



Safety Action Notice Policy

Distribution, implementation and monitoring of safety action notices

Lead Manager	Head of Health and Safety
Responsible Director	Director of Human Resources and Organisational Development
Approved By	Health and Safety Forum
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1.0 Introduction

- 1.1 NHS Greater Glasgow and Clyde will take all reasonable steps to minimise any risk that patients, staff and other persons may be exposed to as a result of the organisation's undertakings.
- 1.2 This policy sets out the guiding principles to promote patient and staff safety where information identifying potential risk is received by NHS Greater Glasgow and Clyde from external bodies or agencies, and information regarding potential risk is identified from within the organisation and shared with the wider NHS Scotland.
- 1.3 The most common types of alerts and notices include:
 - Health Facilities Scotland (HFS)
 - **Medical device alerts:** important safety advice on patient related equipment
 - **Estates and Facilities Alerts:** important safety advice on estates and facilities equipment
 - **Device Bulletins:** guidance and information on specific medical devices
 - **Field Safety Notices:** alerts issued by manufacturers of medical devices regarding a safety related issue
 - **Hazard notifications:** important and urgent safety advice on equipment
 - NHS Greater Glasgow and Clyde
 - Internal safety action notices following personal knowledge or experience
 - Notices received independently by individual members of staff for further distribution.

For the purpose of this policy, all such documents will be referred to as **safety action notices**.

- 1.4 The principles and processes set out within this policy are in keeping with Chief Executives Letter CEL 43 (2009) *Safety of Health, Social Care, Estates and Facilities Equipment*. In particular the **Nominated Equipment Controller** for NHSGGC is the **Head of Health and Safety**, or nominated Deputy during periods of absence.
- 1.5 Directors are responsible for Health and Safety within their area of responsibility and this includes ensuring procedures are in place for responding to safety action notices. Support will be provided as detailed in this Policy through specialist advisors.
- 1.6 Directors are responsible for the development and maintenance of distribution lists as detailed in this Policy, and ensuring appropriate action is taken on receipt of safety action notices.
- 1.7 In exceptional circumstances where the SAN only refers to equipment or activities related to a specific single service then only that service will receive notification. E.g. Central Decontamination Unit.

2.0 The scope of the policy

- 2.1 This policy and supporting procedures applies to all employees working within all areas of NHS Greater Glasgow and Clyde.
- 2.2 Procedures will be established to ensure primary care contractors receive copies of safety action notices for information. Responsibility for action lies with the contractors and will not form part of the monitoring arrangements in this Policy.
- 2.3 Procedures will be developed within the Facilities Directorate to ensure Providers and Maintenance Contractors for PFI facilities will receive links to relevant notices. Responsibility for action will remain with the parties concerned and will not form part of the monitoring of this policy, though may be part of the established monitoring arrangements between NHS GGC and the PFI providers.

3.0 Safety action notice principles: external information

This refers to safety information coming into the organisation, for example from Health Facilities Scotland.

- 3.1 NHS Greater Glasgow and Clyde has a duty to disseminate safety action notice information throughout the organisation and to ensure that appropriate action is taken in order to minimise risk to staff and patients. This is shown in the flowchart of the process - **see appendix one**.
- 3.2 The Director responsible for Health and Safety, the Director of HR, will ensure a suitable Policy and procedure is in place. The responsibilities of the Director responsible for Health and Safety are detailed in **appendix two**.
- 3.3 The central distribution and return point (CDRP) will email an alert regarding the safety action notices to the agreed distribution lists including the nominated contacts. The actual Notice will be posted on StaffNet for viewing and /or printing. The responsibilities of the CDRP are detailed in **appendix three**. The responsibilities of nominated contacts are detailed in **appendix four**.
- 3.4 Technical and specialist managers will support the process by providing guidance and instruction. This information will be e-mailed directly to nominated contacts and will also be published on StaffNet. The responsibilities of the technical and specialist managers are detailed in **appendix five**.
- 3.5 Depending on the nature and content of the notice, a co-ordinated approach may be required to provide advice and appropriate documentation, such as risk assessments, throughout the organisation. In this situation, the Head of Health and Safety will inform responsible managers and will arrange a meeting of the relevant technical and specialist managers, in order to provide a co-ordinated and integrated response to notices.
- 3.6 Staff on the agreed distribution lists will receive copies of all safety action notices and will play a key role in ensuring appropriate dissemination of safety action notices and the action to be taken. Where the nominated contact, who will coordinate the responses for their area, is unable or believes it would be inappropriate to implement certain actions, this should be recorded in the safety action notice return report form –

see appendix six. These returns are included in the final quarterly report by the Head of Health and Safety and reviewed by the NHS GGC Risk Committee.

- 3.7 All staff have a duty to read the notices they receive and implement measures introduced in response to safety action notices.
- 3.8 Any member of staff independently receiving any type of 'safety action notice', such as a manufacturer's safety sheet issued directly to the member of staff, should forward the notice to the Head of Health and Safety, and seek appropriate advice before the formal distribution process is initiated.

4.0 Safety action notice principles: internal information

This refers to information which has become known within the organisation as a result of local incidents and near misses:

- 4.1 All staff must use the organisation's incident reporting systems to report incidents or near misses (DATIX) involving:
 - Medical equipment and supplies. This includes medical devices, laboratory equipment and medical supplies and / or:
 - Estates equipment, including engineering plant, installed services, piped medical gas and gas scavenging system, buildings, building fabrics and vehicles.
- 4.2 NHS Greater Glasgow and Clyde has a duty to review incidents or near misses as described above.
- 4.2.1 Where appropriate, such incidents or near misses will be reported to the Scottish Healthcare Supplies Incident Reporting and Investigation Centre (IRIC) in the format required by Chief Executives Letter CEL 43 (2009) *Safety of Health, Social Care, Estates and Facilities Equipment*. The relevant technical and specialist managers will report to the IRIC, and will inform the Head of Health and Safety. Where appropriate, an internal safety action notice will be prepared for formal distribution and appropriate action throughout the organisation.

5.0 Storage and Retention of Safety action notices

- 5.1 All safety action notices and supporting technical guidance and instruction will be available on StaffNet.
- 5.2 A list of all safety action notices and hazard notifications is available on the Health Facilities Scotland website:
<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/>
- 5.3 The CDRP will store the original safety action notices and all responses from nominated contacts.
- 5.4 Those staff who are responsible for a specific area, such as a ward, clinic or non-clinical area, must ensure that safety action notices relating to their area are easily accessible to all staff, and that all staff are made aware of relevant notices. Where bank staff, agency staff or staff from other areas are working in a particular location,

safety action notices directly relating to patient safety, need and/or relevant equipment, must be highlighted.

- 5.5 Where appropriate it is recommended that the nominated contacts include the departmental 'medical device controllers' (see **Appendix seven** - definition), where these are currently in place. Where this is not possible a nominated lead should be appointed.

6.0 Monitoring and review

- 6.1 NHS GGC requires assurance that the duty of care is satisfied in respect of the dissemination of safety action notices, action taken and monitoring of the process. A quarterly report provided by the CDRP to the Nominated Equipment Controller (Head of Health and Safety) should show the status of safety action notices issued within the quarter. The NHS GGC Risk Committee will be regularly updated on the application of this Policy and any issues of corporate significance. The Policy will be reviewed every two years. Responsibility for reviewing the Policy lies with the Director of Human Resources.
- 6.2 The procedures will be audited every two years, and the results will be presented to the NHS GGC Risk Committee and the NHS GGC Health and Safety Forum. Responsibility for undertaking this audit lies with the Head of Health and Safety.
- 6.3 NHS GGC has a duty to conduct periodic reviews of safety action notices, regarding the ongoing implementation of measures introduced in the past. Responsibility for identifying such notices of long-term relevance lies with the NHS GGC Risk Committee.

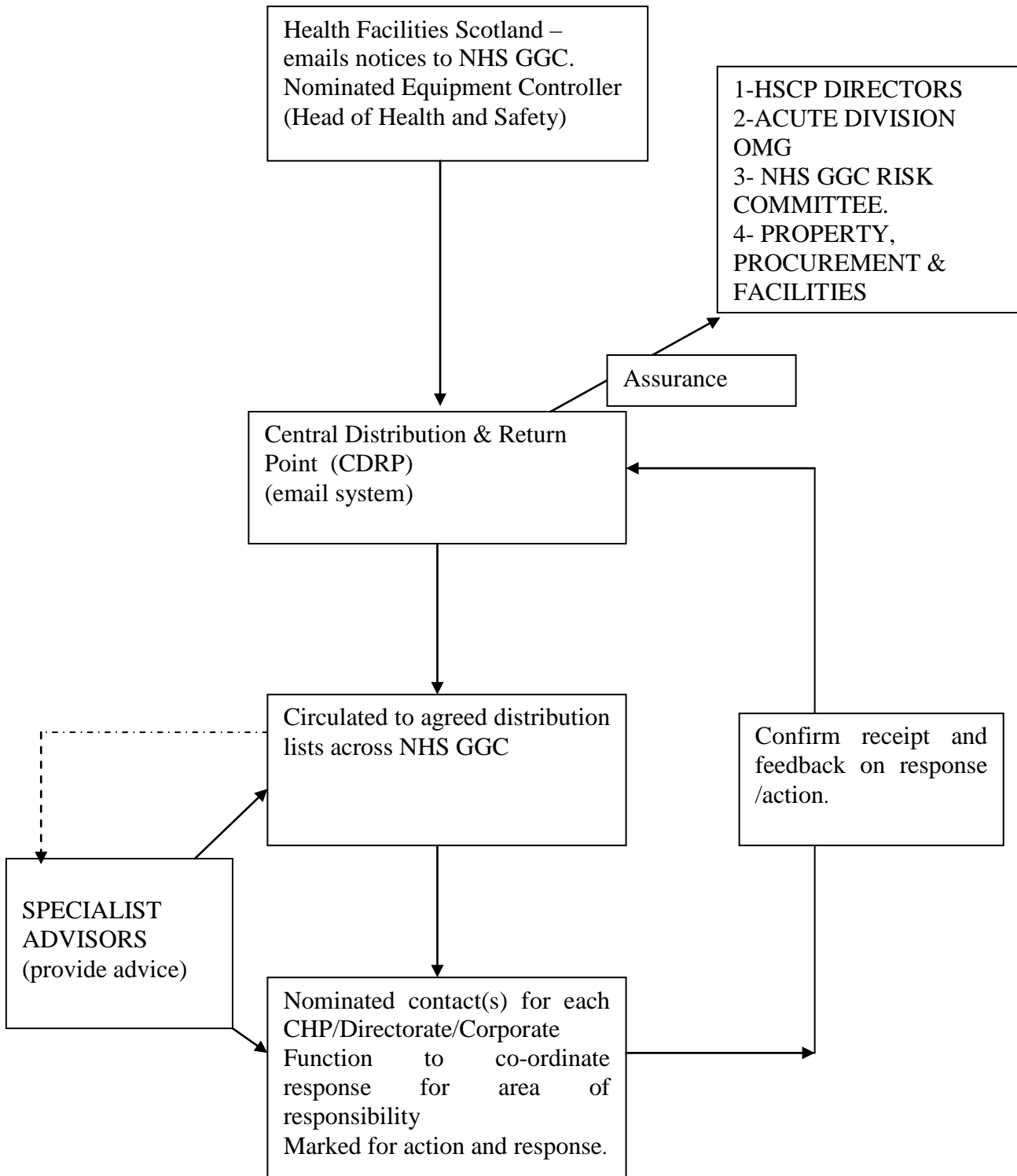
7.0 Staff awareness and training

- 7.1 Awareness of the safety action notice policy will be raised with staff during the induction process. All managers have a responsibility to inform staff, through local induction, of how and where to access the notices relevant to their area of work.
- 7.2 New starts, bank staff, locum staff and staff returning from any form of leave **must** be made aware of the safety action notices which may affect them or the patients in their care.

8.0 Bibliography

- NHS Quality Improvement Scotland: Report on alerts/notices received by NHSScotland: Meeting with NHS Boards (October 2005)
- Scottish Government Health Dept: Chief Executives Letter CEL 43 (2009) *Safety of Health, Social Care, Estates and Facilities Equipment*
- Scottish Government Health Dept: Addendum to CEL 43 Nov 2013: Extension of procedures to all contractors and private or independent service providers

Appendix 1 - SAFETY ACTION NOTICE DISTRIBUTION SYSTEM FLOWCHART



Appendix 2 Responsibilities of the Director responsible for health and safety: Director of Human Resources

To establish and maintain a system to ensure that;

On receipt of all safety action notice information, NHS GGC will have an established system, to ensure that:

Safety action notices received from Health Facilities Scotland, are forwarded to the Central Distribution and Return Point, for distribution throughout NHS Greater Glasgow and Clyde.

The system will ensure adequate procedures are in place for monitoring and support of the Policy.

The system will be designed to ensure that contingency arrangements are in place, in the event that the normal recipient is unable to receive the notices, such as any form or absence or leave.

Appendix 3 Responsibilities of the Nominated Equipment Controller and the Central Distribution and Return Point (CDRP)

The Nominated Equipment Controller will receive a copy of safety action notices directly from Health Facilities Scotland

Within two working days, the Nominated Equipment Controller will forward notification to the CDRP.

Upon receipt the CDRP will:

- Arrange for publication of the safety action notice on StaffNet.
- E-mail all agreed distribution lists recipients and technical or specialist managers, informing them of the publication of the Notice on StaffNet.
- The e-mail will advise nominated contacts of the deadline date for return, and will carry a reminder flag on the deadline date. The email will also have attached a safety action notice return report form. (Appendix six) The safety action notice return report form must be returned within 21 working days.
- Monitor acknowledgements of receipt of the safety action notices from the nominated contacts and, where no acknowledgement is received, email the recipient. Escalation for continued non-response will be through the Nominated Equipment Controller to the relevant Director.

Thereafter, the Nominated Equipment Controller will ensure the following actions will be undertaken:

- Monitor receipt of safety action notice return reports from the nominated contacts.
- Collate responses from the nominated contacts and the technical or specialist managers.
- Record results of audits undertaken in respect of specific safety action notices.
- Compile final report which will be posted on StaffNet.
- Prepare status reports for the HSCP Directors, Facilities and Corporate Services Directors and Acute Services Directors, for subsequent assurance to the NHS GGC Risk Committee and NHS GGC Health and Safety Forum

Appendix 4 Responsibilities of the nominated contacts

All Nominated Contacts have a key role in ensuring the appropriate dissemination of safety action notices and appropriate action within their areas of responsibility. They must assure the organisation of the robustness of the local procedures in place.

Nominated contacts will receive safety action notices by e-mail. This e-mail will require an acknowledgement of receipt. This will be done electronically.

Each nominated contact should have local auditable procedures for:

- Checking if the Notice is relevant to their area of responsibility
- Liaising with technical and specialist managers if required.
- Liaising with other managers within their area of responsibility to establish the status of the Notice in terms of compliance.
- Returning reports (using the Safety Action Notice Return Report (Appendix six) issued with e-mail) back to the CDRP within 21 working days of initial receipt of notice.

Safety action notice return reports must be sent by the nominated contact (unless responsibility is delegated during periods of leave) and returned to the CDRP .

Where there is a change in nominated recipient this must be alerted to the CDRP and acknowledgement of change received.

Please note that even if there is nothing to report, a 'Nothing to Report' should still be forwarded.

It is essential to the efficient function of the system that Nominated Contacts are the only persons to complete and return the Safety Action Notice Return Report (appendix 6). When disseminating the Safety Action Notice further within their area of responsibility, they remove the Safety Action Notice Return Report, which will be an attachment to the original email.

Appendix 5 Responsibilities of the technical and specialist managers (e.g. Clinical Risk Managers, Clinical Physics, Health and Safety Managers, Moving and Handling Service Lead, Fire Officers)

Technical and specialist managers will receive all notices and will have a responsibility:

1. To provide appropriate guidance or instruction, such as reports or position statements, for nominated contacts, in relation to the content of each individual safety action notice received within seven working days. Any such guidance or instruction should be copied to the Head of Clinical Governance and Head of Health & Safety.
2. To distribute, where appropriate, relevant notices to staff within their area as a nominated contact and to send back return response forms to the CDRP accordingly within 21 working days.

In relation to item one above, technical and specialist managers will:

- Assess if technical action is required in accordance with the notice.
- Ensure that action is taken within a relevant timescale to ensure the safety of patients and staff.
- Prepare and issue reports or position statements to the nominated contacts within seven days of receiving the notices.
- Forward such reports to the Nominated Equipment Co-ordinator which will be placed on StaffNet for information, within seven days of receiving the notices.
- Participate in any co-coordinated responses that are required, as identified by the Head of Health and Safety or Head of Clinical Governance.

Please note that even if there is nothing to report, a 'Nothing to Report' should still be forwarded.

Appendix 6 Safety Action Notice Return Report Form

SAFETY ACTION NOTICE RETURNS (example)

SAN(SC)07/17	13/04/2006	IV cannulas and automatic powered injectors: risk of air embolus during contrast imaging procedures
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Form Completed by: _____

Department/ Ward: _____

Is this notice relevant to your area of responsibility?	
Yes <input type="checkbox"/>	No <input type="checkbox"/>

Has the action recommended in the notice been taken?	
Yes <input type="checkbox"/>	No <input type="checkbox"/>

Please provide which recommendations have been carried out

Please provide details of why you were unable to comply

<p>Please send completed forms to the Health and safety email address within 21 days of the date above.</p>
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Appendix 7 - Definition and Duties of a Medical Device Controller:

A clinically trained person responsible for the safe use of a medical device (e.g. ward manager, superintendent radiographer, laboratory manager) is the definition of a Clinical Supervisor in MDA DB9801, "Medical Devices and Equipment Management" which superseded HEI98 in January 1998. HEI98 identified these staff as Department Equipment Controllers. MDA DB9801 has been superseded by MHRA DB2006(05), "Managing Medical Devices" where all references to Clinical Supervisors and Department Equipment Controllers have been omitted; only professional users and end-users are referred to. The term Medical Device Controller is suggested as appropriate for the Acute Division.

Line Managers have a responsibility for designating Medical Device Controllers for each identified clinical area/ward within their spheres of operation, within the organisation and ensuring that they fulfil their specific responsibilities as recommended for good practice.

Device Controllers are responsible for:

- ◆ Maintaining a local register of medical devices
- ◆ Ensuring that all medical devices have been acceptance tested before being put into use
- ◆ Ensuring adequate user training of all staff in their area, including the availability of operator manuals
- ◆ Ensuring all staff in their area are trained in basic safety and function pre-checks on devices before use
- ◆ Co-ordinating routine maintenance with the Clinical Physics service provider
- ◆ Initiating breakdown maintenance requests according to Clinical Physics procedures
- ◆ Ensuring accidents and malfunctions are reported promptly and that equipment involved is removed, retaining all associated disposables and investigated by a technical officer
- ◆ Ensuring that relevant Hazard and Safety Action Notices are distributed and acted on, as appropriate
- ◆ In collaboration with Clinical Physics, identifying the need for the replacement of devices and the proper disposal of redundant items

Medical Device Controllers: Training

Medical Device Controllers will have to be trained in procedures and full operation of devices before being registered competent to train other staff. It is compulsory that the training records of Medical Device Controllers show that they have been passed as competent by a qualified assessor; particularly on infusion devices. Training records of all staff assigned to use medical devices must show that they have been trained and passed as competent, usually by their Medical Device Controller.