

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/10

Issued: 30 May 2003

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section								
Medical Device/Equipment: Medical gas regulators and flowmeters	▶ ①								
Problem: Risk of rupture, ignition or inadequate therapy.	▶ ②								
Action by: Estates Directors, Estates Managers, Directors of Facilities, Staff responsible for servicing and replacement of gas regulators and flowmeters.	▶ ③								
Action: Ensure a system is in place for the regular inspection and replacement of gas regulators and flowmeters in line with manufacturers' instructions.	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>General Dental Practitioners</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Community Pharmacists</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td>Hospices</td> </tr> </table> For onward distribution see Section 5	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	General Dental Practitioners	Chief Executive of each Agency	Community Pharmacists	NIAIC Liaison Officers	Hospices	▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
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NIAIC Liaison Officers	Hospices								
Contacts NIAIC contact details	▶ ⑥								
Feedback Requirements to NIAIC None.	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Pressure regulators and flow meters for use with gas cylinders or the wall outlets of medical gas pipeline systems. This Notice does **not** apply to pressure regulators or flow meters built in, or permanently attached, to other medical devices and serviced with these devices, e.g. anaesthetic machines, ventilators, insufflators, certain laboratory equipment and gas cylinders with integrated regulators.

2. PROBLEM:

NIAIC has been informed that the MHRA has received a number of incident reports involving the rupture and ignition, or gross inaccuracy, of pressure regulators and flow meters that have not been appropriately serviced as recommended by the manufacturer. Poor servicing by a third party agent contributed to a further incident of regulator ignition.

Pressure regulators and flow meters that are built in, or permanently attached, to other medical devices are not always covered by the servicing arrangements for these devices.

This Alert is intended to supplement advice given in Hazard Notice HN(NI)2003/05 "Medical Gas Hoses for Oxygen" and Safety Notice SAN (NI) 2000/15 "Medical Gas Cylinders: Risk of Fire".

3. ACTION BY:

Estates Directors, Estates Managers, Directors of Facilities and Staff responsible for servicing and replacement of gas regulators and flowmeters.

4. ACTION:

- Ensure that medical devices are inspected regularly and serviced according to the manufacturers' instructions/service manuals.
- Ensure that devices have a unique inventory marking to ensure traceability for future servicing.
- If there is any doubt over the service history then ensure that these devices are serviced immediately.
- Ensure that devices on loan or rented are exchanged by the service provider on a regular basis.
- If servicing is to be undertaken by third party agents ensure that this is in line with recommendations outlined in Device Bulletin DB 2000/2 (NI) "Medical Devices and Equipment Management: Repair and Maintenance Provision".
- Ensure that older gas regulators without instructions for servicing, or where spare parts are no longer available, are replaced.
- Ensure that pressure regulators or flow meters that are built in, or permanently attached, to other medical devices are appropriately serviced with those devices.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Device/Equipment Co-ordinators
- Directors of Anaesthetics
- Medical Directors
- Nursing Directors
- Ambulance Staff and Paramedics
- Trust Pharmacy Managers
- Respiratory care nurse specialists
- Practice Nurses
- Practice Managers
- Community Care Staff
- Independent Health and Social Care Providers including residential, nursing homes and private clinics
- Medical Clinical Engineering

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/10 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3714

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2003/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

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