SESLHD PROCEDURE COVER SHEET

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FUNCTIONAL GROUP(S)	Clinical Governance
KEY TERMS	Clinical product, biomedical equipment, safety alert broadcasting system, therapeutic goods association (TGA)
SUMMARY	This procedure outlines the process for managing all clinical product safety notices, alerts and recalls in SESLHD.

Feedback about this document can be sent to SESLHD-Policy@health.nsw.gov.au

Product – Clinical Product Notices, Recalls and Safety Alerts

SESLHDPR/319

1. POLICY STATEMENT

This procedure outlines the process to be undertaken in South Eastern Sydney Local Health District (SESLHD) to ensure compliance with NSW Health Policy Directive PD2024_016 – System-level patient safety risks: Response co-ordination and communication and to ensure that all clinical product safety notices, alerts and recalls from external sources including the Ministry of Health (MOH); Clinical Excellence Commission (CEC); Therapeutic Goods Association (TGA) or suppliers and vendors are appropriately disseminated, monitored and actioned.

This procedure does not include the Drug Recall Process which is addressed in SESLHDPR/438 - Medicine Recall Process.

2. BACKGROUND

SESLHD receives product safety notifications, alerts and recalls from the Clinical Excellence Commission (CEC), as well as occasionally directly from individual suppliers and vendors directly to individual facilities and departments.

TGA Safety Alerts – The CEC distributes a daily tranche via QARS ReACT at 9am each business day. The emails are sent to SESLHD mail, SESLHD products, biomedical department and pharmacy (medications only).

The Safety Alert Broadcast System (SABS) notifications are issued by the MOH and CEC as per NSW Health Policy Directive PD2024_016 – System-level patient safety risks: Response co-ordination and communication. These consist of a three-tiered approach to distribution, prioritisation and management.

Safety Alert – The aim of a safety alert is to quickly disseminate information to health services about a safety matter requiring immediate attention and action which may include a **product recall**. The colour coding for safety alerts is **RED.**

Safety Notice – The aim of a safety notice is to inform health services about potential quality and safety issues requiring risk assessment at the local level. The colour coding for safety notices is **AMBER**.

Safety Information – The aim of safety information is to disseminate quality and safety information to health services to ensure lessons are learnt from state, national and international sources. The colour coding for safety Information is **GREEN**.

Occasionally patient safety information is notified via a direct memo from the CEC to SESLHD mail. These are managed in a similar manner by SESLHD CGU.

The purpose of this document is to establish a clear process within SESLHD for the management of clinical product safety notifications, alerts and recalls received.

2.1 Definitions

- **Clinical Product** - Refers to both clinical consumable and clinical equipment e.g. Any material, instrument, machine, appliance, implant or component of these used in the delivery of healthcare.

- **Clinical Consumable** - Refers to any clinical product that is single use, single patient use or re-usable following re-processing where appropriate.

- **Clinical Equipment** - Refers to any clinical product component or software other than a clinical consumable used in the delivery of patient care.

- **Biomedical Equipment** - Refers to any instrument, apparatus or appliance, including software, whether used alone or in combination, which makes physical or electrical contact with the patient, or transfers energy from or to the patient, or detects such energy transfer to or from the patient, and is intended to diagnose, treat or monitor the patient.

3. RESPONSIBILITIES

3.1 Chief Executive will:

- Ensure there is an efficient and effective process for managing the receipt, distribution, implementation and effectiveness of clinical product safety notices, alerts and recalls.

3.2 District Executive Services (SESLHD-Mail@health.nsw.gov.au) will:

- Catalogue all clinical product safety notices alerts and recalls in Content Manager; and allocate by email to the District Clinical Governance Unit.

3.3 Deputy Director Clinical Governance & Medical Services (DDCGU&MS) will:

- Ensure that all clinical product safety notices; alerts; and recalls are disseminated to relevant staff across the District via the Facility CGU/CPIU Managers and the SESLHD-ProductRecallAndAlert@health.nsw.gov.au
- Identify effected facilities but sent each notice to all facilities, requesting responses from those effected
- Record implementation of nominated actions including recalls
- Maintain a current distribution list
- Monitor risks to the District in relation to safety notices alerts and recalls
- Ensure a response is provided to the CEC if requested with a SAB
- Ensure all correspondence regarding the clinical product safety notice, alert or recall is catalogued in Content Manager
- Provide monthly report to the SESLHD Clinical and Quality Council (CQC)

3.4 General Manager/ Service Directors will:

- Receive all information from the Safety Alert Broadcast system (SABs)
- Notify affected departments within their facilities immediately of any urgent recalls or alerts received into the hospital
- Ensure that Biomedical/Clinical Engineering Managers and Cost Centre Managers affected by the clinical product safety notice, alert or recall act in accordance with this procedure
- Notify the DDCGU&MS of any recalls alerts received directly to the hospital from external sources such as TGA or from the supplier as these may pose a district–wide risk
- Ensure that any risks to the organisation are reported to the DDCGU&MS and CE
- Ensure there is completion of acknowledgement forms and signing off of final response documentation
- Ensure a response is provided to the CEC if requested with a SAB
- Ensure all correspondence regarding the clinical product safety notice, alert or recall is appropriately recorded and documented.

3.5 Facility CGU/CPIU Managers will:

- Ensure dissemination of SABs, clinical product safety notices, alerts and recalls
- Ensure the completion and sending of any required customer acknowledgement forms and actions are implemented
- Notify District CGU when clinical product safety notices alerts and recalls are disseminated and actioned via the Safety Alert Product Recall Response Form (Appendix 1)
- Ensure Safety Alert Product Recall Response Forms are returned to District CGU within two weeks (unless more urgent response is required).
- Ensure that relevant correspondence and actions implemented are saved in Content Manager.

3.6 Biomedical/Clinical Engineering Managers will:

- Receive direct communication from the CEC via QARS ReACT
- Send any clinical product safety notice, alert or recall that was received directly to facility, to District CGU to facilitate an appropriate District response
- Upon receipt of a clinical product safety notice, alert or recall, check asset registers to determine where affected devices are located
- Complete customer acknowledgement forms and send to Facility CGU/CPIU to send to vendor
- Liaise with the device vendor and perform a risk analysis on the notification
- Organise recall/ quarantine of affected devices depending on risk factors and suppliers recommendations
- Notify the General Manager/ Service Director of any significant risk to the organisation
- Send all feedback and correspondence relating to the product recall alert to Facility CGU/CPIU for cataloguing in Content Manager.

3.7 Cost Centre Managers will:

- Send any clinical product safety notice, alert or recall that was not received in the department via the Clinical Governance Unit to SESLHD-Mail@health.nsw.gov.au to ensure the District is aware and can respond appropriately to any District risks
- Upon receipt of a clinical product safety notice, alert or recall, Cost Centre Managers are responsible for:
    - Reviewing their inventory / equipment
    - Completing an acknowledgement form to the vendor when required and notifying Facility CGU/CPIU
    - Removing affected products from shelves and quarantining
    - Labelling affected products with 'do not use' or attach relevant Danger Tags if required by the clinical product safety notice, alert or recall or advised to do so by the DDCG&MS
    - For non-stock recalls, follow proposed customer actions outlined within the recall notice
    - For non-stock recalls, contact HealthShare Procurement on telephone 1800 009 941. The HealthShare Customer Service Officer will coordinate the return of the goods. HealthShare will forward a Non Stock Goods Return Form with Good Return Authority Number (GRD) to the Cost Centre Manager as per SESLHDPR/254 - Goods Return Advice
    - For Stock recalls – liaise with the SESLHD Clinical Product Manager
    - Organising collection of the affected product including replacement or reimbursement
    - Notifying the General Manager/ Service Director of any significant risks to the organisation
    - Recalls such as device upgrades should be actioned in accordance with the manufacturer's guidelines
    - Sending all information correspondence relating the product recall alert to Facility CGU/CPIU for record keeping purposes.

3.8 District Clinical Product Management Team will:

- Send any clinical product recall notice for inventory items recalled with identified cost centres to the District Clinical Governance Unit for cataloguing in Content Manager and dissemination
- Manage the stock recalls in consultation with the District Clinical Governance Unit and affected facilities, HealthShare Inventory Team and Suppliers
- Provide any additional information concerning product safety alerts/recalls to the District Clinical Governance Unit for further dissemination (e.g. product locations or affected facilities where no list is provided by CEC)
- Advise mechanism for replacement and return and credit of stock
- Provide reports regarding purchasing of direct purchased clinical products where data is available.

4. PROCEDURE

4.1 Receipt of Clinical Product Safety Notice, Alert or Recall

A clinical product safety notice, alert or recall will usually be received from the Therapeutic Goods Association (TGA) via the Clinical Excellence Commission (CEC), using QARS ReACT. Occasionally companies will contact facilities directly.

All clinical product safety notices, alerts or recalls that are not received by the District Clinical Governance Unit should be sent to SESLHD-Mail@health.nsw.gov.au to be entered into Content Manager.

4.2 Dissemination of Product Safety Notice, Alert or Recalls

Upon receipt from SESLHD mail, District CGU will process the alert, notice or recall by identifying affected SESLHD sites and facilities.

If affected, District CGU will create a new container in Content Manager, update Safety Alert Database and create a Safety Alert Response Form. All clinical product safety notices, alerts or recalls will be disseminated by the District CGU to the CPIU Managers and SESLHD-ProductRecallAndAlert@health.nsw.gov.au where appropriate for acknowledgement and co-ordination of an appropriate response as required.
The TGA Distribution Lists for recall notices are commercially sensitive and are not to be distributed further.

If no SESLHD sites are affected, the alert, notice or recall is saved in a separate Content Manager container.

Clinical Products Unit can provide advice if there is any uncertainty regarding affected sites in SESLHD.

Safety Information (SI), Safety Alerts (SA) and Safety Notifications (SN) will be sent by District CGU to General Managers at each facility, with a Cc to Facility CGU/CPIUs and others directed within the notice.

5. After Hours Procedure on Receipt of Clinical Product Safety Notice, Alert or Recall

Out of business hours, the MOH or CEC will contact the CE by telephone should there be a need to disseminate a safety alert. For an emergency drug recall – Contact the On-Call pharmacist and Refer to SESLHDPR/438 - Medicine Recall Process.

The General Manager/ Service Director, Executive on call and AH Nurse Manager, when advised of urgent safety alerts / recalls, will notify the relevant departments and ensure that the recommendations of the safety alert recall are actioned.

6. DOCUMENTATION

Safety Alert Product Recall Response Form Appendix 2
Records to be catalogued in the Electronic Document Records Management System (HP Content Manager)

6. REPORTING

Monthly safety alert and product recalls are reported to the SESLHD Clinical and Quality Council, via the Clinical Governance Unit Report.

7. AUDIT

CGU will monitor returns of Safety Alert Product Recall Response Form from affected facilities.

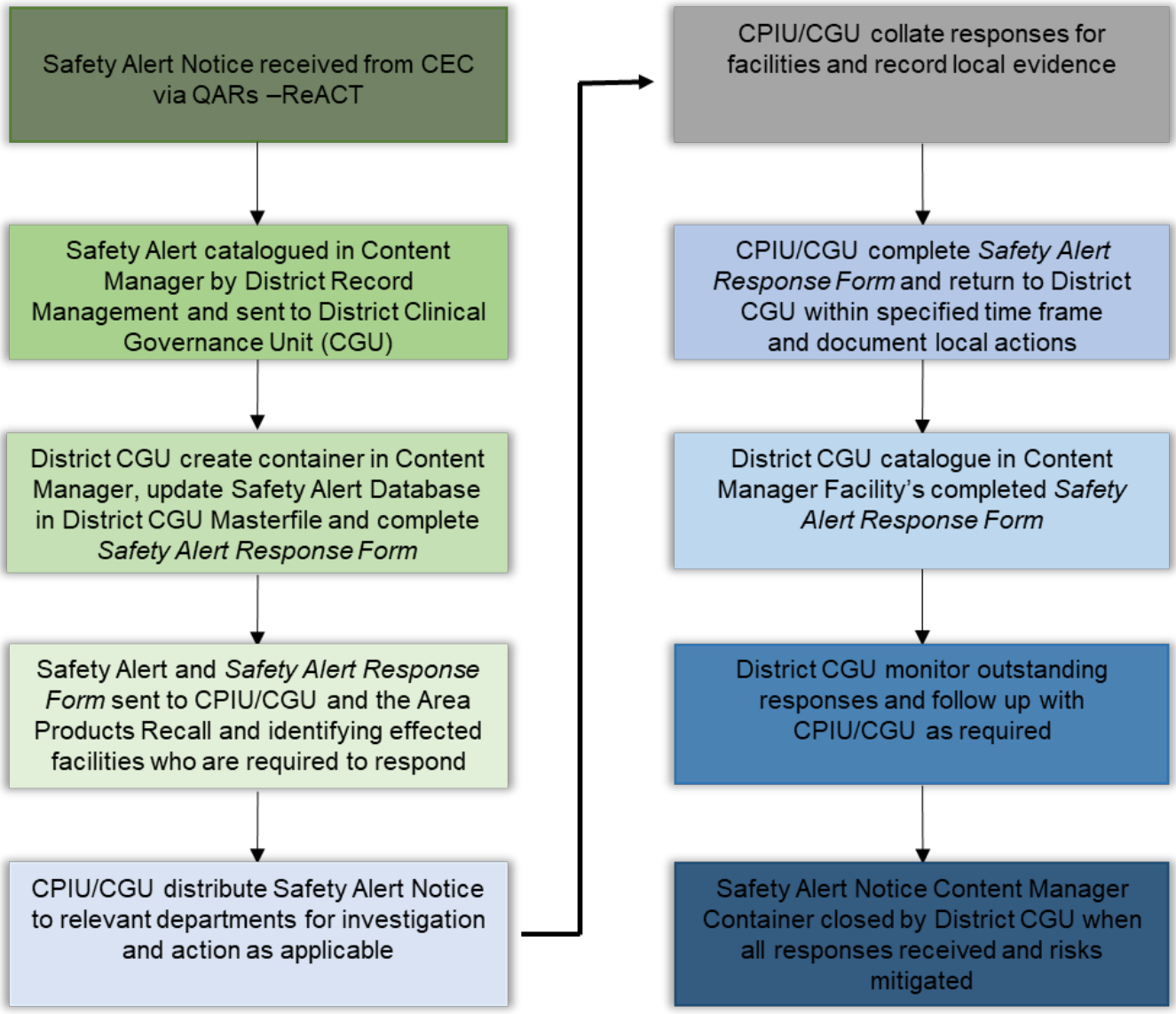
8. REFERENCES

NSW Health Policy Directive PD2024_016 – System-level patient safety risks: Response co-ordination and communication
SESLHDPR/254 - Goods Return Advice
SESLHDPR/438 - Medicine Recall Process

9. VERSION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
Mar 2006	Draft	David Brain, Manager Biomedical Engineering, Southern Hospital Network.
May - Aug 2006	0	Rose Gavin, Manager Systems Integration in consultation with Working Party comprising Helen McKinlay Clinical Products Manager, Alan Leonard, Southern Sector Clinical Products Manager, David Brain, Manger Biomedical Engineering Southern Hospital Network, Director Clinical Governance Unit , Managers Shared Services and Procurement and Logistics.
Jan 2014	1	Kim Brookes; Ashleigh Vinton; Helen McKinlay Approved by DCG Professor George Rubin
Feb 2014	1	Approved by Clinical and Quality Council.
August 2015	1	Minor changes – risk rating changed to medium, hyperlinks updated. Reviewed by Patient Safety and Consumer Feedback Manager and endorsed by Director Clinical Governance.
May 2017	1	Added Contact On - call Pharmacist to Section 5
July 2018	2	Minor review to update Appendix 2 approved by Executive Sponsor
July 2018	2	Processed by Executive Services prior to publishing
June 2021	3	Minor review – Clinical Governance Unit. Clarification of responsibilities and new QARS ReACT system.
November 2021	4	Minor review. Consultation with facility governance staff and SESLHD Products. Updated Appendix 1 and clinical product information.
January 2022	4	Approved by Executive Sponsor.
6 January 2025	4.1	Minor review. Updated reference to PD2024_016.

Appendix 1 – SESLHD Safety Alert and Product Recall Management Process



Appendix 2 – Safety Alert/Product Recall Response Form