

Chief Executive  
Health and Social Services Boards  
Chief Executive  
Health and Social Services Trusts  
General Manager  
Central Services Agency  
Chief Executive  
Regional Medical Physics Agency  
Chief Executive  
Northern Ireland Blood Transfusion Service  
General Medical Practitioners  
General Dental Practitioners  
Community Pharmacists  
Optometrists

Our Ref: PEL (03) 01

Date: 17 January 2003

Dear Sir/Madam

**NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC):  
SAFETY COMMUNICATION WITH THE HPSS AND WIDER HEALTH  
AND SOCIAL CARE COMMUNITY**

**Summary:**

The Northern Ireland Adverse Incident Centre (NIAIC), part of Health Estates, currently investigates over 200 reported adverse incidents involving medical devices, non-medical equipment, plant and building items used in HPSS organisations and the wider health and social care community in Northern Ireland. We work closely with the Medical Devices Agency (MDA) who co-ordinate a UK wide system for issuing of safety advice to the Health Service. In addition, we also work closely with NHS Estates for safety issues connected with estate systems.

The Medical Devices Agency has decided, following consultation with the Committee on the Safety of Devices (CSD), medical device manufacturers and the NHS in England, to revise the format of their safety advice effective from January 2003. Their intended aim is to get the safety message across to readers more effectively.

We are now consulting with the HPSS and wider health and social care community on proposed changes to the format of all NIAIC warning notices, in an attempt to address the need for clarity and simplicity.

We would value comments from anyone who works with these notices - a simple feedback form is attached, should you wish to use it, which can be returned to us by post or by e-mail

(EAdmin@dhsspsni.gov.uk). The reasons in support of this consultation along with examples of the proposed new formats are attached with this letter.

**Action:**

- **Each HPSS organisation should consult with staff to allow an organisational response as necessary using the consultation response form attached. Responses from individual practitioners would also be welcome.**
- **We would particularly welcome views from General Medical Practitioners, General Dental Practitioners, Optometrists, Community Pharmacists and Independent Health and Social Care provider organisations.**
- **Completed questionnaires should be returned or e-mailed to the address provided by 20 February 2003.**

**For Onward Distribution:**

This letter 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:

- Risk Managers
- Health & Safety Officers/Advisors
- Medical Directors
- Clinical Directors
- Executive Social Work Directors
- HSS Trust Pharmacy Managers
- Nursing Directors
- All Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Allied Health Professionals
- Social Care Staff
- Estates Managers
- HV Authorised Persons
- Trust Service Commissioning Managers
- Independent Health and Social Care Providers
- Children's Homes
- Day Care Centres
- Practice Nurses
- Community Nurses
- Practice Managers
- GP Registrars
- Directors of Public Health
- Clinical and Social Care Governance Leads
- Chairs of Local Health and Social Care Groups (LHSCGs).
- Community Care Staff

**Consultation Response:**

Please return your completed organisations response by **20 February 2003** to:

EP Administration  
Estates Policy Directorate  
Health Estates  
Stoney Road  
Belfast  
BT16 1US

Or by e-mail to EAdmin@dhsspsni.gov.uk

Should you require any further information concerning this letter, please contact;

Mr Brian Godfrey  
Manager  
NIAIC  
Room E14  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald, BT16 1US  
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E-mail: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

Yours faithfully

**S Blayney**  
**Director**

## **WHY ARE WE PROPOSING A CHANGE?**

- The aim is to get the safety message across to readers more effectively.
- Address the need for clarity and simplicity.
- Base the safety message on the concept of urgency rather than the level of risk

## **BACKGROUND ON THE EXISTING WARNING NOTICES LEVELS:**

The existing warning notices in order of level of risk as issued by NIAIC, MDA and NHS Estates are as follows:

<b>NIAIC Warning Notice Levels</b>	<b>MDA Warning Notice Levels</b>
NIAIC Hazard Notice	MDA Hazard Notice
NIAIC Advice Notice	MDA Device Alert
NIAIC Safety Notice	MDA Safety Notice
No NIAIC equivalent of PTNs – these are issued directly by MDA to pacing centres in NI.	Pacemaker Technical Note (PTN)
	<b>NHS Estates Warning Notice Levels</b>
NIAIC HV (High Voltage) Hazard Notice	NHS Estates Hazard Notice
NIAIC HV (High Voltage) Safety Notice	NHS Estates Safety Notice
NIAIC HV DIN (Dangerous Incident Notification) - issued by Health Estates HV Authorising Engineer	No NHS Estates equivalent

**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 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 (Device Alerts\*)** 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.

\*This level of notice was introduced because of a legal challenge brought against MDA by a manufacturer (see Medical Device/Equipment Alert below).

**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.

### **PROPOSED NEW FORMATS FOR NORTHERN IRELAND:**

The Committee of the Safety of Devices (CSD) recommended that MDA could merge their four levels of notice together and **base the resultant warning notice on the concept of urgency rather than the level of risk**. MDA have decided on the title "Medical Device Alert" with a highlighted check box indicating the level of urgency. This allows for clarity, as the meaning of the different levels of warning notice was not fully understood which meant that the relative urgency of these notices could have been lost.

The MDA title gives us some problems as our current warning notice format allows us to cover estates issues in addition to medical devices. We are therefore taking this opportunity to review all types of warning notice that we issue, including those involving estates issues.

The view of the CSD was that there was too much information on the front page of the MDA warning notices. In addition, the current formats did not immediately indicate to whom the notice is specifically targeted for action and there was no immediate indication as to who is at risk: the patient/client or the user.

The new format addresses this problem by providing a summary on the front page and expanding this on page 2/3 of the notice.

### **FRONT PAGE SUMMARY:**

The front page of the Alert shows clearly:

<b>Reference on front Page</b>	<b>Contents</b>
Title of Alert	The Nature of the Alert: Medical Device/Equipment Alert or High Voltage Alert
Urgency Check Box	The urgency of the Alert;
Section 1	The device/estates system involved;
Section 2	A summary of the problem
Section 3	Specific target groups for action
Section 4	The action required
Section 5	Distribution by NIAIC
Section 6	Details of Contacts
Section 7	Any feedback requirements

## **Title of Alert:**

**Medical Device/Equipment ALERT (example provided at Annex A)** – This would be based on the MDA Alerts and allows us to co-ordinate our medical device related safety information with MDA guidance. As the vast majority of the warning notices that we issue each year are based on MDA notices, the introduction of a specific medical device/equipment alert gives us an opportunity to give increased attention to this area of safety. We have therefore retained part of the MDA title as this allows us to quickly issue the safety information by avoiding the necessity for local legal clearance. If we had included “Safety” or “Hazard” in the title, we introduce a possible legal problem as medical device manufacturers have brought legal challenges against MDA in the past concerning publishing Hazard and Safety Notices. This is because the safety risks with the device involved an acknowledged degree of uncertainty and the manufacturers considered that the MDA action could be damaging to them in terms of company reputation and trading status.

By including equipment in the title, this also allows us to capture safety issues outside the medical device area such as estates systems in one single form of notice.

**High Voltage ALERT (example provided at Annex B - this is only for HSS Trusts that have HV electrical equipment)** – We currently issue High Voltage Hazard and Safety Notices to those HSS Trusts that have High Voltage electrical distribution equipment installed. The Health Estates High Voltage Authorising Engineer also issues Dangerous Incident Notifications (DINs) to identified Trust staff. We are now taking the opportunity to combine these into a single form of notice **that will be issued by the Health Estates High Voltage Authorising Engineer.**

The way that information is presented in this Alert mainly follows the format of the Medical Device/Equipment Alert, although we will attempt, when possible, to contain the information on one page only. Therefore, when reading the descriptions for the section outlines below, please allow for the slight variations between each type of Alert.

## **Urgency designation check box:**

There is a check box on the front page that indicates the level of urgency that fall into four categories. These are:

- **Immediate Action**  
Used 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 staff or a carer;
  - And where the medical device, non-medical equipment, plant or building item is or likely to be implicated,
  - And where the recipient is expected to take immediate action on the advice.

- **Action**  
Used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems, or to support or follow-up manufacturers field modifications.
- **Update**  
Used when we wish to update the recipient about previously reported incidents or series of incidents, possibly on a topical or device/estates basis, and where further follow-up safety information is judged to be beneficial.
- **Information Request**  
Used to alert recipients about a specific issue that may become a problem and where we are requesting feedback. They may contain a form and/or a specific e-mail or website address for ease of returning information.

### **Section 1 – Device/Equipment:**

This would give a high level, short description of the medical device or equipment involved e.g. Infusion Pump Type XYZ.

### **Section 2 –Problem**

A short summary in 1 to 2 sentences at most.

### **Section 3 – Action By**

This would be specific or generic depending on the nature of the device/equipment i.e. individual clinician e.g. cardiologists, an area in a hospital e.g. operating theatres, or users of a particular device e.g. users of infusion pumps.

### **Section 4 - Action**

This provides a short summary of the action to be taken in 1 or 2 sentences if possible.

### **Section 5 – Distribution by NIAIC to**

The main recipients that NIAIC distribute to, e.g. HSS Trust Chief Executives, GPs etc. A list of intended recipients for onward distribution by the main recipients is listed on page 2.

### **Section 6 - Contacts**

Direction to the contacts section in the body of the Alert where manufacturer or NIAIC contact details can be found.

### **Section 7 - Feedback**

Indicates if feedback is necessary.

## **PAGE 2 CONTENTS:**

Page 2/3 will expand upon the summary information contained on the front page, including an onward distribution list of appropriate recipients. We would welcome feedback on the on whether or not the list of intended recipients is sufficiently comprehensive for your organisational needs.

### **PROPOSED NIAIC DISTRIBUTION OF ALERTS**

To ensure that Alerts are available to recipients as quickly as possible, it is proposed that all Alerts will be e-mailed to HPSS Chief Executives and NIAIC liaison officers in parallel with the normal hard copy distribution by first class post. We do not intend to retain the current warning notice colour coding system (PINK for Hazard Notice, WHITE for Advice Notice and BLUE for Safety Notice) due to merging the existing levels of notice together as an Alert and changing the concept from level of risk to level of urgency. In addition, the availability of Alerts on the NIAIC website negates the colour coding system. However, should you consider that the colour coding system should remain in some form, please respond accordingly on the response form.

In addition to the proposed distribution outlined above, **for High Voltage Alerts only**, it is proposed that these will be e-mailed to identified estates staff in each HSS Trust as outlined in PEL(02) 06. As information contained in High Voltage Alerts is classified as “Commercial in Confidence”, High Voltage Alerts will not be published on the Health Estates website.