



Invitation to Supply

Part 5 - Statement of Requirements

Invitation to Supply Number:	HPVITS2016-022
Invitation to Supply Name:	Medical and Industrial Gases
Closing Date and time:	Tuesday 20 December 2016, 14:00 AEST / AEDT

Authorised Contact Person

David Clarke

Senior Category Advisor

Contact through the [HPV Procurement Portal](#)

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

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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 Invitation to Supply (ITS)
 - (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(s).

2 Scope & Objective

- a. HPV is seeking responses for Medical and Industrial Gases products and services for use in Participating Health Services. The envisaged Term of the Agreement is four (4) years plus two optional two year extension periods to extend the contract term (4+2+2).
- b. The scope of this ITS includes:
- (i) the supply of Medical and Industrial Gases products and services
 - (ii) service requirements
 - (iii) education and training
- c. The scope of this ITS does not include:
- (i) Patented medical gases unless coming off patent during contract term
- d. The objective of this tender is to ensure the supply of medical & industrial gases and associated services is covered by an Agreement
- e. Indicative volumes are listed in Part 6 – Tender Response Worksheet. Respondents are to note that any usage figures provided are indicative only, and are provided to assist Respondent in the preparation of their submission.

3 Product Categories

- a. The categories of Medical and Industrial Gases product and services required under this ITS include:

CATEGORY NUMBER	CATEGORY NAME
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CATEGORY NUMBER	CATEGORY NAME
1	Medical Gases, Compressed Cylinder
2	Industrial including Food Grade Gases, Compressed Cylinder
3	Liquid Bulk Medical Gases
4	Specialty Medical Gases, Compressed
5	Managed Services
6	Other

- b. The Respondent may offer products in one, some or all categories.
- c. Only products that specifically fit within the category descriptions provided will be considered
- d. HPV reserves the right not to consider any additional products offered.
- e. For a 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 may not consider any product that is subject to a current HPV Agreement, other than those listed below:
 - HPVC2012-022 Medical and Industrial Gases

The Respondent will ensure that each product is offered in only **one** subcategory. It is at the Respondent's discretion to ensure that each product is submitted in the most appropriate subcategory.

4.3 Product Information

- a. The Respondent will submit a copy of relevant product diagrams, specifications or brochures to assist in accurately identifying products offered.

- b. Where research papers or relevant scientific information is available, this should be submitted with the Respondent's tender.
- 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, where a physical product is requested, this product needs to be labelled with the relevant HPV category and subcategory number. Supporting material in soft copy must include the HPV Category and subcategory numbers in the filename or identifying metadata.
- HPV may not consider unlabelled submissions.
- e. Product information will not be evaluated, but is necessary to assist in accurately identifying products offered.
- f. HPV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:
- (i) Not labelled as per D above; or
 - (ii) Is incomplete as to C.
- 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 Invitation to Supply.

5 Definitions

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

TERM	DEFINITION
Agreement	A contract entered into by HPV and a Respondent for the provision of Medical and Industrial Gases products. Comprises the General Conditions, and all Schedules, Annexures of any kind and any attachments.
ARTG	Australian Register of Therapeutic Goods under the control of TGA
Business day	Any weekday not gazetted as a public holiday in Melbourne, Victoria.

TERM	DEFINITION
HPV	Health Purchasing Victoria
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 result in the submission being eliminated from further consideration.
normal use	Means the item has undergone use for which it was manufactured and intended, and shows no signs of physical damage other than regular wear and tear
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 .
should	Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may have an impact during evaluation.
SLA	Service Level Agreement
TGA	Therapeutic Goods Administration
will	Indicates an anticipated future condition or requirement to be met.

B Service, delivery and support

1 Delivery

- a. Medical and Industrial Gases must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed the contracted time frame from receipt of order unless otherwise agreed with the Participating Health Service.
- b. Except where there is evidence of inappropriate handling by the receiving Participating Health Services, all damaged or broken products and equipment must be replaced free of charge.
- c. All deliveries are bound as per the Draft Agreement, Part 7 – 9 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 Respondent must be able to receive and action urgent delivery requests
- c. Urgent deliveries should be received by Participating Health Services within the shortest timeframe; however, this should not exceed the following timeframes:
 - (i) Twelve (12) hours from receipt of order for metropolitan Participating Health Services
 - (ii) Twenty-four (24) hours from receipt of order for regional and rural Participating Health Services
- d. The respondent should state if other time frames should apply.

3 Consignment Stock

- a Respondents must advise on the ability to provide cylinders or other goods on consignment and the responsibility for insurance of consigned goods once “in the cage” in the Participating Health Services.
- b Preference will be given to Respondents that are able to provide cylinders or other goods on consignment and replacement stock within a pre-agreed timeframe. Respondents should indicate if this is conditional on the introduction of a managed service arrangement
- c Where cylinders are provided on consignment, the Respondent should advise how stock levels and reporting should be undertaken.
- d The successful Respondent should reach an agreement with each Participating Health Service concerning:
- (i) identification of cylinders and products that lend themselves to consignment
 - (ii) appropriate stock levels
 - (iii) a stock management system to ensure effective and efficient use of goods including identification of slow moving items and the management of short dated stock (if applicable)
 - (iv) The turnaround time for replacement of used cylinders stock following order replacement.
 - (v) reporting of any stock that has been removed and reallocated by the successful Respondent
- e All queries relating to consignment stock must be resolved within two (2) months of item use.
- f Consignment arrangements shall be reviewed by the successful Respondent and the Participating Health Services on a quarterly basis as a minimum or as negotiated. The review should include but not be limited to reporting of backorder, any stock that has been removed and reallocated and queries relating to consignment stock consumption.
- k. Where products are provided on consignment:
- managing stock levels must be undertaken by the successful Respondent, unless negotiated otherwise with the Participating Health Service in a Service Level Agreement
 - all queries relating to consignment stock must be resolved within three months of product use
 - invoices must be received within fourteen days of product use.
- l. The successful Respondent's nominated Representative(s) (as per clause 5b) will be responsible for:
- performing stocktake of consignment stock on a regular basis (as agreed with the Participating Health Service), and replacing used stock
 - checking the expiry date of consigned stock, and replacing any stock that is out of date at no cost

4 Training

- a. Upon request by a Participating Health Service, successful Respondents will deliver a training package and/or training materials to facilitate the introduction of new or existing Medical and Industrial Gases to clinicians in their operating environment.
- b. Training requirements may include (but are not limited to):
 - (i) face-to-face training at Participating Health Service sites (i.e. in-service training)
 - (ii) off-site study days for clinicians
 - (iii) updates and refresher training on new products and/or equipment
 - (iv) training materials

4.2 Compressed Gases

- (i) Successful Tenderers shall provide training at no extra cost in the safe transport, handling, correct storage and usage of compressed gases in cylinders.
- (ii) This training shall be conducted on site within each of the health services for which the Tenderer is successful.
- (iii) This training shall be conducted at least once in every twelve months, or in line with health service protocols, and must be available throughout the term of the Agreement.
- (iv) Tenderers shall provide full details of training that has or will be made available in accordance with the above clauses in HPV Procurement Portal/Bravo/TRW. These details shall include content, duration, location and frequency of training sessions and any conditions applicable.

4.3 Liquid Medical Gases in Fixed Liquid Bulk Medical Gases Vessels

- (i) Successful Tenderers shall provide safety and environment maintenance training at no extra cost with regards to Liquid Bulk Medical Gas Vessels containing liquid medical gas.
- (ii) Training shall be provided upon initial installation, upon replacement of an existing Liquid Bulk Medical Gas Vessel and after modification or major repairs.
- (iii) Training shall also be provided at intervals determined by the health service, to ensure compliance with protocols and/or Australian Council of Healthcare Services guidelines.
- (iv) This training shall be conducted on site at each health service for which the successful Tenderer is providing services.
- (v) Tenderers shall provide full details of training that has or will be made available in accordance with the above clauses in HPV Procurement Portal/Bravo/TRW. These details shall include content and duration of training sessions and any conditions applicable

5 Customer Service and Support

- a. The successful Respondent must be able to deliver prompt customer service and support to Participating Health Services.
- b. Successful Respondents will nominate at least one Representative as the key account manager to work closely with the PHS and HPV to provide support.
- c. Successful Respondents will provide Participating Health Services with representatives that are:
 - (i) inherently familiar with the contracted products
 - (ii) appropriately qualified
 - (iii) technically/clinically knowledgeable about the contracted products
 - (iv) available to respond to Participating Health Services' queries during business hours
 - (v) Participating Health Services may require Respondent's staff to possess police checks or working with children checks though this can be held on the Respondent's records
- d. The level of customer service and support required of Representatives is expected to include (but is not limited to):
 - (i) liaising with clinicians to recommend products and solutions
 - (ii) promptly answering clinicians' queries
 - (iii) liaising with various hospital departments (for example: operating theatre, Nurse Unit Managers)
 - (iv) providing on-site clinical support (if requested)
 - (v) providing informational materials
 - (vi) providing education and in-service training upon request

6 Warranty

- a. A minimum 12-monthly warranty for normal use of devices must be provided from the date of commissioning.
- b. Upon request, the successful Respondent will provide information (printed or electronic) explaining product warranty.

6.2 Repairs and Replacements under Warranty

- a. The repair or 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 repair or replacement under warranty will be borne by the successful Respondent.
- c. Items repaired under warranty must be returned to Participating Health Services within twenty-eight (28) business days from when the item is received by the successful Respondent.

- d. If requested by the Participating Health Services, successful Respondent(s) must provide a suitable replacement item, until the repaired item is returned. This will be done at no cost to Participating Health Services.
- e. It is preferable that the successful Respondent provides Participating Health Services with a replacement or suitable loan item at no cost until the repaired item is returned.

7 Key Performance Indicators

- a. Refer to Schedule 2 of Part 7 - Draft agreement - Performance Indicators.

8 Reporting

- a. Refer to Schedule 3 of Part 7 - Draft agreement - reporting requirements.
- b. Successful Respondent must provide to HPV other reports that may reasonably be required from time to time.

9 Service Level Agreement

- a. Participating Health Services may enter into a Service Level Agreement (SLA) with the successful Respondent(s). The SLA may cover arrangements including, but not limited to:
 - (i) the provision of products on consignment including arrangements and communication requirements for establishment, ongoing management, review and cessation of consignment stock requirements (refer to Part 5 – Section E, 3)
 - (ii) requirements for stock management and rotation
 - (iii) arrangements for ordering, invoicing and delivery
 - (iv) clinical support, including attendance requirements for Representatives in relation to education and training
 - (v) communication arrangements for product recalls and safety alerts (refer to Part 5 – Section E, para 3)
- b. The terms of the SLA are to be agreed between the Participating Health Service and the successful Respondent(s).
- c. The SLA will be in addition to the Agreement between the successful Respondent(s) and HPV, and will not alter any terms of the Agreement.
- d. HPV will not be responsible for monitoring compliance with any SLA. This is a matter of agreement between the parties to the SLA.
- e. Successful Respondent(s) will provide a copy of all Service Level Agreements to HPV within 1 week of being finalised.

10 Cylinder Management

- a. Tenderers are to provide full details in HPV Procurement Portal of the systems and support that they will make available to health services to assist in the management of their cylinders, including but not limited to:
- (i) Their ability to manage imprest levels (monitor inventory holdings and generate replenishment quantities)
 - (ii) Tracking from delivery and invoicing to collection
 - (iii) Capacity to offer bar coding (including barcoding of individual cylinders)
 - (iv) Detailed reconciliation of customers' stocks with supplier's data
 - (v) Audits being undertaken on the minimum of a biannual basis or as determined by the health service
 - (vi) Resolution of discrepancies (e.g. numbers invoiced for rentals versus stock count)
 - (vii) Other services.
- b. Tenderers shall advise in HPV Procurement Portal the availability and details of Enhanced Vendor Managed System services available as an option for consideration and negotiation with health services as part of a Service Level Agreement.

11 Emergency Supplies

- a. Tenderers are to provide full details of availability of medical gases in after hours/emergency situations in HPV Procurement Portal/Bravo/TRW. This includes, but is not limited to:
- (i) Full details of the support that they can provide to maintain supplies during emergency situations (e.g. floods) or from equipment failures
 - (ii) Full details of what service and or support a health service can expect in an emergency and associated timeframes
 - (iii) Details of any extra costs that would have to be met by the health service.
- b. Tenderers shall advise of their:
- (i) Standard customer support and delivery service
 - (ii) Urgent or emergency delivery service order procedure, cut-off times and associated costs
 - (iii) Unscheduled next day delivery service order procedure, cut-off times and associated costs.

12 Hazardous Industrial, Commercial & Household Chemical Substances

- a. The successful Tenderers shall conform to all necessary standards, codes or legislation for the identification of hazardous materials and carry out proper certification and registration procedures.

- b. An appropriate Material Safety Data Sheet (MSDS) for each cylinder type tendered is to be provided to HPV, hospitals and health services in electronic format.
- c. Successful Tenderers shall provide upon commencement of the contract, details for medical gases categorised as Schedule 4 drugs. These details shall be in electronic format and are to include compliance with requirements for ordering/supply, labelling and storage and the name/s of the medical gases subject to these requirements

13 Agents and Depots

- a. Where a successful Tenderer proposes to supply compressed medical gases through local agents/ depots, the Tenderer shall be responsible for the level of service provided by its agents/depots and for ensuring that all services are provided in accordance with the terms and conditions of the Agreement.
- b. Agent charges must be included in the freight charges in accordance with this document.
- c. Details of Agents / Depots are to be submitted in TRW response.

14 Current contract usage data

- a. Respondents should note that the usage figures are indicative of historical usage only and should not be relied upon when completing their tender submission. The information is based on 12months of reports to end September 2016 and will include some off contract items that HPV is now seeking to bring onto contract. More detail is provided within the RFT as to the amount of products within the zones.
- b. Respondents are to note that the categories and subcategories shown in the table below relate to the current contract (HPVC 2012-022 Medical and Industrial Gases, option exercised December 2014) and may not accurately reflect what is requested in the RFT Specification and Product List as categories/subcategories may have been changed, added or removed.

Category	Sub Category	Total Usage Per Annum	
		Number Of Cylinder/Vessels Rented	Number of Cylinders /Cubic Meters
Category 1.0: Medical Gases, Compressed Cylinder	1.01 Medical Oxygen, Compressed Cylinder Gas	203,820	106,108
	1.02 Nitrous Oxide, Compressed Cylinder Gas	11,543	1,672
	1.03 Medical Dry Air, Compressed Cylinder Gas	24,694	8,523
	1.04 Carbon Dioxide, Compressed Cylinder Gas	16,373	9,144
	1.05 Other Compressed Cylinder Medical Gases	3,406	690
Category 1.0 Total		259,836	126,137
Category 2.0: Industrial Gases including Food Grade Gases, Compressed Cylinder	2.01 Industrial Oxygen, Compressed Cylinder Gas	2,015	48
	2.02 Acetylene, Compressed Cylinder Gas	2,056	47
	2.03 Argon, Compressed Cylinder Gas	815	21
	2.04 Food Grade Carbon Dioxide, Compressed Cylinder Gas	2,676	779
	2.05 Dry Ice (KG)	0	49,736
	2.06 Other Compressed Cylinder Industrial Gases	1,711	318
Category 2.0 Total		9,297	50,949
Category 3.0: Liquid Bulk Medical Gases	3.01 Compressed Bulk Medical Oxygen	716	3,479,189
	3.02 Compressed Bulk Medical Nitrogen	12	808,891
	3.03 Other Compressed Bulk Medical Gases		14,959
Category 3.0 Total		728	4,303,039
Category 4.0: Specialty Medical Gases, Compressed	4.01 Compressed Specialty Medical Gases, Compressed Cylinder Gas	4,253	865
Category 4.0 Total		4,253	865

C Installation, Maintenance and Transition Plans

1 Installations

1.1 New Installations of Liquid Bulk Medical Gas Vessels

- a. For any new installations, the successful Tenderer shall be responsible for installation and commissioning of the new Liquid Bulk Medical Gases vessel. This will include the design, supply and commissioning of the vessel.

1.2 Change in Supplier Installations of Existing Liquid Bulk Medical Gas Vessels

- a. For existing installations, HPV considers that if there is a change in supplier, transfer of ownership of the Liquid Bulk Medical Gas Vessel from the existing supplier to the new supplier is the most satisfactory method of avoiding disruption to the hospital or health service.
- b. Tenderers are required to advise if they are prepared to negotiate the transfer of ownership of an existing Liquid Bulk Medical Gas Vessel
- c. Where the changeover involves installation of a new Liquid Bulk Medical Gas Vessel:
 - (i) The existing supplier shall be responsible for decommissioning and removing the existing Liquid Bulk Medical Gas Vessel/s, including ensuring that the area is left in a serviceable manner
 - (ii) The new supplier shall be responsible for negotiating all aspects of the changeover, in agreement with recipient health services engineering or facilities management services.
 - (iii) The new supplier shall be responsible for ensuring supply of medical gases to meet the needs of the affected health service during the interim period covered by the decommissioning and removal of the existing Liquid Bulk Medical Gas Vessel/s and the commissioning of the Liquid Bulk Medical Gas Vessel/s
 - (iv) All resources necessary for the transition process, whether the supplier is outgoing or incumbent, shall be provided by the supplier
 - (v) Where the new supplier proposes to utilise compressed medical gases for the alternative supply, it is expected that there shall be no financial disadvantage to the recipient health service.
 - (vi) The new supplier shall be responsible for negotiating and coordinating all aspects of the changeover in line with their Transition In and Out Plans as provided by the Tenderer in accordance with clause 5.6 of this document
 - (vii) The changeover process shall not be unduly frustrated by either the existing supplier or the new supplier

- (viii) All necessary processes in regards to the above clauses shall be completed within a timeframe negotiated in conjunction with and agreed by an authorised officer of the applicable health service prior to the commencement of any work
- (ix) HPV reserves the right for the health service, during the term of the Agreement, to review the size of their Liquid Bulk Medical Gas Vessel/s due to a change in needs, and to require the supplier to replace the existing vessel to maintain an economic balance between the delivery charges, transfer of current volumes and vessel rental charges.
- (x) New or existing installation should quote their transition out costs for bulk vessels in relation to the end of this agreement. This is subject to the following:
 - This is irrespective of the age of the vessel at the end of the term, for example there being a relatively new replacement due to an irreparable failure of the bulk vessel during the term of the agreement
 - A departure from the above will only be permitted in writing from both HPV and the affected health service

2 Maintenance

2.1 Maintenance of Liquid Bulk Medical Gas Vessels

- (i) Rental charges for Liquid Bulk Medical Gas Vessels shall include all costs incurred by the Tenderers in servicing and maintenance to ensure continued compliance with all the relevant Australian Standards
- (ii) Tenderers shall specify in the HPV Procurement Portal, the frequency and content of service and maintenance, which they will undertake on Liquid Bulk Medical Gas Vessels, rented under the Agreement.
- (iii) Documentary evidence of service and maintenance undertaken (e.g. a detailed service report) must be provided at the time of each service to the health service's Building Engineering and Maintenance Services and/or as nominated. A pro forma of the proposed service report shall be submitted in HPV Procurement Portal
- (iv) Tenderers are to specify average venting rates for each proposed Liquid Bulk Medical Gas Vessel. The cost of replenishing liquid gas lost due to above average venting rates or inadequate maintenance shall be borne by the supplier
- (v) Liquid Bulk Medical Gas Vessels should incorporate a telemetry system to automate the tracking of gas levels and re-ordering of gas stock and this should also reduce attendance at site and potentially minimise delivery charges.

2.2 Maintenance of Cylinders

- a. Cylinders shall be:
 - (i) Supplied clean and in a well maintained condition
 - (ii) Clearly labelled.

- (iii) Barcoded. Some health services use management systems and cylinders must be identifiable to meet future demand for this type of system.

3 Transition In and Out Plans

- a. Tenderers shall provide in HPV Procurement Portal a plan that identifies how, if successful, they would undertake the transition of:
 - (i) A current user to the new contractual arrangement
 - (ii) A new user to the Tenderer's contracted range
 - (iii) A current user out of the contractual arrangement
- b. This plan shall include, but is not limited to:
 - A Gantt Chart or project plan created using a project management tool, for the transition that includes:
 - (i) A timeline
 - (ii) Resourcing
 - (iii) Costs
 - Identification of a health service's product requirements
 - Education and support
 - Education of support staff in ordering of products and maintenance of any loan items
 - Replacement of instrumentation
 - The process for establishing Service Level Agreements with participating health services
 - A risk assessment and mitigation plan
 - All items of costs, defined as either fixed or variable

D Pricing Requirements

The HPV Procurement Portal - Commercial envelope contains a number of pricing schedules for submission. Instructions are included within the portal. The worksheets can be exported into Excel, information provided, then imported back into Bravo. There are separate sections for cylinder and bulk vessel pricing as well as rental and freight where these apply.

1 Pricing for Compressed Gases

- a. Prices tendered for Compressed Medical Gases, Compressed Industrial Gases and Compressed Specialty Gases shall be on the basis of “price per cylinder” or “price per pack of cylinders”.
- b. Pricing and invoicing shall be on the following basis:
 - Base product price (the same for metro and regional)
 - Daily or monthly cylinder rental price (the same for metro and regional). Where daily and cylinder collection is infrequent, Proponents must indicate how costs may be minimised
 - Management costs as defined in the Tender Response Worksheet / Commercial Envelope (where applicable)
 - Freight cost based on region/zones.
- c. Used cylinders shall be collected from the health service at no extra cost.
- d. Invoicing shall include the purchase order number breakdown for all cylinders for rental

2 Pricing for Liquid Bulk Medical Gases & Vessels

- a. Prices tendered for Liquid Bulk Medical gases shall be based on base product “price per cubic metre”, regardless of the vessel size.
- b. Pricing shall be the same for regional and metro.
- c. Delivery fees can be quoted either on a per delivery basis or per cubic metre charge.
- d. Rental charges for vessels and telemetry shall include all costs in servicing and maintenance, ensuring compliance with all relevant Australian standards.
- e. A separate worksheet has been provided where the incumbent provider must provide the installation details of that vessel and the cost to decommission and remove the vessel.
- f. The same worksheet will allow Proponents, to provide an estimate to install a vessel of similar size with a further estimate as to the cost of removing this vessel at the cessation of the Agreement.

3 Additional Charges

- a. There are no provisions for any additional charges in this tender e.g. minimum order charges, handling charges, administration fees.

E 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 Respondent 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

Only that information specific to medical & industrial gases shall apply in the points below.

- a. Products must be packaged to retain the structural integrity of the enclosed product.
- b. Sterile products will be packaged in a manner that protects the contents from contamination during transportation, storage and handling.
- c. All labels must comply with the Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods. All product name and code must be in English and clearly visible on the product pack or labels.
- d. Shelf Life date information, in the form of Use By or Best Before etc. must be clearly visible on individual product packaging.
- e. Items will be delivered in accordance with the manufacturer's instructions.
- f. Individual product packaging to include (where applicable):
 - (i) whether the product is sterile;
 - (ii) whether the product (or packaging) contains latex or is latex-free; and
 - (iii) identifiers for manufacturing batch and expiry date
 - (iv) tracking labels

3 Recall Process

- a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (2004).
- b. Within six (6) months of contract commencement, all recalls and/or hazard alerts will be completed using GS1 Recallnet.

- c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods*) must also meet the requirements under section Part 5 - B66 Warranty, where applicable.

4 Backorders and Discontinued Lines

- a. In the event that a product is unavailable for a period of two or more consecutive weeks, the successful Respondent will contact (at a minimum) the following:
 - (i) Procurement Officers of all Participating Health Services
 - (ii) Supply Manager / Business Managers of all Participating Health Services
 - (iii) HPV; and

provide a backorder report and a list of recommended substituted items (where applicable) to the Participating Health Services and HPV for reference.
- b. In the event that an item is discontinued, successful Respondents must notify Participating Health Service staff and HPV (as per clause a) as soon as possible, but no less than six (6) months before the last date of manufacture.
- c. Successful Respondents must inform the affected Participating Health Services and HPV of:
 - (i) the anticipated timeframe for resolving the issue
 - (ii) the availability of an agreed substitute product

5 Infection Control

- a. Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).
- b. Upon request by Participating Health Services, successful Respondents must provide cleaning details for all reusable products.

F Product Specifications

1 General Specifications

1.1 Category Specifications

- a. A complete range of Medical and Industrial Gases is required for treatment of patients across Victoria Public Health Services

1.2 Compliance with Category Specifications

Category 1 – Compressed Medical Gases

A range of Compressed Medical Gases is required. This includes, but is not limited to:

- Oxygen
- Nitrous Oxide
- Dry Air
- Carbon Dioxide
- Helium

Product Description

- a. For each Compressed Medical Gas offered, Tenderers shall advise the following information in the Product Description of the Tender Response Worksheet:
- Gas type
 - Cylinder size (e.g. Size B)
 - Cylinder volume in cubic metres (m³)
 - Cylinder diameter in centimetres (cm)
 - Cylinder material (steel, aluminium, carbon fibre)
 - With or without a flow metre regulator
 - Other components (e.g. analyser, administrative apparatus).
- b. Compressed medical oxygen in cylinders with integrated regulator/flowmeter are included in this document. Demand for this type of cylinder has grown in recent years. It is expected that demand will increase. Nonetheless, compressed medical oxygen in the standard 'C' sized cylinder without integrated regulator/flowmeter must be available through the term of this Agreement.

Category 2 - Compressed Industrial and Food Grade Gases

A range of Compressed Industrial Gases, including Food Grade Gases is required. This includes, but is not limited to:

- Oxygen
- Acetylene
- Argon
- Food Grade Carbon Dioxide
- Dry ice

Product Description

For each Compressed Industrial or Food Grade Gas offered, Tenderers shall advise the following information in the Product Description of the Tender Response Worksheet:

- Gas type
- Presentation (e.g. cylinder, pellets, block)
- For pellets or block (where applicable)
 - Weight in kilograms
 - Size (e.g. small, large)
- For Cylinders:
 - Cylinder size (e.g. size B)
 - Volume in cubic metres (m³)
 - Diameter in centimetres (cm)
 - Cylinder material (steel, aluminium, carbon fibre)
 - With or without a flow metre regulator.

Category 3 - Liquid Bulk Medical Gases

A range of Liquid Bulk Medical Gases is required. This includes, but is not limited to:

- Oxygen
- Nitrogen
- Carbon Dioxide
- Helium

Product Description

For each Liquid Bulk Medical Gas offered, Tenderers shall confirm the following information in the Product Description of the Tender Response Worksheet:

- Gas type
- Vessel size in cubic metres (m3)
- Vessel capacity in cubic metres (m3).

In the event a different vessel is recommended, please do so.

Category 4 - Compressed Speciality Gases

A range of Compressed Specialty Gases is required. This includes, but is not limited to different grades and presentations of the Compressed Specialty Gases listed at Appendix 1.

Product Description

For each Compressed Specialty Gas offered, Tenderers shall advise the following information in the Product Description of the Tender Response Worksheet:

- Gas name/s in full
- Chemical symbol/s
- Percentage of each component gas
- Grade (e.g. High Purity, Ultra High Purity, Medical Grade, and Industrial Grade)
- Certification (e.g. NATA)
- Presentation (e.g. cylinder, pellets, block)
- For pellets or block (where applicable)
 - Weight in kilograms
 - Size (e.g. small, large)
- For Cylinders:
 - Volume in cubic metres (m³)
 - Diameter in centimetres (cm)
 - Cylinder material (steel, aluminium, carbon fibre)
 - With or without a flow metre regulator

Category 5 - Managed Services (new category)

Details of gases and current annual usages are listed in the Bravo commercial template.

Tenderers are required to indicate which health services would benefit from the addition of either a supplier managed service or self-managed service.

Supplier Managed Service

The Supplier Managed Service must include an onsite staff member to manage the gas services including but not limited to the below points;

- Onsite trained staff member daily, for the agreed number of hours per week split across Monday to Friday to manage, replace, return and reduce gas bottle holdings. Detailed procedures will be determined in discussion with relevant health services.
- ensure correct storage of cylinders in gas cage
- provide recommendation of safety stock holding levels
- ordering of gas cylinders - ensuring the gas quality, collecting and collating data for gases to satisfy requirements.
- distribution of cylinders to wards and departments through the facility using correct gas transport trolleys
- return empty cylinders to approved gas storage room
- replace cylinders that are connected to manifolds
- provide manual refill of liquid nitrogen in dewars (if utilised)
- provide manual refill of liquid nitrogen in tanks (if utilised)
- 6 monthly audits to be performed and stock adjusted in all areas

The service provider must also prepare detailed plans of how emergency and out of hour's issue of cylinders is managed, tracked and costed. Provision of detailed plans of what point the costs are charged for both the replacement of cylinders and the rental.

Provision of all costs associated with this service and the benefits.

Self (hospital) Managed Service

A Self-Managed Service should be proposed where a service provider believes value could be obtained by a health service through implemented a cylinder management system but not necessarily require a representative of the company on site either due to the fact the health service has the requisite in-house support, or there isn't a sufficient number of cylinders to justify.

The requirement for this service is an electronic scanning system/device to enable the management of gas cylinders including but not limited to the below points;

- Electronic scanning system/device to track and record the distribution and return of cylinders by cost centre/departments.
- Electronic re-order of gas cylinders – ability to re-order direct into the supplier system via the system/device
- Ability to perform audits using the system/device
- Ability to store/manage stock holding levels

Please detail all costs associated with this service proposal.

Removal of Cylinders from Health Services

It is understood that cylinders may move between health services, as part of inter-hospital transfers or may potentially be retained by Ambulance Victoria or its sub-contractors following such transfers. Proponents are requested to advise how their internal cylinder management systems account for such activity, how this is tracked and the cost managed from a health service perspective. Proponents should also indicate how cylinders of other suppliers are returned.

Category 6 - Other (new category)

Other items supplied by Respondents to health services such as cylinder trolleys, wall mounts, separate regulators and pressure gauges.

G Appendices

Appendix 1 - Product List

PRODUCT CATEGORY NUMBER	PRODUCT CATEGORY NAME	PRODUCT SUB-CATEGORY NUMBER	Product Sub-Category Name
1.0	Medical Gases, Compressed Cylinder	1.1	Medical Oxygen, Compressed Cylinder Gas
		1.2	1.2 Nitrous Oxide, Compressed Cylinder Gas
		1.3	1.3 Medical Dry Air, Compressed Cylinder Gas
		1.4	1.4 Carbon Dioxide, Compressed Cylinder Gas
		1.5	Other Compressed Cylinder Medical Gases
2.0	Industrial Gases including Food Grade Gases, Compressed Cylinder	2.1	Industrial Oxygen, Compressed Cylinder Gas
		2.2	Acetylene, Compressed Cylinder Gas
		2.3	Argon, Compressed Cylinder Gas
		2.4	Food Grade Carbon Dioxide, Compressed Cylinder Gas
		2.5	Dry Ice
		2.6	Other Compressed Cylinder Industrial Gases
3.0	Liquid Bulk Medical Gases	3.1	Compressed Bulk Medical Oxygen
		3.2	Compressed Bulk Medical Nitrogen
		3.3	Other Compressed Bulk Medical Gases
4.0	Speciality Medical Gases, Compressed	4.1	Compressed Speciality Medical Gases, Compressed Cylinder Gas
5.0	Managed Services	5.1	Managed Services
		5.2	Self Managed Services
6.0	Other	6.1	Additional items, eg., cylinder trolleys, wall mounts, separate regulators, pressure gauges

Appendix 2 - References

A 2.a Standards

All medical gases tendered shall comply with the requirements of the European Pharmacopoeia.

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

All Medical and Industrial Gas products and services offered shall comply with and be tested to the following Australian Standards:

Standard Number	Standard Name (or description)
AS 2030.'X'	Various standards relating to Gas Cylinders pertaining to design, manufacture, inspection and filling
AS 1894-1999	The storage and handling of non-flammable cryogenic and refrigerated liquids
AS 2337.3-2006	Gas cylinder test stations - Transportable gas cylinders - Periodic inspection and testing of composite gas cylinders
AS 4332-2004 (R2016)	The storage and handling of gases in cylinders
AS 2473.3-2007	Valves for Compressed Gas Cylinders (This includes the pin indexing)
AS 4484-2016	Gas cylinders for industrial, scientific, medical and refrigerant use - Labelling and colour coding
AS 4706-2001 (R2016)	Pressure gauges for regulators used with compressed gas cylinders
DR AS 2568-2016	Medical gases – Purity of compressed medical breathing air
DR AS 1210:2010 AMD 2:2014)	Amendment 2 to AS 1210-2010 - Pressure vessels
AS2896-2011	Medical Gas Systems - Installation and testing of non-flammable medical gas pipeline systems
AS3788:2006	Pressure Equipment - In-service Inspection
AS 3840.1-1998 (R2016)	Pressure regulators for use with medical gases - Pressure regulators and pressure regulators with flow-metering devices

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
- Therapeutic Goods Administration - Medicinal gases and good manufacturing practice (GMP) Version 1.0, 25 May 2012

Appendix 3 - Compressed Specialty Medical Gases and products List

- Acetylene
- Air
- Argon
- Dry Ice
- Helium
- Hydrogen
- Nitrogen
- Nitrous Oxide
- Sulfur Hexafluoride
- 0.25% Carbon Dioxide, 9.5% Helium, 21% Oxygen, Balance Nitrogen
- 0.5% Carbon Dioxide, 20% Oxygen, Balance Nitrogen
- 10% Carbon Dioxide, 10% Hydrogen, Balance Nitrogen
- 5% Carbon Dioxide, 1% Oxygen, Balance Nitrogen
- 5% Carbon Dioxide, 12% Oxygen
- 5% Carbon Dioxide, 15% Oxygen, Balance Nitrogen
- 5% Carbon Dioxide, 20% Oxygen, Balance Nitrogen
- 5% Carbon Dioxide, 21% Oxygen, Balance Nitrogen
- 5% Carbon Dioxide, 5% Oxygen, Balance Nitrogen
- 5% Carbon Dioxide, Balance Air
- 5% Carbon Dioxide, Balance Oxygen
- 5% Carbon Dioxide, Balance Nitrogen
- 0.23% Carbon Monoxide, 8% Helium, Balance Air
- 0.3% Carbon Monoxide, 0.3% Methane, Balance Air
- 0.3% Carbon Monoxide, 0.5% Neon, 21% Oxygen, Balance Nitrogen
- 0.3% Carbon Monoxide, 5.0% Neon, 21% Oxygen, Balance Nitrogen
- 50% Oxygen, Balance Carbon Dioxide
- 10% Methane, Balance Argon