# Clinical Products Complaint Policy

## 1. Background

The use of clinical products can result in clinical, financial and operational risks. This policy outlines the process for the reporting of products that do not meet expected clinical performance requirements.

## 2. Policy Statement

Clinical products that do not meet expected clinical performance requirements must be reported via completion of a product complaint form (S1) to Health Support Services (HSS).

Examples of product complaints may include contaminated products, faulty packaging and breakage of a product during routine use, or repeated malfunction of equipment beyond what would be deemed reasonable.

Note: Routine maintenance and repair are outside the scope of this policy.

Where any complaint involves injury or compromise to patient or consumer, a Datix Clinical Incident Management System (Datix CIMS) form is to be completed.

Reporting of the complaint:

- ensures that faults or clinical performance issues associated with a clinical product purchased within WACHS, can be recorded and followed up in a systematic way
- facilitates appropriate action being undertaken which may include the checking and quarantining of remaining stock, identification of suitable substitution of a clinical product, replacement of faulty products by the vendor. Where a risk to patient, staff or visitor is identified, reporting of the product to the Therapeutic Goods Administration (TGA) may be indicated.
- enables suppliers to manage any quality control issues
- allows the WA Health System to identify suppliers whose products have not consistently met clinical performance requirements.

## Process

### 2.1 Keep the Product

2.1.1 Where possible, keep the product/consumable and packaging. It is desirable that any faulty clinical product or consumable is retained for examination - this includes associated packaging (see 2.1.4).

2.1.2 Contaminated products must be placed in a sealed container. Care must be taken to ensure that any products retained for examination are stored in a manner that ensures protection from physical or microbiological hazards. Hazardous items such as sharps, may be deemed unsuitable for retention and discarded.

2.1.3 Take note of "Lot Number" from packaging where available. This is particularly relevant where a “batch” of products may be affected.

2.1.4 Forward the product or packaging, and copy of completed S1 Product Complaint form (as per section 2.2.1, 2.2.2 and 2.2.3), to the Regional Supply Manager or as per operational requirements. If the complaint relates to biomedical equipment, discuss with Biomedical Engineering.

2.1.5 It is the responsibility of the company representative to collect **or** arrange courier collection of the product, at the company's expense.

### 2.2 Communicate the Problem

2.2.1 Inform immediate team. It is the responsibility of the complainant to inform relevant staff when a product or consumable fails to meet clinical performance or is faulty in their clinical area. The urgency and scope of this notification will be determined by the assessed risk and local operational requirements.

2.2.2 Complete S1 Product Complaint form using objective and factual language including location of faulty product if retained.
It is the responsibility of the complainant, who reports the fault or product performance issue, to complete the S1 Product Complaint form available via the HSS Forms/Supply intranet page or via link in Forms section of Clinical Products Procurement Intranet page.“. When opening the electronic form select “enable contents” to enable data entry.

Support for WACHS staff in relation to S1 Product Complaint submission and management can be provided, upon request, from WACHS Product Liaison Officers (PLOs) email: WACHS Product LiaisonOfficers@health.wa.gov.au.

Part (C) of the S1 Product Complaint form requests confirmation that products or packaging are available for investigation. It is important to communicate the location of any retained products in the subsequent complaint description box.

2.2.3 Submit form to HSS with “CC” to appropriate senior nurse, as per local structure.

2.2.4 The senior nurse notifies appropriate stakeholders, for example, Regional Director of Nursing and Midwifery, Regional Medical Director, chair of the Regional Product Evaluation and Standardisation Committee (PESC) and Regional Supply Manager as per local reporting structure and situation.

2.2.5 The senior nurse is the primary point of contact for HSS and company representatives in relation to the product complaint.

2.2.6 Reporting of final outcome to HSS and complainant is the responsibility of the senior nurse and may also include Regional Director of Nursing and Midwifery, Regional Medical Director and/or chair of the Regional PESC as per local reporting structure and situation.

### 2.3 Liaise with HSS

In response to receiving an S1 Product Complaint form, HSS will forward to Contract Management team who is to:

2.3.1 check S1 Product Complaint form and notify the complainant should further information be required

2.3.2 enter complaint into Products Complaints Register.

2.3.3 forward the completed S1 Product Complaint Form to the supplier/company representative

The HSS representative also records progress reports received from the company representative. The company representative is required to provide the HSS with an outcome following internal investigation of the complaint. Follow up is routinely conducted by the HSS six and at ten weeks following submission, if progress reports are not received from the company.

2.3.4 coordinate investigation of S1 Product Complaint

2.3.5 communicate the S1 Product Complaint to stakeholders

HSS reports and records complaints, recommendations and outcomes to relevant stakeholders including:

- PESC Committees
- Contract managers

### 2.4 Respond to Recommendations

2.4.1 The senior nurse is responsible for liaison between the site/region, HSS and the company representative.

2.4.2 The senior nurse is responsible for facilitating a local response to recommendations and communication back to relevant stakeholders, for example, regional / local Supply Manager or regional PESC, as appropriate to the organisation and situation.

Following a S1 Product Complaint, the outcomes and recommendations may include:

a) the problem was considered a one off and unlikely to recur

b) faulty products were supplied and affected stock must be replaced by the supplier.

The response to S1 Product Complaint recall or removal of the product may be initiated by the site *or* supplier where the risk to patient or user is deemed as “high”. Where a recall or exchange of stock is requested the senior nurse facilitates communication of the requirements to the regional / local Supply Manager and clinical areas using the affected product.

c) sourcing of an alternative product. Where product is a contracted item HSS are responsible for sourcing an alternate product. The Contract Manager may investigate the possibility of awarding an alternate, not awarded, “fit for purpose” product.

The regional / local Supply Manager is responsible for removal of affected stock from clinical areas and replacement with either new or alternative products. Updating of imprest lists and barcodes associated with the change is also the responsibility of the regional / local Supply Manager.

d) there is a requirement for additional in-service / education in relation to use of the product.

Where the need for in-service / education is identified the company representative will negotiate with the senior nurse, to establish a suitable process and time-line for provision of this service.

e) there is a requirement for investigation of whole-of-Health use of the product.

Where the risk is assessed to be significant **or** where multiple S1 Product Complaint forms are received for the same clinical product or consumable this may indicate the requirement for reporting to the TGA.

## 3. Definitions

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| **Clinical Products** | Medicine based on or involving medical treatment, practice, observation, or diagnosis Medical Devices, equipment or consumables purchased for the purpose of healthcare delivery.<br>(Retrieved 2016 Encarta Dictionary: English (U.K.)) |
| **Complainant** | Person making “Bringer” of complaint.<br>(Retrieved 2016 Encarta Dictionary: English (U.K.)) |
| **Senior Nurse** | Senior nurse in relation to local structure which may be Clinical Nurse Manager, Nurse Unit Manager, Director of Nursing or Coordinator of Nursing. |

## 4. Roles and Responsibilities

### Product users / clinicians

- All staff are responsible for reporting clinical risks / hazards associated with clinical products or consumables that are faulty or do not meet clinical performance requirements. If there is risk to patient, staff or consumer, a safety report via Datix CIMS reporting system is required in addition to submission of the S1 Product Complaint Form.

### Complainant

- Keep product, packaging and Lot Number of clinical product or consumable for inspection and reference (ensure sealed container where product contaminated).
- Completion and submission of S1 Product Complaint form to HSS.
- Communication of complaint to senior nurse.

### Senior Nurse

- Reporting of complaint, as per local reporting structure and situation and may include Regional Director of Nursing and Midwifery, Regional Medical Director and/or chair of the Regional PESC.
- Facilitation of ongoing communication with HSS and company representative in relation to the complaint in cooperation with the regional / local Supply Manager.
- Management of local response to recommendations i.e. facilitation of in-service.
- Reporting of final outcome to complainant, HSS, and other parties as per local reporting structure and situation which may include; Regional Director of Nursing and Midwifery, Regional Medical Director and/or chair of the Regional PESC.

### Company Representative

- Liaison with HSS and senior nurse to review S1 Product Complaint and escalate, as appropriate, within their organisation.
- Arrangement and financial responsibility for collection of faulty clinical product or consumable from regional / local  or as specified by the senior nurse.
- Provision of in-service / education as required by the WACHS site.
- Provision of replacement stock when the product is confirmed as faulty.

### HSS

- Receipt of S1 Product Complaint Form and forwarding to HSS Contract Management team.
- Checking of information on S1 form page 1 and, if incomplete, contacting the complainant to update.
- Completion of details on part 2 of S1 form and entry of complaint into Product Complaints Register.
- Forwarding of the S1 Product Complaint Form to the supplier/company representative with a copy to the complainant, Product Liaison Officer, Supply Manager and Contract Manager where appropriate.
- Follow up with the company representative in relation to the complaint.
- Monitoring of the complaint and communication of outcomes and recommendations to the relevant stakeholders including site complainant, senior nurse and the company representative.

- Routine reporting of recent product complaints to PLOs, PESC and CRG as appropriate.
- Recording of final outcomes, in relation to complaint, in Product Complaints Register, in consultation with the senior nurse.

### Product Liaison Officer

- Provision of support and assistance to the complainant, the senior nurse or regional / local supply, as requested, in relation to submission and management of Clinical Product Complaints.
- Reporting of recent product complaints at regional PESC meetings to enable regions to assess any potential impact for users of product.

### Regional/Local Supply Manager

- Facilitation of stock recalls, exchanges as directed by HSS.
- Assistance with collection/transport of clinical product or consumable to company representative as required

Note: Costs associated with the transport of a faulty clinical product or consumable, recalls and exchanges are the responsibility of the company.

**All Staff** are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

## 5. Compliance

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. Records Management

All WACHS corporate records must be stored in the approved Electronic Documents and Records Management System.

Records Management Policy

## 7. Evaluation

The evaluation measure is the annual review of product complaints submitted by WACHS regions. Evidence of product complaint reporting is located within the WACHS Product Complaint database.

## 8. Standards

National Safety and Quality Health Service Standards (Second edition 2017) - Standard 1 Governance and Quality Improvement Systems.

## 9. Related Forms

S1 Product Complaint form

## 10. Related Policy Documents

Regional Product Evaluation and Standardisation (PESC) Committee - Terms of Reference

## 11. Related WA Health System Policies

OD 0611/15 - Clinical Incident Management Policy

## 12. Appendix

Appendix 1: How to Manage a Product Complaint Process

## 13. Policy Framework

Clinical Governance, Safety and Quality

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

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| **Contact:** | Clinical Procurement Manager (R. West) | | |
| **Directorate:** | Procurement and Contract Management | **EDRMS Record #** | ED-CO-16-12567 |
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# Appendix 1: How to Manage a Product Complaint Process

**HOW TO MANAGE A PRODUCT COMPLAINT**

What should we do when a Clinical Product or Consumable fails to meet clinical performance required *or* is faulty?

**2.1 Keep the Product**

- Where possible, keep the clinical product/consumable and packaging.
- Use sealed container where product is contaminated.
- Take note of "Lot Number" from packaging.
- Forward product or packaging to Regional Supply Manager.

Note: It is the responsibility of the company representative to collect *or* arrange courier collection of product, at company's expense.

**2.2 Communicate the Problem**

- Inform immediate staff.
- Complete S1 Product Complaint form (S1 Form) using objective and factual language including location of faulty product if retained.
- Submit S1 Form to Health Support Services (HSS) with "CC" to appropriate senior nurse.
- Senior nurse reports complaint, as per local reporting structure and situation. This may include Regional Director of Nursing and Midwifery, Regional Medical Director and/or Chair of the Regional PESC.
- Senior Nurse becomes primary point of contact for HSS and the company.

**2.3 Liaise with Health Support Services (HSS)**

In response to receiving an S1 Form HSS forward to Contract Management team who:

- Ensure S1 Form is complete.
- Enter complaint into Product Complaints Register.
- Forward S1 Form to Supplier/company representative.
- Coordinate investigation of S1 Product Complaint.
- Communicate and record complaint, recommendations and outcomes to relevant stakeholders.

**2.4 Respond to Recommednations**

- Senior nurse is responsible for liaison between site, HSS and company representative.
- Senior nurse is responsible for facilitating a local response to recommendations and communicating outcomes back to complainant, HSS and, as per local reporting structure and situation. This may include Regional Director of Nursing and Midwifery, Regional Medical Director and/or Chair of the Regional PESC.