

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
NIAIC Liaison Officers

Our Ref: PEL (03) 08

Date: 27 March 2003

Dear Sir/Madam

INTRODUCTION OF MEDICAL DEVICE/EQUIPMENT ALERTS AND HIGH VOLTAGE ALERTS

Summary:

Following consultation with the customer and stakeholders of the Northern Ireland Adverse Incident Centre (NIAIC) about revising the format of our safety advice as outlined in Professional Estates Letter PEL (03) 03, **we are introducing from 2 April 2003 the following Alerts that replace Hazard Notices, Advice Notices, Safety Notices and DINs:**

- Medical Device/Equipment Alert
- HV Alert (Applicable to specific HSS Trusts only)

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 | • Independent Health and Social Care Providers |
| • Health & Safety Officers/Advisors | • Children's Homes |
| • Medical Directors | • Day Care Centres |
| • Clinical Directors | • Practice Nurses |
| • Executive Social Work Directors | • Community Nurses |
| • HSS Trust Pharmacy Managers | • Practice 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
- GP Registrars
- Directors of Public Health
- Clinical and Social Care Governance Leads
- Chairs of Local Health and Social Care Groups (LHSCGs).
- Community Care Staff

Why Are We Introducing this Change?

- 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

The New Alert Format:

Front Page Summary: The front page of the Alert shows:-

Reference on front Page	Contents
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

Medical Device/Equipment ALERT: This Alert will give safety advice concerning medical devices, non-medical equipment, buildings and plant.

High Voltage ALERT (only for HSS Trusts that have HV electrical equipment). The Health Estates High Voltage Authorising Engineer will issue this Alert. 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.

NIAIC Distribution Of Alerts

Medical Device/Equipment Alert: To ensure that Alerts are available to recipients as quickly as possible, 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. The Alerts will not be colour coded.

High Voltage Alerts: These will be e-mailed to HPSS Chief Executives, NIAIC liaison officers and identified estates staff in each HSS Trust as outlined in PEL (02) 06 in parallel with the normal hard copy distribution by first class post.

What Should Be Done When A NIAIC Alert is received?

Onward distribution guidance for HPSS bodies, independent contractors and independent health and social care providers is provided in Safety Notice SN (NI) 2003/01 available on the NIAIC website at <http://www.dhsspsni.gov.uk/niaic>.

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

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Yours faithfully

S Blayney
Director