TGA Notification and Recall for Medical Devices Policy

1. Background

The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health and is responsible for regulating medicines and medical devices under the *Therapeutic Goods Act 1989* (Cwth). This legislation ensures that therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy.

The Uniform Recall Procedure for Therapeutic Goods is an agreement between industry and Commonwealth and State/ Territory Health Services outlining the process of determining when goods are required to be removed from supply/use or subject to corrective action for reasons relating to safety, quality or efficacy.

A recall action may be initiated in response to reports from a variety of sources including consumers, manufacturers and health professionals. The TGA may also issue other notifications relating to therapeutic goods.

Recalls are generally sponsor initiated, however in extreme cases mandatory recalls may be issued requiring the therapeutic goods to be removed from the Australian Register.

WA Health receives around 350-400 product related TGA recall/notifications per year. This policy outlines the process to be followed in response to recalls and notifications issued by the TGA in relation to medical devices. It aligns with EQuIP National Corporate Standard 15.15.1 which states "*medical devices, equipment, supplies, utilities and consumables are managed safely and used efficiently and effectively*".

2. Policy Statement

TGA issued recalls and notifications relating to medical devices are to be managed in a consistent, effective, timely and accountable manner as described in this policy to ensure a safe healthcare environment.

2.1 Process

The management of a product recall has five (5) phases:

1. Notification issued by TGA/ sponsor.
2. HSS obtain usage report and distribute with TGA notification to the nominated HSP representatives.
3. Regional contacts review and prioritise.
4. Required actions undertaken.
5. Outcome recorded and closed by Regional Product Evaluation and Standardisation Committee (PESC).

Phase 1. Notification issued by TGA/ sponsor

Notifications are usually sent to Health Support Services (HSS) but may also be received by Health Service Chief Executive Officers (CEOs), Biomedical Engineering (BME), hospital sites and clinicians. If a site receives a notification from a source other than HSS, it is to be forwarded to HSS.ContractManagement@health.wa.gov.au and wachs.plo@health.wa.gov.au.

There are four (4) distinct types of **recall issued by the TGA**:

1. **Recall** is conducted to remove therapeutic goods **permanently** from the market or from use when there are deficiencies or potential deficiencies in safety, quality, efficacy, performance or presentation.

2. **Product Defect Correction** is undertaken to correct a specific or potential deficiency. In some instances the product can be continued to be used if there is robust mitigation in place until a **permanent** correction has been implemented

3. **Hazard Alert (implanted medical devices and biologicals)** is issued for an implanted therapeutic good with a deficiency or potential deficiency relating to its safety, quality, performance or efficacy because implanted goods (medical devices or biologicals) cannot be recalled. A hazard alert may be issued in conjunction with a recall notice for affected products that have not been implanted.

4. **Product Defect Alert** occurs for critical therapeutic goods for which there is no alternative product or for which a recall action will result in interruption of patient treatment or a medicine shortage. A product defect alert may later be followed by a recall once unaffected or alternative products become available.

Recalls are classified in one of the following three (3) categories

- Class 1: Use or exposure could cause serious adverse health consequences or death.
- Class 2: Use or exposure may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote
- Class 3: A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences. However if not rectified may present a hazard in the future.

There are also four (4) levels within these notifications

1. **Wholesale -** medicine and medical device wholesalers, who are third parties holding goods to distribute to retailers or other organisations
   State and Territory purchasing authorities

2. **Hospital Level -** wholesale levels, hospitals, nursing homes, clinical investigators, hospital pharmacies, blood banks, pathology laboratories, operating facilities, human tissue banks and other hospital departments, ambulance services including RFDS

3. **Retail -** hospital and wholesale levels, retail pharmacies, dentists, health care professionals, all other outlets such as supermarkets, health food stores and online stores

4. **Consumer Level -** retail, hospital and wholesale levels, patients and other consumers

There are four (4) types of **non-recall action**

1. **Safety Alert** is generally used for reiterating specific precautions or instructions regarding use of goods.

2. **Product Notification** provides information about a therapeutic good in a situation that is unlikely to involve significant adverse health consequences.

3. **Quarantine** suspends further supply pending investigation of an issue or incident. The outcome of the investigation will determine further actions. A recall may occur after quarantine.

4. **Product Withdrawal** is used to withdraw products for reasons that are not related to safety, quality, efficacy, performance or presentation, e.g. removing a previous model from the market when a new model has been released.

Phase 2. HSS obtain usage report and distribute to health sites

HSS will obtain a usage report based on the product vendor codes from Oracle to identify sites that have purchased items subject to notification. It should be noted that the report is dependent on the data entered within Oracle so **will not** identify items not purchased via iProcurement, loan, trial or transferred items.

Where use is uncertain the notification is to be forwarded to potentially affected areas for clarification. Notifications are distributed within WACHS via WACHS recalls Distribution List (DL), wachs.productrecall@health.wa.gov.au.

This list includes the Regional Nurse Directors, Regional Supply Managers, Biomedical Engineering and Product Liaison Officers. Changes to the distribution list may be requested via a Product Liaison Officer wachs.plo@health.wa.gov.au

Phase 3. Regional contacts review and prioritise

The notification is to be triaged as per the following table:

Type	Class	Priority
Recall	Class 1	Urgent
Recall	Class 2	High
Recall	Class 3	Medium
Recall for Product Defect Correction	Class 1	Urgent
Recall for Product Defect Correction	Class 2	High
Recall for Product Defect Correction	Class 3	Medium
Hazard Alert		Medium
Safety Alert		Medium
Product Defect Alert		Medium
Recovery		Low

Biomedical Engineering will review equipment related notifications and identify affected items and locations from the BME database. Updates will be provided via the WACHS recall distribution list.

Following completion of the review process by the nominated regional contact the issue may either be:

- deemed not relevant and forwarded to the Regional PESC to be recorded
- forwarded to the relevant stakeholders for specific actions to be undertaken.

Phase 4. Required actions undertaken

The regional contact may delegate an appropriate person to undertake the required action. Impact to patient care and service delivery must be considered in order that any risks can be identified and mitigated as appropriate. Dependant on the type of notification the following actions may be indicated:

- Removal of affected items for return to supplier.
- Removal of items in order for any corrective actions to be undertaken by the supplier.
- Identification and sourcing of alternative or replacement products where removal will have an impact on patient care or service delivery.
- Communication of safety alert/ precautionary information to relevant product users.

The Regional PESC should be informed of progress and advised when actions are completed to facilitate recording/closure of the recall/ notification.

Phase 5. Outcome recorded and closed by Regional PESC

The Regional PESC must maintain a record to demonstrate that TGA Recall and notifications are either deemed not relevant or, where relevant, the necessary actions have been completed.

3. Definitions

Therapeutic Goods	In relation to the evaluation, assessment and monitoring done by the TGA, therapeutic goods are broadly defined as products for use in humans in connection with: · preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury · influencing inhibiting or modifying a physiological process · influencing, controlling or preventing conception · testing for pregnancy.
Medical Device	A medical device is: any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: · diagnosis, prevention, monitoring, treatment or alleviation of disease · diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap · investigation, replacement or modification of the anatomy or of a physiological process · control of conception. Or an accessory to such an instrument, apparatus, appliance, material or other article. *Therapeutic Goods Act 1989* (Cwth)

Sponsor	The person, business or company that has the primary responsibility for the supply, including for clinical investigational use, of the product in Australia. The sponsor may also be the manufacturer of the goods.

4. Roles and Responsibilities

The **Regional Nurse Director** is responsible for:

- clinical analysis of the risk/ potential risk presented by the TGA notice
- facilitating communication of recall notice as per their local structure
- allocation of proxy for this role when required.

The **Biomedical Engineering Department** is responsible for:

- analysis of the risk/ potential risk presented by the TGA notice for equipment
- identifying affected equipment that is within scope of BME service/database
- liaise/communicate additional information with WACHS PESC distribution list regional contacts in relation to high risk and recall / notifications to assist in their management
- facilitate completion of production correction actions when required
- allocation of nominee for this role when required.

The **Regional Supply Manager** is responsible for:

- facilitating communication of recall notice as per their local structure
- assist with recovering recalled goods
- quarantining affected goods
- assist with return of affected goods to the sponsor or BME.

The **Clinical Leads of areas of affected by recall/notification** are responsible for:

- facilitating communication of recall notice as per their local structure
- assist with identifying affected goods
- quarantining/ removal affected goods
- assist with return of affected goods to the supply manager.

The **Product Liaison Officer** is responsible for:

- updating the WACHS recall email distribution list as advised by regions
- maintaining a spreadsheet listing recalls /notifications and highlighting recalls/ notifications that may present higher risk
- providing monthly report of recalls for tabling at Central PESC and distribution to Regional PESCs
- liaise/communicate additional information with regional contacts in relation to high risk and recall / notifications to assist in their management.

The **Regional PESC** is responsible for:

- ensuring recalls are reviewed, prioritised and actioned as required
- maintaining a record of responses to recalls/ notifications.

The **Central Product Evaluation and Standardisation Committee** is responsible for:

- reviewing actions for relevant high risk TGA recall / notifications
- provide discussion forum for relevant high risk recalls/ notifications
- reviewing and maintaining the TGA product recall / notification policy.

HSS are responsible for:

- identifying end users of products affected by TGA recall / notifications
- disseminate usage report to relevant health sites
- maintain central recall register
- forward recall register in a timely manner to Central PESC chair for discussion at PESC meeting.

5. Compliance

The *Therapeutic Goods Act 1989* (Cwth) articulates legislative obligations relating to this policy where non-compliance under some sections may result in a penalty and offence.

Failure to comply with this policy may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Employment Policy Framework issued pursuant to section 26 of the *Health Services Act 2016* (HSA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies is mandatory.

6. Evaluation

This policy is to be reviewed by the Central Product Evaluation and Standardisation Committee and other relevant stakeholders every three (3) years to ensure that it reflects current guidelines and processes.

7. Standards

National Safety and Quality Health Care Standards
Standard 1 Clinical Governance and Quality Improvement Systems

EQuIPNational Standards
Standard 15.15.1 Corporate Systems and Safety

8. Legislation

Therapeutic Goods Act 1989 (Cwth)

9. References

Uniform Recall Procedure for Therapeutic Goods, 2017 edition v2.0

10. Related Policy Documents

WACHS Clinical Product Evaluation Policy
WACHS Product Evaluation and Standardisation Terms of Reference (Central)
WACHS Product Evaluation and Standardisation Terms of Reference (Regional)

11. Policy Framework

Clinical Governance, Safety and Quality Policy Framework

12. Appendix

Appendix 1 - Recall Issue Process Flowchart

This document can be made available in alternative formats on request for a person with a disability

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Appendix 1