SESLHD GUIDELINE COVER SHEET

NAME OF DOCUMENT	Guidelines for visiting company representatives to South Eastern Sydney Local Health District
TYPE OF DOCUMENT	GUIDELINE
DOCUMENT NUMBER	SESLHDGL/036
DATE OF PUBLICATION	October 2022
RISK RATING	Medium
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 2 – Partnering with Consumers
REVIEW DATE	October 2025
FORMER REFERENCE(S)	N/A
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director, Finance
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FUNCTIONAL GROUP(S)	Finance
KEY TERMS	Visiting company representatives, PHO
SUMMARY	This guideline is for company representatives intending to visit NSW Public Health Organisations (PHO) to promote and assist in the management of their company's medical devices.

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Guidelines for visiting company representatives to South Eastern Sydney Local Health District

Section 1 – Background

This guideline is for company representatives intending to visit NSW Public Health Organisations (PHOs) to promote and assist in the management of their company's medical devices. This guideline is intended to contribute to a wider PHO risk management strategy and should be read in conjunction with local PHO company representative policies/guidelines.

The main purpose of this document is to provide essential information that will ensure both the PHO and company representatives conduct business in accordance to set guidelines. These guidelines are in place to ensure the following:

- Strict adherence to related NSW Ministry of Health Policies
- Companies shall adhere to local PHO company representative policies/ guidelines
- Disruption to PHO operations and patient care is prevented
- Risk to the PHO including staff, patients and company representatives is mitigated

Visits to PHO are by appointment only

COVID-19 RESTRICTION – LATEST ADVICE ON VISITING OUR HOSPITAL

https://seslhd.health.nsw.gov.au/latest-advice-on-visiting-our-hospitals

NSW Health is comprised largely of Local Health Districts (LHD's). Details of the boundaries can be viewed on this link: http://www.health.nsw.gov.au/lhd/

Section 2 – Responsibilities

2.1 Clinical Products Role and Responsibilities:

- Coordination of selection, evaluation and introduction of all new clinical products and or equipment, and those existing products with significant changes to specifications.
- Assist process of rationalisation, reduction and standardisation of range of products available for use.
- Provides a multidisciplinary approach to consult over a wide range of specialties in the assessment of equipment and products.
- Local Co-ordination of product recalls/TGA alerts related to inventory. Advise clinical governance regarding non stock.

South Eastern Sydney LHD
Clinical Products Manager
Ph: (02) 95407731

2.2 Distribution Centre

HSNSW Product Management staff work closely with Customer Clinical Product Managers and Distribution Centre staff to:

- Engage with customers to review State Health contracts to select inventory products with a focus on contract compliance and savings.
- Assist site clinical product mangers in standardising clinical products associated with inventory where appropriate.
- co-ordinate product recalls related to inventory from distribution centre perspective
- Assist in the management of inventory backorders, nil-stocks and product substitutions.

Section 3 – Definitions

IVD medical devices: definitions and links

Adverse Event (or Adverse Experience): any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product which does not necessarily have to have a causal relationship with this treatment.

An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Medical device: is defined in the legislation as any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related device (including any diagnostic product for *in vitro* use) that is intended by the manufacturer to be used, alone or in combination, for human beings for the specific purpose of one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

PHO: Public Health Organisations

Quality Issue: refers to when a medical device fails to perform according to purpose or as specified, produces 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.

SCIS: the Supply Chain Information System provides all the essential detail about a specific product. This is normally submitted to the PHO prior to evaluation and may include the following forms:

- Clinical Product Presentation Form
- Clinical Equipment Presentation Form
- Indemnity Form – Evaluation Clinical Equipment
- Indemnity Form – Loan or Rental of Clinical Equipment

TGA Recall Action: is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. Company representative shall assist in the timely correspondence of information and product replacement as required.

Section 4 – The importance of visits by company representatives

It is recognised that company representatives perform a valuable function to the PHO's through the provision of medical devices, education and dissemination of updates in research and technology to clinical areas in conjunction with the authorised health representative.

Company representatives are permitted fair and reasonable access to specific personnel within the organisation in accordance to PHO protocols.

4.1 Appointments and site visits

Visits to PHO's are by **appointment only**. Company representatives are expected to arrange an appointment prior to any contact with any personnel within a PHO on a timely manner.

Company representatives are not permitted to visit wards and departments on the chance that a staff member may be available to see them.

Company representatives are expected to abide by relevant MOH and local POH policies that relates to access and entry into health facilities. Unproved promotions and trials in clinical areas and uncontrolled access to other areas of the Hospitals are not permitted. In some cases the PHO will require the company representative to register their visit at a central registration area and may be issued with a "Visitor's Badge" and will be required to display their Company Identification Badge (ID's) Photo identification preferred. Please contact the local CPM for specific instructions per PHO local policy.

4.2 Patient Contact

Company representatives are not permitted to participate in direct patient care. Any company representatives visiting clinical areas shall be under the direct supervision of an authorised PHO representative. Patient confidentiality and dignity shall be maintained at all times.

Other PHO Policies – must be observed in accordance with the NSW Health Code of Conduct.

4.3 Demonstrate honesty and integrity

Staff must:

- avoid situations which may give rise to pecuniary or other conflicts of interest, and should any conflicts or possible perceptions of such conflicts arise declare them immediately to their manager;
- not accept gifts where they are, or could be reasonably interpreted as being, designed to secure influence or preferential treatment in favour of the giver, which means that token or inexpensive gifts offered as an expression of gratitude, such as chocolates from a patient, can be accepted.

4.4 Orientation Program

Some PHO's require company representatives to complete an "Orientation Program" prior to the initial site visit being conducted. Orientation programs may include briefing on hospital site visit protocols, fire and safety, work health and safety, criminal record requirements. It is therefore a responsibility of company representatives to investigate and comply with PHO requirements.

The NSW Ministry of Health Guideline GL2005_045 - Mobile Phones and Wireless Communication Devices – Interference with Medical Equipment – Use of must also be observed.

Company representatives found in breach of the above or any NSW Health policy may be refused access to the PHO's. For information on other PHO policies please visit the Ministry of Health Internet page: www.health.nsw.gov.au .

Section 5 – Clinical Product Evaluation

The company representative must approach the Clinical Product Manager prior to any evaluations. Local process will be advised at this point. The Health Procurement Supply Chain Information System is used by all PHO's to maintain a registry/record of all medical device evaluations. It enables PHO's to efficiently record, maintain and update, monitor and share information. The SCIS, as described above, allows the Company Representative to assist in the evaluation registry process. Furthermore, the system enables a supplier to attach information in a variety of formats such as diagrams, brochures, or pictures, through the "attach" or "upload" function. The Clinical Product Managers/Biomedical Engineer/Clinical Technology Service initiate the process.

5.1 Clinical Equipment

Clinical equipment requires inspection and approval by the Biomedical Engineering / Clinical Technology Services Department before evaluation.

The completion of the Health Procurement Generic "Indemnity Agreement Form" is required. Completion of this form is a declaration that the device complies with all Statutory Regulations and is both safe for use and fit for purpose is required.

5.2 Product Presentations

Prior to promoting medical devices for use in any PHO, company representatives in the first instance, must seek approval from the Clinical Product Manager/Biomedical Engineer/Clinical Technology Service at each PHO. Note: This protocol may slightly differ from one PHO to another. However, the concept of central control is consistent at all sites.

A Product Evaluation Form and Indemnity Form (where appropriate) **MUST** be completed on the CPER and forwarded to the PHO prior to any samples being delivered. No medical device will be considered for evaluation or use without these documents being completed.

Product Evaluations may be discussed at local PHO's for suitability and if appropriate for further evaluation. **Samples ARE NOT to be left in ward areas or departments without prior arrangement with the authorised Public Health Officer.**

Products that are not yet TGA approved are not to be left in any PHO areas where there is risk of use in patient care.

5.3 Accessing Perioperative and Procedural Areas

Company Representatives must abide by the ACORN standards when visiting Perioperative and procedural areas. For further information and to obtain a copy of these standards please go to the following link. Particular attention should be made to the Standard: Visitors to the Perioperative Environment. https://www.acorn.org.au/standards/

5.4 Quotes, Proposals and Agreements

Quotes and proposals are to be directed to the authorised officer with the correct delegation. Refer to the MOH Procurement manual for further information on the correct delegations. Please be aware that some PHO's may also have their own internal delegation

requirements. **Please be aware that incorrect sign off could result in the process being made null and void.**

All proposals regarding items currently under NSW Contract **must** be in line with the contract documents. Please view the below link for a copy of the NSW Health Goods and Services Procurement Policy. http://www.health.nsw.gov.au/policies/manuals/pages/default.aspx

Section 6 – Risk Management

Each PHO has in place a risk management policy. This includes a policy for the safe introduction of new interventional procedures into clinical practice and includes any equipment or consumables, which may be required for those procedures. Company Representatives should be aware of, report on and play a role in managing risks for medical devices being presented to the PHO.

Section 7 – Quality Issues

When medical devices fail and/or cause adverse events, the Company Representative must consult with the authorised Public Health Officer and report such event(s) to the Therapeutic Goods Authority (TGA) where relevant.

It is the responsibilities of suppliers to investigate quality concerns as a priority and report any outcomes to the CPM and / or Biomedical Engineer.

Clinical Products Faults: all faults with products devices and pharmaceutical are to be reported to Clinical Products team / Biomedical Engineers or Pharmacy as appropriate.

Step 1: Complete Product/Equipment Problem Report Form found on the SESLHD Intranet @ Forms and Templates, Procurement.

Send to Clinical product Managers DL email:

SESLHD-ClinicalProductManager@health.nsw.gov.au

Step 2: Retain affected product/packaging and forward to Clinical Products Manager for further advice on return/credit process/outcome.

SESLHD-ClinicalProductManager@health.nsw.gov.au

Step 3: Advise senior manager and complete IMMS if appropriate.
Refer to https://www.tga.gov.au/about-tga Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95).

Section 8 – References and Revision and Approval History

References

- HealthShare Procurement Services
- NSW Health Code of Conduct PD2015_049
- http://www.icac.nsw.gov.au/
- http://seslhdweb.seslhd.health.nsw.gov.au/SESLHD_Procurement/Clincal_Products/representatives.asp
  http://seslhdweb.seslhd.health.nsw.gov.au/SESLHD_Procurement/Clincal_Products/default.asp
- HealthShare, Guidelines for Visiting Company Representatives to NSW Public Health Organisation (PHOs)
- SESLHDPR/333 – Contractor Management Procedure

Revision and Approval History

Date	Revision no:	Author and approval
June 2015	1	Endorsed by Executive Sponsor – SESLHD Director of Finance
July 2019	2	Minor review updated references and hyperlinks. Approved by Executive Sponsor.
August 2019	2	Formatted and published by Executive Services.
October 2022	3	Minor review. Contact information and links updated. Approved by Executive Sponsor.