRILUCENT BREAST IMPLANTS Voluntary recall

SAFETY NOTICES

SN(NI)2000/NIAIC	REPORTING ADVERSE INCIDENTS AND DISSEMINATING WARNING NOTICES RELATING TO MEDICAL DEVICES, NON-MEDICAL EQUIPMENT, BUILDINGS AND PLANT
SN(NI)2000/47	ENTERAL FEEDING SYSTEMS Risk of infection
SN(NI)2000/46	ABBOTT PROVIDER 5500 INFUSION PUMP Recall

SN(NI)2000/45	ALARIS (IVAC)597 AND 598 PUMPS Risk of over-infusion
SN(NI)2000/44	HEWLETT-PACKARD END-TIDAL CO2 MONITORING STANDARD AIRWAY ADAPTOR MODEL M1465A Expanded medical device recall
SAN(NI)2000/43	CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) Risk of misassembly
SAN(NI)2000/42	THORN BEDHEAD LUMINAIRES Risk of open/short circuit
SAN(NI)2000/41	KESTRON 'GET' STARTER SWITCHES IN KESTRON LUMINAIRES Risk of heat damage and fire
SAN(NI)2000/40	HENLEY 6 WAY OPEN TYPE LV FUSEBOARD FLASHOVER Update on SAN(NI)2000/18
SAN(NI)2000/39	PORTEX SINGLE USE INTUBATION STYLET SIZE 2.2mm OD Product information notice
SAN(NI)2000/38	LAERDAL PREMIER SUCTION UNIT Incompatibility with mains battery charger
SAN(NI)2000/37	CARDADON MK ELECTRIC FILTERED SOCKETS - K1816 WH1 AND K1826 WH1 Risk of electric shock/fire
SAN(NI)2000/36	ABB NITRAN OUTDOOR LV CABINET Flashover - update on san 2000/05
SAN(NI)2000/35	LONG&CRAWFORD GF3D FUSED OIL SWITCH(11KV) Flashover
SAN(NI)2000/34	LOMAX MOBILITY VITESSE 3HD AND XHD POWERED WHEELCHAIRS Front castor assemblies field replacement
SAN(NI)2000/33	ELECTRICALLY OPERATED LIFT AND RECLINER CHAIRS Fatality
SAN(NI)2000/32	USE OF SPIRIT BASED SOLUTIONS DURING SURGICAL PROCEDURES REQUIRING THE USE OF ELECTROSURGICAL EQUIPMENT
SAN(NI)2000/31	HANDLING OF SURGICAL INSTRUMENTS ON LOAN FROM ANOTHER ORGANISATION

SAN(NI)2000/30	BLATCHFORD ENDOLITE EXTERNAL LIMB PROTHESES BILATERAL USERS Product recall
SAN(NI)2000/29	CENTURY XXII ALIGNABLE THERMOPLASTIC SOCKET ADAPTOR 2065 FOR EXTERNAL LOWER LIMB PROTHESES Product recall
SAN(NI)2000/28	STEAM STERILISERS (BENCH TOP) FOR INSTRUMENTS AND UTENSILS Incorrect chamber/reservoir water
SAN(NI)2000/27	MEDITECK LTD STERILE PRODUCTS Enforcement action lifted
SAN(NI)2000/26	CODEMASTER XL/XL+ DEFIBRILLATOR/MONITORS Unexpected device failure
SAN(NI)2000/25	PATIENT HANDLING SLINGS Correct laundering process
SAN(NI)2000/24	MEDITECK LTD NON-STERILE PRODUCTS Enforcement action now lifted
SAN(NI)2000/23	MBL SINGLE HAND USE, PROPELLING WHEEL SYSTEM FOR WHEELCHAIRS Risk of injury from spring loaded detachable cross tube during removal
SAN(NI)2000/22	SIGMAFORM(UK) HV CABLE Flashover
SAN(NI)2000/21	VAS-CATH HAEMODIALYSIS CATHETERS Urgent product recall
SAN(NI)2000/20	PRESSURE TRANSDUCER COVER(SENSONOR PRESSURE DOME) FOR URODYNAMIC SYSTEM OF BLADDER PRESSURE MEASUREMENT Risk of cross-infection if the cover is reused
SAN(NI)2000/19	LONG AND CRAWFORD (11kv) J3 OIL SWITCH Disruptive failure
SAN(NI)2000/18	HENLEY 6 WAY OPEN TYPE INDOOR LV FUSE CABINET Flashover
SAN(NI)2000/17	REXAM SHARPS BOXES Lids becoming detached

SAN(NI)2000/16	BOHLE PLASTIC SIDE PANELS FOR WHEELCHAIR ARMRESTE(SKIRTGUARDS) Reduced fire retardancy
SAN(NI)2000/15	MEDICAL GAS CYLINDERS Risk of fire
SAN(NI)2000/14	GROUND MOUNTED CABLE CONNECTED 200kVA 11/0.433kV TRANSFORMER
SAN(NI)2000/13	ALSTHOM UNELEC AIR CIRCUIT BREAKER Failed to trip
SAN(NI)2000/12	GEC M PACT (LV) 4 POLE MANUAL SPRING CLOSING AIR CIRCUIT BREAKER Loss of settings
SAN(NI)2000/11	EXIDE ELECTRONICS BATTERY PACKS Risk of overheating and fire
SAN(NI)2000/10	ABB 6 WAY SHIELDED FUSE CABINET Flashover
SAN(NI)2000/09	INVACARE FOLDING TYPE DELTA WALKERS Risk of collapse
SAN(NI)2000/08	INVACARE CELT AND ZIPPER 1 WHEELCHAIRS Reduced fire retardancy of upholstery from cse
SAN(NI)2000/07	WHEELCHAIR SEATING & ACCESSORIES: Inspection, maintenance & repair procedures
SAN(NI)2000/06	HEWLETT PACKARD PAGE WRITER AND STRESS WRITER ELECTROCARDIOGRAPHS Distorted waveforms
SAN(NI)2000/05	ABB NITRAN OUTDOOR LV CABINET Flashover
SAN(NI)2000/04	ALVEMA MAX AND PIXI BUGGIES Failure of push handles in use
SAN(NI)2000/03	STOLEN PROSTHETIC HEART VALVES Not to be used
SAN(NI)2000/02	UNWIN WHEELCHAIR CLAMPS Improved user instructions
SAN(NI)2000/01	STRANRAER MOBILE SHOWER COMMUNE CHAIR Risk of rear legs failure

SAN99/62	REYROLLE CABLE BOX JS 11KV
SAN99/61	REYROLLE C TYPE CT CHAMBER Update on SAN(NI)99/38
SAN99/60	PIDCER EXPLORER MOBILE X RAY UNIT: Risk of hand entrapment
SAN99/59	CONDUTIVE GEL PADS FOR DEFIBRILLATION OR CARDIOVERSION Potential loss of ECG trace on screen
SAN99/58	MOBILE COMMUNICATIONS: INTERFERENCE WITH MEDICAL DEVICES DURING THE MILLENNIUM PERIOD
SAN99/57	ZIP HYDROBOIL SERIES 2000 INSTANT BOILING WATER HEATER: Risk of scalding
SAN99/56	REYROLLE C TYPE CT CHAMBER DISRUPTIVE FAILURE
SAN99/55	PATIENT LIFTING AND TRANSFER DEVICES: ARJO STRAP STRETCHERS
SAN99/54	POTENTIAL TISSUE DAMAGE CAUSED BY LARYNGOSCOPE LIGHT SOURCE AND BLADE SET DURING USE
SAN99/53	WHEELCHAIR HEADREST Risk to users
SAN99/52	ATLAS AND FIRE AND WORMALD SPRINKLER SYSTEMS WITH 'R' TYPE HEADS: 'O' RING GRADATION
SAN99/51	BED SIDE RAILS (COTSIDES) Risk of movement
SAN99/50	WALSALL E-X LTD FLAMEPROOF 9FLP0 FUSE UNITS Missing insulation plate
SAN99/49	WT HENLEY SERIES 7 (LV) ELECTRICAL SERVICE CUTOUTS Overheating
SAN99/48	MEDICAL GAS TERMINAL UNITS Risk of loss of service
SAN99/47	SAFETY OF WHEELCHAIR PASSENGERS IN VEHICLES
SAN99/46	WHEELCHAIRS, SEATING & WHEELCHAIR ACCESSORIES Inappropriate use

SAN99/45	STORAGE OF STERILE MEDICAL DEVICES
SAN99/44	FOAM MATTRESSES Prevention of cross infection
SAN99/43	LIGHT DUTY BEDS Care in handling
SAN99/42	ANGIOGRAPHY PROCEDURES Failure of general purposes syringes
SAN99/41	PATIENT LIFTING & TRANSFER DEVICES SLING,STRAP & CLIP FEATURES
SAN99/40	HAWKER SIDDLEY 1250A INDOOR CIRCUIT BREAKER Flashover in red phase busbar spout
SAN99/39	REYROLLE LMT BUSBARS Flashed over
SAN99/38	REYROLLE C-TYPE CT CHAMBER Damaged by flashover
SAN99/37	REYROLLE LMTX2 Disruptive failure of busbar
SAN99/36	3M XLPE/PILC VERTICAL TRIFURCATING JOINT Update on SAN(NI)99/21
SAN99/35	APC MEDICAL LTD EXTERNAL PACEMAKERS
SAN99/34	SURGICAL TOURNIQUET CUFFS
SAN99/33	XONICS OTS CEILING- MOUNTED CRANE FOR X-RAY TUBES
SAN99/32	HIGHLY CROSSLINKED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE) COMPONENTS FOR JOINT REPLACEMENT IMPLANTS
SAN99/31	GYNE -T R 380 INTRA-UTERINE CONTRACEPTIVE DEVICE
SAN99/30	ELECTRO-SURGERY AND LAPAROSCOPIC EQUIPMENT
SAN99/29	CAL CONTROLS 9000/9900 STERILIZER TEMPERATURE INDICATORS/CONTROLLERS
SAN99/28	SIMS GRASEBY SYRINGE PUMPS 3000 SERIES Clamp open alarm malfunction

SAN99/27	BAXTER HEALTHCARE DCR FLOGARD INFUSION PUMP Incorrectly unloading and loading of giving set
SAN99/26	MAXIMUM ENERGY ANGIOPLASTY BALLOON CATHETER Balloon sticks within coronary stents
SAN99/25	DRAEGER PHOTOTHERAPY 4000 UNITS Recall of mains input filter on all
SAN99/24	DEVICES USED FOR ENDOMETRIAL ABLATION Update
SAN99/23	MALLINCKRODT 'TRACHEOSOFT' TRACHEOSTOMY TUBES 15mm flange connector separating from body of tube
SAN99/22	MYERS METAL H-FRAME DIVAN BEDS Risk of bed legs collapsing
SAN99/21	3M XLPE/PILC VERTICAL TRIFURCATING JOINT
SAN99/20	ELECTRICALLY POWERED WHEELCHAIRS & SCOOTERS
SAN99/19	BONAR LONG LV PILLAR Suspended operational practice
SAN99/18	PHOENIX DETACHABLE PRAM HANDLE WHEELCHAIR May detach
SAN99/17	LONG & CRAWFORD T4GF3 RMU Internal flashover
SAN99/16	ESCHMANN & AMC ELECTROSURGICAL FINGERSWITCHES Faulty
SAN99/15	HOSKINS MODEL 3143 ELECTRICALLY ADJUSTABLE BEDS Instances of weld failure
SAN99/14	HEARTSTART DEFIBRILLATOR ELECTRODES X/REF SAN99/07
SAN99/13	THORNE ELECTRIUM MEDIHEAT MH2 CAPD FLUID WARMERS Plastic casing may warp and crack
SAN99/12	KRUPP DENTA-GEL HEATERS Risk of overheating and fire
SAN99/11	MEDAES GEM 10 MEDICAL GAS TERMINAL Disconnection and loss of supply

SAN99/10	ENDOLITE EXTERNAL LOWER LIMB PROTHESES
SAN99/09	PHILIPS JUG KETTLES TYPE NOS HD4388,4389,4390&4391 Possible fault which could render them unsafe
SAN99/08	HP CODEMASTER AND CODEMASTER 100 DEFIBRILLATORS Multifunction defibrillation electrode pads
SAN99/06	CARDIOAID MC/MC+ & LS DEFIBRILLATORS R2610 ADULT DEFIBRILLATION & PACING ELECTRODES & R2612 CHILD DEFIBRILLATION ELECTRODES USED WITH MFT Recall
SAN99/05	DEFIBRILLATOR BATTERIES FOR THE CODEMASTER 100 DEFIBRILLATOR/MONITOR
SAN99/04	PREVENTION OF BURNS DURING IONTOPHORESIS (SWEAT TESTING)
SAN99/03	CARDIO AID MC + DEFIBRILLATORS Locks up during charging
SAN99/02	VANGUARD ENDOVASCULAR AORTIC GRAFT Late complications
SAN99/01	MOBILE X-RAY EQUIPMENT Faulty or missing stops
SAN98/64	PARAGON CORONARY STENT Unsuccessful stent deployment
SAN98/63	LATEX MEDICAL GLOVES(SURGEONS&EXAMINATION) POWDERED LATEX GLOVES(SURGEONS&EXAMINATION)
SAN98/62	FIBRE OPTIC LIGHT SOURCE Risk of burns and/or fire
SAN98/61	ICEX SOCKET LOCK - EXTERNAL LOWER LIMB PROSTHETIC SUSPENSION Failures caused by excessive wear
SAN98/60	TRANSIX 800s, R703, R500 AND R501 X-RAY ANODE STARTER - HS150 HIGH SPEED STARTER USED WITH PICKER GENERATORS Faults in x-ray tube anode breaking
SAN98/59	CHILTERN WISPO MOBILE PATIENT HOIST Potential for mast failure

SAN98/58	NEI ELECTRONICS - EDGECOMBE HV TEST STICKS Failure to correctly indicate circuit status
SAN98/57	YORKSHIRE YSF6 VOLTAGE TRANSFORMER Failure
SAN98/56	ABB POWER T&D LTD LV FUSE CABINETS Flashover - suspension of operational practice
SAN98/55	INVACARE ACTION 2000 WHEELCHAIRS Failures of backrest hinges
SAN98/54	BIOCOMPATIBLE OSTEOCONDUCTIVE POLYMER (BOP) Risk of damage to surrounding tissue
SAN98/53	CURTAIN TRACKS POINTS OF LIGATURE Perform risk assessment
SAN98/52	PICKER EXPLORER MK1 MOBILE X-RAY UNIT Users hands can become trapped
SAN98/51	APPLICATOR SYSTEMS FOR FALLOPIAN TUBE STERILIZATION CLIPS AND RINGS
SAN98/50	NEONATAL SUCTION CATHETER Failure to operate
SAN98/49	LIFT DOOR OPERATING MECHANISMS Risk of fire
SAN98/48	POLO & PICKLE POWER ASSISTED TRICYCLES No overcurrent protection system
SAN98/47	CAITHNESS, CAIRNGORM AND CLANSMAN SELF LIFT CHAIR Occupant thrown from chair
SAN98/46	BREATHING SYSTEMS DEVICES INAPPROPRIATE USE WITH ANY CUFFED ENDOTRACHEAL TUBE
SAN98/45	LONG & CRAWFORD T4GF3 RMU :HV (11KV) Disruptive failure
SAN98/44	POWERSTAR BIOPOLAR ELECTROSURGERY SCISSORS Causing burns
SAN98/43	BLATCHFORD ENDOLITE AND VESSA QUANTOM 30 EXTERNAL LOWER LIMB PROTHESES Risk of rotation between shintube and tube clamp housing

SAN98/42	ARJO PATIENT HOIST SLINGS Reports of cracking
SAN98/41	ARJO MAXILIFT PATIENT HOISTS Risk of collapse
SAN98/40	IMMUNOASSAY TESTING Use of validation swabs for sample collection
SAN98/39	MEDISCO RESUSCITATION TROLLEYS PRE-JUNE 1991 Potential difficulty in unlocking drawers
SAN98/38	ABB SENTINEL 2 RING MAIN UNIT(RMU) Faulty switchgear
SAN98/37	FLEXIFLO II ENTENAL FEEDING PUMP TRANSFORMER May break
SAN98/36	FLEXIBLE FIBRE OPTIC ENDOSCOPES Modification made to some models
SAN98/35	STOTT STEAMING IRON Failure of cold water supply cut-off
SAN98/34	HENDERSON HIDE-A-WAY PASSENGER TAIL LIFT Failure at weld
SAN98/33	ENDOLITE ANKLE DISARTICULATION(SYMES) EXTERNAL PROSTHETIC SOCKETS Risk of collapse
SAN98/32	YAMASU MERCURY SPHYGMOMANOMETER DESK MODELS UN600 & UN605P Mercury leakage and possible sluggish performance
SAN98/31	TRAILBLAZER MODEL TI100 TRANSPORT INCUBATOR Electrical wiring burnt through - producing smoke
SAN98/30	SYSTEM COVERED BALE LOCK 17B33,17B23,17B44 KNEE JOINT Disengaged
SAN98/29	NO-VISIBILITY POST/LETTER BOXES Possible risk of injury
SAN98/28	HEATRAE SADIA SUPREME BOILING WATER DISPENSERS Risk of fire
SAN98/27	CONSTANT TEMPERATURE LABORATORY WATER BATHS Possibility of overheating

SAN98/26	HEARTSTART DEFIBRILLATORS ELECTRODES VARIOUS CODES
SAN98/25	VISOLITE WALL-MOUNTED ELECTRIC HEATERS Risk of fire
SAN98/24	PICKER INTERNATIONAL MOBILE X-RAY MACHINES Replacement batteries renamed exide porta-power 679
SAN98/23	HEWLETT PACKARD CODEMASTER XL, XL+, 100 DEFIBRILLATORS Possible loss of ECG monitoring
SAN98/22	ABB INDOOR TYPE 1600A, 5WAY MANUFACTURED 1994 LV BOARD WITH TOP ENTRY OF TRANSFORMER CABLES
SAN98/21	ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE) COMPONENTS OF JOINT REPLACEMENT IMPLANTS
SAN98/20	ELECTROSURGERY ACCESSORIES Malfunction and failure during use
SAN98/19	CARDIOTOLOGRAPH (CTG) MONITORING OF FOETUS DURING LABOUR
SAN98/18	OXFORD MAJOR ELECTRIC & HYDRAULIC PATIENT HOISTS Mast failure
SAN98/17	DEVICES USED IN ENDOMETRIAL ABLATION Risk of perforation of uterine wall
SAN98/16	JAY CARE SUPPORTIVE WHEELCHAIR BACKRESTS Failure of fixing systems
SAN98/15	WITHDRAWAL OF DH SPECS AND PRODUCT APPROVAL SCHEMES FOR CHEMICAL INDICATORS USED IN BOWIE&DICK TEST
SAN98/14	HP CODEMASTER AND CODEMASTER 100 DEFIBRILLATORS MULTIFUNCTION DEFIBRILLATION ELECTRODE PADS Conductive gel deteriorates to a liquid
SAN98/13	HEARTSTART DEFIBRILLATION ELECTRODES Female connectors may become detached
SAN98/12	PROPULSE EAR IRRIGATOR (PULSED WATER SYRINGE) Risk of electric shock should water leak

SAN98/11	PATIENT BED MOVEMENT WITHIN WARD LOCATIONS WHEN BRAKES ARE APPLIED AND WORKING
SAN98/10	PICKER INTERNATIONAL 'D' SERIES MOBILE X-RAY MACHINE Only recommended batteries to be used
SAN98/09	BAXTER HEALTHCARE STERILE BLOOD ADMINISTRATION SETS CODE NOS C2071A & C2071B Spike detaches
SAN98/08	15MM NON-METALLIC CONICAL CONNECTORS ATTACHED TO ET TUBES
SAN98/07	UV TUBES FOR THERAPEUTIC USE Injury through over-exposure
SAN98/06	MERLIN GERIN YORKSHIRE SWITCHGEAR 12KV SWITCHGEAR FEEDER MOUNTED VT
SAN98/05	GEC VOLTAGE TRANSFORMER (11KV MX TYPE CAST RESIN) Bushing failure resulting in flashover
SAN98/04	LIGHT BEAM DIAPHRAGMS Becoming detached during use
SAN98/03	APOLLO X-RAY TUBE CEILING SUSPENSION EXTENSION SHAFT Not to design specification
SAN98/02	QUIKLOK WHEELCHAIR CLAMPS Incorrect use
SAN98/01	BRITISH STERILIZER MOTOCLAVE STERILIZER MANUFACTURED PRIOR TO 1 JANUARY 1994 Failure of door locking mechanism

DEVICE BULLETINS

- DB2000/06 (NI) EQUIPPED TO CARE: THE SAFE USE OF MEDICAL DEVICES IN THE 21st CENTURY: A GUIDE FOR HEALTH CARE PROFESSIONALS, SUPPORT WORKERS AND MANAGERS. This bulletin helps nurses, midwives, health visitors , other health care professionals and support workers understand their role in the safe use, purchase and management of medical devices.
- DB2000/05 (NI) GUIDANCE ON THE PURCHASE, OPERATION AND MAINTENANCE OF VACUUM BENCHTOP STEAM STERILIZERS. This bulletin provides guidance on the purchase, operation and maintenance of vacuum benchtop steam sterilizers that have a forced air removal system to provide Type B or Type S sterilization cycles.
- DB2000/04 (NI) SINGLE-USE MEDICAL DEVICES: IMPLICATIONS AND CONSEQUENCIES OF REUSE. This bulletin replaces the earlier bulletin - The Reuse of Medical Devices Supplied for Single-use Only (DB 9501) published in 1995.
- DB2000/03 (NI) BLOOD PRESSURE MEASUREMENT DEVICES - MERCURY AND NON-MERCURY. This document reviews the current situation regarding the use of mercury, and the issue associated with electronic blood pressure measuring devices, which should ensure the most appropriate technology is selected for use.
- DB2000/02 (NI) MEDICAL DEVICES AND EQUIPMENT MANAGEMENT: REPAIR AND MAINTENANCE PROVISION. This bulletin builds on and provides additional guidance to that contained in Device Bulletin DB 9904, but can be used as a stand-alone document.
- DB9904 (NI) MEDICAL DEVICE AND EQUIPMENT MANAGEMENT FOR HOSPITAL AND COMMUNITY-BASED ORGANISATIONS.
- DB9903 (NI) EMERGENCY SERVICE RADIOS AND MOBILE DATA TERMINALS: COMPATIBILITY PROBLEMS WITH MEDICAL DEVICES.
- DB9902 (NI) THE SAFE AND EFFECTIVE USE OF BATTERIES FOR MEDICAL DEVICES.
- DB9901 (NI) THE VALIDATION AND PERIODIC TESTING OF BENCHTOP VACUUM STEAM STERILIZERS.
- DB9803 (NI) MRI STATIC MAGNETIC FIELD SAFETY CONSIDERATIONS.

PACEMAKER TECHNICAL NOTES

Pacemaker technical notes are issued directly by MDA to clinicians in Northern Ireland.

MDA PTN 84	NON MANUFACTURER/MODEL SPECIFIC. Activation of magnetic reed-switches in implantable pacemakers and defibrillators from concealed magnets, especially clothing and fashion accessories, giving rise to asynchronous mode pacing in pacemakers and inhibition of shock therapy in implantable defibrillators. November 2000
MDA PTN 83	CPI GUIDANT Discovery: Models 1174, 1175, 1273, 1274, 1275 Meridian: Models 476, 976, 1176,1276 Pulsar/Pulsar Max: Models 470, 870, 970, 972, 1170, 1171, 1172, 1270, 1272 Further recommendations regarding premature battery depletion. May 2000
MDA PTN 82	ST JUDE MEDICAL/ TRILOGY FAMILY OF PACEMAKERS; MODELS 2264L 2308L, 2318L, 2350L, 2364L. Pacemaker microprocessor failure. March 2000
MDA PTN 81	SORIN BIOMEDICA - Minidual 50 Pacemaker; Product Code ICV0095. Possible malfunction including premature battery depletion and loss of output. February 2000
MDA PTN 80	MEDTRONIC - Micro Jewel II Model 7223 - Implantable Cardioverter Defibrillator (ICD). Potential for delayed delivery or shock therapy due to excessive capacitor charge time. October 1999
MDA PTN 79	MEDTRONIC - SIGMA(tm) Pacemaker Models: SDR303, SDR306, DR203, SD203, SVDD303, SSR303, SSR306, SSR203, SS203, SS303, SS103, SS106, SVVI103. Potential for loss of sensing or pacing and rate response function. October 1999
MDA PTN 78	CPI/GUIDANT Endotak DSP 0095 & Endotak DSP 0125 Implantable Defibrillator Leads. Potential for inappropriate sensing and delivery of therapy. September 1999
MDA PTN 77	ST JUDE MEDICAL Trilogy family of pacemakers; Models 2264, 2308, 2318, 2350, 2364 Premature battery depletion. May 1999
MDA PTN 76	MEDTRONIC - GEM(tm) 7227Cx Implantable Cardioverter Defibrillator (ICD) Potential for premature battery depletion. May 1999

MDA PTN 75	<p>CPI GUIDANT Discovery: Models 1174, 1175, 1273, 1274, 1275 Meridian: Models 476, 976, 1176, 1276 Pulsar/Pulsar Max: Models 470, 870, 970, 972, 1170, 1171, 1172, 1270, 1272.. May 1999</p>
MDA PTN 74	<p>NON MANUFACTURER SPECIFIC Possible interference effects between electronic article surveillance security systems and implantable pacemakers/defibrillators. March 1999</p>
MDA PTN 73	<p>CPI GUIDANT : VIGOR-ALL MODELS Additional recommendations for follow up and the correct detection of elective replacement indicators for all Vigor Pacemakers. August 1998</p>
MDA PTN 72	<p>TELECTRONICS: ENCOR passive fixation atrial-J pacemaker leads. August 1998</p>
MDA PTN 71	<p>SORIN BIOMEDICA; PHYSIOCOR 400T/TB PACEMAKERS (PRODUCT CODES P0040 & P0004). March 1998</p>
MDA PTN 70	<p>MEDICO/JPR Medical (UK distributor) 830-S Ad-V PACING LEADS. (11cm, 13cm, 15cm) March 1998</p>

NIAIC PROFESSIONAL ESTATE LETTERS (PELS) ISSUED IN 2000

PEL(00)2	<p>ADVERSE INCIDENT REPORTING - QUESTIONNAIRE Requested completion of questionnaire to enable a review of niaic documentation and procedures</p>
PEL(00)3	<p>HAZARD NOTICES, ADVICE NOTICES AND SAFETY ACTION NOTICES Outlines the types of warning notices issued and alerted recipients to a new series of warning notices entitled "Advice Notice</p>
PEL(00)9	<p>MOBILE COMMUNICATIONS IN A HOSPITAL SETTING Review policy in relation to the use of mobile communications with reference to the findings of the Stewart Report</p>
PEL(00)14	<p>NATIONAL AUDIT OFFICE REPORT - MANAGEMENT OF MEDICAL EQUIPMENT IN NHS ACTUTE TRUSTS Advised HPSS organisations to review medical equipment management policies and procedures taking into account the NAO report</p>

- PEL(00)15 REPORTING ADVERSE INCIDENTS
Replaces PEL(93)35 and PEL(93)36 concerning the procedures for reporting adverse incidents
- PEL(00)20 DISSEMINATION OF NIAIC WARNING NOTICES, DEVICE BULLETINS AND EVALUATION REPORTS
Summary of arrangements now in place for the issue of NIAIC warning notices, device bulletins and evaluation reports

OTHER PUBLICATIONS

STERILIZATION, DISINFECTION AND CLEANING OF MEDICAL EQUIPMENT:
guidance on decontamination from the Microbiology Advisory Committee to Department of Health, Medical Devices Agency, Section 2 of Part 3. MDA, October 2000.

APPENDIX 2.

TEXT OF NIAIC SAFETY NOTICE SN(NI)2001/01

SN (NI) 2001/01

DATE: 15 JANUARY 2001

For Attention and Action by:

Chief Executive of each HSS Trust

General Manager/Chief Executive of each HSS Board

Chief Executive of each Agency

TITLE:

**REPORTING ADVERSE INCIDENTS AND DISSEMINATING
WARNING NOTICES RELATING TO MEDICAL DEVICES,
NON-MEDICAL EQUIPMENT, BUILDINGS, AND PLANT**

SUMMARY

General Managers and Chief Executives are responsible for ensuring prompt reporting of adverse incidents. This Safety Notice provides information on:

- The Northern Ireland Adverse Incident Centre (NIAIC) adverse incident reporting system;
- Encourages the reporting of adverse incidents involving medical devices, non-medical equipment, buildings and plant;
- and provides information on the dissemination of NIAIC warning notices.

The text of this notice updates and replaces SN(NI)2000/NIAIC.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Medical Directors
- Clinical Directors
- Nursing Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- General Medical Practitioners
- General Dental Practitioners
- Opticians
- Community Pharmacists
- Professions Allied to Medicine
- Social Care Staff
- Community Care Staff
- Trust Pharmacists

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

ACTION

The following actions should be taken:

- establish and maintain procedures to ensure the prompt reporting of adverse incidents relating to medical devices, non-medical equipment, buildings and plant to NIAIC in accordance with this Notice;
- If they have not already done so, HPSS organisations should nominate a Liaison Officer to co-ordinate the reporting of incidents and the local dissemination of NIAIC warnings notices and other guidance material;
- regularly review these procedures and update as necessary.

Further guidance is provided in the Annexes to this Notice.

BACKGROUND

The Health Estates Health & Social Services Agency (Health Estates) is an Executive Agency of the Department of Health, Social Services and Public Safety. The aim of the NIAIC, part of Health Estates, is to take all reasonable steps to protect the health of patients, staff and clients. One way in which we aim to achieve this is by investigating reports of adverse incidents involving medical devices, non-medical equipment, plant and buildings. See Annex A and B for a list of examples of medical devices, non-medical equipment, plant and buildings.

Where the results of investigations have implications for patients, staff, clients or users, NIAIC issues a Hazard Notice, Advice Notice or Safety Notice advising of hazardous products or unsafe procedures.

WHAT IS AN ADVERSE INCIDENT?

An adverse incident is an event which causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, staff and clients. Every Health & Personal Social Services employee has a duty to see that all safety related incidents and potentially harmful products are reported, even on suspicion. For example, adverse incidents may arise due to:

- *shortcomings in the medical device, non-medical equipment, plant or building item*
- *inadequate instructions for use*
- *inadequate servicing and maintenance*
- *locally initiated modifications or adjustments*
- *inappropriate user practices, (which may in turn result from inadequate training)*
- *inappropriate management procedures*
- *the environment in which it is used or stored*
- *selection of the incorrect type of device for the patient**

Conditions of use may also give rise to adverse incidents, e.g.:

- *environmental conditions (e.g. electromagnetic interference)*
- *location (e.g. devices designed for hospitals may not be suitable for use in the Community or ambulances).*

* This would not apply to non-medical equipment, plant and buildings.

WHAT TO REPORT

An adverse incident should be reported to NIAIC if the incident has led to, or were it to occur again could lead to:

- *death, life-threatening illness or injury;*
- *deterioration in health;*
- *the necessity for medical or surgical intervention;*
- *unreliable test results leading to inappropriate diagnosis or therapy.*

NIAIC should also be informed of any other related adverse incidents or minor faults and discrepancies, since they may take on a greater significance when aggregated with other similar events in demonstrating trends or may be indicators of inadequate quality assurance on the part of the manufacturer or supplier.

NIAIC should be informed of adverse incidents even if they appear to be caused by human error as:

- *the error may be partly (or wholly) due to deficiencies in the design of the device, non-medical equipment, plant or building item or instructions for their use;*
- *it will help prevent repetition of the same mistake, possibly by promulgating advice or improving the design of future devices, non-medical equipment, plant and building items.*

NIAIC is concerned with preventing adverse incidents occurring, not with assigning blame or liability.

ADVERSE INCIDENT REPORTING PROCEDURES

All staff who work in Health and Personal Social Services, including contractors and those in the Private Sector, should be regularly reminded of their responsibilities with regard to adverse incident reporting and of the relevant local procedures including the need to isolate and retain defective or suspect items. This information should also be conveyed to new and agency staff as part of their induction training.

The procedures should ensure that:

- *where appropriate, a liaison officer is appointed in each HPSS organisation with the necessary authority to take responsibility for the reporting of adverse incidents to NIAIC as detailed in Annex C to this notice and that NIAIC is informed of any changes to liaison officer contact details when they occur;*
- *devices/equipment or plant involved in an adverse incident together with other material evidence (e.g. packaging of a single use device, giving sets used with infusion pumps etc.) should be clearly identified and kept in quarantine, where appropriate, until NIAIC's investigating officers have been consulted. Where quarantine is not practicable, the state of the device(s) at the time of the incident should be recorded for use in any subsequent investigation. Please refer to Annex D;*
- *local action is taken as necessary to ensure the safety of patients, staff and clients.*

Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

HOW TO REPORT AN INCIDENT

Adverse Incidents should be reported to NIAIC as soon as possible by completing an Adverse Incident Report Form A1 (Annex F). Serious cases should be reported to NIAIC by the fastest means available e.g. telephone, fax or e-mail. Telephone reports should be followed up as soon as possible by completing an Adverse Incident Report Form.

The initial report of an incident should contain as much relevant detail including information about any device or equipment involved such as the manufacturer and supplier names, addresses and telephone numbers, product names and serial numbers etc. Having this information available allows us to begin the investigation immediately. Names and contact details of persons who may be contacted for further information should be included. The Adverse Incident form may be photocopied for local use. It is also available in electronic format for completion and return by e-mail. Please contact the NIAIC at NIAIC@dhsspsni.gov.uk, requesting the form by return.

Outside normal office hours, the Department's Duty Officer can be contacted at Stormont House telephone 02890 520700 giving an indication that the report is for the NIAIC, Health Estates. Otherwise, if a case is less serious it should be reported on the next working day.

IMPORTANT INFORMATION

General Information on how NIAIC deals with received incident reports, the investigation process, including manufacturer's legal responsibilities and the criteria for the various levels of warning notice are given in Annex E.

REPORTING TO OTHER ORGANISATIONS INVOLVED WITH ADVERSE INCIDENTS

Please report adverse incidents to the appropriate organisation. All those involving medical device, non-medical equipment, plant or building items should be reported to NIAIC.

This reporting system does not affect the statutory or other duties of staff locally to take appropriate actions as required legally and/or by line management, as a result of an adverse incident. These include:

- *to safeguard patients, staff, clients and others*
- *to prevent further use of a product which may be defective*

As part of the above actions, Regional Supplies Service may issue their own notices, which identify problems and are used to bring them to the attention of users. These Notices should not be confused with NIAIC's Hazard, Advice and Safety Notices.

RIDDOR

Incidents involving certain types of injury, occupational disease or dangerous occurrence, whether involving medical devices, non-medical equipment, buildings or plant or not, are legally notifiable to the Health & Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997 (RIDDOR), and the Ionising Radiation Regulations (Northern Ireland) 2000.

Notification to NIAIC does not count as, or substitute for, any other report, which should be sent (e.g., in respect of an employee's industrial injury).

MEDICINES

Incidents involving medicines should be reported to Pharmaceutical Branch of the Department of Health, Social Services and Public Safety.

FOOD

Incidents relating to foods involving contamination or potential contamination should be reported immediately to the local Environment Health Officer (EHO) who will decide on what, if any, further action will be taken. The EHO will also report the incident to the Food Standards Agency as necessary.

Enquires to NIAIC about this notice should quote the reference number SN (NI) 2001/01 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

RoomA7

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast BT16 1US

Tel: 02890 523714

Fax: 02890 523900

Email: NIAIC@dhsspsni.gov.uk

Brian Godfrey

NIAIC Manager

Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Áisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí

ANNEX A

ADVERSE INCIDENT REPORTS CONCERNING MEDICAL DEVICES AND EQUIPMENT

The following list provides some examples of medical devices. It is not a comprehensive list and is provided for guidance only.

- Medical Devices and equipment for the diagnosis or treatment of disease, or monitoring of patients e.g.: non-medicated dressings; surgical instruments and equipment; IV administration sets and pumps; anaesthetic equipment; powered implants (e.g. pacemakers); implantable defibrillators; radiotherapy equipment (brachytherapy, external beam); ophthalmic equipment; sphygmomanometers; vaginal speculae; examination gloves; catheters (e.g. urinary, cardiac); endoscopes; patient monitoring equipment (e.g. cardiac monitors); surgical implants (e.g. orthopaedic prostheses, bone cements, heart valves); x-ray systems, ultrasound imagers and CT/MR scanners; dental equipment and materials; chiropody equipment; thermometers; physiotherapy equipment; syringes and needles; blood warming cabinets.
- Medical Devices and equipment for critical care, e.g.: ventilators; defibrillators.
- Medical Devices and equipment used in the care of patients, e.g.: wheelchairs and special support seating; walking aids; patient hoists; orthotic and prosthetic appliances; pressure relief equipment.
- Medical Devices and equipment used by ambulance services, e.g.: stretchers and trolleys; resuscitators
- Medical Devices and equipment for daily living, e.g.: commodes, urine drainage systems; incontinence products; hearing aids; domiciliary oxygen therapy systems; prescribable footwear; bathing and showering equipment; special chairs.

Medical devices and equipment also include the following:

- *In-vitro* diagnostic medical devices and their accessories, e.g.: devices for blood glucose measurement; pregnancy test kits; urine test strips; hepatitis and HIV test kits; blood gas analysers; specimen collection tubes.
- intra-uterine devices (IUDs); contact lenses and care products; condoms.

We are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices, e.g.: blood and tissue storage systems; disinfecting and sterilizing equipment e.g. bench top sterilizers; chemical and biological indicators used in sterilization processes.

Medical devices do not include general workshop equipment such as power or machine tools.

Some equipment is designed to be permanently connected to installed services, e.g. medical gas pipework, ducting or electrical supply. In these cases, the device should be regarded as comprising all parts up to and including the means of connection to the installed service.

ANNEX B

ADVERSE INCIDENT REPORTS CONCERNING NON-MEDICAL EQUIPMENT, PLANT AND BUILDINGS

The following list provides some examples of non-medical equipment, plant and building fabric that we are interested in:

- Engineering plant and services of all types e.g. boilers, generators, heating, ventilation, water, drainage, and electrical installations and any other fixed plant.
- Fire Protection installations and equipment.
- Permanently installed sterilizers, bedpan washers and disposal units.
- Equipment in laundries, catering departments, workshops and any plant or equipment used for maintenance or cleaning.
- Piped medical gas and vacuum installations, Vacuum Insulated Evaporators (VIE) and anaesthetic gas scavenging systems.
- Fixed luminaires, including operating and examination lamps
- Communications equipment e.g. telephone, nurse call, paging, alarms and radio.
- Lightning protection and anti-static precautions.
- Built environmental aspects of COSHH
- Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems.
- Buildings and building components and plant used in maintenance and construction.
- Ambulances but excluding motor vehicles such as those for disabled persons and lease hire and goods vehicles.

ANNEX C

ROLE OF LIAISON OFFICERS

Each HPSS organisation has now nominated a liaison officer. If you need to let us know about a change in liaison officer details e.g. name, address, phone, fax numbers and e-mail address, please contact us at telephone number 02890 523704; fax: 02890 523900, e-mail: NIAIC@dhsspsni.gov.uk.

Reporting Adverse Incidents

Guidance for establishing procedures for reporting adverse incidents to NIAIC is outlined in this Notice. Local procedures for adverse incident reporting should also ensure that relevant local staff are kept informed of any adverse incidents e.g. by copying any report made to NIAIC to relevant staff or forwarding all reports to NIAIC via the Liaison Officer. This is the preferred procedure as it allows the HPSS organisation to demonstrate compliance with Health & Safety legislation by having a record of all reports of adverse incidents. A sample staff information sheet is provided at Annex G.

Dissemination of NIAIC warning notices (Hazard Notices, Advice Notices and Safety Notices)

One colour coded copy (PINK for Hazard Notice, WHITE for Advice Notice and BLUE for Safety Notice) of warning notice is sent by first class post to the Chief Executive/General Manager and the Liaison Officer in all HPSS organisations. Hazard Notices & Advice Notices are faxed in advance to Liaison Officers. Liaison Officers who have provided NIAIC with an e-mail address will also receive all warning notices by e-mail (Notices will be in Microsoft Word2000 format).

Warning notices concerning High Voltage equipment will be distributed to HPSS Trusts only (some community Trusts have indicated that they do not wish to receive such notices). This will ensure that all warning notices are relevant to the organisations concerned.

There may be occasions when the warning notice refers to a medical device, non-medical equipment, plant or building item that users do not use. When a safety related concern arises, NIAIC's priority is to alert all potential users of the particular device, equipment, plant or building item. NIAIC therefore targets the whole HPSS. In the interests of patient, staff and client safety it is vital that each warning notice received is checked and acted upon as necessary.

Organisations should:

- identify a fax number and e-mail address for the primary receipt of Hazard Notices and Advice Notices;
- arrange for someone to deputise in the Liaison Officer's absence;
- distribute Hazard Notices and Advice Notices immediately. Safety Notices could take a less immediate route depending on the subject and the local situation;
- ensure that each Hazard Notice, Advice Notice and Safety Notice is distributed individually. Do not accumulate and staple warning notices together;
- target Hazard Notices, Advice Notices and Safety Notices to the appropriate recipient

- identified on each notice and is brought to the attention of all who need to know or be aware of it in accordance with local procedures;
- establish control procedures to record action taken following the receipt of Hazard Notices, Advice Notice and Safety Notices indicating to whom they have been sent;
 - maintain records to show (for example):
 1. date issued;
 2. signed assurance from recipient that required action has been taken (for example - appropriate staff have been made aware of the Notice);
 3. general comments to assist equipment knowledge (for example: “Not relevant for this Unit - this type of equipment not used here”);
 - establish follow up procedures to ensure that returns are received;
 - develop procedures to ensure that new staff are made aware of recent Hazard Notices, Advice Notices and Safety Notices (for example: establish the procedure in codes of practice wherever possible; set up a folder of Hazard Notices, Advice Notices and Safety Notices for all unit staff to see).

Dissemination of NIAIC Device Bulletins and Evaluation Reports

Device Bulletins are issued when guidance and information is needed over an extended area, for example, decontaminating endoscopes. They deal effectively with problems which keep recurring and which can be solved by good training and practice, rather than by modifying or withdrawing a particular product. It is vital that they are issued to all staff with responsibility for training, staff responsible for setting organisational policies for equipment management and any other relevant staff. Similarly, Evaluation Reports, Disability Equipment Assessments and Pressure Sore Prevention Reports should be made available to staff responsible for equipment purchasing in these specific areas.

ANNEX D

DEFECTIVE OR CONTAMINATED ITEMS AND EVIDENCE

Defective Items

Defective items should not be repaired (either in-house or by a third party), returned to the manufacturer/supplier or discarded before an investigation has been carried out. The manufacturer or supplier should be informed promptly, and allowed to inspect the items if accompanied by an appropriate person. To facilitate an investigation, it may be possible to provide the manufacturer with a sample(s) of unused stock from a large batch. However, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident if this would prejudice NIAIC investigations, or those of other official bodies.

If medical devices or other equipment are required to be kept in use, where possible remove defective parts so that the equipment may be repaired for re-use. Any parts so removed must be quarantined and securely stored pending investigation. NIAIC's advice should be sought and, in all cases, the defective parts should be clearly identified and kept secure. If it is not possible to remove defective parts or withdraw the machine from use, staff should be made aware of the need for increased vigilance and extra caution during use (see Evidence below).

Contaminated Items

Advice on procedures to be followed if healthcare equipment is contaminated and constitutes a biohazard is contained in PEL(94)34 and SAN(NI) 95/24. NIAIC can provide advice where necessary, particularly on whether arrangements should be made for the item to be examined prior to any decontamination.

Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. NIAIC and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST

Evidence

All material evidence should be labelled and kept secure under the charge of a responsible officer. This includes the products themselves and, where appropriate, packaging material or other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

ANNEX E

INVESTIGATION OF ADVERSE INCIDENTS

INITIAL ACTION

When a report is received by NIAIC:

- It is logged on to the NIAIC database;
- an acknowledgement is sent to the reporter; and
- senior management are alerted if a fatality is involved
- MDA are contacted to determine if similar incidents have been reported

The report is passed to one of NIAIC Investigation Officers to review the report and decide on the most appropriate method of investigation.

INVESTIGATION

In the course of an investigation, staff may:

- talk with the user and manufacturer;
- visit the site of the incident when necessary;
- review evidence; and
- if appropriate, issue safety advice to the HPSS.
- notify the Medical Devices Agency of investigation outcomes for incidents involving medical devices and NHS Estates for incidents involving non-medical equipment, plant and buildings.

LEGAL RESPONSIBILITIES OF MEDICAL DEVICE MANUFACTURERS

As a result of UK Medical Device Regulations implementing the EC Medical Devices Directives concerning medical devices, manufacturers of medical devices are required by law to report to the UK Competent Authority (Medical Devices Agency) certain incidents involving their products. This system is known as the ‘Vigilance System’ and it covers incidents which have led to, or which might have led to, death or serious deterioration in health and/or product recall.

When an incident is reported to NIAIC, the manufacturer is provided with information about the incident, where it occurred and the device involved. **The manufacturer takes responsibility for resolving the incident** but NIAIC monitors progress and reviews the manufacturer’s response. If an adverse incident involved death or serious injury, or the potential to do so is high, NIAIC may ask MDA to take the lead on the investigation due to their responsibility as the UK Competent Authority.

An investigation is re-appraised if new information comes to light. Outcomes of investigations are reviewed in order to identify patterns or clusters of incidents, which may require possible further investigation.

NIAIC REPORT

On investigation completion, NIAIC investigation officers will review the information available and provide the reporter of the incident with a report.

TYPES OF WARNING NOTICE ISSUED

Where necessary, NIAIC will issue advice in the form of warning notices. The criteria for the various warning notices, in broad terms, are as follows:

Hazard Notices are issued: -

- in cases of **actual** death or serious injury, or when death or serious injury **would have occurred**, but for fortuitous circumstances or the timely intervention of health care staff or a carer, and
- where the medical device, non-medical equipment, plant or building item is **clearly** implicated, and
- where **immediate** action is necessary to **prevent** recurrence.

Advice Notices are issued: -

- in cases where there is the **potential** for death or serious injury, or there **may be implications arising from long term use**, and
- where the medical device, non-medical equipment, plant or building item is **likely** to be implicated, and
- where the recipient is expected to take **immediate** action on the advice.

Safety Notices are used to recommend or inform: -

- where **action** by the recipient will **improve** safety,
- where it is necessary to **repeat** warnings on long standing problems,
- to **support or follow up** manufacturers' field modifications.

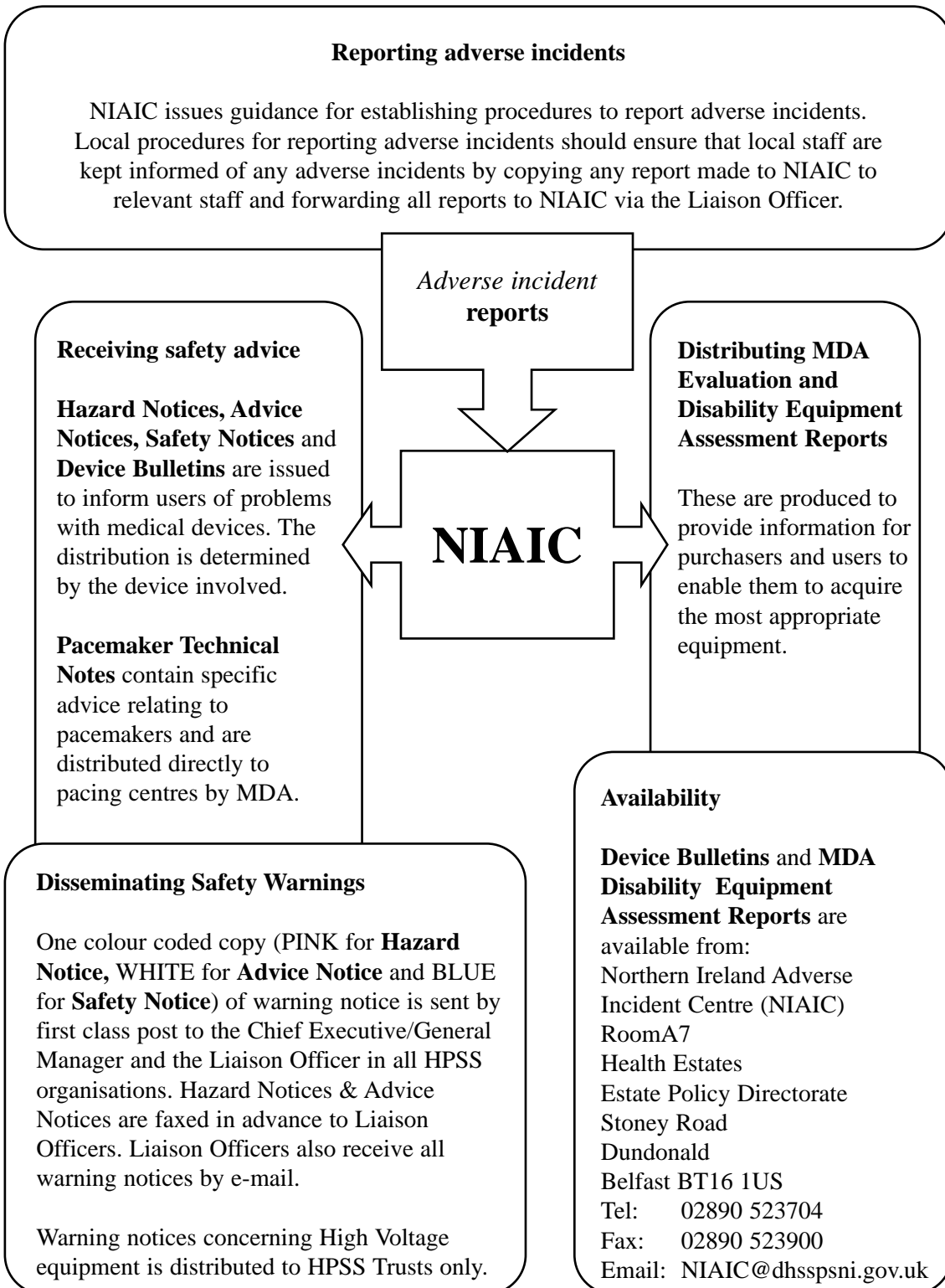
Professional Officer Letters are issued: -

- by the Chief Officer in any of the professional disciplines, e.g. Medical, Nursing, Pharmaceutical, Dental, etc. They are normally used when **improper use or misuse of equipment has contributed to an occurrence**.

Please note that Hazard Notices and Advice Notices specify immediate actions and it is extremely important that all personnel are instructed in the proper procedures for dealing with safety information and reporting of adverse incidents.

APPENDIX 3. ROLE OF NIAIC LIAISON OFFICERS

Guidance on reporting adverse incidents and the role of NIAIC Liaison Officers is given in SN(NI) 2001/01



DISTRIBUTION

This Device Bulletin should be brought to the attention of general medical practitioners, community healthcare workers, general dental practitioners, podiatrists, practice nurses, dental nurses, operating theatre staff, infection control teams, risk managers and environmental health officers.

TECHNICAL ENQUIRIES

Enquiries regarding the content of this Device Bulletin should be addressed to:

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FURTHER COPIES

Further copies of this Device Bulletin are free to Health and Social Care providers and may be obtained on written request from:

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Health Estates

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