Policy

Policy Directive: compliance is mandatory

Medical Gas System Policy Directive

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Summary	Medical gas pipelines are a life support system and SA Health has a systematic and consistent approach to installation, modification, testing, commissioning and maintenance. The Medical Gas System Policy Directive documents the principles of supporting medical gas systems used within SA Health facilities. It is to be read in conjunction with AS2896 Medical gas systems – installation and testing of non-flammable medical gas pipeline systems.
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Government of South Australia
SA Health

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16/06/17	V.1	Policy Committee	PE Approved version.

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1. Objective

SA Health is committed to and acknowledges its responsibility to the safety of biomedical technologies used within its facilities.

Medical gas pipelines are a life support system and as such require careful consideration in their design, construction, installation, modification, testing, and commissioning (AS 2896-2011).

This policy guideline documents the principles of supporting medical gas systems used within SA Health facilities. It is to be read in conjunction with AS2896 Medical gas systems – installation and testing of non-flammable medical gas pipeline systems (available in SAI Global through SA Library).

2. Scope

This policy guideline applies to all SA Health workers, including employees, volunteers, contractors, labour hire workers, agency workers, and occupiers of premises who have management or control of installation, modification, testing, commissioning and maintenance of medical gas systems and associated pipelines used within SA Health.

3. Principles

SA Health will take reasonably practicable steps to develop and implement a systematic and consistent approach to installation, modification, testing, commissioning and maintenance of medical gas systems in accordance with AS2896.

Engineering and Building Services at each site will be responsible for the management of medical gas systems:

- Design and installation by competent people.
- Testing and commissioning by appropriate people using SA Health endorsed test certificates.
- Maintenance (including corrective maintenance, and scheduled maintenance) by appropriate people.
- Commissioning certificates for installations and modifications will be stored on and made accessible through the statewide Biomedical Asset Management System

4. Detail

4.1 Hazards

The hazards for medical gas systems usually relate to their original installation or modification rather than to problems arising during their working life. As they are a life support system, any hazards tend to have critical and life threatening consequences.

This policy guideline will reduce the likelihood of the well-known hazards from occurring:

- Plumbing errors, cross-connections
- Use of materials incompatible with the gases to be delivered
- Use of pipes that have not been cleaned and sealed before transport to site
- Obstruction of flow by material left in the pipeline
- Gas contamination by residual debris, accumulated foreign matter, chemical interaction between the gases and pipeline components

- Condensation in pipelines
- Grease or oil coming in contact with oxygen or nitrous oxide.

4.2 Medical gas

Medical gases include those defined in AS2896, and other medical gas installations in use within SA Health.

4.2.1 Medical gas defined in AS2896

Medical gas systems defined in AS 2896 applies to pipeline systems providing the following gases for medical use:

- Oxygen
- Nitrous oxide
- Medical air
- Surgical tool gas
- CO2 (less than or equal to 7%) in oxygen
- Nitrous oxide/oxygen 50/50
- Helium-oxygen mixtures
- Carbon dioxide
- Medical suction (vacuum), and
- Scavenging.

4.2.2 Medical gases not defined in AS2896

This policy directive will also apply to other gases used for medical purposes with pipeline infrastructure, particularly if the gas is non-respirable:

- Nitric oxide, NO
- Respiratory laboratory gas mixtures
- Research laboratory gas mixtures

4.3 Medical gas system components

A medical gas system may include the following components:

- Source – cylinders, packs of cylinders, vacuum insulated evaporator (VIE), cryogenic liquids, compressors (and associated infrastructure), suction system and turbine tools system
- Pipeline – infrastructure or localised piping, manifold
- Regulator – valves, gauges
- Panel – monitoring and alarms
- Detector – moisture, carbon dioxide, oxygen
- Terminal unit – gas outlet or suction inlet, the point at which the user makes connection or disconnection.

4.4 Are medical gas systems a medical device?

The Therapeutic Goods Administration has multiple definitions relating to medical gases:

- Medical gas systems installed to comply with AS2896 are declared not to be therapeutic goods and are outside the scope of the Therapeutic Goods Act (see Therapeutic Goods (Excluded Goods) Order No.1 of 2011).
- Medicinal gases are classified as medicines under the Therapeutic Goods Act 1989. Also Schedule 7, entry 17 of the Therapeutic Goods Regulations 1990 exempts bulk liquefied medical gases from the operation of Part 3-3 of the Therapeutic Goods Act 1989.
- Cylinders (empty) that hold medical gases are medical devices

A therapy device with associated medical gases is a Medical Device when they use (see Australian medical devices guidelines: 35 Device–medicine boundary products):

- Cryogenic and refrigerant gases
- Medical gases for mechanical use

4.5 Scope beyond AS 2896

The risks of medical gas systems in SA Health extend beyond the scope of medical gas systems defined by AS2896 and includes localised infrastructure with pipelines that shall comply as far as reasonable with AS2896 and/or AS5034 Installation and use of inert gases for beverage dispensing:

- Medical gas systems defined in AS2896
- Medical gas systems not defined in AS2896
  E.g. nitric oxide (NO) in neonatal areas
- Non-medical gases: tool gases, high purity calibration gases.

Out-of-scope are individual cylinders regardless of the gas:

- Medical gas cylinders
  Treated as either medicines (full cylinders), or medical devices (empty cylinders)
- Non-medical gases in cylinders
  Treated as gas cylinders.

4.6 Management within SA Health

Medical gas systems within SA Health will be managed by Engineering and Building Services.

Medical gas systems will be registered as biomedical technology assets to enable locatable and accessible documents (i.e. test certificates) that validate compliance with AS2896.

The health care facility should ensure that persons within the health care facility engaging in the maintenance of medical gas pipeline activities are suitably trained to do so and ensure that where maintained by contractors they are competent in this work.

4.7 Installation

Construction and supply of central supply systems should only be undertaken by experienced personnel. Components of medical gas systems should be obtained and installed under the supervision of a person familiar with proper practices for their construction, installation, and use.

The previous experience of any constructor or installer should be examined closely and also their familiarity with the contents of AS2896.

All companies involved in the design, installation, testing, commissioning and maintenance of medical gas systems should have suitable quality management systems.

4.8 Modification or upgrade to medical gas system

Any change to a medical gas system requires the same tests, certification, and documentation as installation including:

- Non-conformance report form (T8)

- Permit to work form (T7).
- Testing and commissioning as appropriate (T1-T6)
- Contract completion certificate form (T9)

For ANY rooms or areas which have non-respirable gases (note: these pipes may be completely concealed):

ANY structural modifications to the pipeline (i.e: cut ins or new connections, whether purposeful or accidental) needs to be re-commissioned with the anaesthetist involved. This acknowledges the risk of accidentally connecting or cross connecting a pipe with non-respirable gases into an oxygen or medical airline.

4.9 Testing and Commissioning

Independent inspection of the medical gas system by the health care facility is needed to avoid gas pipeline hazards and to confirm and document the system's satisfactory operation.

Multiple people are needed for the testing and commissioning (**Table 1**). The health care facility may use its own qualified personnel, or an experienced agent, which may be an independent outside contractor.

Testing and commissioning is performed in three main stages:

- Pre-concealment tests
  Scheduled during the installation period, may require multiple inspections.

- System gas tests
  Tests of the entire medical gas pipeline system are performed after the installation is complete. Some tests are carried out with different test gases within the pipeline (i.e. CO_2, then breathing air, then proper gas). These tests need to be scheduled with the installer.

- Operational tests
  Final tests before commissioning is complete.
  Register asset and store copies of all documentation at site
  - test records
  - handover instructions
  - commissioning certificate
  - operation manuals
  - certificate of compliance
  - as-installed drawings

All tests described in AS2896 Clause 5.1 shall be performed using test certificates endorsed by SA Health, equivalent to those in AS2896 Appendix H & I.

Table 1 Persons required to test or witness medical gas systems for commissioning

Medical gas system test	Installer	Contractor	HCF *1	HCF *2 gas user	HCF *3 Anae
1. Before concealment					
a) Visual check	Y	Y	Y		
b) Initial pressure test	Y	Y	Y		
c) Valve tightness and zoning	Y	Y	Y		
d) Particulate matter	Y	Y	Y		
e) Cross-connection	Y	Y		Y	Y
2. Complete pipeline	-				
f) Total system pressure	Y	Y	Y		
g) Terminal units flow & pressure	Y	Y	Y		
h) Total flow and pressure	Y	Y	Y		
3. Proper gas & final commissioning	-				
i) Operation of all plant functions	Y	Y	Y		
j) Alarm systems	Y	Y	Y		
k) Gas concentration	Y	Y		Y	Y
l) Odour	Y	Y	Y		
m) Medical air to AS2568	Y	Y	Y		
4. Operational test	Y	Y		Y	Y
5. Certificates	Y	Y	Y	Y	Y

Notes:

*1 Health care facility (HCF) representative, usually Engineering and Building Services, shall designate competent person/s to carry out all tests to certify to administration that the results of the tests are in accordance with AS2896. The designated person/s shall be competent in medical gas testing and verification of piping system. The HCF may use its own qualified personnel, or an experienced agent, which may be an independent outside contractor, to confirm and document the system's satisfactory operation.
This person may be an experienced medical gas system tester from SA BME working in collaboration with Engineering and Building Services.

*2 Health care facility member experienced in administration of medical gases to patients shall be present and witness the tests if there are only respirable gases present.

*3 Where non-respirable medical gases, e.g. nitrous oxide and carbon dioxide, are piped, tests shall be performed by the anaesthetist in-charge or a delegated anaesthetist.

4.10 Maintenance

Maintenance of medical gas systems within SA Health shall be managed by E&BS. Sites may vary in their use of sub-contractors.

Maintenance of the medical gas system includes:

- Corrective maintenance
  Abnormalities shall be reported and rectified with the minimum of delay
- Maintenance planning (risk assessments, schedules) in accordance with AS2896 (Table 2) unless risk assessments performed
- Scheduled maintenance
  Includes preventive maintenance(PM) & performance verification (PV)
- Documentation of work done and test results
  All tests and observations shall be recorded in a permanent log.

Table 2 Schedules for planned maintenance

Schedules	AS2896
1. Safety	
Safety valves	<= 12mth
Gas failure warning system	>= 1yr
2. Source	
Proper operation	<= 12mth
Inspection of manifold	<= 6mth
Checking of manifold	weekly
Inspection of air compressor and suction pump system	As per manufacturer
3. Purity of medical air (compressor)	<= 12mth
4. Terminal units	>= 2yr
5. Pressure gauges and pressure switches	<= 2yr
6. Service manuals	
7. Low pressure flexible hose assemblies	<= 1yr

4.11 Handling incidents, hazards & recalls

Engineering and Building Services will manage risks for medical gas systems:

- Incidents identified from SLS
- Hazard and Recall notices issued by:
  - Manufacturer or supplier advice to organisation through CEO.
  - Safety and Quality Unit in the SA Health Safety Alert Broadcast System for TGA Alerts

4.12 Governance of medical gas systems

Local health networks shall have an operational sub-committee for medical gas systems that meets at least annually with representatives from: sites, operations, E&BS, Anaesthetics, clinical users and SA BME to discuss at a minimum:

- Test certificates and test reports
  - new infrastructure or localised gas systems
  - modification to any gas system
- Scheduled maintenance results
- Repairs, improvements or upgrades needed

- Incidents (SLS), hazards or recalls
- Business continuity
- Resource outage contingency plan

5. Roles and Responsibilities

The importance of fully understanding the great danger to patients from improperly installed, modified, tested and commissioned medical gas life support systems cannot be underestimated.

5.1 Chief Executive / Deputy Chief Executive

Will take reasonably practicable steps to:

- Exercise due diligence to ensure compliance with the intent of this policy guideline
- Establish awareness of and accountability for the implementation and application of this policy guideline

5.2 SA Health Executives, Directors and Chief Operating Officers

Be aware of the intent of this policy.

- Determine the accepted level of risk and provide financial and physical resources needed to support medical gas systems
- Designate a competent person experienced in administration of medical gases to patients as the health care facility representative to witness and participate in tests as specified in AS2896 after installation or modification of medical gas systems. Where non-respirable gases are present in an area, this person shall be an anaesthetist.

5.3 Executive Director – Infrastructure

Will take reasonably practicable steps to:

- Exercise due diligence to ensure compliance with the intent of this policy guideline
- Establish awareness of an accountability of the implementation and application of this policy guideline
- Enable financial and physical resources needed for the implementation and support of this policy guideline
- Ensure that this policy guideline is applied consistently across SA Health sites

5.4 Engineering & Building Services Managers, E&BS

Will take reasonable practicable steps to:

- Exercise due diligence to ensure compliance with the intent of this policy guideline
- Assure SA Health medical gas systems are managed to comply with AS 2896
- Manage all documentation associated with medical gas systems installations, modifications and maintenance.
- Ensure that any site specific variations to the policy are recorded in the Service Level Agreements with other parties (e.g. SA BME or AGFMA).
- Ensure that available resources are appropriately allocated to enable implementation of this policy guideline
- Ensure that staff under their management are provided with adequate direction and support to fulfil their responsibilities in the application of this policy guideline
- Ensure installers and those working on medical gas systems:

- Provide evidence of quality management system
- Show experience in installation of medical gas systems to AS 2896
- Provide references for 3 most recent medical gas installations
  - For company
  - For individual doing work
- Provide notification to arrange for HCF witness before concealment
- Provide notification of time work being done, and final testing date
- Provide clear instruction on extent of modifications (with drawing plans) to test witnesses
- Recommend which test certificates are needed
- Provide non-conformance report before starting modifications to an existing system
- Provide Contract Completion Certificate after all work is complete

5.5 Healthcare Facility Witness for installations and modifications

The Healthcare Facility representative shall designate competent person/s to carry out all tests to certify to administration that the results of the tests are in accordance with AS2896. The designated person/s shall be competent in medical gas testing and verification of piping system. The HCF may use its own qualified personnel, or an experienced agent, which may be an independent outside contractor, to confirm and document the system's satisfactory operation. This person may be an experienced medical gas system tester from SA BME.

For the tests of cross-connection (1e), gas concentration (3k), and operation (4), this shall be a person experienced in administration of medical gases to patients, and if gases are non-respirable, shall be an anaesthetist.

Will take reasonably practicable steps to:

- Exercise due diligence to ensure compliance with the intent of this policy guideline
- Read and understand the tests in AS2896 to ensure compliance
- Be experienced in testing medical gas systems
- Approve the selection of necessary test certificates
- Witness the medical gas system pre-concealment
- Witness all the agreed tests for the installation or modification test certificates
- Witness the terminal outlet tests
- Sign the documentation and forward a copy to E&BS

5.6 State-wide Director – SA Biomedical Engineering

Will take reasonably practicable steps to:

- Exercise due diligence to ensure compliance with the intent of this policy guideline
- Ensure available resources are appropriately allocated to enable implementation of this policy guideline to the level of risk required by the SA Health Executives and Directors
- Ensure that relevant staff within SABME have the required knowledge and skills to equip them to implement the policy directive across all SA Health sites
- Monitor the effectiveness of this policy directive in the control of identified risks

5.7 SABME Area and Site Managers

Will take reasonably practicable steps to:

- Exercise due diligence to ensure compliance with the intent of this policy guideline

- Assure SA Health medical gas systems are managed consistently and appropriately across SA Health
- Ensure that available resources are appropriately allocated to enable implementation of this policy guideline
- Ensure that staff under their management are provided with adequate direction and support to fulfil their responsibilities in the application of this policy guideline
- Register all medical gas systems in BAMS with commissioning documents
- Ensure SA BME test instruments used for commissioning are tested 12 monthly (or less if recommended by manufacturer) with test results and testing schedules available on BAMS

5.8 Clinical Gas Users

Will take reasonably practicable steps to:

- Test medical gas panels weekly.
- Report problems to Engineering and Building Services.

6. Reporting

Forms and Test Certificates endorsed by SA Health (equivalent to those in AS2896) will be used to record tests performed, test results, and witnessing for both installations and modifications or upgrades to Medical Gas Systems.
Test records must be kept for the life of the facility.

7. EPAS

N/A

8. Exemption

N/A

9. National Safety and Quality Health Service Standards

National Standard 1 Governance for Safety and Quality in Health Care	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare associated infections	National Standard 4 Medication Safety	National Standard 5 Patient Identification & Procedure Matching	National Standard 6 Clinical Handover	National Standard 7 Blood and Blood Products	National Standard 8 Preventing & Managing Pressure Injuries	National Standard 9 Recognising & Responding to Clinical Deterioration	National Standard 10 Preventing Falls & Harm from Falls
☒	☐	☐	☐	☐	☐	☐	☐	☐	☐

National Standard 1
1.29 The health service organisation maximises safety and quality of care: a. through the design of the environment; b. by maintaining buildings, plant, equipment, utilities and devices
National Standard 15 Corporate Systems and Safety
15.12-14: Safety management systems ensure the safety and wellbeing of consumers / patients, staff, visitors and contractors.

15.15-16: Buildings, signage, plant, medical devices, equipment, supplies, utilities and consumables are managed safely and used efficiently and effectively.

10. Risk Management

The content of this policy guideline is expressly intended to address risks associated with the management of medical gas systems within SA Health. The risk management process is in alignment with:

- SA Health Risk Management Framework 2014
- AS/NZS 3551 Technical Management Programs for Medical Devices
- AS2896 Medical gas systems – installation and testing of non-flammable medical gas pipeline systems

There are two main risks associated with Medical Gas Systems:

- Inappropriate commissioning
- Inappropriate maintenance

10.1 Inappropriate Medical Gas System commissioning

Medical gas pipelines are a life support system and as such require careful consideration in their design, construction and installation (AS 2896-2011). Inappropriate Medical gas system installation, modification, testing and commissioning may lead to patient harm and patient deaths.

	Consequence	Likelihood	Risk Rating
Inherent	Critical	Likely	Extreme (25)
Controlled	Critical	Possible	High (15)
Treated	Critical	Unlikely	High (10)

Causes:

- Inappropriate personnel: designing, constructing, installing (or modifying)
- Installation (or modification) not complying to standard AS2896
- Commissioning: team inappropriate, not to standard AS2896
- Records of design, modifications and tests not kept and available

Consequences:

- Patient harm due to:
  - Wrong gas
  - Insufficient gas/suction
  - Contamination of gas caused by debris or chemical interaction
  - Foreign matter
  - Condensation
  - Grease or oil mixing with oxygen and nitrous oxide

Controls

- Experienced SA Health staff manage installation, modification, testing and compliance
- Competent persons employed to install, modify and test medical gas systems
- Workshop conducted to review process

Treatments, further actions needed

- Develop Policy for clear delineation of responsibilities, requirements for witnesses, and for records management
- Organisation-based operational sub-committees for medical gas
- Develop SA Health-endorsed versions of AS 2896 test certificates and forms
- Develop training program with work instructions

10.2 Inappropriate Medical Gas System maintenance

Medical gas pipelines are a life support system and shall only be maintained by persons suitably trained in the maintenance of medical gas pipelines (AS 2896-2011). Inappropriate Medical gas system maintenance can lead to patient harm.

	Consequence	Likelihood	Risk Rating
Inherent	Major	Possible	High (12)
Controlled	Major	Unlikely	Moderate (8)
Treated	Major	Unlikely	Moderate (8)

Causes:

- Maintenance by inappropriate persons
- Maintenance not at intervals recommended by AS2896
- Maintenance tests and inspections not as recommended by AS2896
- Records not kept and available

Consequences:

- Patient harm due to:
  - Contamination of gas caused by debris or chemical interaction
  - Foreign matter
  - Condensation
  - Grease or oil mixing with oxygen and nitrous oxide

Controls

- Experienced SA Health staff manage maintenance
- Competent persons employed to do maintenance

Treatments, further actions needed

- Policy to establish: clear delineation of responsibilities, maintenance intervals and tests as specified AS 2896
- Organisation-based operational sub-committees for medical gas systems

11. Evaluation

- All new medical gas system installations are registered as biomedical technologies within Biomedical Asset Management System
- All commissioning reports are attached to the biomedical technology within the Biomedical Asset Management System
- All handover documents for installations and modification are kept by Engineering & Building Services at each site
- All maintenance reports are kept by Engineering & Building Services at each site

12. Definitions

In the context of this document:

- **Biomedical Asset Management System** (BAMS) means: a database comprising a record with unique identifying number for each item of biomedical technology to provide evidence of adequate and effective operation of the biomedical technology management program. The database shall contain a history for each item of biomedical technology (from AS/NZS3551 Section 2.5).

- **biomedical technology** means: any electronic, electro-mechanical, mechanical, optical or pneumatic instrument, device, equipment, apparatus, appliance,

material or other article, (whether used alone or in combination, and including the software necessary for its proper application) intended, by the assigned SA Health manager, to be used either in-vitro or in-vivo for human beings for the purpose of, or research into, 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 or modification of the anatomy or of a physiological process, or
- control of conception;

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

or an accessory to such an instrument, device, equipment, apparatus, appliance, material or other article.

NOTE 1: Any device, instrument, apparatus, accessory or consumable attached to the item of biomedical technology whether by direct or indirect (e.g. wireless connection) means is to be considered part of the biomedical technology.

NOTE 2: The Director SA BME will maintain a list of biomedical technology that is either exempt from this policy or included where such inclusion was either considered to be ambiguous or subject to a specific determination.

- **commissioning** means: the process of assuring that all systems and components of a medical gas system are designed, installed, tested, operated, and maintained according to the operational requirements of SA Health.

- **competent person** (for commissioning) means: a person designated by a representative of the health care facility, competent in medical gas testing and verification of piping systems (AS2896 section 5.2) and for tests of cross-connection, gas concentration, and operation, shall be a medical gas user, and for non-respirable gases, an anaesthetist. For the other tests, may be from E&BS or SA BME.

- **Engineering & Building Services**, E&BS means: organisation-based group responsible for building assets and infrastructure, also known as strategic assets.

- **medical gas system** means: gas pipeline systems providing the following gases for medical use:
  - Oxygen
  - Nitrous oxide
  - Medical air
  - Surgical tool gas
  - CO2 (less than or equal to 7%) in oxygen
  - Nitrous oxide/oxygen 50/50
  - Helium-oxygen mixtures
  - Carbon dioxide
  - Medical suction (vacuum), and
  - Scavenging.

- **performance verification** (PV) means: testing the essential performance parameters of the biomedical technology. This will require a range of physical, functional and electrical tests to confirm it is capable of performing safely and as intended by the manufacturer.

- **preventive maintenance** (PM) means: maintenance carried out at predetermined intervals, or according to prescribed criteria, and intended to reduce the probability of failure or the degradation of the functioning of an item.
  Examples; replacing parts (e.g. PM kits, O rings, batteries, filters), or lubrication.
  Note: PM is intentionally designed to exclude routine testing or PV that, whilst it may confirm function at a certain point in time, does nothing to reduce the probability of failure.

- **SA BME** means: South Australia Biomedical Engineering, a statewide service managing the biomedical technology used by SA Health.

13. Associated Policy Directives / Policy Guidelines

- Management of Biomedical Technology Policy Directive
- SA Health Risk Management Framework 2014

14. References, Resources and Related Documents

- AS 2896 Medical gas systems – installation and testing of non-flammable medical gas pipeline systems (available in SAI Global through SA Library)
- AS 2902:2005 Medical gas systems - Low pressure flexible hose assemblies (available in SAI Global through SA Library)
- AS/NZS 3551 Technical Management Programs for Medical Devices
- AS 4484:2016 Gas cylinders for industrial, scientific, medical and refrigerant use - Labelling and colour coding (available in SAI Global through SA Library)
- AS5034 – Installation and use of inert gases for beverage dispensing
- The Therapeutic Goods Act 1989 and associated Regulations
  - Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 (items 4 g, h)
  - Australian Regulatory Guidelines for Medical Devices, ARGMD, V1.1 May 2011, Rule 4.4 Active medical devices intended to administer or remove medicines, etc from a patient's body (pg 96) and Medical gas and connection systems (pgs 155-156)
  - Australian medical devices guidelines: 35. Device–medicine boundary products
- SA Health Medical Gas System – Test Forms and Certificates