

GUIDELINES

FOR

CLINICAL PRODUCTS

RELEASE TWO

01 March 2005

1. Authorisation

NSW Health Peak Purchasing Council Secretariat prepared this report on behalf of

Clinical Product Managers Networking Group
Clinical Equipment Procurement Working Party

For additional information or comment please contact

Valentino Bulaon
Phone 02 9816 0456
E-Mail vbula@doh.health.nsw.gov.au

2. Document Control*

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3. Document Distribution

All NSW Public Health Organisations

4. Acknowledgements

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SECTION A
GENERAL INFORMATION

SECTION A – GENERAL INFORMATION

1. INTRODUCTION

The purpose of this guideline is to assist Public Health Organisations develop and / or enhance local policies and procedures to maximise the effectiveness of personnel involved in the “Clinical Product Procurement Process”.

2. DEFINITIONS

- Authorised Public Health Organisation Personnel – An employee of the Public Health Organisation that is nominated for the task.
- Clinical Product – refers to both clinical consumables and clinical equipment, e.g. any material, instrument, machine, appliance, implant or component of these used in the delivery of health care.
 - ✓ Clinical Consumables - any clinical product that is single use, single patient use or re-usable following re-processing [where appropriate].
 - ✓ Clinical Equipment – any clinical product other than a clinical consumable used for the delivery of patient care.
- Procurement –is the rigorous process of research and analysis with a view to obtaining clinical products.

3. CLINICAL PRODUCT PROCUREMENT COMMITTEE

It is recommended that each Public Health Organisation establish a committee or committees to manage clinical products. Clinical products may be managed through one committee, or a committee for Clinical Consumables and Clinical Equipment may be independently established.

Clinical Product Procurement Committees are to ensure that clinical product procurement supports evidence-based practice in the most cost effective manner.

Clinical Product Procurement Committees will address the following:

- Duplication of effort
- Rationalisation
- Appropriate for use
- Monitoring of evaluations
- Coordination of in-service training
- Compliance with PHO protocols
- Liaison with industry
- Conflict of interests
- Compliance with standards
- Risk Management
- Compliance to relevant Health policy
- Quality issues
- Life Cycle cost

3.1 Purpose

The scope of the Clinical Product Procurement Committees may include clinical products with a broad application within Public Health Organisations, which may be categorised as:

- Clinical Consumable items
- Clinical Equipment

The Clinical Product Procurement Committees should be multi-disciplinary and responsible for examining new and alternative clinical products paying particular attention to safety, price, quality and suitability for use, in accordance with the Department of Health's Purchasing & Supply Manual, guidelines and relevant standards.

The committee should be a forum where other committees and interested groups, [e.g. Infection Control, Occupational Health & Safety, Wound Care, patient care] unite to share information.

3.2 Membership

Membership on the Clinical Product Procurement Committees may be any but not exclusive to of the following:

- Clinical Product Manager
- Purchasing Representative
- Clinical Representatives
- Biomedical Engineer
- Occupational Health & Safety Practitioner
- Infection Control Officer
- Quality Manager
- Environmental Management
- Sterile Services Representative
- Other Public Health Organisation Authorised Officer
- Other advisers may be co-opted as deemed necessary including Finance, Engineering, Radiology / Medical Imaging, and Wound Care Committee.

3.3 Terms of Reference

3.3.1 Purpose

- a) Ensure that clinical products are evaluated, costed and results documented prior to acceptance / rejection;
- b) Monitor the appropriateness, performance of new alternative and current clinical products and;
- c) Rationalise clinical products where possible.

3.3.2 Objectives

- a) Formulate / endorse and support policies for the selection and purchase of clinical products, with respect to adherence to Australian and other relevant standards, compliance with Therapeutic Goods Requirements, the State Procurement Contracts and relevant Department of Health policies.
- b) Review relevant State Procurement state contracts in order to select the most efficient and economical clinical products.

- c) Consider requests and review applications for contracts exemptions.
- d) Consider requests and review the results of evaluations of new and alternative clinical products.
- e) Ensure that clinical products introduced have the prior approval of the Clinical Product Procurement Committees.
- f) Ensure clinical products are evaluated on the basis of the following criteria:
 - Agreed evaluation criteria
 - Suitability of purpose
 - Value for money
 - Availability
 - Proven performance in respect of evidence-based practice.
 - Compliance with Infection Control, Occupational Health & Safety Policies, recommendations.
 - Maintenance requirements
 - Environmental management concerns
 - Compliance with appropriate Standards
- g) Provide a forum for consultation
- h) Identify and notify Public Health Organisation Executives of changes that will impact on budget
- i) Promote the reporting of clinical products and supplier performance in accordance with Public Health Organisation policy.

3.3.3 Outcomes

The committee may:

- Endorse new or replacement clinical products
- Recommend appropriate training and education
- Inform the appropriate department of any apparent breach of policy
- Review of existing product range to ensure ongoing effectiveness
- Review procurement process

3.3.4 Code of Conduct

- a) In line with current Department of Health and Public Health Organisation's code of conduct, all members of Clinical Product Procurement Committees are to ensure that this code is brought to the attention of all staff.
- b) Participants in any clinical product selection process should disclose in writing any pecuniary or other definite interest which could lead to a conflict of interest

3.3.5 Cross Linkage of Committee

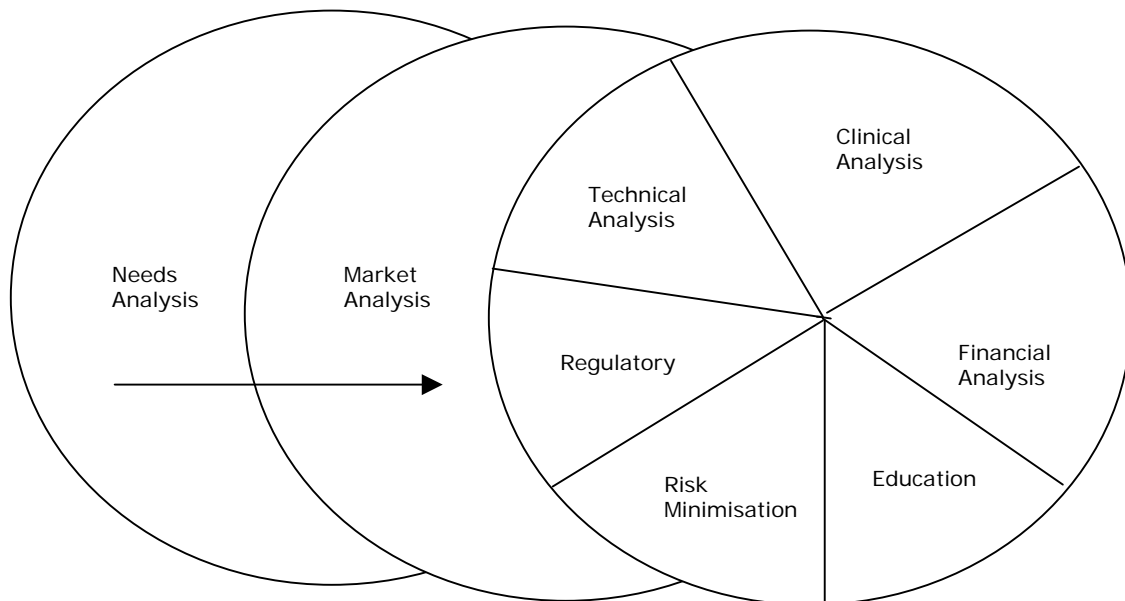
Cross linkages may be established but is not limited to the following groups.

- [Health Peak Purchasing Council \[HPPC\]](#)
- [Patient Care Technology Group](#)
- [Occupational & Health & Safety Group](#)
- [State Procurement Group](#)
- [Environmental Management Committee](#)
- [Infection Control Association](#)
- Biomedical Engineering Advisory Group
- [Sterilization Research Advisory Council](#)

4. CLINICAL PRODUCT EVALUATION PROCESS

- a) The request to evaluate a clinical product may originate from a Clinician or a Supplier. Before any new clinical product is evaluated it should come under the scrutiny of the Public Health Organisation's Authorised Personnel. [e.g. Clinical Product Managers, Biomedical Engineers]
- b) The Public Health Organisation's Authorised Personnel is to determine if the Health Service is willing and able to evaluate the clinical product being requested [per point a)] and liaise with appropriate suppliers
- c) If evaluations are to proceed, the Public Health Organisation's Authorised Personnel is to arrange the completion of the product presentation form by the supplier. This form is required for all clinical products submitted to Public Health Organisation for evaluation. Refer to Section A – Systems and Databases
- d) If evaluation is not to proceed the Public Health Organisation's Authorised Personnel is to inform the Supplier of the outcome and enter recommendations onto the appropriate database.
- e) If evaluation is to proceed, recommendations should be forwarded to the Clinical Product Procurement Committee.
- f) Upon review and acceptance by the Clinical Product Procurement Committee the Public Health Organisation's Authorised Personnel is to:
 - Organise / coordinate evaluation at appropriate sites
 - Organise / coordinate / monitor in-service
- g) On completion of the evaluation all clinical product evaluation forms will be completed and returned to the Public Health Organisation Authorised Personnel for collation and presentation to the Clinical Product Procurement Committees.
- g) The results of the evaluation are entered onto the HPPC Clinical Consumables / Equipment databases. Refer to Section 7 – Systems and Databases
- h) The Public Health Organisation's Authorised Officer is to notify the requestor of the final outcome.
- i) Results of evaluations completed for consideration /acceptance onto state contracts shall be forwarded to State Procurement, Department of Commerce.
- j) The Public Health Organisation's Authorised Personnel is to organise a 6 to 12 months review

4.1 Diagram a – Elements of the Clinical Product Evaluation Process



4.2 Checklist - Elements of the Clinical Product Evaluation Process

- a) Needs Analysis
- b) Market Analysis through
 - Networking
 - Research
 - Supplier Liaison
 - Vendor Performance Review
 - State Contract Control Board Contracts
- c) Pre-Procurement Checklist [not in any order]
 - Indemnity considerations
 - Clinical Analysis
 - ✓ End User Evaluation
 - ✓ Patient Feedback
 - Financial Analysis
 - ✓ Life Cycle Costing / Standardisation
 - ✓ Funds Availability
 - ✓ Cost of Education
 - ✓ Clinical consumables
 - ✓ Savings from Rationalisation
 - Technical Analysis
 - ✓ Installation, cost & Impact
 - ✓ Maintenance / Engineering considerations
 - ✓ Occupational Health & Safety considerations
 - ✓ Infection Control considerations
 - ✓ Risk Management considerations
 - ✓ Clinical Accuracy
 - ✓ Biomedical Analysis
 - ✓ Sterilisation requirements
 - ✓ Waste Management / Environmental impact

- Regulatory
 - ✓ TGA
 - ✓ Department of Health
 - ✓ Standards
- Education
 - ✓ Technical
 - ✓ Clinical
- Risk Minimisation
 - ✓ Indemnity
 - ✓ Education
 - ✓ Risk Assessment

5. COLLABORATIVE PROCUREMENT

The HPPC encourages maximization of Health's buying power through collaborate efforts amongst Public Health Organisations. A number of special procurement options exist, e.g. "Tender Networking", "Piggy Back" on existing Tenders and "Quadrangle Arrangements"

[Refer HPPC Tender Networking Guidelines for Public Health Organisations located at: <http://internal.health.nsw.gov.au/business/ppc/Library.htm>]

To progress collaborative procurement it is recommended that established networking groups be contacted. In most instances, the Public Health Organisations representation on these groups may use these networking groups as an avenue to establish collaborative arrangements. It is recommended that liaison with these groups be established where such liaison does not exist. Some of these groups are:

- ✓ Clinical Equipment Procurement Working Party
<http://internal.health.nsw.gov.au/business/ppc/SIClinicalEquipment.htm>
- ✓ Clinical Product Managers Networking Group
<http://internal.health.nsw.gov.au/business/ppc/SIClinicalConsumables.htm>
- ✓ Working Party for the Implementation of AS4187-9
<http://internal.health.nsw.gov.au/business/ppc/SIAS4187.htm>
- ✓ Tenders & Contracts Officers / Managers Networking Group
<http://internal.health.nsw.gov.au/business/ppc/SITCNG.htm>
- ✓ Public Health Organisations Supply Quadrangles

Consultation with other groups / associations should also be considered. Some of these groups are

- ✓ Patient Care Technology Group
<http://www.pctg.com.au>
- ✓ Health Services Supply Association
<http://www.hssa.com.au>
- ✓ Biomedical Engineers Advisory Group
- ✓ Sterilisation Research Advisory Council of NSW

Public Health Organisations should also explore other procurement arrangements that may maximise other opportunities, e.g. standing / blanket order, consignments and supplier partnering arrangements.

6. OTHER CONSIDERATIONS

6.1 Occupational Health & Safety

Occupational Health & Safety aspects of clinical products need to be considered prior to their introduction into Public Health Organisations, and must comply with the selection of clinical products to:

- a) Comply with legislative obligations under the NSW Occupational Health & Safety Act 2000 and NSW Occupational Health & Safety Regulation 2001, to ensure the health, safety and welfare of employees at work. For more information, refer to: <http://www.workcover.nsw.gov.au>
- b) Address health and safety requirements with reference to relevant codes of practice, health industry guidelines and Standards.
- c) Ensure clinical product selections are not purely dictated by cost, which may compromise clinical product efficiency and / or the safety of employees, patients and visitors.
- d) Reduce the incidence of clinical product related injury and subsequent Worker's Compensation and indirect costs.
- e) Implement Work Cover Code of Practice

6.2 Infection Control

NSW Health is committed to ensuring the health and safety of all patients in health care settings and to provide a safe and healthy working environment for all employees. It is therefore imperative that the following policies / standards be adhered to:

- ✓ The NSW Health Infection Control Policy is accessible via the Department of Health Intranet Site as per the address listed below:

["http://internal.health.nsw.gov.au/fcsd/rmc/cib/circulars/2002/cir2002-45.pdf"](http://internal.health.nsw.gov.au/fcsd/rmc/cib/circulars/2002/cir2002-45.pdf)

- ✓ The Australian Standards 4187 [current edition], Cleaning, Disinfecting and Sterilising Reusable Medical and Surgical Instruments and Equipment and Maintenance of Associated Environments in Public Health Organisations.

6.3 Environmental Purchasing Guidelines

In striving for "Health Gains" for the community, the public must not be disadvantaged as a result of any waste generated during the course of meeting our service obligations. NSW Health is committed to minimizing all waste generated in the normal course of pursuing a high standard of health care. Where the generation of waste cannot be avoided, the waste should be disposed of by methods with the least impact on health and the environment. For more information, refer to the NSW Health's Environmental Purchasing Policy Guidelines located at:

<http://internal.health.nsw.gov.au/fcsd/rmc/cib/circulars/1998/cir98-89.pdf>

6.4 Reducing Public Health Risks Associated with Reusable Medical Devices

Reducing the Public Health Risks Associated With Reusable Medical Devices is a document produced by a National Coordinating Committee on Therapeutic Goods (NCCTG) Expert Working Group that was convened in 2003 to examine the public health issues associated with reusable medical devices that are difficult to clean, disinfect and sterilize. To access this document please go to http://www.tga.gov.au/devices/reusdev_phr.htm

7. SUPPLIER REPRESENTATIVES ACCESSING PUBLIC HEALTH ORGANISATIONS

Points to consider when arranging suppliers representatives to visit Public Health Organisations.

- a) All clinical product evaluations for units of Public Health Organisations are to be coordinated through the Public Health Organisations Authorized Personnel
- b) After initial consultation with the Public Health Organisations Authorised Personnel, Supplier representatives are permitted fair and reasonable access to nominated Public Health Organisations personnel.
- c) Access to areas of Hospitals is not permitted without prior consultation/ approval of the Public Health Organisations Authorised Personnel.
- d) Visits are by appointment only and representatives are expected to display identification with photo.
- e) All clinical products for evaluation must have the appropriate documentation completed (available from the Public Health Organisations Authorised Personnel) prior to consideration.
- f) Samples are not to be left in ward areas or departments without prior arrangements with the Public Health Organisations Authorised Personnel
- g) A clinical product is not to be introduced or evaluated without being inspected and approved by the appropriate department.
- h) An appropriate product presentation form and indemnity form (where applicable) is to be completed prior to any evaluations.
- i) Pharmaceutical samples and evaluations are to be coordinated through the Chief Pharmacist.
- j) Representatives found in breach of this policy may be refused access to the hospital.
- k) Criminal records check / Child Protection ACT
 - The Public Health Organisation is responsible for ensuring that Sales Representatives / Contractor accessing Public Health Organisations sites have up-to-date Criminal records checks and complies with the requirements of the Child Protection (Prohibited Employment) ACT 1998 – Sect 3. This is required if the Sales Representative / Contractor is accessing the Public Health Organisations site or any Public Health Organisations clients sites "unsupervised" or

"unaccompanied" including direct contact with children here that contact is not directly supervised. Where the Sales Representative / Contractor is accompanied at all times by an employee of the Public Health Organisations, Criminal records check is not necessary.

- In instances where the Public Health Organisations require criminal records checks, this may be completed through the Department of Health's Employee Screening Branch, which is a sub branch of Department of Health Audit Branch.
- It is current policy of the NSW Department of Health that potential employees, contractors and / or consultants may be required to undergo criminal records checks prior to employment or engagement.
- Public Health Organisations reserves the right to undertake relevant record checks prior to entering into any agreement with a representative
- Any information gained from criminal record checks shall be treated entirely in accordance with the guidelines, as documented by the NSW Department of Health and NSW Government.
- An adverse finding from a Criminal Record Check needs to be reviewed with the applicant and a risk Assessment undertaken. Refer to NSW Department of Health Circulars 97/80 and 2000/69 and the FAQs located at:

<http://internal.health.nsw.gov.au/audit/empprisk.html>

<http://internal.health.nsw.gov.au/fcsd/rmc/cib/circulars/1997/cir97-80.pdf>

<http://internal.health.nsw.gov.au/fcsd/rmc/cib/circulars/2000/cir2000-69.pdf>

<http://internal.health.nsw.gov.au/audit/faqs.html#crim>

- l) Representatives are expected to abide by relevant Department of Health and Public Health Organisations Policies that relates to access and entry into Health grounds and facilities, e.g. "no smoking policy" & "policy on mobile phone use in critical areas".
- m) Suppliers and their representatives should not knowingly place the public health organisation staff in circumstances which might lead them to breach of the Code of Conduct e.g. offering gifts / benefits in contravention of the Code. The code of conduct may be access via <http://internal.health.nsw.gov.au/health-public-affairs/ar9697/a2700.html>
- n) Representatives shall not interfere with professional responsibilities or access confidential patient information and violate patient confidentiality or interfere with the ability to care for patients.
- o) Representatives are not permitted to negotiate price with unauthorised Public Health Organisations personnel. Negotiations should be consistent with the public health organisation's internal policy.
- p) The Public Health Organisation will not accept responsibility for payment of any goods delivered to any Hospital or associated department of the Public Health Organisation without a purchase order number. Representatives should refuse all requests for delivery of goods unless an official purchase order has been received from the Public Health Organisation. Failure to comply with this requirement will result in invoices for the goods not being paid.

For more details on the above, please refer to the NSW Health Purchasing & Supply Manual for Public Health Organisations located at http://internal.health.nsw.gov.au/audit/manuals/purch_supply.pdf

8. HEALTH REPORTING SYSTEMS

There are currently a number of reporting systems in use within the Health Services; this section provides preliminary information on some of these systems. As each system has its own specific purpose, it is important to obtain further information on each system prior to reporting quality concerns and incidents, e.g. the HQRS extends the reporting process to external organisation such as the Therapeutic Goods Administration, suppliers, State Procurement, etc. Whilst the IIMS is for internal health management of incidents, the AMMS is for equipment registry and management, etc.

8.1 HPPC CLINICAL PRODUCT EVALUATION DATABASES

The "Clinical Consumables Evaluation Database" and the "Clinical Equipment Evaluation Database" were developed as a central evaluation information registry for both state contract and non-state contract clinical products. The databases enable NSW Public Health Organisations to:

- ✓ Initiate and track evaluations
- ✓ Assign suppliers to enter data via the HPPC Internet gateway
- ✓ Share information across the state
- ✓ Access other sites evaluations, including all supporting information and attachments.

The Clinical Consumables Evaluation Database is located at <http://internal2.health.nsw.gov.au/ppcdb/ppc.cfm>

The Clinical Equipment Evaluation Database is located at <http://internal2.health.nsw.gov.au/ceedb/form/index.cfm>

8.2 HPPC ELECTRONIC PRODUCT PRESENTATION FORMS

All clinical products being submitted to Public Health Organisation for evaluation should have a clinical product presentation forms completed. Electronic product presentation forms are generated using the evaluation databases. This process enables Health Services to generate user "ID's" and "password" for suppliers. Suppliers upon receipt of access details by email may then access the "HPPC Clinical Evaluations Internet Gateway" and enter product presentation information.

Upon entry of information by Suppliers, the originating Authorised Officer will receive a system-generated email confirming successful lodgement of requested information. The Public Health Organisation's Authorised Personnel is to view information entered and re-review if evaluation may proceed.

The "Electronic Product Presentation Form" is located at <http://internal2.health.nsw.gov.au/ppcdb/ppcexternal.cfm>

8.3 HPPC HEALTH QUALITY REPORTING SYSTEM [HQRS]

The HQRS was developed as a central system for reporting and monitoring clinical product quality issues, concerns, difficulties, and incidents for both state contract and non-state contract clinical products.

The HQRS system is used to process information such as:

- ✓ Incident reports for the attention of Therapeutic Goods Authority [Information required when submitting TGA Incident Reports].
- ✓ Incident reports and state contract items quality concerns for the attention of State Procurement, suppliers and the HPPC
- ✓ Application for state contract exemption for the attention of HPPC

The HQRS is located at

<http://internal2.health.nsw.gov.au/hqrs/form/index.cfm>

NOTES ON HPPC SYSTEMS & DATABASES

CONDITIONS OF USE

Accredited users of HPPC system and databases abide by the following conditions:

- a) Evaluations & quality reports entered onto the HPPC systems and databases are entered as a form of Public Health Organisation records keeping" and "information sharing".
- b) Public Health Organisation viewing information described in point a) do so as a guide / reference only and is not to be used as the sole reason to conduct or not to conduct business with a supplier.
- c) Public Health Organisations acknowledge information described in point a) may be based on specific criteria or environment of other Public Health Organisations and may not be consistent with their own criteria or environment. This in effect supports conditions as stipulated in point b).
- d) Suppliers are to be advised by the Public Health Organisation that evaluation / quality reports are to be entered onto the statewide system and that said information will be accessible by all Public Health Organisations subject to conditions as stipulated in point b)

ACCREDITATION OF USERS

Access to HPPC systems and databases are assigned to authorised Health Service representatives, after completion of a comprehensive training session, as organised by the NSW Health Peak Purchasing Council - Secretariat. For more information on this matter, send an email to vbula@doh.health.nsw.gov.au

CONFIDENTIALITY

Information entered onto the HPPC systems and databases are confidential and specific for internal NSW Health use only. Users are to ensure that they take reasonable care when forwarding extracted information to other Public Health Organisation personnel, i.e. ensure the recipients are aware of the conditions of use as stipulated above.

8.4 NSW INCIDENT INFORMATION MANAGEMENT SYSTEM (IIMS) POLICY

In reference to NSW Health Department circular 2004/82, incidents to be entered into IIMS include any unplanned event resulting in, or having the potential for injury, ill health, damage or other loss. The system also captures near misses, i.e. any event that could have had adverse consequences but did not, and is indistinguishable from actual events in all but outcome.

Adverse events that will be recorded in IIMS include unintended patient injury or complications from treatment that result in disability, death or prolonged hospital stay and are caused by health care management.

Hazards recorded in IIMS relate to source or situation with a potential for harm in terms of human injury or ill health, damage to property, damage to environment or combination of these.

The "IIMS" is located at <http://internal.health.nsw.gov.au/quality/iims>

Incident categories

There are four categories of incident occurring in the health care setting. The IIMS has a separate form for each of these incident types. They are:

- a) Clinical incidents – any incident, adverse event or near miss involving patient care: for example some deaths, falls, pressure ulcers and including those that may be caused by medical equipment (such as infusion pumps) or those due to system issues such as access block.
- b) Staff visitor, contractor incidents – any incident or near miss pertaining to the health of any staff (permanent or casual), visitor, volunteer or contractor. This category includes occupational health and safety type issues and body substance exposure incidents.
- c) Property, security, hazard incidents – any incident or near miss that involves these elements, for example theft or damage to property or issues identified after routine OH&S inspection.
- d) Complaints – an expression of dissatisfaction by a complainant, which may have one or more issues associated.

8.5 Asset Management & Maintenance System [AMMS]

The AMMS is a system in use for the management of buildings, building services, land, land improvements, "Bio-medical equipment" and other maintainable assets of the NSW Health system.

Purpose

The AMMS provides an accurate storage of asset maintenance information, records and historic data. This enables the alignment of asset with service requirements; planned & transparent prioritization of maintenance tasks;

reporting on performance and cost of assets; and provides information to support capital works decision making

Further information on this system is available at <http://internal.health.nsw.gov.au/operations/apmd/amsb/healthamms/healthamms.html>

8.6 Advanced Incident Monitoring System [AIMS]

The AIMS is a risk management system that enables the user to manage incident data. The system enables the recording and classification of incidents and generation of standard and user-defined reports. At the time of printing of this report, the AIMS is only used in selected Health Services and is "under assessment". No further information or policy directive is available from the Department of Health at this stage.

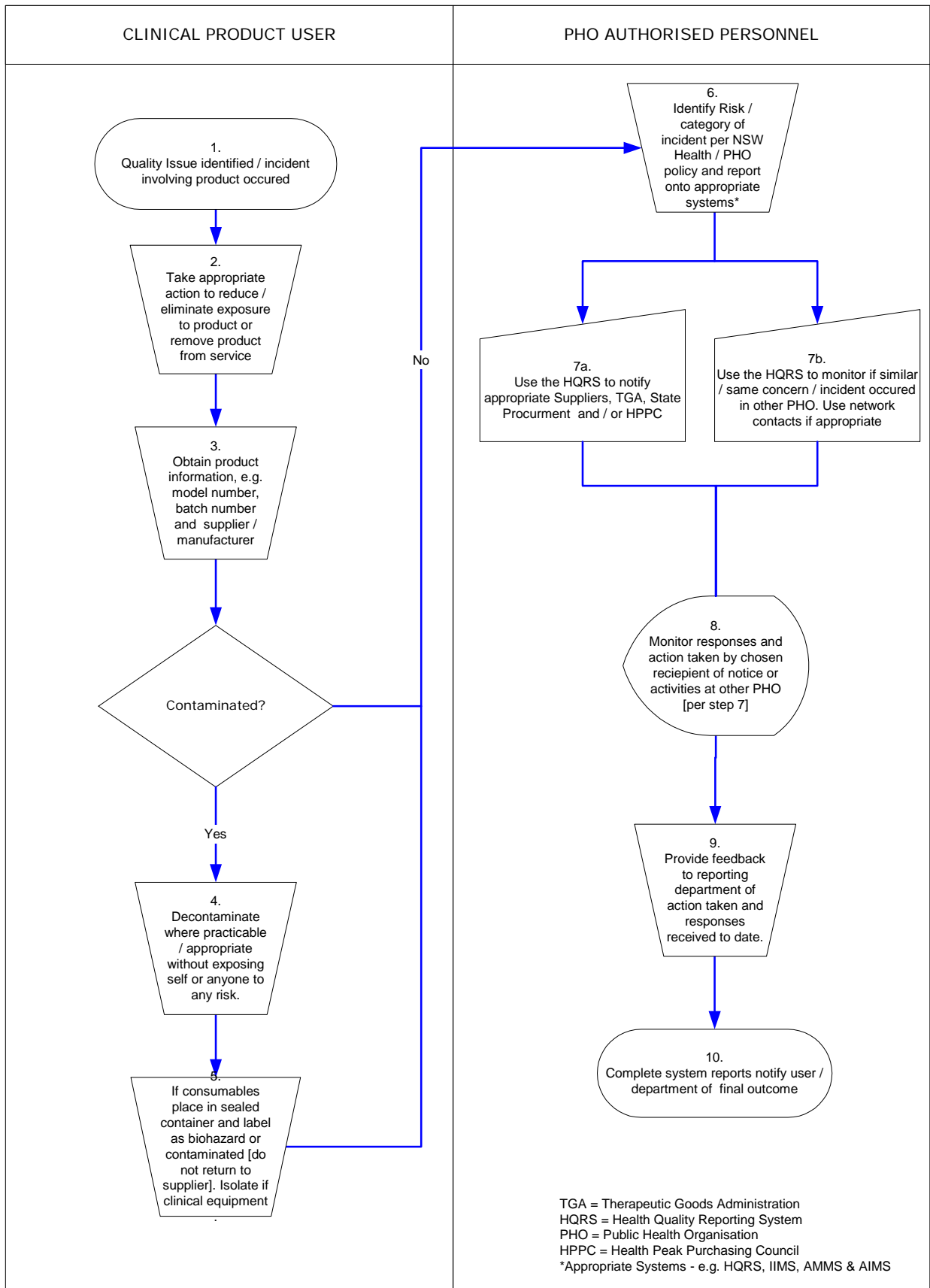
To assist in the reporting process, the following policies should be read in conjunction with other NSW Health Policies:

2003/88	Reportable incident Briefs to the NSW Department of Health	This circular details the processes required by PHO in response to an incident and how to notify that incident to the department. The data elements and incident notification and management processes in IIMS were developed to meet the requirements outlined in this policy
www.health.nsw.gov.au/publications/quality	Better Practice Guidelines for Frontline Complaints Management	Provides a framework to enable a consistent and continuous improvement approach to frontline complaints handling in the NSW Health system. IIMS will facilitate the notification and management processes of complaints as outlined in this document and will meet the quarterly Statewide Complaints Data Collection requirements.
www.health.nsw.gov.au/publications/quality	Guideline on the Management of a Complaint or Concern about a Clinician	The purpose of this guideline is to provide assistance to Public Health Organisations in the development of local policies for managing a concern or complaint about a clinician. These concerns should be managed separately to the incident management processes and as such findings relating to Concern or Complaint about a Clinician should not be documented in detail in IIMS

97/131	NSW Healthplan – Counter disaster planning and coordination	Outlines the system for early notification of all major incidents or disasters to allow rapid coordination of health resources.
2002/19	Effective Incident Response: A Framework For Prevention and Management in the Health Workplace	This policy and guideline details the requirements to ensure that health services minimise the potential for incidents to occur, and that if they do occur, to ensure a planned and effective response is in place to effectively manage the incident and minimise its impact on those involved. This document also includes information on timely reporting, incident investigation and post-incident management
2001/22	Wokplace Health and Safety: A Better Practice Guide	This policy informs staff of the legislative framework and responsibilities relating to occupational health and safety and to explain how occupational health and safety is managed in NSW Health.
2001/55	Management of Reportable Infection Control Incidents	Contains policy guidelines for use in the event of a critical infection control incident and must be used by health care facilities as the basis for development of detailed local guidelines relevant to their individual setting
2004/23	Coroners Cases and Amendments to Coroner's Act 1980	Details the circumstances under which a death must be referred to the coroner and the process to be followed in doing so.
2003/47	NSW Health Electronic Information Security policy	Describes the process for ensuring that the particular security needs of electronic health information are met, in view of the sensitive nature of the material they contain.
2004/34	NSW Health Privacy Manual (Version 1) 2004	The main privacy document for NSW Health it is a manual that has been designed to assist with compliance with current legislation.

www.health.nsw.gov.au/ publications	Patient Matters Manual	Is one of a series of Public Hospital Procedure Manuals produced as a joint project by the NSW Department of Health and the Australian College of Health Service Administrators (NSW Branch). It reflects current Departmental policies and is a live document to which amendments are issued on a regular basis. The section in regard to Health Records was last updated in August 2004.
2003/75	NSW Health Policy and Procedure for Injury Management and Return to Work	The purpose of the policy is to assist health services to develop local programs that meet legislative requirements and ensure that appropriate action is taken in the event of workplace illness or injury. This includes ensuring early notification and prompt management of the illness or injury
2003/92	Protecting People and Property: NSW Health Policy and Guidelines for Security Risk Management in Health Facilities	Known as the "Security Manual", this document outlines NSW Health policy on key aspects of personal and property security and provides information to assist health services maintain an effective security program based on structured risk management processes, consultation, incident reporting, documentation, program monitoring and evaluation
2000/41	Reporting Possible Corrupt Conduct to the Independent Commission Against Corruption	Defines what is corrupt conduct, how to report such conduct to ICAC and the process followed by ICAC when a report is received.
Premier's Department 2004/21	Procedures for reporting security incidents	This document outlines the required response for Public Sector organisations when a real or alleged threat to security is identified.

8.4 CLINICAL PRODUCT QUALITY REPORTING FLOW CHART



SECTION B

CLINICAL CONSUMABLES

MANAGEMENT

SECTION B – CLINICAL CONSUMABLES MANAGEMENT

1. OVERVIEW

Management in this context covers all the processes required for the effective and efficient acquisition of clinical consumables. These processes include research, analysis, reporting, procurement and monitoring.

Overall management of clinical consumables within Public Health Organisation may be assigned to an Authorised Personnel. It is recommended that the Authorised Personnel be a registered nurse.

In this section the authorised Public Health Organisation Authorised Personnel refers to the Clinical Product Manager [CPM]

2. PROCESSES

Clinical consumables management includes the following processes.

a. Needs analysis - research or systematic enquiry when a request for clinical consumables is raised. The process involves the identification / justification of need by reviewing a number of elements, i.e.:

- Current clinical practice - to determine relevancy of requirements, consider the following points:
 - ✓ Is the “need” a result of the introduction of a new product? Will the new product replace an existing one in use?
 - ✓ Will the introduction of the new product impact on clinical practice? Will change to clinical practice be required?
 - ✓ Is the “need” a result of change to clinical practice?

b. Market Analysis – understand the market, i.e. sources of supply and determine the most appropriate strategy that can bring about value for money arrangements. Consider the following points.

- Determine if the clinical consumable is on state contract. If it is on state contract, evaluation may not be necessary. However, this is to the discretion of the Public Health Organisations. To access the most recent state contract list go to

<http://www.supply.dpws.nsw.gov.au/Contract+Information+and+User+Guides/Health+Consumables+and+Equipment/Health+Consumables+and+Equipment.htm>

- Some Public Health Organisations choose to evaluate clinical consumables on state contracts where “Organisation-specific-requirement” exists. The view is that such requirement may not have been considered at the time the clinical consumable was evaluated by the HPPC Contract Advisory Group.

If the decision is to evaluate a state contract item, check the HPPC Clinical Consumables Evaluation Database to establish if the preferred consumables are in use or have already been evaluated by other Public Health Organisations. [Refer to Systems and databases in section 8]

- If the clinical consumable is not on State Contract, Public Health Organisations should explore other arrangements that may maximise other opportunities, e.g. collaborative procurement and supplier partnering arrangements. Note: During the recent review of this guideline, the collaborative procurement arrangement called “Quadrangles” was under review in the context of the shared corporate services program. It is yet to be determined if such arrangements will still exist when the restructure of Health Services is completed.
- c. Clinical Analysis – analysis of suitable clinical consumables by reviewing perceived and apparent advantages, disadvantages and other value added benefits. Consider the following points.
- Evaluate the clinical consumable as to its clinical performance.
 - ✓ Does the clinical consumable perform according to its purpose?
 - ✓ Does the clinical consumable perform effectively and efficiently?
 - ✓ Does the clinical consumable provide the user with confidence through its reliability?
 - Determine in-service requirements to educate and support the user before and during the use of the clinical consumables.
 - ✓ Can the preferred supplier meet such requirements?
 - ✓ Are there additional costs to be incurred by the Public Health Organisations?
 - Identify possible risks to Health Care Workers and to patients.
 - ✓ What steps should be taken to eliminate the risk?
 - ✓ What steps should be taken to minimise the risk if it is unavoidable?
 - ✓ What are the impacts to occupational health and safety?
 - Ensure that it does not impinge on any policy, NSW Health and PHO have existing policies that may need to be considered when selecting or using clinical consumables, e.g. infection control / latex content policies. It is to be ensured that the clinical consumables to be selected do not impinge on any of these policies.
- d. Procurement – in this instance is a rigorous process of obtaining clinical consumables. Such process is the result of systematic research and analysis.

In this section, the word procurement describes the whole process involved in determining the appropriateness of products in relation to identified needs. The end result of the process is either the recommendation to purchase the product as it has been determined appropriate for the requirement or not to purchase, as it has been determined that it did not meet the requirements. The following are some elements that may be considered as part of the procurement process.

- NSW Health Policy stipulates that all clinical consumables shall be obtained at the lowest possible price consistent with quality. However, this is subject to the following conditions.
- State Contract Items, NSW Health policy stipulates that if clinical consumables are available under contracts arranged by the State Contract Control Board, they shall be obtained from those sources [no matter the source of funds] unless there are specific reasons justifying an application for exemption.

- Exemptions from state contracts or from the use of specific common period contracts may be granted by the NSW Health Department upon the recommendation of the HPPC. The duration of the exemption will be noted at the time the exemption is granted. It should be noted that application for exemptions for clinical consumables should have supporting clinical reasons and that exemptions are granted only on rare occasions. Such reasons must be specifically approved by the Director General of the Department of Health, following advice from the HPPC, prior to the purchase being made. PHO are to advise the respective Contract Officers at State Procurement of the reasons for dissatisfaction with contract items. [Revise and make consistent with Health Quality Reporting System]
- e. Reporting – is the process of recording or relating information that has been obtained or learned from research and analysis. This process may eventuate prior or after procurement. Reporting is a critical part of clinical consumables management as it enables monitoring, further research and reviews and information sharing. [Refer to Systems and databases in section A].
- f. Monitoring
 - Continuous performance review of clinical consumables is recommended at least every six to twelve months.
 - Continuous review of new state contracts, notice of price adjustments and contract amendments is recommended to ensure that clinical consumables in use are current on the state contract listing and that prices are up to date.
 - Supply continuity - In instances where suppliers are unable to supply, it is important to maintain dialogue with the supplier to ensure that Public Health Organisation operations are not at risk. State Procurement should be alerted of the Supplier's failure to rectify any supply difficulties

3. QUALITY ISSUES

All clinical consumables quality issues shall be reported using the HQRS [Refer to Section A]. The reporting of a quality issue is an opportunity for improvement to promptly address any complaint / problem which creates hazard, or places the health care worker and patients at risk, e.g.

- Compromised sterility
- Incomplete instructions
- Poor construction or design
- Packaging or labeling defects
- Defective components
- Equipment malfunction
- Presence of foreign object.

Action required to address quality issues

- a) DO NOT THROW THE FAULTY ITEM OUT. If contaminated or if personnel may be exposed to any form of risk, decontaminate and / or place item in a sealed container and label as biohazard or contaminated.
- b) Where available, attach packaging & batch number for tracking purposes. If not available, determine source;

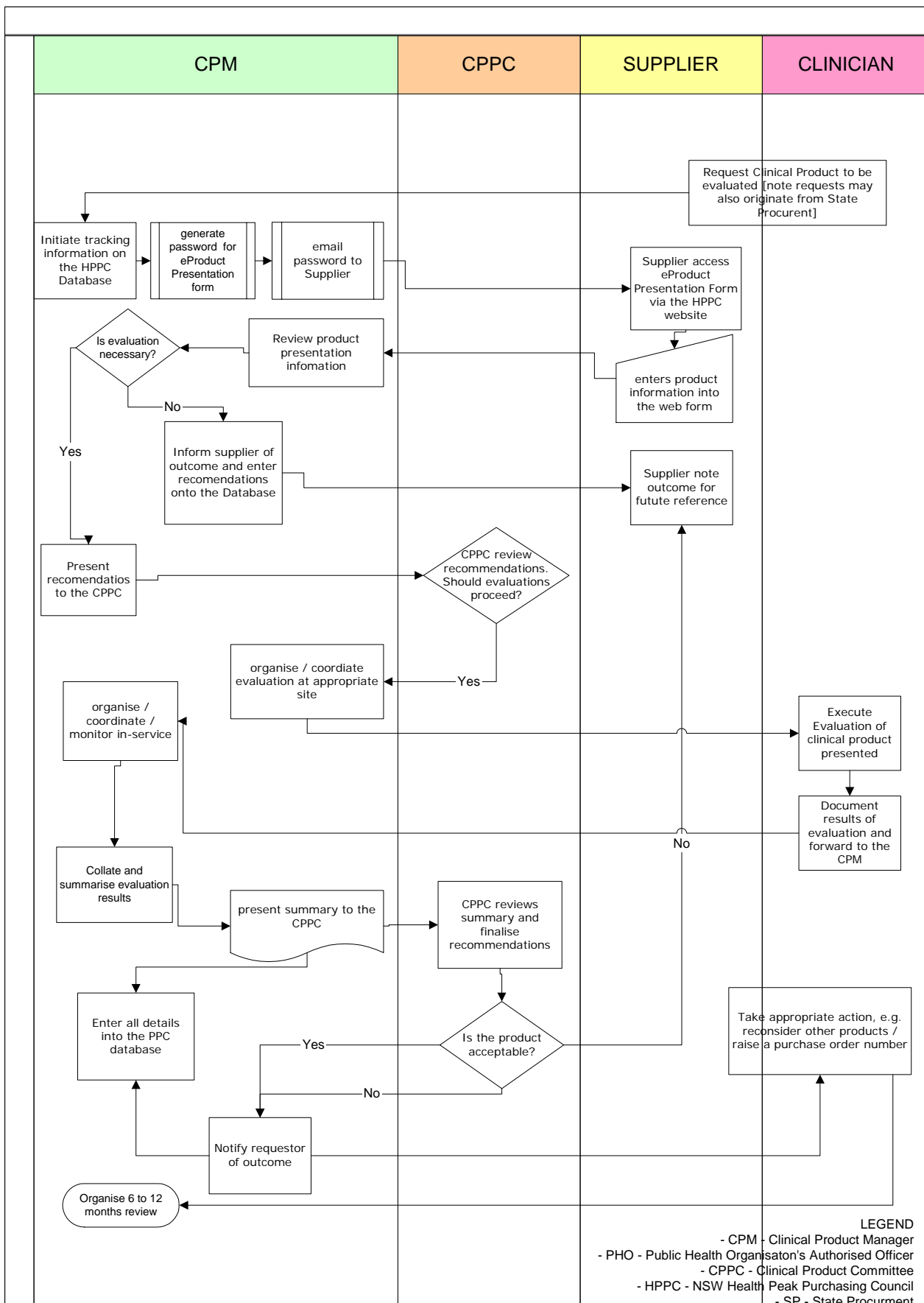
- c) Contact the nominated Public Health Organisations Authorised Personnel. In all instances the Public Health Organisations Authorised Personnel is to be advised as soon as practicable, in order to ensure the appropriate response is taken, actioned and Area / Hospital Supply Services Management notified.
- d) The nominated Public Health Organisations Authorised Personnel is to use the HQRS to report and monitor action taken by appropriate groups to address the concern. [Appropriate groups in this instance refers to the Supplier, HPPC, State Procurement or TGA]

4. CLINICAL PRODUCT RECALL PROCEDURE

Initiated by Supplier / TGA

- a) Supplier issues clinical product recall notice.
- b) Notice received by Chief Executive Officer / Director of Nursing and promptly forwarded to Public Health Organisations Authorised Personnel. The recipient may choose to forward the notice to other Health Services, if deemed appropriate, via existing networking groups through the use of the HQRS [Refer section A]
- c) The Public Health Organisations Authorised Personnel in collaboration with supplier identifies area/s of product use and isolates any affected stock.
- d) The Public Health Organisations Authorised Personnel notifies the Supplier and Public Health Organisations executive. If appropriate, a memorandum may be issued, or a copy of the recall notice placed where stock is held.
- e) The Public Health Organisations Authorised Personnel ensures documentation is completed. Affected stock is isolated for recovery by the supplier.
- f) The Public Health Organisations Authorised Personnel ensures replacement stock is arranged for distribution. If this is not possible, an alternative supplier is sought.
- g) The Public Health Organisations Authorised Personnel ensures that the product recall is registered onto the HQRS and the message is sent to all HQRS registered users. Note: This is precautionary in case other Public Health Organisations who may be using the same product have not received the recall alert. It is the responsibility of recipients of the HQRS "Product Alert" email message to investigate the case further before executing the most appropriate action.

5. CLINICAL CONSUMABLES EVALUATION FLOW CHART



6. CLINICAL CONSUMABLES EVALUATION FORMS



Reference Number [Public Health use only]:	Date
--	------

CLINICAL PRODUCT PRESENTATION FORM
For all Clinical Consumables Evaluations
Form 1 of 3

PRODUCT INFORMATION

Description of Product:

Description of Product Use:

Brand Name: Supplier Item Number:

Current NSW State Contract or CAG Evaluation: Yes No EAN / HIBCC Compliant: Yes No

If YES identify: Contract Number: Contract Item Number:

Performance Indicators:

Product Being Substituted if applicable:

Number of samples & Units:

Batch Numbers:

Method of Sterilization:

SUPPLIER INFORMATION

Name of Supplier:

Telephone: Supplier E-Mail:

PRODUCT PACKAGING INFORMATION

Package Sterile: Yes No

Product Packaging Information: Single Use Single Patient Use Reusable Not Applicable

List Applicable Standards:

Identify TGA Number

Availability of Material Safety Data Sheets: Yes No

Meet Infection Control Requirements:

Yes

No



Reference Number [Public Health use only]:

Date

CLINICAL PRODUCT PRESENTATION FORM

For all Clinical Consumables Evaluations

Form 2 of 3

PRICE INFORMATION

Cost per Unit:

Delivery cost if not FIS:

Unit:

Lead Time:

Quantity per Unit:

Minimum Purchase Qty:

Each price:

Minimum Purchase Value:

ENVIRONMENTAL INFORMATION

Method of disposal:

Landfill

Incineration

Recyclable

Additional Information:

OCCUPATIONAL HEALTH & SAFETY INFORMATION

Contain Hazardous Substances:

Yes

No

Contain Sharps:

Yes

No

Manual Handling Issues:

Ye

No

Contain Latex:

Yes

No

Additional Information:

GENERAL EVALUATION INFORMATION

Product in use at:

Previously evaluated at:

Advantage:

Disadvantage:



Reference Number [Public Health use only]:

Date

CLINICAL PRODUCT PRESENTATION FORM

For all Clinical Consumables Evaluations

Form 3 of 3

TRAINING & SUPPORT

Available Training & Education:

Yes

No

Comments

Available Ongoing In-service Training:

Yes

No

Comments

Easy to follow documentations:

Yes

No

Comments

Available after-sales support:

Yes

No

Comments

Please forward Completed forms to the Clinical Product Manager [PHO' AUTHORISED PERSONNEL]

Date Tabled at the PMC ____/____/____

Request Approved:

Yes

No

Signed _____



Reference Number [Public Health use only]:	Date
--	------

CLINICAL PRODUCT EVALUATION FORM
 For all Clinical Consumables Evaluations
 Form 1 of 3

PRODUCT INFORMATION

Description of Product

Description of Product Use

Brand Name:

Supplier Item Number:

- Reason for Evaluation:
- | | | |
|--|---------------------------------------|--------------------------------------|
| <input type="checkbox"/> New to Market | <input type="checkbox"/> Substitution | <input type="checkbox"/> Upgrade |
| <input type="checkbox"/> Review | <input type="checkbox"/> CMC | <input type="checkbox"/> Area Tender |

Evaluation Criteria

Product Being Substituted [if applicable]

Number of samples & Units:

Batch Numbers:

- Method of Sterilisation
- | | | |
|---|--------------------------------------|---|
| <input type="checkbox"/> Steam | <input type="checkbox"/> Dry Heat | <input type="checkbox"/> Other |
| <input type="checkbox"/> Ethylene Oxide | <input type="checkbox"/> Chemical | <input type="checkbox"/> Not Applicable |
| <input type="checkbox"/> Glow Plasma | <input type="checkbox"/> Combination | |

Name of Supplier:

Telephone: Supplier E-Mail:

PRODUCT PACKAGING INFORMATION

Package Sterile: Yes No

- Product Packaging Information
- | | |
|-------------------------------------|---|
| <input type="checkbox"/> Single Use | <input type="checkbox"/> Single Patient Use |
| <input type="checkbox"/> Reusable | <input type="checkbox"/> Not Applicable |



Reference Number [Public Health use only]:	Date
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CLINICAL PRODUCT EVALUATION FORM

For all Clinical Consumables Evaluations
Form 2 of 3

STANDARDS / INFECTION CONTROL INFORMATION

- Meet Infection Control Requirements: Yes No
- Use of Product Requires Change to Policy: Yes No
- Cleaning of Product Requires Change to Policy: Yes No

OCCUPATIONAL HEALTH & SAFETY INFORMATION

- Contain Hazardous Substances: Yes No
- Manual Handling Issues: Yes No

GENERAL EVALUATION INFORMATION

Advantages:

Disadvantages:

TRAINING & SUPPORT

- Available Training & Education: Yes No

Comments

- Available Ongoing In-service Training: Yes No

Comments

- Easy to follow documentations: Yes No

Comments



Reference Number [Public Health use only]:

Date

CLINICAL PRODUCT EVALUATION FORM

For all Clinical Consumables Evaluations
Form 3 of 3

EVALUATOR / COORDINATOR DETAILS

Name:

Title:

Organisation:

Evaluation Site:

- Medical Surgical Obstetrics Theatre Mental Health Critical Care
 Emergency Dental Community Pediatrics Endoscopy Other

EVALUATION OUTCOME

Acceptable Packaging Conditions: Yes No

Comments

Easy to Open Pack: Yes No

Comments

Easy to remove from pack aseptically: Yes No

Comments

Product Performance:



Reference Number [Public Health use only]:	Date
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CLINICAL PRODUCT PERFORMANCE REVIEW

For all Clinical Consumables Evaluations
Form 1 of 2

Description of Product:

Item Number:	<input style="width: 150px; height: 15px;" type="text"/>
Contract Number:	<input style="width: 150px; height: 15px;" type="text"/>
Initial Cost:	<input style="width: 150px; height: 15px;" type="text"/>
Past Usage:	<input style="width: 150px; height: 15px;" type="text"/>

Stores Number:	<input style="width: 150px; height: 15px;" type="text"/>
Contract item Number:	<input style="width: 150px; height: 15px;" type="text"/>
Current Cost:	<input style="width: 150px; height: 15px;" type="text"/>
Current Usage:	<input style="width: 150px; height: 15px;" type="text"/>

Available Training & Education Yes No

Comments:

Available after sales report Yes No

Comments:

Alternative Supplier / Product

Out of stock / Back orders

Packaging:

Changes to product:

Problem Faults:



Reference Number [Public Health use only]:	Date
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CLINICAL PRODUCT PERFORMANCE REVIEW
For all Clinical Consumables Evaluations
Form 2 of 2

Number of Faults Batch Number(s)

User's Name

Location

Comments:

Action:

Outcome:

Feedback:

Follow Up:

Signature: _____

Date: ____/____/____



Reference Number [Public Health use only]:	Date
--	------

CLINICAL PRODUCT QUALITY REPORT
Page 1 of 3

This form is to be completed and sent to the Clinical Product Manager [PHO' AUTHORISED PERSONNEL]

Product Type / Application:

Brand / Trade Name / Model Number

Serial / Batch / Lot Number: AustL / AustR Number:

Date of Manufacture: Date Purchased: Date Expire:

Manufacturer:

Supplier:

Has the Manufacturer been informed of the problem? Yes No

Manufacturer's Contact Name: Date:

CONTRACT INFORMATION

Contract type: N/A AHS contract State contract

State Contract:

Contract Item Number: System Number Oracle / Sun Number

PERFORMANCE MEASUREMENT

DELIVERY:

- Shippers Packaging (Damaged on delivery)
- Delivery Time
- Out of Stock / Backorders
- Damaged Goods
- Incorrect Goods
- Incomplete Goods
- Incomplete Order
- Poor delivery documentation

SERVICE SUPPORT:

- Unsatisfactory in-service / training
- Poor response time
- Poor documentation (Technical)
- Poor documentation (Financial)
- Poor ongoing support

USER ISSUES:

- Compromised sterility
- Incomplete instructions
- Poor construction / design
- Packaging / labeling defects
- Defective components
- Equipment malfunction
- Presence of foreign objects



Reference Number [Public Health use only]:	Date
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CLINICAL PRODUCT QUALITY REPORT
Page 2 of 3

Detailed Description:

Supporting Notes:

REPORTED BY:

Reporter's Name:

Position Title:

Department:

Hospital:

Phone Number: Fax Number:

Email Address:

SUBMITTED BY:

Submitter's Name:

Health Service:

Phone Number: Fax Number:

Email Address:



Reference Number [Public Health use only]:	Date
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CLINICAL PRODUCT QUALITY REPORT
Page 2 of 3

OUTCOMES [Responses received from]

TGA Response	Date Received	

Supplier Response	Date Received	

State Procurement Response	Date Received	

HPPC Response	Date Received	

OUTCOMES [Ratings]

- | | | | |
|--|---|---------------------------------------|--------------------------------|
| 1. Supplier management of issues raised | <input type="checkbox"/> Unsatisfactory | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> N / A |
| 2. Acceptability of replacement by supplier | <input type="checkbox"/> Unsatisfactory | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> N / A |
| 3. TGA Management of issues raised | <input type="checkbox"/> Unsatisfactory | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> N / A |
| 4. State Procurement management of issues raised | <input type="checkbox"/> Unsatisfactory | <input type="checkbox"/> Satisfactory | <input type="checkbox"/> N / A |

5. PPC Management of issues raised

Unsatisfactory

Satisfactory

N / A

SECTION C

CLINICAL EQUIPMENT

PROCUREMENT

SECTION C – CLINICAL EQUIPMENT PROCUREMENT

1. OVERVIEW

Procurement in this context covers all processes required for the effective and efficient acquisition of clinical equipment. These processes include research, analysis, reporting, procurement and monitoring.

Procurement of clinical equipment within Public Health Organisations includes input from Biomedical Engineers and other specialists. Input may be in the form of checks, trials or verification of compliance with standards or policies.

2. PROCESSES

Clinical equipment procurement includes the following processes:

a. Needs analysis – research or systematic enquiry when a request for new equipment is raised. The process involves the identification / justification of need by reviewing a number of elements, i.e.:

- Current clinical practice - to determine relevancy of requirements, consider the following points:
 - ✓ Is the need for the equipment a result of new technology / new product?
 - ✓ How will these impacts on current clinical practice?
 - ✓ Is change to clinical practice required?
 - ✓ Is the new equipment required due to change in clinical practice?

A complete description of the clinical and user requirements should be created. This will allow a clearly defined specification to be written and a basis for evaluation.

- If replacement equipment, what is the status of existing equipment?
 - ✓ Obsolete
 - ✓ Uneconomic to repair
 - ✓ Uneconomic to use (e.g. cost of consumables, service)

b. Consistency with existing strategies – determine if the strategy is consistent with the equipment standardisation / harmonisation strategies. Consider the following points.

- ✓ Is the purchase of the equipment in line with PHO / NSW Health strategic plan?
- ✓ Is the need brought about by equipment obsolescence?
- ✓ Determine consistency of consumables for the new equipment with consumables for existing equipment. Will the use of the new equipment impact on standardisation / harmonisation of not only existing equipment but dependant consumables as well? Does the equipment require specific or dedicated consumables?

- ✓ What impact will the use of equipment have with key stakeholders, will the equipment be readily accepted or will other strategies be required to ensure acceptability of equipment?

c. **Research / Market Analysis** – understanding the market, i.e. sources of supply and determine the most appropriate strategy that can bring about value for money arrangements. Consider the following points:

- Determine if the preferred clinical equipment is on state contract. NSW Health policy stipulates that if clinical equipment is available under contracts arranged by the State Contract Control Board, they shall be obtained from those sources [no matter the source of funds] unless there are specific reasons justifying an application for exemption.

A note on clinical equipment on state contract, in some instances evaluation prior to purchase may not be necessary. However, this is to the discretion of Public Health Organisation. Some Public Health Organisation chooses to evaluate clinical equipment on state contracts where "Organisation-specific-requirement" exists. The view is that such requirement may not have been considered at the time the clinical equipment was evaluated by the HPPC Advisory Group.

- Exemptions from state contracts or from the use of specific common period contracts may be granted by the NSW Health Department upon the recommendation of the HPPC. The duration of the exemption will be noted at the time the exemption is granted. It should be noted that application for exemptions for clinical equipment should have supporting clinical reasons and that exemptions are granted only on rare occasions. Such reasons must be specifically approved by the Director General of the Department of Health, following advice from the HPPC, prior to the purchase being made. Public Health Organisation are to advise the respective Contract Officers at State Procurement of the reasons for dissatisfaction with contract
- Investigate similar or competitive clinical equipment in the market, including identification of similar equipment in use at other Public Health Organisation. This process will enable an understanding of local and global trends.

To assist in the investigation it is recommended to obtain further information from other international organisations such as:

- ECRI [Emergency Care Research Institute] **ECRI** (formerly the Emergency Care Research Institute) is an independent nonprofit health services research agency.
<http://www.ecri.org>
- AUNTMINNIE – a web page for the medical imaging community
<http://www.auntminnie.com>
- Medical Devices Agency (MDA) www.medical-devices.gov.uk
- If the equipment is not on State Contract, Public Health Organisation should explore other arrangements that may maximise other opportunities, e.g. leasing, collaborative procurement and supplier partnering arrangements [refer to section A]

d. **Financial Analysis** – examine critically all elements that contribute to the cost of acquiring and using the equipment, i.e. Life cycle cost. Consider the following points:

- ✓ Initial cost of equipment including alternatives such as operational lease or non-capital outlay arrangement.
- ✓ Trade in/sale of replaced equipment
- ✓ Cost of utilities and Infrastructure - the cost of essential adjustment to infrastructure to accommodate the new equipment, e.g. breaking down walls, building platforms, etc. The cost of utilities, e.g. power supply, addition of air vents, noise reduction, etc.
- ✓ Operational cost – the cost of operating the equipment inclusive of regular, periodic, ad hoc service and maintenance. The cost of consumables required running the equipment, etc.
- ✓ Cost of education – including in-service and training inclusive of user / operators manual, technical documentation, etc.

e. **Clinical / User analysis** - analysis of suitable clinical equipment by reviewing perceived and apparent advantages, disadvantages and other value-added benefits. Consider the following issues.

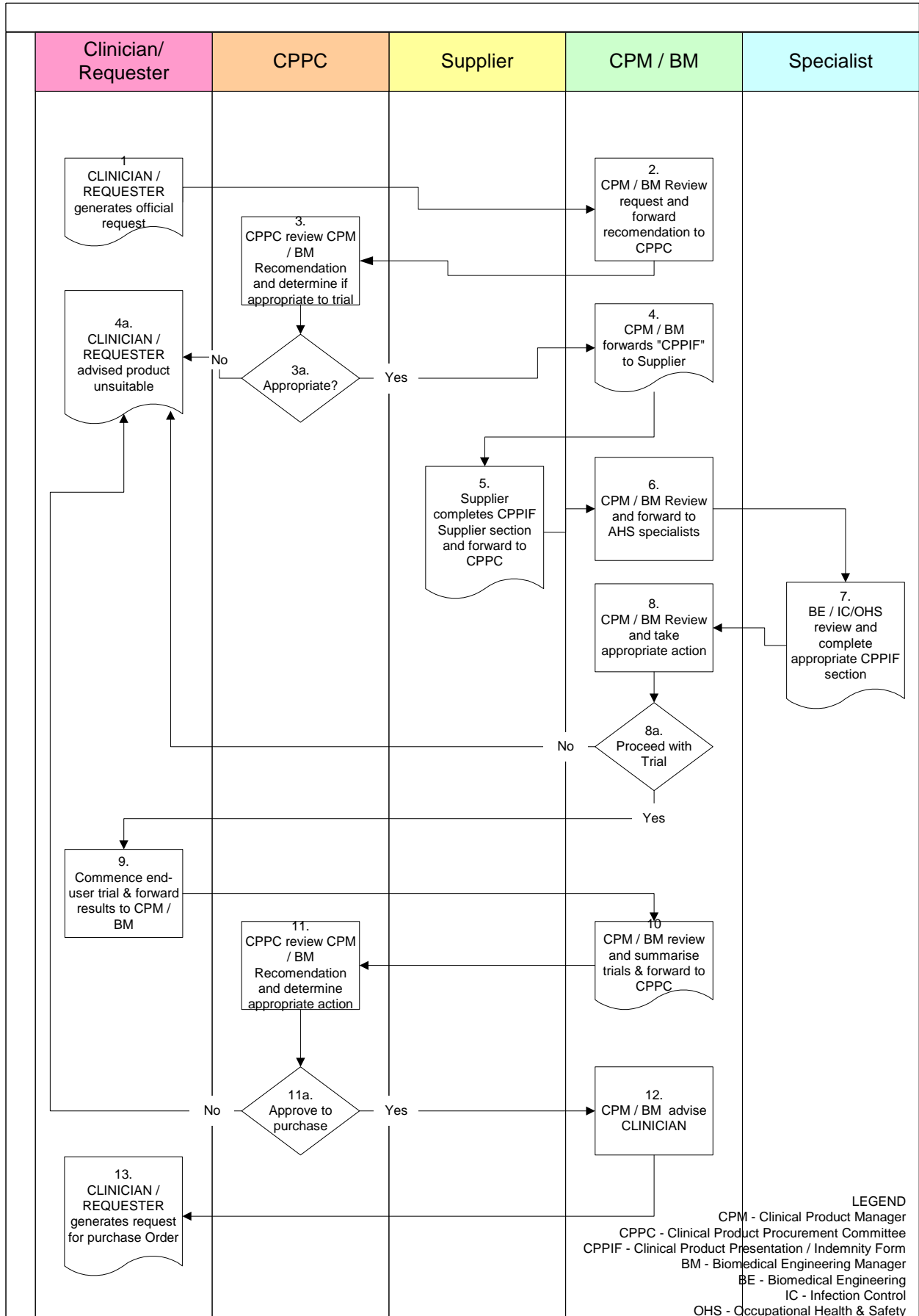
- Evaluate the equipment as to its clinical performance.
 - ✓ Does the equipment function according to its purpose?
 - ✓ Does the equipment perform effectively and efficiently?
 - ✓ Does the equipment provide the user with confidence through its reliability?
 - ✓ Is the equipment easy to use
- Determine in-service requirements to educate and support the user before and during use of the equipment
 - ✓ Can the preferred supplier meet such requirements?
 - ✓ Are required documents such as user's manual, technical diagrams readily available and can be easily read and understood?
- Identify possible risks to the Health Care Worker and to patients
 - ✓ What steps should be taken to eliminate the risk?
 - ✓ What steps should be taken to minimise the risk if it is unavoidable?
 - ✓ What are the impacts to occupational health and safety?
- Ensure that it does not impinge on any policy. NSW Health and PHO have existing policies that may need to be considered when selecting or using clinical equipment, e.g. infection control / latex content policies. Ensure that the equipment to be selected does not impinge on any elements of these policies.

f. Technical Analysis – examine critical elements of the equipment that impacts its performance and the environment, i.e.

- ✓ Biomedical Analysis
- ✓ Regulatory Compliance
- ✓ Hazard Alerts
- ✓ Service and Support
- ✓ Training - clinical/technical
- ✓ Documentation - operator/technical
- ✓ Installation cost and impact to existing infrastructure
- ✓ Waste management considerations
- ✓ Disposal and environmental issues
- ✓ Infection control
- ✓ Risk analysis; is there sufficient indemnity coverage?
- ✓ Other OH&S issues.

g. Reporting – it is critical that information obtained from research and analysis be reported, this process may be initiated before or after procurement. Reporting enables monitoring, further research and information sharing. [Refer to Section A]

3. CLINICAL EQUIPMENT EVALUATION FLOW CHART



4. QUALITY ISSUES

Quality issues are encountered in instances where clinical equipment performance creates hazard or places the health care worker and patients at risk.

During the use of clinical equipment, quality issues may arise when the clinical equipment;

- Failed to perform according to purpose or as specified
- Produced undesirable results or creates a hazard to patient or staff
- Becomes unreliable
- Is poorly supported by the supplier
- Is poorly designed resulting in user problems and errors

Any of the above encounters should be regarded as a Quality Issue. The reporting of a quality issue is an opportunity for improvement.

Action required addressing quality issues

- a) Complete the Product Quality Report form
- b) Quality issues should be referred to the Biomedical Engineering Department and registered onto the HQRS [Refer to Section A]
- c) The equipment should be labelled, briefly indicating the problem and removed from service.
- d) Where accessories and disposables are integral to the problem, these should be retained with the equipment.
- e) Contaminated equipment should be appropriately bagged and labelled.
- f) Contact the nominated Public Health Organisation Authorised Personnel" who will liaise with Biomedical Engineering Department.
- g) **It is the responsibility of the person initiating the complaint** to categorise the complaint and instigate appropriate procedures, the complaint may be categorised according to the potential to injure, as follows:

Important Note:

Quality issues that do not have potential to injure should be reported

A number of reporting systems are available as explained briefly in section A; it is imperative that the appropriate systems are used to lodge reports and monitor outcomes.

No Potential to Injure:

The Public Health Organisation Authorised Personnel is to confirm the category and raise the concern with the supplier.

The Biomedical Engineer or Public Health Organisation Authorised Personnel will reply to the initiator advising the action taken and the response from the supplier.

May Injure:

All products should be presumed affected and treated in the same manner.

The Biomedical Engineer or Public Health Organisation Authorised Personnel will confirm the category, and:

- a) Advise the initiator
- b) Request information relating to product / batch
- c) Advise supplier that all product, in known locations, must be removed from Area / Hospital premises as soon as possible
- d) Request lead time of replacement stock
- e) Advise if equipment is to be replaced / repaired by supplier or another equipment is to be made available as an interim measure.
- f) Using the HQRS, formally notify the supplier, TGA and State Procurement if appropriate.
- g) Ensure that the complaint is minuted in Clinical Product Procurement Committees meeting minutes.

Has Injured

- a) As per point 2 [Potential to Injure]
- b) Where appropriate, the Public Health Organisation Authorised Personnel will ensure all affected equipment in all hospitals are isolated or removed.
- c) Where appropriate, the Public Health Organisation Authorised Personnel reports the consequence action of the event to the relevant executive.
- d) For out of hours incidents the after hours Nurse Manager is to be notified immediately and may contact the appropriate personnel.

5. CLINICAL EQUIPMENT RECALL PROCEDURE

Initiated by Supplier / TGA

- a) Supplier issues clinical product recall notice.
- b) Notice received by Chief Executive Officer / Director of Nursing and promptly forwarded to Public Health Organisation Authorised Personnel. The recipient may choose to forward the notice to other Health Services, if deemed appropriate, via existing networking groups through the use of the HQRS [Refer section A]
- c) The Public Health Organisation Authorised Personnel in collaboration with supplier identifies area/s of equipment use and isolates any affected equipment.
- d) The Public Health Organisation Authorised Personnel notifies the Supplier and PHO Executive. If appropriate, a memorandum may be issued, or a copy of the recall notice placed where equipment is located.
- e) The Public Health Organisation Authorised Personnel ensures documentation is

completed. Affected equipment is isolated for ready for supplier to take appropriate action to rectify

- f) The Public Health Organisation Authorised Personnel monitors the Suppliers action to rectify and ensures equipment is working in order or alternative equipment is made available if existing equipment cannot be repaired on a timely manner.

6. CLINICAL EQUIPMENT EVALUATION FORMS



Reference Number [Public Health use only]:	Date
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PART A - CLINICAL EQUIPMENT PRESENTATION & INDEMNITY FORM
To be completed by Suppliers - [Page 1 of 4]

Note: Referencing suitable code & guidelines is acceptable when answering some parts of this form. Supporting documents may be attached to answer questions where space provided is insufficient.

PRODUCT INFORMATION

Description of Equipment [Attach relevant brochures]

Description of Clinical Application

Brand Name	<input style="width: 95%;" type="text"/>	Manufacturer	<input style="width: 95%;" type="text"/>
Model Number	<input style="width: 95%;" type="text"/>	Model Name	<input style="width: 95%;" type="text"/>
EAN / HIBCC Compliant	<input type="checkbox"/> Yes <input type="checkbox"/> No	NSW State Contract	<input type="checkbox"/> Yes <input type="checkbox"/> No
Contract Number	<input style="width: 95%;" type="text"/>	Department of Commerce Contract	<input type="checkbox"/> Yes <input type="checkbox"/> No
Contract Item Number	<input style="width: 95%;" type="text"/>		

Describe any re-processing requirements

SUPPLIER INFORMATION

Name of Supplier	<input style="width: 95%;" type="text"/>		
Address	<input style="width: 95%;" type="text"/>		
Phone	<input style="width: 95%;" type="text"/>	Facsimile	<input style="width: 95%;" type="text"/>
E-Mail	<input style="width: 95%;" type="text"/>		
Web Address	<input style="width: 95%;" type="text"/>		
Representative	<input style="width: 95%;" type="text"/>		
Phone	<input style="width: 95%;" type="text"/>	Mobile	<input style="width: 95%;" type="text"/>
E-Mail	<input style="width: 95%;" type="text"/>		

REGULATORY COMPLIANCE

TGA number	<input style="width: 95%;" type="text"/>	Applicable standards	<input style="width: 95%;" type="text"/>
------------	--	----------------------	--

Details of regulatory conformance [attached certificates]



Reference Number [Public Health use only]:	Date
--	------



Reference Number [Public Health use only]:	Date
--	------

PART A - CLINICAL EQUIPMENT PRESENTATION & INDEMNITY FORM
To be completed by Suppliers- [Page 2 of 4]

EVALUATION REQUESTED BY

Name

Organisation

Phone Facsimile

PRICE INFORMATION

Indicative value may typically be represented by "list price"

Indicative value of equipment \$ Discount available Yes No

Are other methods for purchasing available, e.g. leasing, cost per test Yes No

List accessories available Indicative cost of accessories

1.	1. \$
2.	2. \$
3.	3. \$
4.	4. \$
5.	5. \$

Are accessories available from other sources? Yes No

Discount available for consumables Yes No

List consumables available Indicative cost of accessories

1.	1. \$
2.	2. \$
3.	3. \$
4.	4. \$
5.	5. \$

Are dedicated consumables necessary? Yes No

Delivery cost if not FIS \$ Lead time Days
 Indicative installation cost \$

Installation issues

Method of disposal for:

Equipment	<input style="width: 570px; height: 20px;" type="text"/>
Packaging	<input style="width: 570px; height: 20px;" type="text"/>
Consumables	<input style="width: 570px; height: 20px;" type="text"/>
Replaceable components	<input style="width: 570px; height: 20px;" type="text"/>

Additional Information supporting environmental friendliness of product



Reference Number [Public Health use only]:	Date
--	------

PART A - CLINICAL EQUIPMENT PRESENTATION & INDEMNITY FORM

To be completed by Suppliers- [Page 3 of 4]

OCCUPATIONAL HEALTH & SAFETY INFORMATION

Contain hazardous substances Yes No Manual handling issues Yes No
 Contain sharps Yes No Contain latex Yes No
 Does the device contain or emit radioactivity? Yes No

Provide details if answered Yes to any of the above

GENERAL EVALUATION INFORMATION

Reference site(s):

Contact person(s) at reference site:

Equipment Status: New to market Yes No Upgradeable Yes No

Upgrade Supplier's Policy & Detail(s):

HAZARD ALERTS

Have there been any alert in Australia or international regarding this equipment? Yes No

Action taken to address the alert:

TRAINING AND SUPPORT INFORMATION [After Purchase]

User training & education available Yes No Cost [if any] \$

Description of user training & education

Technical support training available Yes No Cost [if any] \$

Description of available technical support training

- Comprehensive workshop manufacture service manual Yes No Cost [if any] \$



Reference Number [Public Health use only]:	Date
--	------

PART A - CLINICAL EQUIPMENT PRESENTATION & INDEMNITY FORM
To be completed by Suppliers - [Page 4 of 4]

- After sales "user" support available Yes No Cost [if any] \$
- After sales "technical" support available Yes No
- After sales technical support provided by: Supplier Third Party

Identify third party provider

Technical / Maintenance service support agreement available Yes No

Description of Technical / Maintenance service support agreement

Accessories for trial

List accessories supplied	Serial number	Indicative cost	Quantity
1.		\$	
2.		\$	
3.		\$	
4.		\$	
5.		\$	
6.		\$	

- a) Supplementary specifications - where the PHO provided specifications for equipment and / or terms for purchase, has these been adhered to and a copy attached? Yes No
- b) Alternative sources of accessories provided Yes No
- c) Proof of acceptance testing per AS3551 provided Yes No
- d) Service manual provided Yes No
- e) Operator's manual provided Yes No
- f) Signed "Indemnity Agreement for Equipment on Loan or Trial" provided (Appendix A) Yes No**

Signed on behalf of the Supplier who declares that this device complies with all Statutory Regulations and is both safe to use and fit for purpose.

Name of Supplier Representative

Signature _____

Date ____/____/____



Reference Number [Public Health use only]:	Date
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PART B - CLINICAL EQUIPMENT SPECIALIST REVIEW FORM

To be completed by Biomedical Engineering / Infection Control / OH&S Specialists – [Page 1 of 3]

- Reason for Evaluation:
- | | | |
|--------------------------------------|---------------------------------------|--|
| <input type="checkbox"/> Upgrade | <input type="checkbox"/> Substitution | <input type="checkbox"/> Review |
| <input type="checkbox"/> Area Tender | <input type="checkbox"/> CAG | <input type="checkbox"/> New to Market |

BIOMEDICAL REVIEW

Is the purchase of this equipment in line with the Organisation's equipment standardisation / harmonisation strategies? Yes No

Provide details / explanation if you answer "No" to the above

- Are accessories necessary? Yes No
- Are there alternate sources of accessories? Yes No
- Are dedicated consumables necessary? Yes No

Comments on accessories / consumables:

Has evidence been provided to confirm compliance to the following?

- | | |
|--|--|
| g) Regulatory Compliance | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| h) Quality Certification [ISO 9000]? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| i) Legible manufacturer / brand name on equipment? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| j) Date of manufacture stamp on equipment? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| k) Country of manufacture stamp on equipment? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Estimated routine maintenance cost \$ Per annum

Installation issues:



Reference Number [Public Health use only]:	Date
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Reference Number [Public Health use only]:	Date
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PART B - CLINICAL EQUIPMENT SPECIALIST REVIEW FORM

To be completed by Biomedical Engineering / Infection Control / OH&S Specialists – [Page 2 of 3]

BIOMEDICAL REVIEW CONTINUED

Acceptance testing as per AS3551 [Refer Part A – Form 4 of 4]

- | | | |
|--|------------------------------|-----------------------------|
| l) Is there an "Acceptance Test" done by supplier? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| o Is the supplier provided "Acceptance Test" acceptable? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| o Is the documentation acceptable? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| o Is the date of testing acceptable? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| m) If answered NO to any of the above, Biomedical testing is required. | | |

Has acceptance testing been carried out	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Document attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Comments & recommendations

Maintenance issues e.g. can preventative maintenance be carried out in-house? Special tool(s) required?

Known problems or hazards with this equipment

Comment on expected clinical effectiveness

DOCUMENTATION EVALUATION REVIEW [Refer Part A – Form 4 of 4]

- | | | | |
|--|-------------------------------------|-----------------------------|---|
| Availability of service manual | <input type="checkbox"/> Paper | <input type="checkbox"/> CD | <input type="checkbox"/> Internet site |
| n) Technical manual | <input type="checkbox"/> Acceptable | | <input type="checkbox"/> Not acceptable |
| o) Full service information | <input type="checkbox"/> Acceptable | | <input type="checkbox"/> Not acceptable |
| p) Description of circuits | <input type="checkbox"/> Acceptable | | <input type="checkbox"/> Not acceptable |
| q) Description of spare parts | <input type="checkbox"/> Acceptable | | <input type="checkbox"/> Not acceptable |
| r) Operators manual | <input type="checkbox"/> Acceptable | | <input type="checkbox"/> Not acceptable |
| s) All necessary clinical information required to evaluate | <input type="checkbox"/> Acceptable | | <input type="checkbox"/> Not acceptable |

Comments & recommendations

Market assessment – should other suppliers be assessed	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------

Evaluating Officer – Biomedical Engineering

Name <input style="width: 90%;" type="text"/>	Position <input style="width: 90%;" type="text"/>
---	---

Signature _____	Date ____/____/____
-----------------	---------------------



Reference Number [Public Health use only]:	Date
--	------



Reference Number [Public Health use only]:	Date
--	------

PART B - CLINICAL EQUIPMENT SPECIALIST REVIEW FORM

To be completed by Biomedical Engineering / Infection Control / OH&S Specialists – [Page 3 of 3]

INFECTION CONTROL REVIEW

- | | | |
|--|------------------------------|-----------------------------|
| Does the item require disinfections or sterilisation? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Does the equipment meet infection control standards? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Are policies & procedures changes required? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the equipment easy to clean? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Are manufacturers instructions for cleaning / sterilisation available? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Are cleaning / sterilising instructions provided appropriate? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Comments & recommendations

Evaluating Officer – Infection Control

Name

Position

Signature _____

Date ____/____/____

OCCUPATIONAL HEALTH & SAFETY REVIEW [Refer Part A – Form 4 of 4]

- | | | |
|------------------------------|------------------------------|-----------------------------|
| Contain Hazardous substances | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Manual Handling issues | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Comments & recommendations

Evaluating Officer – Occupational Health & Safety

Name

Position

Signature _____

Date ____/____/____



Reference Number [Public Health use only]:	Date
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PART C - CLINICAL EQUIPMENT EVALUATION RESULTS
To be completed by "Trial Coordinator" – [Page 1 of 1]

EQUIPMENT USER EVALUATION CHECKLIST

- Does the equipment do what it is expected to? Yes No
- Are accessories, e.g. connectors easy to use Yes No
- Is the equipment easy to use in general? Yes No
- Are safety features appropriate? Yes No
- Are there any OH&S issues? Yes No
- Are there any storage issues? Yes No
- Are there any cleaning issues? Yes No
- Is operator's manual provided acceptable? Yes No
- Functionality Acceptable Not acceptable
- Ease of use Acceptable Not acceptable

Rate [tick] the overall acceptability of the equipment [10 being the best]

1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	----

General comments

Trial Coordinator – Sign- Off

Name

Position

Signature _____

Date ____/____/____



Reference Number [Public Health use only]:	Date
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PART D - COMMITTEE RECOMMENDATIONS FORM

To be completed by "Clinical Product Procurement Committee" – [Page 1 of 1]

COMMITTEE RECOMENDATION

Clinical Product Procurement Committee Chairperson

Name

Position

Signature _____

Date ____/____/____



Reference Number [Public Health use only]:

Date

This "INDEMNITY AGREEMENT FOR CLINICAL EQUIPMENT ON LOAN OR TRIAL" made on ____/____/____ between

_____ [Health Service] and

_____ [Supplier]

Background Information:

The Health Service has agreed to trial the use of the equipment as supplied by the supplier on the terms and conditions stipulated below:

Definitions:

- ✓ Equipment – means the equipment specified in the schedule and any other property supplied by the Supplier on loan to the Health Service under this agreement.
- ✓ Health Service – any body corporate, government department or body into which it may be merged or subsumed or which may replace it and its successors and assigns.
- ✓ Supplier – means the party whose details are specified in the schedule and his/her/its executors, administrators, and successors and permitted assigns, as the case may be.

Terms & Conditions:

1. The supplier agrees to deliver and install "with reasonable care" (where needed / required) the equipment at the Health Service's premises at the beginning of the trial / loan period and to remove the equipment from the Health Service's premises at the end of the period.
2. The Health Service may direct the Supplier to remove the equipment at any time.
3. The Health Service and Supplier may agree in writing to extend the trial / loan period or by completing another Indemnity Agreement.
4. If the Supplier does not remove the equipment at the end of the said period, the Health Service may, after the expiration of 28 days from the end of the trial / loan period, and at the Supplier's expense, have the equipment removed from the Health Service's premises and returned to the Supplier's premises.
5. The Supplier agrees to provide training for staff and all information necessary for the safe operation of the equipment on trial / loan.
6. Subject to point 5, the Health Service agrees to utilise the equipment with reasonable care and is not liable for any damage to, or loss of the equipment, whilst it is in the Health Service's premises. This excludes loss or damage to the equipment that is directly caused by the willful criminal act of an employee of the Health Service.
7. The Supplier warrants that they are liable for any damage to the Health Service's property or injury to persons (including death) caused by the equipment when the equipment is used with reasonable care and according to the information given by the Supplier.
8. The Supplier agrees to indemnify the Health Service in regards to any claims, which arise as a result of negligence for any injury to persons (including death) or any damage to any property that may arise from manufacture, servicing, transport, or installation of the equipment, or any other negligence of the Supplier.
9. All costs including rent or licence fee for loan / use of equipment and any other cost associated with delivery, installation, servicing, maintenance, and removal shall be borne by the Supplier unless otherwise agreed in writing.
10. The Supplier at no cost shall provide all consumable items required for normal operation of the equipment over the period of the trial or loan unless otherwise agreed in writing.
11. During the trial or loan period, the Health Service agrees to give the Supplier reasonable access to the equipment for the purpose of demonstration to interested parties, provided the Supplier gives at least 24 hours notice. The Health Service reserves the right to deny access at any stage.
12. The Health Service authorised representative agrees to give verbal reports to the Supplier regarding the function of the equipment if requested to do so.
13. Prior to demonstration or use, all items of loan or trial equipment are to be tested for safety as specified in AS 3551 by the Health Service's Department of Biomedical Engineering. The Department of Biomedical Engineering may refuse to accept any trial or loan equipment that is considered unsafe or does not comply with Australian Standards. The Supplier warrants and agrees that:
 - a) The Equipment is fit for the purpose for which it is to be used by the Health Service the Equipment complies with all relevant quality and safety standards and is approved for use by all necessary authorities;
 - b) The Equipment, if used according to the manufacturer's or Supplier's specifications, will not cause injury or death to any person and will not damage or destroy any property of the Health Service or any person;
 - c) The Equipment will not cause the Health Service any loss of data and will not damage any software of the Health Service and will not infect it with any virus or other malicious or damaging code; and if the Health Service determined to acquire the Equipment, the Supplier can supply it to Health Service for the price advertised prior to the date of this agreement or lower, as the case may be.
14. The Supplier will remain the owner of the Equipment throughout the term of this agreement. The Supplier must ensure that the Equipment is labelled "Loan Equipment" and must keep accurate details of the serial and other identification markings on the Equipment. The Supplier acknowledges and agrees that nothing in this agreement creates any obligation on the part of the Health Service to:
 - a) Purchase the Equipment from the Supplier or any distributor of the Supplier;
 - b) Purchase equipment similar to the Equipment from the Supplier or any other seller or to request expressions of interest or tenders for the purchase of such equipment;
 - c) Include the Supplier in any selective tender for acquisition of any product;
 - d) Treat the Supplier favorably or give the Supplier any advantage or credit in any expression of interest, tender or other procurement procedure;
 - e) Provide any information concerning the Health Service or its procurement procedures to the Supplier.



Reference Number [Public Health use only]:	Date:
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- 15. The Supplier must take out and keep in force, during the life of the agreement a Broad Form Contractual Third Party Limited Insurance in the amount of not less than \$20 million in respect to each and every occurrence and unlimited in the aggregate for any one period of cover. A certificate of currency(s) for the policy(s) shall be made to the Health Service on demand.
- 16. The Health Service may attach additional requirements to this generic form if / when deemed appropriate.

SCHEDULE:

Trial / Loan start date: Trial / Loan end date:

Description of Equipment:

Manufacturer:

Model Number:

Serial Numbers:

Accessories:

SUPPLIER:

Signed on behalf of the Supplier: _____

Name: Position:

Supplier: Date:

Address:

ABN:

Contact Details: Phone: Email:
 Fax:

HEALTH SERVICE:

Signed on behalf of the Health Service: _____

Name: Position:

Health Service: Date:

Contact Details: Phone: Email:
 Fax:

Signed by Witness: _____

Name: Position:

Date:

SECTION D

LIBRARY OF FORMS & SUPPORTING DOCUMENTS

SECTION D – LIBRARY OF FORMS AND SUPPORTING DOCUMENTS

1. SAMPLE FORM 1
Product Management Committee Request for Evaluation Form
[Courtesy of B. Murray, Northern Sydney & Central Coast AHS – Central Coast Sector]
2. SAMPLE FORM 2
Checklist for Evaluation and Selection Reusable Devices
[Courtesy of B. Murray, Northern Sydney & Central Coast AHS – Central Coast Sector]
3. SAMPLE FORM 3
SD CP SAC – Risk Management for Clinical Product Quality Issues
[Courtesy of L. Shepherd, Hunter & New England AHS – Hunter Sector]
4. SAMPLE CHART 4
Flow chart for equipment product notification for Hunter & New England Health [Courtesy of L. Shepherd, Hunter & New England AHS – Hunter Sector]
5. SAMPLE FORM 5
Product / Equipment Problem Report
[Adapted from the Therapeutic Device Problem Report Sheet]
[Courtesy of L. Shepherd, Hunter & New England AHS – Hunter Sector]
6. SAMPLE FORM 6
Request for Product / Equipment Evaluation
[Courtesy of M. McLennan, Greater Southern AHS]
7. SAMPLE FORM 7
Infusion Pump Evaluation Sheet [May be amended to suit other equipment]
[Courtesy of M. McLennan, Greater Southern AHS]

SAMPLE FORM 1

**PRODUCT MANAGEMENT COMMITTEE
REQUEST FOR EVALUATION FORM
PAGE 1 OF 2**

1. Product Description:

Brand:

Catalogue Number: Box size:

Cost:

Other Relevant Information:

2. Why do you want to conduct the evaluation?

3. What are the advantages of the product?

a) To patients:

b) To staff:

c) To the Health Service:

d) Cost effectiveness

4. What are the disadvantages of the product?

5. How did you learn about the product?

PRODUCT MANAGEMENT COMMITTEE
REQUEST FOR EVALUATION FORM
PAGE 2 OF 2

6. Is there any literature / research available to support the product? Yes No

7. Do you require extra funding to purchase the product? Yes No

8. Will the cost be recurrent? Yes No

9. Has this request been discussed with any other staff Yes No

10. Are they in agreement with this trial? Yes No

11. If you answered, "yes" to points "8 & 9" please Identify:

12. Describe the education / in service that is to be provided:

13. Please identify product type: New Replacement

14. If replacement, please identify product to be replaced:

Details of requestor:

Name:

Position / Title:

Department

Date:

___/___/___

SAMPLE FORM 2

Checklist for Evaluation and Selection Reusable Devices [Including instruments]

	YES	NO
Is this a replacement instrument?	<input type="checkbox"/>	<input type="checkbox"/>
Is this a new instrument?	<input type="checkbox"/>	<input type="checkbox"/>
Is a trial being conducted?	<input type="checkbox"/>	<input type="checkbox"/>
Device Characteristics		
Is the instrument easily recognisable as reusable as opposed to single use?	<input type="checkbox"/>	<input type="checkbox"/>
What is the limit on the number of times the instrument may be reprocessed?		
Can the device be disassembled for cleaning and reprocessing?	<input type="checkbox"/>	<input type="checkbox"/>
Are there any features of the device that create difficulties for cleaning and reprocessing?	<input type="checkbox"/>	<input type="checkbox"/>
Will repeated reprocessing affect the integrity or longevity of the instrument?	<input type="checkbox"/>	<input type="checkbox"/>
Manufacturers Instructions		
Have the instructions for reprocessing been provided?	<input type="checkbox"/>	<input type="checkbox"/>
Are the instructions for reprocessing adequate?	<input type="checkbox"/>	<input type="checkbox"/>
Do the instructions include disassembly and reassembly?	<input type="checkbox"/>	<input type="checkbox"/>
Are there specific cleaning requirements?	<input type="checkbox"/>	<input type="checkbox"/>
Are accessory aids for cleaning provided or available?	<input type="checkbox"/>	<input type="checkbox"/>
Are there specific sterilization requirements?	<input type="checkbox"/>	<input type="checkbox"/>
Do the instructions offer alternative methods for cleaning, disinfection and/or sterilization?	<input type="checkbox"/>	<input type="checkbox"/>
Capabilities of the Facility to Reprocess the Device		
Does the facility have the appropriate cleaning, disinfection and/or sterilization equipment?	<input type="checkbox"/>	<input type="checkbox"/>
Is the sterilization cycle specific for this device and has it been validated on-site?	<input type="checkbox"/>	<input type="checkbox"/>
Does the sterilization cycle require adjustments for this instrument?	<input type="checkbox"/>	<input type="checkbox"/>
If so, can these adjustments be conducted in the facility?	<input type="checkbox"/>	<input type="checkbox"/>
Can the instrument be serviced by the facility?	<input type="checkbox"/>	<input type="checkbox"/>
Is additional equipment required for the cleaning and reprocessing of the device?	<input type="checkbox"/>	<input type="checkbox"/>
Do staffs require additional training to clean and reprocess the device?	<input type="checkbox"/>	<input type="checkbox"/>
What is the timeframe for reprocessing the device ready for reuse?	<input type="checkbox"/>	<input type="checkbox"/>
How frequently will this device be required in one operating session?	<input type="checkbox"/>	<input type="checkbox"/>
How frequently will this device be required in one operating day?	<input type="checkbox"/>	<input type="checkbox"/>
How many are needed to ensure they can be reprocessed within reasonable timeframes?	<input type="checkbox"/>	<input type="checkbox"/>
Warranty, Repair and Replacement Services		
What warranty is offered on the device?	<input type="checkbox"/>	<input type="checkbox"/>
Will the warranty be voided if an alternative method for reprocessing is used?	<input type="checkbox"/>	<input type="checkbox"/>
Does the device need to be returned to the manufacturer for servicing/repair?	<input type="checkbox"/>	<input type="checkbox"/>
What are the timeframes for servicing and repair?	<input type="checkbox"/>	<input type="checkbox"/>
Does the supplier have replacement loan devices in the case of device failure?	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

Not applicable

Instrument trialed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommended for Purchase:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Signature:		Print Name:	
Title:		Date:	

Not applicable

Approved for Purchase:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Signature:		Print Name:	
Title:		Date:	

SAMPLE FORM 3				
SD CP SAC – Risk Management for Clinical Product Quality Issues				
Serious	Major	Moderate	Minor	Minimum
Product Fault may have contributed to permanent disability and or contributed to death	Product Fault contributed to a review by doctor, diagnostic investigation, required treatment and or surgical intervention.	Product Fault led to increase length of stay and or surgical intervention.	Product Fault did not contribute to any significant outcome.	There was no direct harm or potential problem identified.
TGA definition Death or Serious injury, is not specifically defined, but is taken to be: Life threatening Resulting in permanent damage to a body structure Resulting in permanent impairment of a body function.	TGA definition Conditional serious injury is not specifically defined, but is taken to be: An injury requiring clinical intervention to prevent serious injury	TGA Definition Malfunction is not specifically defined, but is taken to be: A failure of the device to perform as expected which has the potential to compromise patient or operator safety. Such a failure may be caused by design, excessive claims, specification or labelling or device/component failure in which the device/system did not fail-safe	TGA definition User error is not specifically defined, but is taken to be: A situation where patient or operator injury, or near injury, is caused by incorrect use, i.e. not following instructions or labelling when these are assessed as adequate for a "normal" or "reasonable" user. "Off label" use when either the device is not specified for the application or specifically contra-indicated within the instructions for use or labelling	TGA definition As for minor

Adapted from the clinical risk management formate and TGA definition - Prepared by Lyn Shepherd, Hunter Health

Probability Categories	Definition
Frequency (80% - 90%)	Is expected to occur again either immediately or within a short period of time (likely to occur most weeks or months).
Likely (60% - 70%)	Will probably occur in most circumstances (several times a year).
Possible (50%)	Possibly will recur, Might occur at some time (may happen every 1 to 2 years)
Unlikely (20% - 40%)	Possibly will recur - Could occur at some time in 2 to 5 years.
Rare (10%)	Unlikely to recur - may occur only in exceptional circumstances (may happen every 5 to 30 years)

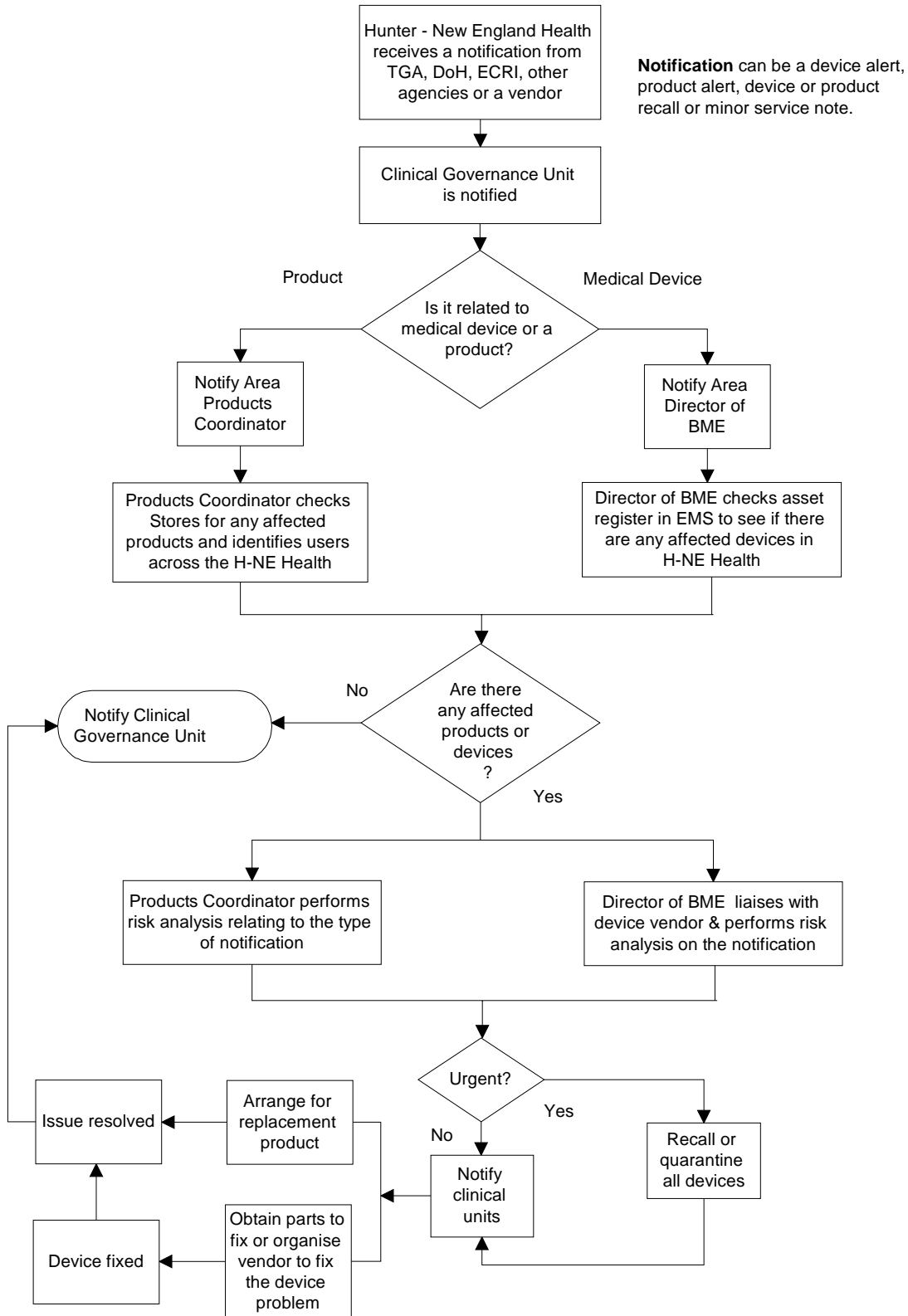
Action required
1= Extreme Risk (serious adverse event) - immediate action - report incident to delegated senior Manager of AHS and facility –internal or external recall product - notify supplier – Removal all affected batch - Identify and Alert other end users -enter details onto HQRS - Send product to TGA not the Supplier
2= High Risk – (potential harm) - - immediate action - report incident to delegated senior Manager of AHS and facility –internal or external recall product - notify supplier – Removal all affected batch - Identify and Alert other end users -enter details onto HQRS - Send product to TGA not the Supplier
3=Medium Risk - (may cause harm) - remove affected product – alert users and/or recall product if necessary - notify supplier – enter details onto HQRS – continue to monitor and review- Send product to TGA not the Supplier
4 = Low risk – (no harm) – alert users as required– if necessary, remove and retain affected product - notify supplier – enter details onto HQRS – continue to monitor and review- Send product to TGA not the Supplier
NB- An incident that rates a SAC of 3 or 4 should be only be reported to DOH if it is likely to attract external attention or requires notification under existing DOH legislative reporting requirement – do not re score the SAC

CONSEQUENCE LIKELIHOOD	Serious	Major	Moderate	Minor	Minimum
Frequency	1	1	2	3	3
Likely	1	1	2	3	4
Possible	1	2	2	3	4
Unlikely	1	2	3	4	4
Rare	2	3	3	4	4

Adapted from the clinical risk management formate and TGA definition - Prepared by Lyn Shepherd, Hunter Health

SAMPLE CHART 4

FLOWCHART FOR EQUIPMENT/PRODUCT NOTIFICATIONS



PRODUCT/EQUIPMENT PROBLEM REPORT

Please complete this form to report any suspected problems associated with a Clinical/Therapeutic Device, which may create a Health Hazard.

A therapeutic device is any material instrument, apparatus, machine, implement contrivance, implant, etc including any component, part or accessory, which is used in health care (Adapted from the Therapeutic Device Problem Report Sheet).

PRODUCT DETAILS

Description:

Brand Name:

Supplier Name:

Supplier Catalogue Number:

Batch
Number:

Supplier has been notified on
____/____/____

Contact name

The problem has been verified Yes No

Date of Manufacture	Date of Purchase	Date or Expiry	AUSTL/AUSTR Number

Is the product / packaging available for inspection?

Yes No

Quantity of product affected:

Note: Do not discard the product, if contaminated, place item in a sealed container & contact the Area Product Coordinator OR Area Director of Hunter Clinical Technology

PROBLEM DESCRIPTION:

CONSEQUENCES AND HISTORY OF PROBLEMS

(Please indicate history circumstances and where relevant sketches or explanatory notes)

REPORTER'S DETAILS

Reporter's Name:

Position / Title:

Department: Phone:

Hospital: Date:

E-Mail:

Do you want your identify to remain confidential? Yes No

Please send form and product to either the Area Clinical Product Manager or the Biomedical Engineer

SAMPLE FORM 6

**AREA CLINICAL PRODUCTS / EQUIPMENT COMMITTEE
REQUEST FOR PRODUCT / EQUIPMENT EVALUATION**

Page 1 of 2

1. Product / Equipment Identification

Supplier / Brand:	
Catalogue / Model Number:	
Other relevant details:	

2. Needs Analysis

Why is this clinical product / equipment required?

Is Purpose of this evaluation / trial for product knowledge / information? Please explain.

3. What are the advantages of this new product / equipment?

i) For Patients:

ii) For Staff:

iii) For the Health Service:

**AREA CLINICAL PRODUCTS / EQUIPMENT COMMITTEE
REQUEST FOR PRODUCT / EQUIPMENT EVALUATION
Page 2 of 2**

4. Estimated Monthly UsageAnnual Expenditure: \$.....
Procurement Cost: \$

5. How did you learn about the product / equipment?

6. Is there any literature / research supporting this new product / equipment? (Attach data)

7. Has this request been discussed with other appropriate staff? Yes No
if yes please identify and indicate if they are in agreement with this proposal

Contact Person:

Print Name & Title.....

Signature.....

Date___/___/___

Department / Campus..... Phone number (...)

Approved By: (Nursing Unit Manager or relevant Manager)

Print Name & Title.....

Signature.....

Date___/___/___

** Please attach minutes of meeting if application is coming from a committee.

Minutes attached: Yes No

Send form to appropriate manager

Clinical Products Manager: Fax: _____

Manager Medical Equipment, Asset Management: Fax: _____

Area Clinical Products / Equipment Committee Comments:

Approved / Rejected..... Date: ___/___/___

Commencement date for evaluation / trial (if applicable): ___/___/___

SAMPLE FORM 7 – INFUSION PUMP EVALUATION SHEET

Manufacturer														
Model														
Rating	DISPLAY (SCREEN) SIZE & EASE OF VIEW													
	PORTABILITY													
	SET INSERTION / REMOVAL													
	GIVING SETS													
	NEEDLE LESS VALVE													
	ACCURACY													
	ALARMS (features / volume levels)													
	OCCULSION PRESSURES													
	EASE OF OPERATION (GENERAL)													
	NOISE LEVELS (background whilst operating)													
	DATA INFORMATION (History)													
	DOSE CALCULATIONS													
	BATTERY OPERATION													
	FREE FLOW DEVICE													
3-CHANEL MODEL														
MANUFACTURER SUPPORT														
Below Average														
Average														
Above Average														
Excellent														

Comments

Advantages

Disadvantages

Do you recommend the pump for your department? [√]

Strongly Agree / Agree / Disagree / Undecided

Signature:	
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Name:	
Hospital:	
Department:	
Date:	

ACKNOWLEDGEMENTS:

1. The Patient Care Technology Group [<http://www.pctg.com.au>]
2. HPPC Clinical Product Managers Networking Group – Review Subcommittee 2004
 - Bernadine Murray, Area Product Manager
Northern Sydney & Central Coast AHS - Central Coast Sector
 - Lyn Shepherd, Area Products Manager
Hunter & New England AHS - Hunter Sector
 - Margaret Sullivan, Area Clinical Product Advisor
Sydney South West AHS
 - Susi Garrett, Nurse Manager Area Clinical Products,
Northern Sydney & Central Coast AHS - Northern Sydney Sector
 - Helen McKinlay-Hogan, Area Clinical Nurse Manager
South Eastern Sydney & Illawarra AHS - South Eastern Sydney Sector
 - Leonie Hardy, Clinical Product Nurse
Sydney West AHS - Western Sydney Sector
 - Cathy O'Hara, Clinical Product Nurse
Sydney West AHS - Western Sydney Sector
3. HPPC Clinical Equipment Procurement Working Party - Review Subcommittee 2004
 - James McCauley, Director Biomedical Engineering,
Northern Sydney & Central Coast AHS - Central Coast Sector
 - Craig Walton, Consultant Biomedical Engineering,
Northern Sydney & Central Coast AHS - Northern Sydney Sector
 - Marcia Stinson, Equipment Support Officer
Ambulance Service NSW
 - Linda Jones, Procurement Officer
Sydney South West AHS - Central Sydney Sector
 - Michael McLennan, Manager Medical Equipment
Greater Southern AHS
 - John Symonds, Department Head Biomedical Engineering
Childrens Hospital Westmead

4. HPPC Clinical Product Managers Networking Group [CPMNG] &
Clinical Equipment Procurement Working Party Members [CEPWP]
Health Service Members as of 01 March 2005

- Anne Taylor, Infection Control Consultant
Greater Western AHS – Macquarie Sector [CPMNG]
- Bernadine Murray [Chair], Area Product Manager
Northern Sydney & Central Coast AHS - Central Coast Sector [CPMNG]
- Bruce Morrison, Biomedical Engineer
Hunter & New England AHS - Hunter Sector [CEPWP]
- Camillo Pavan, Senior Biomedical Engineer
South Eastern Sydney & Illawarra AHS - South Eastern Sydney Sector [CEPWP]
- Craig Walton, Consultant Biomedical Engineering
Northern Sydney & Central Coast AHS – Northern Sydney Sector [CEPWP]
- David Brain, Manager, Biomedical Services
South Eastern Sydney & Illawarra AHS – Illawarra Sector [CEPWP]
- Denise Cane, Clinical Product Manager, Area Supply Services,
Sydney West AHS – Western Sydney Sector [CPMNG & CEPWP]
- Faye Ruthledge, Clinical Products Manager
Greater Southern AHS [CPMNG]
- Gary Vincent, Clinical Product Manager
NSW Ambulance Service [CPMNG]
- Gwyn Wensley, Environmental / Production Coordinator
Greater Western - Mid West Sector [CPMNG & CEPWP]
- Helen McKinlay – Hogan, Clinical Products Manager, Materials Resources Division
South Eastern Sydney & Illawarra – South Eastern Sydney Sector [CPMNG & CEPWP]
- James McCauley, Director Biomedical Engineering
Northern Sydney & Central Coast AHS – Central Coast Sector [CPMNG & CEPWP
Chair]
- John Symonds, Department Head Biomedical Engineering
Children’s Hospital Westmead [CPMNG & CEPWP]
- Leica Mackaway, Area Clinical Products Manager
Sydney West AHS – Wentworth Sector [CPMNG & CEPWP]
- Linda Jones, Procurement Officer
Sydney South West AHS - Central Sydney Sector [CEPWP]
- Lyn Shepherd, Products Manager
Hunter & New England AHS – Hunter Sector [CPMNG & CEPWP]
- Marcia Stinson, Equipment Support Officer, Infrastructure and Asset Services
NSW Ambulance Service [CEPWP]
- Margaret Sullivan, Area Clinical Product Advisor
Sydney South West AHS [CPMNG & CEPWP]
- Maureen Kable, Contracts Manager
Sydney South West - Central Sydney Sector [CPMNG]
- Merrilyn Birrell, Infection Control
Greater Western AHS - Far West Sector [CPMNG]
- Michael McLennan, Manager, Medical Equipment
Greater Southern AHS [CEPWP]
- Rosemary Terry, Clinical Product Manager
Justice Health [CPMNG]
- Sarah Ashton, Area Clinical Products Manager
North Coast AHS - Mid North Coast Sector [CPMNG & CEPWP]
- Stephen Winters, Clinical Products Coordinator
Children’s Hospital Westmead [CPMNG]
- Susi Garrett, Nurse Manager, Area Clinical Product
Northern Sydney & Central Coast AHS – Northern Sydney Sector [CPMNG & CEPWP]
- Trish Alexander, Clinical Products Advisor
Hunter & New England AHS – New England Sector [CPMNG]