HEALTH PURCHASING VICTORIA

Invitation to Supply
Request for Tender

Part 5

Statement of Requirements

Invitation to Supply Number:	**HPVITS2015-051**
Invitation to Supply Name:	**Drapes And Clinical Protective Apparel**
HPVITS2015-051 Closing Date and time:	**24 June 2015, 14:00 AEST**

Authorised Contact Person

Hassan Pirov

Category Manager

Contact through the HPV Procurement Portal

https://www.hpv.org.au/

Published: 27/05/2015

Table of Contents

A Introduction

1. Purpose

a. The purpose of this Part 5 – Statement of Requirements, is to:

(i) detail the scope and range of products sought under this Request for Tender (RFT)

(ii) specify the requirements that Respondents and / or their offered products must meet (these requirements also form part of any resulting Agreement between HPV and any successful Respondent)

2. Scope

a. HPV is seeking responses for Drapes and Clinical Protective Apparel for use in Participating Health Services. The envisaged Term of the Agreement is four (4) years with one possible two (2) year extension (4+2). The principal term also includes a mid-term contract review.

b. The scope of this RFT includes:

(i) the supply of Drapes and Clinical Protective Apparel

c. The scope of this RFT does not include:

(i) supply of Customised Sterile Packs

d. Indicative volumes are listed **in Part 6**

3. Product Categories

a. The categories of Drapes and Clinical Protective Apparel required under this RFT include:

Category 1 High Filtration and Respiratory Protective Face Masks

Category 2 Eye and Face Protective Device

Category 3 Shoe Covers

Category 4 Headwear

Category 5 Single Use Patient Underwear

Category 6 Single Use Gowns for Patient Use

Category 7 Single Use Gowns for Clinical Use

Category 8 Single Use Surgical Gowns

Category 9 Plastic Aprons

Category 10 Adhesive Incise Drapes

Category 11 General Purpose Drapes

Category 12 Speciality Drapes

Category 13 Composite Drape Packs

Category 14 Plastic Drapes

b. The Respondent may offer products in one, some or all categories.

c. HPV reserves the right not to consider any additional products offered.

d. For a full list of product categories and subcategories, see Appendix 1 - Product List.

4. Product Conditions

4.1. Clinical Trials

a. Participating Health Services may, at their discretion, research or trial new technology or use non-contracted products to perform clinical trials at any time during the Term of any resulting Agreement.

4.2. Product Duplication

a. HPV will not consider any product that is subject to a current HPV Agreement, other than those listed below:

HPVC2010-051 Drapes & Clinical Protective Apparel

b. The Respondent must ensure that each product offered is in only **one** subcategory.

It is at the Respondent's discretion to ensure that each product submitted is in the most appropriate subcategory.

4.3. Product Information

a. Upon request from HPV the Respondent must submit a copy of relevant product diagrams, specifications or brochures to assist in accurately identifying products offered. See Part 6, Tender Response Worksheet.

b. Research papers, relevant scientific information and samples are not to be provided unless specifically requested by HPV.

c. All product information submitted should:

(i) be in electronic format

(ii) be in English

(iii) be specific to the product offered

(iv) contain the Respondent's company name

(v) include the product code

(vi) include a detailed specification of the product

(vii) include clear diagrams/pictures of the product.

d. To assist in managing this material, all product information submitted must be labelled with the relevant HPV category and subcategory number.

Electronic copies must include the HPV Category and subcategory numbers in the filename or identifying metadata.

HPV may not consider unlabelled submissions.

e. Product information is not evaluated, but is necessary to assist in accurately identifying products offered.

f. Where offered products are unidentifiable and the product information provided is not clearly labelled, HPV reserves the right to remove these products from evaluation.

g. Product samples are **not** to be provided unless specifically requested by HPV, as per **Part 3 – 8 Samples**.

h. The Respondent should not submit information relating to products that are not called for in this RFT.

5. Definitions

a. The following definitions apply to this Part 5 – Statement of Requirements, unless otherwise stated.

TERM	DEFINITION
business day	Any weekday that is not gazetted as a public holiday in Melbourne, Victoria.
Consumable	A component that is used continually until it is exhausted and needs to be replaced.
GS1	Global Standards One
GTIN	Global Trade Identification Number
HPV	Health Purchasing Victoria
Fenestrated Drape	A drape with a round or slit-like opening in the centre.
May	Indicates an optional element; it is at the Respondent's discretion to either meet or not meet this element, and failure to meet this element will not have an impact during evaluation.
Must	Indicates a mandatory requirement; failure to meet this requirement will have a significant negative impact during evaluation.
NEHTA	National E-Health Transition Authority
NPC	National Product Catalogue

TERM	DEFINITION
Participating Health Services	Public Hospitals and other Health or Related Services, as those terms are defined in Section 3 of the *Health Services Act 1988 (Vic),* that are described in **Appendix 4 of Part 8**.
Respondent	Any person, company or organisation responding to this ITS and, unless the context otherwise requires, includes those who may access the ITS for the purpose of submitting a Tender.
Reusable	A device designed or intended by the manufacturer as suitable for reprocessing and reuse.
semi-consumable	A component that is used continuously until it deteriorates or fails and needs to be replaced.
Should	Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may have a medium impact during evaluation.
single use	A device that is intended to be used on an individual patient, during a single procedure, and then discarded (source: TGA, *Regulation of the Re-Manufacture of Single Use Medical Devices*).
single-patient use	A device that can potentially undergo more than one episode of use on one patient only. The device may need to undergo some form of reprocessing between each use (in accordance with manufacturers' instructions). (source: TGA*, Regulation of the Re-Manufacture of Single Use Medical Devices*)
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration
Will	Indicates an anticipated future condition or requirement.

B Service, Delivery, and Support

1. Delivery

a. Drapes and Clinical Protective Apparel must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed **two (2) business days** from receipt of order unless otherwise agreed with the Participating Health Service.

b. All deliveries are bound as per the Draft Agreement, Part 7.11, Acceptance and Rejection of Deliverables.

2. Urgent Deliveries

a. For the purposes of this section, urgent deliveries refers to urgent requests placed by an individual Participating Health Service, and does not include state-wide emergency situations.

b. The Respondents must be able to receive and action urgent delivery requests 24 hours a day, seven (7) days a week.

c. Urgent deliveries are to be received by Participating Health Services within **24 hours** from receipt of order.

3. Training and Support

a. Successful Respondents may be required to provide timely training and/or training materials to facilitate the introduction of their product to clinicians in their operating environment. Such training and/or materials must be available to Participating Health Services upon request.

b. If requested by a Participating Health Service, successful Respondents must provide a plan detailing how they will provide training to nominated staff. The number of staff involved in training may vary greatly between Participating Health Services.

c. Successful Respondents must ensure that the required training and/or training materials is scheduled for delivery to Participating Health Services within a two week timeframe from the date the request is sent or as agreed by the Participating Health Service.

d. Successful Respondents must ensure that the following is available to Participating Health Services (in either hard-copy or electronic format):

(i) the credentials of any staff who would be providing support

(ii) the hours of availability for support

(iii) the geographical area covered by the support (if support is available on-site)

(iv) details of educational and/or support materials available to clinicians.

e. All training regimes must include appropriate levels of training to meet Workplace Health & Safety issues as required by WorkSafe Victoria.

4. Warranty

a. Product must be warranted for normal use

b. All products covered in this RFT are to have a warranty for a minimum of twelve (12) months from the delivery date for normal use.

c. Upon request, the successful Respondent must provide information (printed or electronic) explaining product warranty.

4.2. Replacements Under Warranty

a. The replacement of any item under warranty will be at no cost to the Participating Health Service.

b. The cost of any pickup or delivery associated with a replacement under warranty will be borne by the successful Respondent.

c. Successful Respondents must provide Participating Health Services with a replacement at no cost until the repaired item is returned.

5. Key Performance Indicators

a. The successful Respondent must agree to work with HPV to develop measurable KPIs, based on the measurable requirements of the Response and Agreement.

b. Refer to Part 7, Schedule 6 - Draft Agreement – Key Performance Indicators.

6. Reporting

a. Refer to Part 7, Schedule 7 Draft Agreement – HPV reporting template and timing of reports.

b. The successful Respondents must provide to HPV other reports that may reasonably be required from time to time.

C General Requirements

1. Standards and Compliance

a. All items offered must comply with relevant Australian Standards (or their equivalent International Standards). Refer to Appendix 2 - References for a list of the minimum relevant standards.

b. All items offered must be approved by the Australian Therapeutic Goods Administration (TGA), unless exempt. The Respondents must provide evidence of this (i.e. ARTG certificates) in its response.

c. The successful Respondent must provide evidence of ARTG certification to Participating Health Services upon request.

2. Packaging and Labelling

a. Sterile products must be packaged in a manner that protects the contents from contamination during transportation, storage and handling.

b. All labels must comply with the Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods.

c. Items must be delivered in accordance with the manufacturer's instructions.

d. It is desirable for individual product packaging to include (where applicable):

(i) whether the product is sterile;
(ii) whether the product is MRI compatible ;
(iii) whether the product (or packaging) contains latex or is latex-free; and
(iv) tracking labels.

3. Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (2004).

b. All recalls and/or hazard alerts must be completed using GS1 Recallnet no later than **30 April, 2016**, as endorsed by the NEHTA

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods*) must also meet the warranty requirements under section B.4.2 where applicable.

4. Product Information and Identification

a. By contract commencement , all consumables and semi-consumables must be identifiable using GTINs and must be listed on the National Product Catalogue (NPC).

5. Backorders and Discontinued lines

a. In the event that a product is unavailable successful Respondents must immediately contact (at a minimum):

(i) supply departments

(ii) the Clinical Product Advisor (where applicable)

(iii) the Nurse Unit Manager (where applicable).

b. In the event that a product is unavailable for a period of two or more consecutive weeks, the successful Respondent must contact (at a minimum) the following:

(i) Procurement Officers of all Participating Health Services

(ii) Supply Manager / Business Managers of all Participating Health Services; and

(iii) HPV

c. In the event that an item is discontinued, successful Respondents must notify Participating Health Service staff and HPV (as per Clause b) as soon as possible, but no less than six (6) months before the last date of manufacture.

d. Successful Respondents must inform the affected Participating Health Services and HPV of:

(i) the anticipated timeframe for resolving the issue; and

(ii) the availability of an agreed substitute product

6. Superseded Products

a. Where a new product supersedes a contracted item, the new product must be offered at the price of the original item.

7. Infection Control

a. Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2014).

b. Upon request by Participating Health Services, successful Respondents must provide cleaning details for all products.

D Product Specifications

1. Substances of Concern

a. Preference will be given to products (including their accompanying packaging) that are latex-free, unless otherwise stated.

b. Preference will be given to products that are free of phthalate content, particularly diethylhexyl phthalate (DEHP).

2. Compliance with Category Specifications

a. Products offered with optional components must also comply with the specifications for other relevant categories (where applicable).

3. Category Specifications

a. A complete range of Drapes and Clinical Protective Apparel is required for treatment of patients across Victorian Public Health Services.

Category 1 High Filtration and Respiratory Protective Face Masks

a A range of single use face masks including respiratory protective face masks is required to meet clinical needs. This includes:

- a range of sizes
- general purpose
- sub-micron filtering (high filtration)
- fluid resistant
- P2/N95 disposable particulate respirators
- LASER plume protective masks.

a Variations include:

with ties and head bands;

with and without:

- anti-fog feature;
- a visor;
- anti-glare strips.

b Preference will be given to particulate filter respirator masks that are National Institute for Occupational Safety and Health (NIOSH) approved.

c Masks for LASER plume protection shall provide filtration of particles to 0.1 micron.

d All masks offered shall have a minimum nominal tie length of greater than 300 millimetres.

e Masks with ties shall be packaged in a manner that facilitates easy individual separation upon removal from packaging and dispensing boxes.

f For each mask offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

- brand name;
- size e.g. small, medium;
- state micron filtration

presence of:

- anti-fog feature;
- a visor;
- anti-glare strip;
- method of securement e.g. ties.

g Respondents shall advise on the Tender Response Worksheet the availability, ordering details and any costs associated with brackets for dispensing boxes.

h Respondents of P2/N95 particulate filter respirator masks must advise:

if a mask-fitting education program is available to support users in effective use of this device; and

details of the education program including associated resources that will be provided to health services e.g. in-service training, instructions for use

i Preference will be given to Respondents who provide an education program.

Category 2 Eye and Face Protective Device

a A range of both single use and reusable personal eye and face protective devices are required to protect health care workers and patients from the risk of splashing, splattering or spraying of blood or body substances

b Supplier should provide guidance in the cleaning of their reusable personal eye and face protective devices upon request.

b. This includes:

(i) safety spectacles;

(ii) wide vision goggles;

(iii) eye shields;

(iv) face shields, half and full length;

(v) a range of sizes to suit most face and head shapes.

c. Variations include:

(i) splash resistant and low impact rated;

(ii) one and two piece;

(iii) with and without replaceable lenses and visors.

d. Eye and face protective devices shall:

(i) incorporate side protection;

(ii) be shaped and sized to fit the majority of users.

e. The frames of eye and face protective devices shall be:

(i) non metallic;

(ii) made of lightweight material.

f. The lenses or visors of eye and face protective devices shall be:

(i) optically clear and non tinted, non-reflective and distortion free;

(ii) have no rough or sharp edges or protuberances that may cause discomfort or injury to the user.

g. Preference will be given to eye and face protective devices that incorporate scratch-resistant lenses and visors.

h. Materials used in construction of any portion of eye and face protective devices that come into contact with the skin shall:

(i) be non irritant when subjected to perspiration;

(ii) not discolour the skin;

(iii) be designed to minimise any risk of skin irritation or abrasion.

i. Eye and face protective devices with replaceable parts shall be accompanied by manufacturer's instructions for wear and fitting.

j. Cleaning instructions shall also be provided where any portion of the face or eye shields is indicated to be reusable.

k. Adjustable or interchangeable parts or components shall be simple to adjust, interchange or replace.

l. Replacement visors and lenses shall be packaged in a manner that protects them from damage and contamination during normal storage, fitting and handling.

m. For each device offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) if the device is:

- splash resistant;
- low-impact;
- one or two piece;
- single use
- reusable

(iii) Presence of lenses or shields.

n. Respondents shall advise on the Tender Response Worksheet whether the eye and face protective devices indicate for clinical use on the unit packaging. Preference shall be given to products that include this information on the unit packaging.

o. Respondents note: this category does not include eye or face protective devices for laser protection.

Category 3 Shoe Covers

a A range of single use shoe covers for indoor use is required to meet clinical needs. This includes:

(i) plastic;

(ii) spun bonded polypropylene fabric;

(iii) a full range of sizes

b All polypropylene shoe covers shall be non-slip.

c Shoe covers shall be sufficiently robust and durable to maintain structure during recommended use.

d Elastic shall be securely bonded around the opening edge of the overshoe in a manner that permits full stretch of the opening.

e Plastic shoe covers shall have a minimum nominal stretched:

(i) length of 350mm;

(ii) opening of 350mm.

f Polypropylene shoe covers shall have a minimum nominal stretched:

(i) length of 390mm;

(ii) opening of 230mm.

g Polypropylene fabrics shall be:

(i) soft, lightweight and breathable;

(ii) low linting.

h The non-skid layer on the polypropylene shoe covers shall not peel off or mark floor surfaces during recommended use.

i For each shoe cover offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) size e.g. adult -small, medium, large, paediatric-small, medium, large

(iii) Latex Free

Category 4 Headwear

a A range of single use headwear is required to meet clinical needs. This includes:

(i) bouffant and beret style caps;

(ii) surgeon caps with tie-back;

(iii) balaclavas with tie-back;

(iv) scarves.

b Variations include:

(i) a full range of colours and patterns;

(ii) a full range of sizes,

c Headwear shall be designed, sized and constructed to provide full coverage of hair on the majority of users.

d Headwear shall be made of non-woven polypropylene or similar fabric that is:

(i) low linting and breathable;

(ii) of sufficient tensile strength to avoid being torn during normal donning and wear.

e Elastic shall be securely bonded around the circumference of the bouffant and beret caps in a manner that permits full stretch of the opening.

f Bouffant and beret style caps shall have a minimum nominal stretched diameter of 500mm.

g Surgeon caps shall have a minimum nominal lower border length (circumference of cap plus ties) of 1000mm.

h Balaclavas shall have a minimum nominal lower border length (circumference of balaclava plus ties) of 1200mm.

i Scarves shall be triangular and have a minimum nominal diagonal length of 1350 mm.

j For each item offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) colour or pattern;

(iii) size e.g. adult -small, medium, large, paediatric-small, medium, large;

(iv) dimensions in millimetres e.g. 550mm.

Category 5 Single Use Patient Underwear

a A range of non sterile, non-woven underwear for single patient use is required to meet clinical needs. This includes:

(i) a full range of sizes

(ii) for male, female or unisex

b Each undergarment shall be made of non-woven polypropylene or similar fabric that is:

(i) low linting and breathable;

(ii) of sufficient tensile strength to avoid being torn during normal donning and wear.

c Elastic shall be securely bonded around the circumference of the waist and leg openings in a manner that permits full stretch of the opening.

d For each item offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) size e.g. adult -small, medium, large, paediatric-small, medium, large

(iii) sex e.g. male, female, unisex

Category 6 Single Use Gowns for Patient Use

a A range of non sterile, non-woven gowns for patient use is required to meet clinical needs. This includes:

(i) long and short sleeved;

(ii) with ties or Velcro, or equivalent, for securement;

(iii) a range of sizes.

b All single use patient gowns offered shall be opaque to maintain patient dignity.

c For each patient gown offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) size e.g. adult -small, medium, large, paediatric-small, medium, large;

(iii) sleeve length in centimetres;

(iv) method of securement e.g. ties or Velcro or equivalent.

(v) Supplier must indicate in the Tender Response Worksheet the applicable standard (e.g. AAMI PB70 and/or EN13795) and levels for liquid barrier performance and protection.

Category 7 Single Use Gowns for Clinical Use

a A range of non-woven long sleeve gowns is required to meet clinical needs. This includes:

(i) sterile and non sterile;

(ii) fluid repellent;

(iii) impervious;

(iv) with a high cut neckline.

b Variations include:

(i) a full range of colours and patterns;

(ii) a range of sizes

c Gowns for clinical application shall be manufactured from non-woven fabric that is:

(i) air and moisture vapour permeable;

(ii) low linting and low noise.

d Single use gowns for clinical use shall incorporate elastic sleeve ends or knitted cuffs.

e Where cuffs are incorporated, they shall be securely bonded to the sleeves of the gown.

f Sterile, single use gowns for clinical use shall be:

(i) individually wrapped with the expiry date printed clearly on the outer packaging;

(ii) packaged in a manner that facilitates removal from the outer wrap without compromising the sterility of the inner wrap and contents.

g For each clinical gown offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) colour;

(iii) size e.g. full range;

(iv) length in centimetres;

(v) length of sleeve in centimetres.

(vi) Supplier must indicate in the Tender Response Worksheet the applicable standard (e.g. AAMI PB70 and/or EN13795) and levels for liquid barrier performance and protection.

Category 8 Single Use Surgical Gowns

A range of sterile, single and /or double wrapped, non-woven surgical gowns is required to meet clinical needs. This includes a range of:

(i) sizes;

(ii) lengths;

(iii) fluid repellent;

(iv) impervious;

(v) with and without areas of additional reinforcement and fluid protection to prevent fluid strikethrough;

(vi) presentation, single and/or double packs.

b Surgical gowns shall:

(i) be manufactured from non-woven fabric that is fluid repellent or impervious;

(ii) be air and moisture vapour permeable;

(iii) be low linting and low noise;

(iv) be long sleeved with knitted cuffs that are securely bonded to the sleeves of the gown;

(v) be wrap around style, incorporating a tie carrier to facilitate tying of the external tie;

(vi) be folded in a manner that facilitates donning without compromising the sterility of the product;

(vii) incorporate a high cut neckline.

(viii) Impermeable sturdy study for cytotoxic drugs where applicable

(ix) Indicate level of fluid repellence

c Single use surgical gowns shall be:

(i) individually wrapped with the expiry date printed clearly on the outer packaging;

(ii) packaged in a manner that facilitates removal from the outer wrap without compromising the sterility of the inner wrap and contents.

d The contents shall be wrapped in the inner wrap in a manner that allows:

(i) the inner wrap to be opened and draped to form a sterile field for the contents;

(ii) opening to expose and remove the sterile contents without compromising the sterility of the enclosed gown.

e The inner wrap shall:

(i) have a minimum dimension of 90 x 90cms.

f Each single gown shall be packaged with a minimum of:

(i) one woven towel; or

(ii) two non-woven towels.

g Woven towels shall be:

(i) low linting;

(ii) of various sizes but not less than 35cm X 55cm to allow for effective hand drying; and

(iii) non-white.

h Non-woven towels shall be:

(i) made of suitably absorbent material that will not tear or break up when in normal use;

(ii) low linting;

(iii) of sufficient size to allow for effective hand drying.

i For each surgical gown offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) size e.g. Adult – small, medium, large, XL, XXL

(iii) the number of towels in the pack;

(iv) if the towel is woven or non-woven;

(v) the dimensions of the towel in centimetres.

(vi) Supplier must indicate in the Tender Response Worksheet the applicable standard (e.g. AAMI PB70 and/or EN13795) and levels for liquid barrier performance and protection.

Category 9 Plastic Aprons

a A range of single use plastic aprons is required to meet clinical needs. This includes:

(i) non-sterile and sterile;

(ii) low and high density polyethylene or similar plastic material;

(iii) a range of sizes and lengths;

(iv) presentation: rolled and folded.

b Apron ties shall be a minimum length of 450mm.

c Sterile plastic aprons shall be individually packaged with the expiry date on the outer packaging.

d Non sterile aprons shall be packed in a manner that facilitates the easy selection of a single apron.

e For each plastic apron offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) the type of plastic used

(iii) the grade of plastic used e.g. low or high density;

(iv) size e.g. regular or large;

(v) length and width in centimetres.

Category 10 Adhesive Incise Drapes

a A range of single use, sterile adhesive incise drapes is required to meet clinical needs. This includes:

(i) a full range of sizes and shapes;

(ii) plain and antimicrobial impregnated.

b adhesive incise drapes shall:

(i) be soft and flexible;

(ii) be resistant to tears, abrasions and punctures;

(iii) have a transparent non glare surface;

(iv) be manufactured to be cleanly cut with a scalpel;

(v) retain their adhesiveness throughout the procedure;

(vi) be individually wrapped in a manner that allows the packaging to open cleanly to expose the inner contents without compromising the sterility of the drape.

c All antimicrobial impregnated drapes shall have the expiry date printed on the outer packaging.

d All adhesive incise drapes shall have backing film that is removed evenly and cleanly to expose the adhesive surface.

e For each item offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) if adhesive window present;

(iii) length and width in centimetres of:

- window
- overall drape;

(iv) size e.g. small, medium, where applicable.

(v) Supplier must indicate in the Tender Response Worksheet the applicable standard (e.g. AAMI PB70 and/or EN13795) and levels for liquid barrier performance and protection.

f Respondents shall advise on the Tender Response Worksheet whether the incise drapes have a description of the position of the adhesive window on the outer packaging.

g Preference will be given to incise drapes that have a description of the position of the adhesive window on the outer packaging.

Category 11 General Purpose Drapes

a A range of sterile, single use, single and/or double wrapped, non-woven, general purpose drapes is required to meet clinical needs. This includes:

(i) a full range of sizes and shapes;

(ii) for equipment including trolleys, tables, stands and bowls;

(iii) with and without:

- tapes for positioning of drapes;
- fenestrations;
- split and non split;

(iv) leggings.

b General purpose drapes shall be manufactured from non-woven fabric that is:

(i) low linting;

(ii) impervious;

(iii) resistant to tears, punctures and abrasions;

(iv) comfortable and incorporates a soft layer for the patient.

c General purpose drapes shall:

(i) not form a crease when folded ;

(ii) be folded and packaged in a sequence that facilitates their positioning without compromising the sterility of the drapes.

d Drape seams must be constructed to prevent fluid strikethrough.

e Where adhesive tape is incorporated for positioning purposes, the backing paper shall be opaque or coloured to distinguish it from the operating field.

f For each item offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) length and width in centimetres;

(iii) with or without:

- tapes for positioning of drapes;
- fenestrations;
- split;

- instrument securement tapes and tabs.

(iv) Supplier must indicate in the Tender Response Worksheet the applicable standard (e.g. AAMI PB70 and/or EN13795) and rating Level for liquid barrier performance and protection.

g Respondents shall advise on the Tender Response Worksheet if drapes incorporate:

(i) an absorbent area to assist in fluid management;

(ii) a skin contact layer to enhance patient comfort.

h Respondents shall advise on the Tender Response Worksheet if the general drapes indicate the sequence for opening the drape on the underside of the drape.

i Preference will be given to general drapes that indicate the sequence for opening the drape.

j A range of sizes of sterile impervious stockinette is required to meet clinical needs. Stockinette shall consist of a soft inner layer and an impervious outer layer.

k Stockinette shall be:

(i) soft and conformable;

(ii) manufactured from low linting fabric;

(iii) resistant to tears, punctures and abrasions;

(iv) tapered to suit application to limbs;

(v) packaged in a manner that facilitates application in an aseptic manner.

l For each item offered, Tenderers shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) width and length in centimetres;

(iii) sizes in the full range.

Category 12 Speciality Drapes

a A range of sterile, single use, single or double wrapped, non-woven specialty drapes is required to meet clinical needs. This includes:

(i) a full range of sizes and shapes;

(ii) for use across the full range of surgical specialities including laparoscopic surgery and robotic surgery;

(iii) split and non split;

(iv) with and without:

- tapes for positioning of drapes;
- fenestrations;
- windows of adhesive incise film, plain and antimicrobial;
- incorporated fluid collection pouches with and without drainage ports;
- instrument securement tapes and tabs.

b Specialty drapes shall be manufactured from non-woven fabric that is:

(i) low linting;

(ii) impervious:

(iii) resistant to tears, punctures and abrasions;

(iv) soft and comfortable.

c Non woven specialty drapes shall:

(i) not form a memory;

(ii) be folded and packaged in a sequence that facilitates their positioning without compromising the sterility of the drapes.

(iii) include tracking sticker for all items

d Where a drape incorporates seams, they shall be constructed to prevent fluid strikethrough.

e Where adhesive tape is incorporated for positioning purposes, the backing paper shall be opaque or coloured to distinguish it from the operating field.

f Specialty drapes that incorporate an adhesive incise drape shall comply with the specification for adhesive incise drapes as described in Category 10 .

g Instructions for application shall be included on the unit packaging and box.

h For each item offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) width and length in centimetres;

(iii) presence of:

- split;
- fenestration;
- tape/s for positioning;
- incorporated fluid collection pouch/es with and without drainage port/s;
- instrument securement tape/s or tab/s.

(iv) Supplier must indicate in the Tender Response Worksheet the applicable standard (e.g. AAMI PB70 and/or EN13795) and rating Level for liquid barrier performance and protection.

i Where a window of adhesive incise film is present, Respondents shall advise:

(i) length and width in centimetres of:

- adhesive window;
- total size of specialty drape.

j Where instrument securement tapes or tabs are present, Respondents shall advise the number of tapes or tabs.

k Respondents shall advise on the Tender Response Worksheet whether the specialty drapes indicate the sequence for opening the drape on the underside of the drape.

l Preference will be given to specialty drapes that indicate the sequence for opening the drape.

Category 13 Composite Drape Packs

a Commercially available composite drape packs containing a range of sterile, single use, non-woven drapes, with and without non-woven surgical gowns and towels are required to meet clinical needs. This includes for use across the full range of surgical specialities including laparoscopic surgery.

b All commercially available composite drape pack must be TGA registered (ARTG)

c Drapes incorporated within a composite drape pack shall comply with the specifications as described in Category 10 , Category 11 , and Category 12 .

d For each item offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) components of each composite pack;

(iii) dimensions of each component including: width and length in centimetres, or size e.g. regular, XL.

e Respondents shall advise on the Tender Response Worksheet if composite drapes indicate the sequence for opening the drape on the underside of the drape.

f Preference will be given to composite drapes that indicate the sequence for opening the drape.

g Respondents are requested to offer composite drape packs in Category 12 , Surgical Specialty, on the Tender Response Worksheet that best fits their purpose.

h Respondents should not submit drape packs in more than one category.

Category 14 Plastic Drapes

a A range of sterile, single use, plastic drapes is required to meet clinical needs. This includes:

(i) a full range of sizes and shapes;

(ii) for equipment including trolleys, tables, stands and bowls;

(iii) for equipment including but not limited to:

(iv) microscopes, x-ray cassettes, fluoroscopy units, ice machines, video cameras, ultrasound probes, LASER arms;

(v) with and without adhesive tabs to facilitate positioning and gathering of any excess drape material;

(vi) double wrapped.

b Plastic drapes shall be packaged in a manner that allows opening to expose and remove the sterile contents without compromising the sterility of the drapes.

c Equipment drapes shall incorporate labels to assist with correct application.

d Lens and eye piece covers incorporated in camera and microscope drapes shall not adversely affect visual quality. The cover shall be removable upon application of the drape.

e Where adhesive tape is incorporated for positioning purposes, the backing paper shall be opaque or coloured to distinguish it from the operating field.

f For each item offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;

(ii) where drapes are designed for a brand-specific piece of equipment, Respondents shall include the compatible equipment brand;

(iii) width and length in centimetres;

(iv) presence of adhesive tabs.

(v) Supplier must indicate in the Tender Response Worksheet the applicable standard (e.g. AAMI PB70 and/or EN13795) and AAMI rating level for liquid barrier performance and protection.

E Appendices

Appendix 1 - Product List

CATEGORY		SUBCATEGORY	
1	High filtration and respiratory protective face masks	1.01	General Purpose
		1.02	Sub Micron
		1.03	Fluid Resistant with Visor
		1.04	Fluid Resistant without Visor
		1.05	Disposable Particulate Respirator with Visor
		1.06	Disposable Particulate Respirator without Visor
		1.07	LASER Plume Protective
		1.08	Dispenser/Brackets
2	Eye and Face Protective Devices	2.01	Safety Spectacles
		2.02	Wide Vision Goggles
		2.03	Eye Shields
		2.04	Face Shields
		2.05	Replacement parts
3	Shoe covers	3.01	Plastic
		3.02	Polypropylene, non-slip base
4	Headwear	4.01	Cap bouffant
		4.02	Cap beret
		4.03	Cap surgeons
		4.04	Balaclava
		4.05	Scarf
5	Single Use Patient Underwear	5.01	Patient Underwear

CATEGORY		SUBCATEGORY	
6	Single Use Gowns for Patient Use	6.01	Short sleeved, non-sterile
		6.02	Long sleeved, non-sterile
7	Single Use Gowns for Clinical Use	7.01	Long sleeved, non-sterile
		7.02	Long sleeved, non-sterile, cytotoxic
		7.03	Long sleeved, sterile
		7.04	Long sleeved, sterile, cytotoxic
8	Single Use Surgical Gowns	8.01	Long Sleeved Sterile, Tie Back or Wraparound, Fluid Repellant (single pack) (AAMI level 2)
		8.02	Long Sleeved Sterile, Tie Back or Wraparound, Fluid Repellant (double pack) (AAMI level 2)
		8.03	Long Sleeved Sterile, Tie Back or Wraparound, Impervious (single pack) (AAMI level 3)
		8.04	Long Sleeved Sterile, Tie Back or Wraparound, Impervious (double Pack) (AAMI level 3)
		8.05	Long Sleeved Sterile, Tie Back or Wraparound, Impervious (single Pack) (AAMI level 4)
		8.06	Long Sleeved Sterile, Tie Back or Wraparound, Impervious (double pack) (AAMI level 4)
		8.07	Long Sleeved Sterile, Tie Back or Wraparound, With Areas of Additional Protection (single pack)
		8.08	Long Sleeved Sterile, Tie Back or Wraparound, With Areas of Additional Protection (double pack)
9	Plastic Aprons	9.01	single use, non-sterile
		9.02	single use, sterile
10	Adhesive Incise Drapes	10.01	Plain
		10.02	Antimicrobial Impregnated
11	General Purpose Drapes	11.01	Adhesive Drapes
		11.02	Non Adhesive Drapes
		11.03	Stockinette
12	Specialty	12.01	Angiography

CATEGORY		SUBCATEGORY	
	Drapes	12.02	Burns
		12.03	Cardiothoracic Surgery
		12.04	Dental
		12.05	General Surgery
		12.06	Head & Neck and ENT Surgery
		12.07	Neonatal & Paediatric Surgery
		12.08	Neurosurgery
		12.09	Obstetrics & Gynaecology
		12.10	Ophthalmology
		12.11	Orthopaedic Surgery
		12.12	Plastic Surgery
		12.13	Urology
		12.14	Robotic Surgery
		12.15	Vascular Surgery
13	Composite Drape Packs	13.01	Angiography
		13.02	Burns
		13.03	Cardiothoracic Surgery
		13.04	Dental
		13.05	General Surgey
		13.06	Head & Neck And ENT Surgery
		13.07	Neonatal & Paediatric Surgery
		13.08	Neurosurgery
		13.09	Obstetrics & Gynaecology
		13.10	Ophthalmology
		13.11	Orthopaedic Surgery

CATEGORY		SUBCATEGORY	
		13.12	Plastic Surgery
		13.13	Robotic Surgery
		13.14	Urology
		13.15	Vascular Surgery
14	Plastic Drapes	14.01	Equipment Drapes
		14.02	Microscope
		14.03	Fluroscopy Unit
		14.04	LASER Arm
		14.05	Multipurpose plastic drapes
		14.06	Probe Cover

Appendix 2 - References

A 2.a Standards

The references to the below standards include any amendments, revisions or consolidations to those standards.

For each standard listed, respondents are to ensure the latest publication of each standard is used.

STANDARD NUMBER	Standard Name
AS/NZS 4187	Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities
AAMI PB70	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities
EN 13795	European Standard for Surgical Drapes and Gowns
AS/NZS 1337.1	Eye and face protectors for occupational applications

A 2.b Legislation

The references to the below legislation include any amendments, revisions or consolidations to those references.

- Therapeutic Goods (Medical Devices) Regulations 2002
- Therapeutic Goods Act 1989

A 2.c Guidelines and Other References

The references to the below guidelines include any amendments, revisions or consolidations to those guidelines.

- NHMRC (2010), *Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia*
- Therapeutic Goods Administration (1991), *Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods*
- Therapeutic Goods Administration (2004*), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia*