SESLHD PROCEDURE COVER SHEET

Health
South Eastern Sydney
Local Health District

NAME OF DOCUMENT	Product – Clinical Product Notices, Recalls and Safety Alerts
TYPE OF DOCUMENT	Procedure
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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-ExecutiveServices@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 SESLHD to ensure compliance with NSW Ministry of Health PD2013_009 - Safety Alert Broadcast System 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 Drug Recall Process.

2. BACKGROUND

SESLHD receives product safety notifications, alerts and recalls from various sources including MOH, CEC, and TGA; as well as directly from individual suppliers and vendors directly to individual facilities and departments.

The Safety Alert Broadcast System (SABS) notifications are issued by the MOH and CEC as per NSW Ministry of Health PD2013_009 - Safety Alert Broadcast System. 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**.

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 from all external sources

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 Director of Clinical Governance.

3.3 Director Clinical Governance (DCG) will:

- Ensure that all clinical product safety notices; alerts; and recalls are disseminated to relevant staff across the District via the CPIU Managers and the SESLHD-ProductRecallAndAlert@health.nsw.gov.au
- Send an acknowledgement form on behalf of SESLHD when requested
- Ensure implementation of nominated actions including recalls
- Monitor risks to the District in relation to safety notices alerts and recalls
- Monitor the effectiveness of actions implemented
- Ensure a response is provided to the CEC if requested with a SAB.

3.4 General Manager/ Service Directors will:

- 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 DCG 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 DCG 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 catalogued in Content Manager.

3.5 CPIU Managers will:

- Ensure dissemination of clinical product safety notices, alerts and recalls
- Monitor that appropriate acknowledgements are made and actions are implemented
- Notify CGU when clinical product safety notices alerts and recalls are disseminated and actioned via the Safety Alert Product Recall Response Form (Appendix 1)
- Ensure that relevant correspondence and actions implemented are saved in Content Manager.

3.6 Biomedical/Clinical Engineering Managers will:

- Send any clinical product safety notice, alert or recall that was not received in the department via the Clinical Governance Unit to District Executive Services for cataloguing in Content Manager; and dissemination via the Clinical Governance Unit
- Upon receipt of a clinical product safety notice, alert or recall, check asset registers to determine where affected devices are located
- Send acknowledgement form to the vendor when required and inform the CPIU
- 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 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 for cataloguing in Content Manager; and dissemination via the Clinical Governance Unit
- 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 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 DCG
- 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 CPIU for cataloguing in Content Manager.

3.8 District Clinical Product Manager will:

- Send any clinical product recall notice for inventory items recall with identified cost centres to SESLHD-Mail@health.nsw.gov.au for cataloguing in Content Manager; and dissemination via the Clinical Governance Unit
- Manage the stock recalls in consultation with the affected facilities
- Arrange for replacement of Recall Items or confirm credit has been issued to the cost centre.

4. PROCEDURE

4.1 Receipt of Clinical Product Safety Notice, Alert or Recall

A clinical product safety notice, alert or recall may be received from external sources such as MOH, Clinical Excellence Commission (CEC), Therapeutic Goods Association (TGA) or suppliers and vendors via the Chief Executive and Clinical Governance Unit, as well as directly from individual companies to individual departments within the organisation.

All clinical product safety notices, alerts or recalls that are not received by the 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

All clinical product safety notices, alerts or recalls will be disseminated by the DCG to the CPIU Managers and SESLHD-ProductRecallAndAlert@health.nsw.gov.au where appropriate for acknowledgement and co-ordination of an appropriate response as required.

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 Drug 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)

7. AUDIT

Monthly compliance reports will be generated by the DCG.

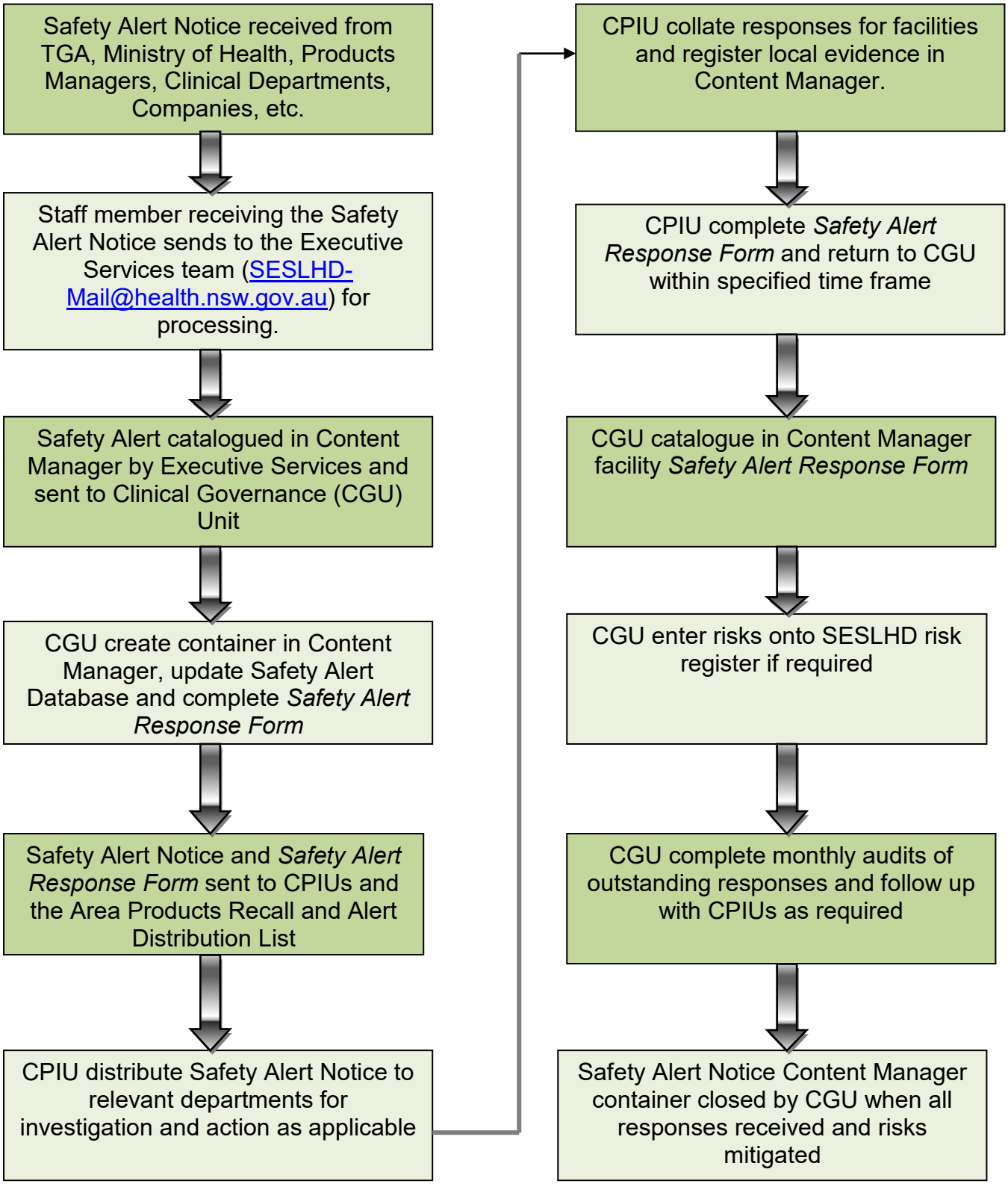
8. REFERENCES

NSW Ministry of Health PD2013_009 - Safety Alert Broadcast System
SESLHDPR/254 Goods Return Advice
SESLHDPR/438 Drug Recall Process

9. REVISION 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

Appendix 1 – SESLHD Safety Alert and Product Recall Management Process



Appendix 2 – Safety Alert/Product Recall Response Form

Health
South Eastern Sydney
Local Health District

SAFETY ALERT / PRODUCT RECALL RESPONSE FORM
Clinical Governance Unit

SAPR18/ T18/

CONTACT OFFICER: Ms Debbie Jones **CONTACT TEL: 9540 3766** **Email: Deborah.Jones@health.nsw.gov.au**

Date Safety Alert / Product Recall Response Form Sent:	**Company and Product:**	**Date Response Due:**
Sent to the following facilities:		

Clinical Practice Improvement Unit complete the table below and return completed response to CGU by the due date

Name of Facility / Service:		
Impact (please tick) ☐ Affected ☐ Not Affected	**Safety Alert / Product Recall notice distributed to relevant departments** ☑ Yes ☑ Affected	**Action Taken** ☐ All actions recommended by company implemented ☐ Other (please specify)
Acknowledgement (please tick) ☐ Sent ☐ Not Applicable	**Risk Rating as per NSW Health Risk Matrix** (please tick) ☑ Low - manage by routine procedures, monitor trends ☑ Medium - specify management accountability and responsibility, monitor trends and plan for improvement ☐ High - escalate to Facility Senior Managment and implement detailed action plan ☐ Extreme - escalate to DCG / CE and implement detailed action plan	**Safety Alert / Product Recall notice complete** ☐ Yes ☐ No If no, please comment

Completed by: **Phone:** **Date:**	**Comments:**