SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Reporting of Clinical Product Faults/Quality Issues
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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director of Finance Peter Eaton
AUTHOR	Kate Dobinson- District Clinical Products manager Vesna Trajceska – District Clinical Products Advisor
POSITION RESPONSIBLE FOR THE DOCUMENT	District Clinical Product Manager Kate.dobinson@health.nsw.gov.au
KEY TERMS	Fault, device, product
SUMMARY	A procedure for staff to follow if they encounter a medical product or device fault

1. POLICY STATEMENT

To ensure that all quality issues related to Clinical Products are dealt with expediently and in line with the Therapeutics Goods Administration (TGA), HealthShare and NSW Health Guidelines. Compliance with this procedure is required to maintain a safe working environment.

2. BACKGROUND

While every effort is made to procure goods that are safe and effective for use, from time to time there are unforeseen circumstances that result in products being unsuitable for the purpose for which they were intended.

The reporting of a medical product/ device issue provides an opportunity for safety and quality improvement and/or risk reduction. Typical problems include but are not limited to:

- a batch of products may be faulty, as a result of a quality control problem within the manufacture cycle;
- there may be faulty packaging on sterile products which renders contents unsterile and therefore has compromised the product;
- incomplete instruction for proper use of the product;
- the presence of a foreign body that has compromised the product for safe use;
- there may be insufficient labelling to identify the product correctly;
- the product is poorly designed and does not function for its intended use or has the potential to cause harm;
- the product malfunctions; and
- a product change has occurred without advice.

3. DEFINITIONS

3.1 Clinical Product - any material, instrument, appliance, implant or component of any of these used in the delivery of healthcare. A clinical product can be single use, single patient use, or reusable. A clinical product can also be referred to as a consumable.

Examples of a clinical product can include (but not limited to):

- Wound dressings;
- Instruments;
- Catheters (indwelling, intravenous, central venous);
- Bandages;
- IV fluids and accessories;
- Needles and syringes;
- Continence products;
- Hand hygiene products;
- Operating theater consumables.

3.2 Health Quality Reporting System (HQRS) - is a secure statewide system which provides Public Health Organisations (PHOs) with a mechanism for the lodgment of quality reports for state contracts and non-state contracts clinical products. Through the HQRS, PHOs can electronically communicate to suppliers, the Therapeutic Goods Administration and HealthShare NSW Business Procurement Services Unit, about products quality/performance issues that require immediate action, or for information only. HQRS

summaries are used in the review of supplier performance and is a vital tool for the renewal of contracts - PHOs or State.

3.3 Therapeutic Goods Administration (TGA) - is part of the Australian Government Department of Health and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

4. RESPONSIBILITIES

4.1 Employees will:

- report all clinical product faults to the SESLHD Clinical Products Team.

4.2 SESLHD Clinical Products Team will:

- review all clinical product fault reports and upload them to the NSW HQRS.

5. PROCEDURE

When a clinical product problem is identified, the following steps must be taken:

Step 1 - Contact the SESLHD Clinical Products Team via email SESLHDClinicalProductManager@health.nsw.gov.au or phone 9540 7731 as soon as practicable, in order to ensure the appropriate action is taken.

Step 2 - Do not discard the faulty item

- Retain the faulty product, if contaminated, or if any person may be exposed to any form of risk, decontaminate and/or place the item in a sealed container and label as biohazard or contaminated. In some cases CSSD may be able to assist in the decontamination process.
- If possible retrieve packaging and obtain information:
  - Supplier
  - Product description
  - Product code or reference number
  - Expiry date
  - Batch or lot number
- Where it is not possible to return the faulty item to the Clinical Products Team for investigation, a digital photograph may be provided to illustrate the problem and to retain in our records.
- Do not give the product to Company Representatives unless advised to do so by the Clinical Products Team.

Step 3 - Download and complete the Product/Problem Report Form (under Procurement and Logistics heading) and return along with the faulty product to the Clinical Products Team. Email forms to SESLHDClinicalProductManager@health.nsw.gov.au and send faulty product to the following internal address:
Attention: Clinical Products Team
The Sutherland Hospital – District Finance

Step 4 - The information will be entered into the NSW Health Quality Reporting System (HQRS).

Step 5 - The Clinical Product Team will review the report and contact the vendor and other regulatory bodies via the HQRS.

Step 6 - Reported faults will be assessed based on risk and any required further information.

6. DOCUMENTATION

- Product/Problem Report Form (under the heading *Procurement and Logistics*)
- Reporting of Clinical Product Faults / Quality Issues Intranet Page

7. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
July 2019	2	
February 2016	1	Endorsed by SESLHD Clinical and Quality Council
June 2015	1	Document developed and approved by Executive Sponsor
July 2019	2	Minor review approved by Executive Sponsor. Updated references and hyperlinks.
August 2019	2	Processed by Executive Services prior to publishing.