

**FROM THE CHIEF EXECUTIVE
HEALTH ESTATES
Mr John Cole**



Department of
**Health, Social Services
and Public Safety**

An Roinn

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

www.dhsspsni.gov.uk

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Health and Social Services Trusts
For Information: Chief Executives
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Dear Sir/Madam

STRENGTHENING ASSURANCE OF HSS TRUST COMPLIANCE WITH NIAIC MEDICAL DEVICE/EQUIPMENT ALERTS

Summary

The purpose of this letter is to alert you to the introduction of an assurance mechanism for HSS compliance with safety guidance issued by Health Estates. This will initially cover "Immediate Action" designated Medical Device/Equipment Alerts (MDEAs) issued by NIAIC.

HSS Trusts will be required to provide acknowledgment that MDEAs have been received and provide confirmation to Health Estates that the actions recommended in the MDEAs have been implemented. Target timescales for HSS Trust action will be included on specific MDEA and Trusts will be required to acknowledge receipt of the MDEA and indicate when action is completed.

Information is also provided on the proposed NI Safety Alert Broadcast System project being taken forward by Health Estates.

Background

Don Hill recently brought to your attention a framework for discharging the respective accountability roles and responsibilities of the DHSSPS Principal Accounting Officer, the Health Estates Chief Executive and HSS Accountable Officers across a range of functions and services presently undertaken and provided by Health Estates. The framework was produced following Internal Audit recommendations that management should ensure that clear accountability boundaries are established between the Department, HE and HSS Trusts, and that explicit roles and responsibilities are assigned to ensure compliance, as appropriate, with the advice, standards and guidance issued by Health Estates. As Health Estates Chief

Executive, I am also responsible for providing assurance to the DHSSPS Principal Accounting Officer on the level of compliance by HSS Trusts with the standards, guidance and advice issued by Health Estates.

In regard to HSS Trust compliance with the safety guidance contained in Medical Device and Equipment Alerts (MDEAs) issued by the Health Estates Northern Ireland Adverse Incident Centre (NIAIC), HSS Accountable Officers are responsible for ensuring that these are appropriately assessed, communicated and actioned. We currently gain limited assurance that HSS Trusts are in compliance with the guidance through a limited feedback mechanism that is integral to the MDEA distribution system. This currently allows Trusts to confirm completion of the action required in a limited number of "Immediate Action" designated MDEAs.

NI Safety Alert Broadcast System Project

Following the establishment of the accountability framework, there is now a need to strengthen the current assurance mechanism to allow me to provide a greater degree of assurance to the DHSSPS Principal Accounting Officer that will cover the range of safety guidance issued by Health Estates.

We are currently taking forward the development of a suitable system that will enable us to work in partnership with HSS Trusts to achieve this efficiently and effectively at a local level. Such a system is the Safety Alert Broadcast System (SABS) as used in England. This is an electronic web-based system used for the distribution of National Patient Safety Agency (NPSA) Alerts, Medicines and Healthcare products Regulatory Agency (MHRA) Medical Device Alerts and Estates & Facilities Alerts to NHS trusts in England. Before the introduction of SABS, these organisations issued alerts by a number of different methods and had a number of methods in place to gain feedback on whether they have been implemented, some of which were ad hoc in response to specific concerns.

The purpose of the NI Safety Alert Broadcast System project is to eventually allow different types of alert to be brought together into one electronic system and improve the way in which they are issued to the HPSS. The aim is also to improve the DHSSPS and HSS Trusts own systems for assuring that they have been received and implemented. This should minimise the administrative burden for all concerned, while collecting information which is useful to Trusts (for example, in demonstrating they can meet controls assurance risk management standards) and to clinical governance leads HSS Trusts and eventually the Health and Social Services Authority.

It incorporates a feedback mechanism to record action taken by trusts following the receipt of alerts. Target timescales for Trust action are included on the specific alert, and Trusts are required to acknowledge receipt of the alert and indicate when action is completed.

Interim Assurance Arrangements

Until we have such a comprehensive system established in Northern Ireland, Health Estates will be introducing with immediate effect an interim assurance mechanism that will cover initially those "Immediate Action" designated MDEAs issued by NIAIC that are assessed as requiring a higher level of assurance of HSS organisation

compliance. This will be kept under review, as there may be other MDEAs with levels of alert urgency designation that may also require an increased level of assurance to be obtained.

I would therefore encourage you to ensure that your present operational arrangements have a robust procedure for the effective risk assessment, distribution, action and confirmation that action has been taken of NIAIC MDEAs and other safety related guidance. It is appropriate that staff integral to your organisational risk management structure should manage this and should have clear lines of accountability that can satisfy your governance responsibilities.

When a MDEA is received, the NIAIC Liaison Officer should:

1. Acknowledge receipt of the MDEA by return e-mail to NIAIC;
2. Determine whether the MDEA is relevant to their organisation and undertake an appropriate risk assessment;
3. Distribute it to the appropriate people in the organisation who will need to be aware of the contents of the notice for action or for information. It is important, therefore, that your distribution procedure should be suitably robust to ensure that those individuals who have been sent copies or details of any MDEA containing specific action points take the necessary action. The procedure should include a follow-up to ensure that any actions have been implemented;
4. Provide feedback to NIAIC via e-mail when action is in hand to implement the actions contained in the MDEA or to record that the MDEA is not relevant to the organisation;
5. Provide feedback to NIAIC if the organisation is going to delay implementation of the actions contained in the MDEA and record such outcomes in the organisational risk register;
6. Provide feedback to NIAIC when action has been completed by the organisation to implement the actions contained in the MDEA;

In addition to feedback requirements being included on specific MDEAs, the issuing e-mail to NIAIC Liaison Officers will also provide additional notification that feedback is required.

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

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Yours faithfully

John Cole
Chief Executive