1.0 **Introduction**

This protocol describes the process which the Health and Social Care Board (HSCB) and Public Health Agency (PHA) will use to oversee implementation of Safety and Quality Alerts (SQAs) by Health and Social Care (HSC) Trusts, including actions relevant to primary care providers. It applies to SQAs issued since 1 April 2012.

2.0 **Context**

SQAs may arise from a variety of sources, including serious adverse incidents, reviews by the Regulation and Quality Improvement Authority (RQIA), safeguarding reports, legislative changes, medicines regulators, equipment or device failures, national safety systems, and independent reviews. The volume of SQAs is challenging for providers and commissioners to manage. Some SQAs relate to substantive safety issues that require a high level of assurance, while others relate to risk which can be managed within existing clinical and social care governance and risk management arrangements. The information systems to measure clinical and social care safety and quality are limited at present. For some actions, it is more efficient and effective to have one regional process, rather than each provider taking action individually.

This protocol was designed in that context.

3.0 **Scope of Safety Quality Alerts (SQAs)**

This protocol covers SQAs and equivalent correspondence as outlined below. It applies to health and social care-related SQAs though the vast majority relate to health care. Specific arrangements for the independent sector and for SQAs that relate mainly to primary care are described later.
Category 1 SQAs include:

- DHSSPS Safety Quality & Standards (SQS) guidance and letters/circulars;
- Learning Letters or Learning Reminders arising from serious adverse incidents (SAIs);
- National Patient Safety Alerting System (NPSAS) alerts;
- Safety or quality-related professional letters from DHSSPS;
- Regulation and Quality Improvement Authority (RQIA) Reports and other independent reviews;
- National Confidential Enquiry into Patient Outcome and Death (NCEPOD) reports and equivalent robust other national enquiries/audits;
- Guidelines and Audit Implementation Network (GAIN) Reports.

Category 2 SQAs include:

- Medicines and Healthcare products Regulatory Agency (MHRA) notices;
- Safety Alert Broadcast System (SABS) notifications.

A separate process is in place for the following:

- NICE guidance. Appendix 1 gives a schematic overview of the interfaces between this process and the process for NICE guidance;
- Drug alerts and recalls;
- Professional In-Confidence alerts regarding individual practitioners.

4.0 Dissemination of Safety Quality Alerts (SQAs) issued by DHSSPS

If an SQA from DHSSPS includes an assurance template or other form of assurance loop, DHSSPS will send the SQA in Draft form to the lead Director in PHA/HSCB for the SQA process (the Medical Director/DPH), copied to the HSCB lead Director for the HSCB/PHA Coordinating Office (the Director of Performance and Corporate
Services). Through them, and with input from relevant health and social care professionals within HSCB and PHA, the nature and timing of the assurance required, and the distribution list, will be agreed. DHSSPS will then issue the final version of the SQA to the agreed distribution list. This approach is intended to ensure that the actions required of organisations are clear through a single communication. Under the arrangements to date, two communications are required on some occasions.

DHSSPS will issue SQAs that do not have an assurance loop directly to relevant organisations.

SQAs will be issued to the Chief Executive’s office of relevant organisations, and copied to the HSCB/PHA Central Coordinating Office, the Governance Leads in Trusts and other relevant Directors. A standard distribution list is given in Appendix 2.

5.0 Dissemination of Learning Letters/Learning Reminders issued by PHA/HSCB

When regional learning is identified following the review of an SAI, complaint or other incident a learning letter/learning reminder may be issued to the appropriate HSC organisations for wider circulation, application of learning and assurance that learning has been embedded.

For learning letters prior to issue the Central Co-ordinating Office (CCO) (see section 6.0) will forward the draft Learning Letter and distribution list to DHSSPS Safety & Quality Standards Directorate for issue to relevant Policy Leads for review to ensure compatibility with DHSSPS policy in advance of SQAT meeting.

Following finalisation of the learning letter/learning reminder the HSCB/PHA will then issue the final version to the agreed distribution list. (see Appendix 2)
The Safety and Quality Alert Team will consider responses to learning letters/learning reminders and close the Alert when it is assured that actions have been implemented, or there is an existing robust system in place to ensure implementation.

6.0 **HSCB Central Coordinating Office**
SQAs where Trusts or the independent sector have a primary role in implementation will be logged by a central coordinating office (CCO) managed by the Governance Team within HSCB Corporate Services. All correspondence in relation to alerts will be channelled through the HSCB Alerts mailbox at Alerts.HSCB@hscni.net. The CCO will maintain a system to track progress on implementation. The CCO will also provide 6-monthly summary reports for the HSCB/PHA Safety Quality Alerts Team, HSCB Senior Management Team, Local Commissioning Group (LCG) Chairs, HSCB Governance Committee, HSCB Board and others as required.

A Programme Manager will oversee the process, maintain an up-to-date log, prepare for and support team meetings, and prepare an annual and mid-year report. They will be supported by a Database Officer, Administrative Officer, and members of the Safety Quality Alerts Team.

7.0 **HSCB/PHA Safety Quality Alerts Team**
HSCB and PHA will manage arrangements for the implementation and assurance of Category 1 SQAs through the Safety Quality Alerts Team (SQAT). Serious Adverse Incidents and Complaints are managed through their respective teams and reports to the Quality, Safety and Experience Group (QSE).

The SQA Team will include HSCB & PHA representatives from professional groups, and Corporate Services (Appendix 3). It will be sponsored, and chaired as necessary, by the Medical Director/Director
of Public Health. It will report through the Senior Management Team of HSCB to the HSCB Governance Committee and Board at the frequency outlined in the HSCB safety quality reporting framework. To ensure timely processing of Alerts, the Team will meet every 2 weeks. HSCB/PHA will put arrangements in place to ensure that any immediate issues that need to be addressed are processed immediately.

8.0 Trust Input
To ensure input from Trusts, the SQA Team will seek advice from relevant Trust professionals. Each Trust has identified a first point of contact for queries regarding SQAs (Appendix 3).

9.0 Interface with other Safety/Quality-related organisations
To ensure coordinated action across the wider system, the HSCB/PHA SQA Team will also seek input from the range of organisations and bodies that contribute to safety and quality of health and social care (Appendix 3), as required.

10.0 Process for Determining Appropriate Arrangements
Category 1 Alerts will be reviewed by the Safety Quality Alerts Team to make an initial determination on

- Whether or not regional action is required to assist Trusts or primary care with implementation, and
- The nature of the assurance required regarding implementation.

The default position is for Trusts to take action locally. It is likely that regional action will be by exception, and only where it adds real value.

If regional action is required, the proposed actions will be discussed where necessary with Trusts and/or other relevant organisations to agree the precise task. It is important to note that any regional actions do not
in any way negate the responsibilities of Trusts or other organisations to take necessary actions to implement the Alert; immediate necessary action should not be delayed. However, it is recognised that some aspects of implementation may be more efficient, and may ensure a better outcome for patients, clients, staff and the public if they are developed in a standard way across the region. Training modules, quality improvement projects, regional procurement are examples of regional action that could help to ensure standardised good quality care within the NI context, taking account of resources and service configuration.

To take forward work for the region, the principle of using existing systems as much as possible, will apply. However, if necessary, a Task and Finish Group may be established, including all relevant professionals and managers from relevant providers, and as appropriate, service users and/or the public.

Category 2 Alerts will be implemented primarily through existing systems. If on occasion explicit assurance or other action is required, it will be identified by the Safety Quality Alerts Team and described to Trusts and primary care providers as outlined for Category 1 Alerts.

11.0 Criteria for Regional Action and Assurance Levels
To assist the assurance process and without cutting across existing systems, the Team will determine the detail of the method of assuring implementation of an Alert. The method of assurance will be proportionate to the assessed level of risk associated with the issue covered by the Alert and will work on a principle of using existing systems of assurance as much as possible. Options for assurance methods include:

- Level 1 – material risks which cannot be managed within normal Trust clinical and social care governance arrangements;
• Level 2 – explicit assurance by Trusts, and where appropriate, other organisations, that key actions have been implemented; the key actions may be specified by the HSCB/PHA;
• Level 3 – completion of an audit specified by HSCB/PHA.

The following criteria will be used to assess whether or not regional action is required to assist implementation, and to determine the level of assurance required:
• The risk to an individual patient, client, staff member or member of the public, is high (impact);
• The number of patients, clients, staff or public who may be exposed to the risk is high (likelihood);
• Aspects of implementation are complex and outwith the control of Trusts or relevant organisations (complexity);
• A regional approach is achievable (deliverability & stakeholder agreement);
• Regional action will not introduce undue delay (timeliness);
• The Alert relates to an issue with a high public/political profile (public confidence);
• Other reasons (professional judgment).

In making its decisions, the Team will take account of:
• Other Alerts relating to the service area in question;
• Common themes within a range of Alerts;
• Learning from Serious Adverse Incidents and Complaints;
• Existing safety and quality initiatives in health and social care.

12.0 Informing Trusts and Primary Care of the Outcome
On completion of the processes outlined above, if regional action or assurance is required, the Chair of the Safety Quality Alerts Team will inform Trusts, primary care, and other relevant providers or stakeholders of the next steps or requirements. Communication will be
to the Trust Chief Executive’s office, copied to the Trust Governance Lead.

13.0 Alerts Relating to Independent Sector Providers
Independent providers are already required to respond to many of the types of Alerts covered by this protocol. In addition, DHSSPS or HSCB/PHA will send Alerts that they issue to RQIA for dissemination to relevant independent providers. DHSSPS also agree the annual work programme of RQIA which may include reviews of governance systems in independent providers, and/or assurance on implementation of specific SQAs.

14.0 Review of this protocol
This protocol will be refined on an on-going basis and not less than annually.
Range of organisations

- NI Social Care Council
- Safeguarding Board NI
- NI Adult Safeguarding Partnership
- Trust Leads for professional education
- NI Medical and Dental Training Agency
- NI Practice and Education Council
- Under and postgraduate training bodies
- GAIN, RQIA, NCEPOD
- BSO Procurement, Health Estates

**HSC System for Managing Safety and Quality Alerts – Structural Overview**

Alerts from NPSAS, SABS*, other organisations

Logged

HSCB/PHA (Central Coordinating office)

- NICE Guidelines

HSCB/PHA (NICE Coordinating process)

- Alerts from HSCB/PHA
  - Learning from SAIs & Complaints
  - Safety Quality Alerts Team

Inform regional action

Trusts, GPs, HSCB/PHA, RQIA, others as required

DHSSPS Alerts

Confirm implementation & assurance arrangements to relevant organisations

Relevant organisations implement & provide assurance in line with the agreed approach

Appendix 1
## Template Distribution List

<table>
<thead>
<tr>
<th>To – for Action</th>
<th>Copy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HSC Trusts</strong></td>
<td><strong>PHA</strong></td>
</tr>
<tr>
<td>CEXs</td>
<td>CEX</td>
</tr>
<tr>
<td>Medical Director</td>
<td>Medical Director/Director of Public Health</td>
</tr>
<tr>
<td>Directors of Nursing</td>
<td>Director of Nursing/AHPs</td>
</tr>
<tr>
<td>Directors of Social Services</td>
<td>PHA Duty Room</td>
</tr>
<tr>
<td>Governance Leads</td>
<td>AD Health Protection</td>
</tr>
<tr>
<td>Directors of Acute Services</td>
<td>AD Service Development/Screening</td>
</tr>
<tr>
<td>Directors of Community/Elderly Services</td>
<td>AD Health Improvement</td>
</tr>
<tr>
<td>Heads of Pharmacy</td>
<td>AD Nursing</td>
</tr>
<tr>
<td>Allied Health Professional Leads</td>
<td>AD Allied Health Professionals</td>
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<td><strong>NIAS</strong></td>
<td><strong>CEX</strong></td>
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<tr>
<td>CEX</td>
<td>CEX</td>
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<td>Director of Integrated Care</td>
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<td><strong>HSCB</strong></td>
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<tr>
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<td>CEX</td>
</tr>
<tr>
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<td>Director of Social Services</td>
</tr>
<tr>
<td>Director of Nursing</td>
<td>Director of Commissioning</td>
</tr>
<tr>
<td>Director for Social Care</td>
<td>Alerts Office</td>
</tr>
<tr>
<td>Director for Social Care</td>
<td>Dir PMSI &amp; Corporate Services</td>
</tr>
<tr>
<td><strong>NIMDTA</strong></td>
<td><strong>Primary Care (through Integrated Care)</strong></td>
</tr>
<tr>
<td>CEX / PG Dean</td>
<td>GPs</td>
</tr>
<tr>
<td><strong>QUB</strong></td>
<td><strong>Community Pharmacists</strong></td>
</tr>
<tr>
<td>Dean of Medical School</td>
<td>Dentists</td>
</tr>
<tr>
<td>Head of Nursing School</td>
<td>Open University</td>
</tr>
<tr>
<td>Head of Social Work School</td>
<td>Head of Nursing Branch</td>
</tr>
<tr>
<td>Head of Pharmacy School</td>
<td><strong>DHSSPS</strong></td>
</tr>
<tr>
<td>Head of Dentistry School</td>
<td>CMO office</td>
</tr>
<tr>
<td><strong>UU</strong></td>
<td><strong>CMO office</strong></td>
</tr>
<tr>
<td>Head of Nursing School</td>
<td>CNO office</td>
</tr>
<tr>
<td>Head of Social Work School</td>
<td>CPO office</td>
</tr>
<tr>
<td>Head of Pharmacy School</td>
<td>CSSO office</td>
</tr>
<tr>
<td>Head of School of Health Sciences (AHP Lead)</td>
<td>CDO office</td>
</tr>
<tr>
<td><strong>Clinical Education Centre</strong></td>
<td><strong>NI Social Care Council</strong></td>
</tr>
<tr>
<td><strong>NIPEC</strong></td>
<td><strong>Safeguarding Board NI</strong></td>
</tr>
<tr>
<td><strong>GAIN Office</strong></td>
<td><strong>NICE Implementation Facilitator</strong></td>
</tr>
<tr>
<td><strong>NICPLD</strong></td>
<td><strong>Coroners Service for Northern Ireland</strong></td>
</tr>
</tbody>
</table>
HSCB/PHA Safety Quality Alerts Team

- Medical Director/DPH, PHA (Chair)
- Director of Performance and Corporate Services
- Assistant Director Nursing, Safety & Quality & Patient Experience
- Assistant Director Service Development & Screening
- Pharmacy Lead – Medicines Governance and Public Heath, HSCB
- Consultant in Public Health, PHA
- Safety, Quality and Patient Experience Nurse, PHA
- Assistant Governance Manager, Safety and Quality, HSCB
- Clinical Director for Safety Forum, PHA
- GP Input via Assistant Director of Integrated Care (Head of GMS) HSCB - when required
- Social Care and AHP input for Alerts relevant to those professions

SQA Team Roles

- Lead Social Worker – through Fionnuala McAndrew
- Lead AHP – through Michelle Tennyson
- Lead Public Health Doctor – Jackie McCall
- Lead Nurse – Mary McElroy
- Lead Pharmacist – Brenda Bradley
- Lead GP – Dr Margaret O’Brien
- Programme Manager – Margaret McNally
- Admin Support – Christine Thompson / Mareth Campbell

Trust Governance Lead Contacts

- Belfast – Dr Cathy Jack and Claire Cairns/Christine Murphy
- South East – Dr Charlie Martyn and Irene Low/Liz Campbell
- Southern – Dr John Simpson and Margaret Marshall/Dawn Mackin
- Northern – Dr Ken Lowry and Suzanne Pullins/Ruth McDonald
- Western – Dr Alan McKinney and Therese Brown/Teresa Murray
Link as required with

- NI Social Care Council
- Safeguarding Board NI
- NI Adult Safeguarding Partnership
- Trust Leads for professional education
- NI Medical and Dental Training Agency
- NI Practice and Education Council
- Under and postgraduate training bodies
- GAIN
- RQIA
- BSO Procurement
- Health Estates, DHSSPS
Appendix 4

HSCB/PHA Process for the Management of Safety and Quality Alerts

Safety and Quality Alert and PHA/HSCB Learning Letters received by the Central Coordinating Office (CCO) (alerts.hscb@hscni.net)

CCO will log the Alert onto the Safety and Quality Alerts Database

CCO will circulate Alert / Letter to: Safety and Quality Alerts Team (SQAT) Chair, Assistant Director Service Development and Screening, Director of Social Services, SQAT Programme Manager and Administrator. Administrator adds the Alert to the agenda for the next SQAT meeting

A PHA/HSCB Professional Lead will be identified at SQAT Meeting along with action & next steps. Programme Manager will notify Professional Lead. Professional Lead will receive input from other relevant HSCB/PHA staff & if necessary, Trust/primary care staff

What level of assurance is required?

Assurance Required

Chair of SQAT will write to Trusts advising level of assurance required & if applicable, include completion of DHSSPS assurance template, expected actions and date for completion. Programme Manager forwards letter, template and timescales identified to Professional Lead and schedules date to attend SQAT meeting to provide feedback on compliance

Responses received from Trust/s will be copied to Programme Manager & the Professional Lead

Programme Manager will advise DHSSPS if a delay is anticipated in responding within DHSSPS specified timescales

Professional Lead completes SQAT template highlighting areas of non-compliance

Professional Lead attends the SQAT meeting and responses from Trusts are discussed

Has full compliance been achieved?

No

Yes

If required completed Assurance Template will be forwarded to SMT for noting and then to DHSSPS

Programme Manager will record decision on database and Alert/Learning Letter can be closed

Safety and Quality Alerts Database will be updated on a continual basis

SQAT and Professional Lead to agree next steps and action