



Department of

**Health, Social Services  
and Public Safety**

An Roinn

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

[www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

To: Chief Executives of  
Health & Social Care Trusts

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Chief Executives of:

Our Ref: PEL(07)05

Health and Social Services Boards  
Central Services Agency  
Special Agencies  
Regulation, Quality and Improvement Authority

Date: 30 May 2007

Dear Colleague

## **FIELD SERVICE NOTICES**

It has been brought to my attention that there is confusion, across Northern Ireland, regarding the publishing and action required for Field Safety Notices (FSNs) and Field Safety Corrective Action documents (FSCAs). Under the terms of the European Medical Devices Directive, the manufacturer has a legal responsibility to issue a FSN or a FSCA where death or serious injury may occur as a result of a failure in their equipment.

FSN/FSCAs (sometimes called Dear Doctor Letters or Advisory Notices) take the form of a letter sent directly to known customers. The manufacturer/supplier will inform users of the potential problem with the medical devices and the appropriate action to be taken and they are also required to send a copy to the Competent Authority (the MHRA in the UK) who record and monitor the action taken by the manufacturer. Should the MHRA deem that the response to a FSN/FSCA has not been effective in resolving the particular problem, they can request the manufacturer to take further action or they can decide to reinforce the message by publishing a MHRA Medical Device Alert (mirrored in Northern Ireland by an equivalent Medical Device/Equipment Alert).

Within Trusts the end user should be made aware of the potential issues highlighted in the FSN/FSCAs and be instructed on the appropriate action. Trusts should not wait for further guidance from NIAIC, but should proceed with the guidance given by the manufacturer or supplier. Trusts should inform NIAIC of any operational issues which result from the implementation of the manufacturers' guidance given in the FSN/FSCA. At present the NIAIC does not plan to monitor or distribute FSN/FSCAs and will only take local action as the need arises.

The MHRA has set up a section on their website to record the progress on each FSN/FSCA issued by a manufacturer. While all Trusts should receive, directly from the manufacturer, a copy of each FSN/FSCA which is applicable to them, an individual Trust can choose to sign up to a service from the MHRA, to receive copies of all FSN/FSCAs on the MHRA website at:

[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodId=340](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodId=340)

Trusts should however note that currently there are approximately 400-500 FSN/FSCAs issued annually.

In many cases the contact point for manufacturers and suppliers within a Trust may not be the Medical Device Coordinator and therefore it is essential to ensure all staff are aware that **FSN/FSCAs must be forwarded to the Medical Device Coordinator** who will be responsible for monitoring action within the Trust.

### **Further Distribution**

It is recommended that this document should be made immediately available to Medical Directors, Nursing Directors, Estates and Facilities Directors, Medical Device Coordinators, Infection Control Teams, Microbiologists, Haematology Units, Oncology Units and to Directors of Public Health, CCDCs and Private Hospitals

Any queries concerning this letter should also be addressed to Mr R Sergeant (028 9052 3744).

Yours sincerely

A handwritten signature in black ink, appearing to read 'John Cole', with a long horizontal stroke extending to the right.

**JOHN COLE**  
Chief Executive