Faulty Products & Problem Reporting

Faulty products should be reported to enable the cause of the fault to be identified and corrective action taken. Of particular importance is patient and staff safety. There is also an obligation to inform the supplier/manufacturer if necessary and ensure the Department is not financially disadvantaged because of faulty or inferior goods.

Faulty or problem products fall into two categories:

- products used in the patient care environment; and
- all other items.

Products used in the patient care environment

It is essential that if any product used in the patient care environment fails to perform as expected, it must be reported to the Product Manager. If a product demonstrates a safety, packaging, manufacturing or integrity problem, it should be reported.

Any product that meets the broad definition of a *therapeutic device* should be reported. A therapeutic device can be defined as:

> *any material, instrument, machine, appliance, implant or component of these, which is used in the delivery of health care.*

A hospital bed, a surgical instrument, catheter, drainage bag, dressing or complex physiological monitor are examples of therapeutic devices.

Any product, regardless of whether it is a stock line, purchased non-stock, or even samples, are subject to reporting action.

When should you report it?

You should report a problem when something happens with a device which creates a hazard or places the patient or staff at risk. For example:

- sterility is compromised;
- instructions are incomplete or missing;
- poor design, construction or manufacture;
- packaging or labelling defects;
- defective components;
- equipment malfunction.

What to do ...

1. DO NOT THROW THE FAULTY/SUSPECT ITEM AWAY.
2. Try to identify the batch number / lot and manufacture date.
3. Store the item (used or unused) and any recoverable packaging in a safe environment / container.
4. Complete a Product Problem Report (see following page).
5. Contact the Product Manager on 62443312 or (Mob) 0407 495 765 during business hours only.
6. Completed Documents to the Product Manager on (Fax) 62443784

The Product Manager will advise you on what to do with the item and what action will be taken.

Therapeutic Device Alerts and Recalls

We are regularly notified of problems or potential problems with therapeutic items through:

- Health Device Alerts which are notifications from an international organisation that monitors problems with products;
- Urgent Therapeutic Device Recalls - Hospital Level which are sent to hospitals by the Therapeutic Goods Authority (TGA); and
- Written notification from the manufacturer.

Often these authorities are initially made aware of problems by user hospitals - that is why it is essential to report any faults or problems.

When Supply Services is notified of a product recall, action is initiated to check warehouse stocks and to track where the items were issued. Any batches / lots affected by the recall notice must be withdrawn from use and returned to Supply for credit/replacement action. Supply will arrange for replacement stocks from the manufacturer/supplier.

Items affected by a recall must not be used, even if they look 'OK'.

Other Items (not used for patient care)

Acceptable faults with items, other than patient care items, are usually limited to damaged or deficient items inside the manufacturer's packaging, or faulty manufacture.

Customers should assess the benefit of returning or reporting such defects against the value of the item, the likelihood that the fault will be present in other packages, etc and the ability to determine liability.

In any case, customers may return such items to Supply Services (using a 'Red Req'), for assessment by Supply staff. Where possible, a credit for the return will be given, provided the manufacturer / supplier accepts liability.

ACT Government Health

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PRODUCT PROBLEM REPORT (Photocopy this proforma locally, complete and send to: ACT Health Supply Services PO Box 47 Mitchell ACT 2911 (or) Fax: 62050806	Product Problem Report No.: (Product Manager's Use only)	

Date : / / **Originator :** □ TCH □ ACTHealth □ Calvary □ Other:

Reporter's Name :	
Position :	
Ward / Dept :	
Telephone No. :	

Product Identification (Provide all information if known.)

Generic Description :			
Supply Cat No :			
Brand Name :			
Manufacturer / Supplier Name :		**Mfr / Supplier Cat No. / Part No. :**	
Batch / Lot No. :		**Expiry Date :**	
Any Other Product info :			

Problem Details (Briefly describe the problem.)

Performance needs improvement	[Yes]	[No]	May injure Patient / Staff	[Yes]	[No]
Will injure Patient / Staff	[Yes]	[No]	Has injured Patient / Staff	[Yes]	[No]

Retain the problem product and any of its packaging in a safe environment.

PRODUCT MANAGER'S USE ONLY
Action Taken

Notification :	
Recall :	
Replacement :	
Reintroduction :	
Follow up :	