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# **Regulatory scheme for medical gases**

Response to NSW consultation paper

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**July 2020**



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### Regulatory scheme for medical gases

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# 1. Introduction

## 1.1.1 About Engineers Australia

Engineers Australia is the peak member-based professional association for engineers. Established in 1919, Engineers Australia is constituted by Royal Charter to advance the science and practice of engineering for the benefit of the community. Our work is supported by around 100,000 individual members, including about 25,000 in NSW. This submission has been developed with the support of members of Engineers Australia's Biomedical College.

Engineers Australia welcomes the opportunity to provide this submission to the NSW Government Better Regulation Division in response to its Consultation Paper on a *Regulator Scheme for Medical Gases*.

## 1.1.2 Contact details

To discuss the contents of this submission further, please contact Sybilla Grady, Senior Policy Advisor, at [sgrady@engineersaustralia.org.au](mailto:sgrady@engineersaustralia.org.au).

# 2. Core messages

1. The proposed list of medical gases corresponds with those cited in AS 2896:2011 (the Standard) and is sufficiently comprehensive in its inclusion of all gases typically reticulated in health care facilities.
2. It is more important that the bounds of medical gas installation systems are defined by the proposed regulatory framework, rather than the provision of a clear definition of *medical facilities*, or upon system installation location.
3. Aged care facilities should be included within the scope of the proposed regulatory framework to ensure the overall safety of the system.
4. The skill set required for medical gasfitting work is described in AS 2896:2011 and is considered appropriate to ensure competency in installation activities.
5. The competency requirements for medical gasfitting technicians should be expanded to incorporate clinical/engineering professionals experienced in the delivery of medical gases to align with the requirements of AS 2986:2011, the medical gas installation standard.
6. A separate licencing scheme for personnel working on healthcare facility suction systems is unnecessary.
7. It is critical to define four distinct areas relating to medical gas pipeline distribution systems which must be included in the licensing framework in relation to medical gases: engineering design; installation; commissioning; and servicing, inspection, testing and maintenance.
8. The proposed training prerequisites to qualify for a licence to undertake medical gasfitting are appropriate.
9. In contrast, the proposed training prerequisites for qualification as a medical gas technician are insufficient and overly restrictive.
10. Engineers Australia has identified two additional compliance and enforcement provisions:
  - that the design of medical gas pipeline systems must be completed by competent and qualified professional engineers, engineering technologists or engineering associates, and;
  - that serious consideration should be given to introducing restricted or limited licences for servicing of the terminal outlet, replacement of aged seals and the service and maintenance of medical gas equipment distal to the wall outlet or other Non-Interchangeable Screw Thread (NIST) fittings where the gas pipeline system terminates.
11. In implementing the proposed regulation and licencing framework, a transition period to provide for continuity of service provided by those medical gas pipeline system installers who have appropriate knowledge and experience, but not necessarily the formal trade qualifications introduced by the new regulations, is imperative.
12. Legacy systems installed prior to 1998 should be reviewed to ensure compliance with AS 2896:2011.

# 3. Consultation questions and responses

## 3.1 Other gases

### **Question 1 - Should any other gases be included in the definition of medical gas, that are not already listed in the Gas and Electricity (Consumer Safety) Regulation?**

The proposed list corresponds with those cited in AS 2896:2011 (the Standard) and is sufficiently comprehensive in its inclusion of all gases typically reticulated in health care facilities.

Whilst other gases may be used in some medical procedures, such as argon in respiratory medicine, the storage, reticulation and delivery to the patient is localised, without a complex reticulation system between source of supply and point of application. These are also specifically excluded from the scope of AS 2896:2011.

## 3.2 Definition of medical facilities

### **Question 2 - Is the term *medical facilities* appropriately defined? Please explain why or why not.**

It is more important that the bounds of medical gas installation systems are defined by the proposed regulatory framework, rather than the provision of a clear definition of *medical facilities*, or upon system installation location.

AS 2896:2011 does not define the term medical facility, nor any form of institution, or clinical practice. The Standard defines the *Pipeline distribution system* as:

*That part of the medical gas supply system that links the source of supply to the terminal units. It includes isolation valves, pressure relief valves, and any secondary pipeline pressure regulators.*

The proposed regulations must apply to any pipeline distribution system used to reticulate a medical gas or gases in all medical facilities.

Residential premises and veterinary practices should be included in the scope of the proposed regulations. Typically, only oxygen is reticulated in residential premises and cross-connection is therefore highly unlikely. However, to ensure installation personal are adequately trained and the materials and components used are compliant, it is essential that reticulation of high-pressure gas installation and maintenance practices are regulated.

It is also common for multiple gases to be reticulated in veterinary practices. The aim of the regulations should focus on the overall safety of the installation, use of compliant materials and components of the system and installation by competent operators rather than purely on potential cross-connection of medical gases.

By way of a parallel, all electrical installations must be compliant with *AS NZS 3000:2018 – Electrical installations (known as the Australian/New Zealand Wiring Rules)* and this should also apply in the context of medical gases.

Citing from the Standards Australia website abstract for AS NZS 3000:2018, *This Standard sets out requirements for the design, construction and verification of electrical installations, including the selection and installation of electrical equipment forming part of such electrical installations.* Citing from these requirements, they

*...are intended to protect persons, livestock, and property from electric shock, fire and physical injury hazards that may arise from an electrical installation that is used with reasonable care and with due regard to the intended purpose of the electrical installation.*

AS 2896:2011 serves the same function for medical gas pipeline systems and compliance of a system with the standard should be mandated to ensure safety and performance of the system.

### 3.3 Aged care facilities

**Question 3 - Should the definition of *medical facilities* be extended to include aged care facilities (nursing homes) or should aged care facilities be exempt? Please explain why or why not.**

These facilities are care facilities, rather than treatment facilities, and residents requiring medical treatment including delivery of any medical gas, excepting short-term delivery of oxygen from a cylinder, would be transported to an appropriate clinical facility for treatment.

Where aged care facilities choose to incorporate or install a reticulated medical gas facility, aged care facilities should be included within the scope of the proposed regulatory framework to ensure the overall safety of the system for reasons already expounded above for residential and veterinary facilities. However, it is highly irregular to have reticulated medical gases in such facilities.

As noted in the response to question 2, the focus must be on the bounds of medical gas installation systems as defined by the proposed regulatory framework, rather than on provision of a clear definition of the facilities, or upon system installation location.

Essentially, if a gas pipeline system is installed for the reticulation of medical gases for treatment purposes or therapy, it should in scope for the proposed regulations regardless of the nature of the facility.

### 3.4 Medical gas installations

**Question 4 - Should *medical gas installations* be defined as ending at the wall socket or should they also include the outlets in other mechanisms, such as pendants?**

Pendants, booms and columns fitted with medical gas outlets are coupled through Non-Interchangeable Screw Thread (NIST) type couplings into the fixed medical gas *pipeline distribution system*. This has been a mandatory requirement since 1998. These are typically designed to be disconnected from the fixed *pipeline distribution system* for service and maintenance at a site remote from where it is installed.

In practice they present no differently to, for example, an anaesthetic machine coupled to gas specific wall outlets by a flexible hose fitted with ring index fitting to prevent misconnection.

Engineers Australia considers it unnecessary to extend the scope of regulation beyond the gas specific wall or ceiling outlets because, beyond that, gas specific indexed coupling systems preclude the possibility of cross connection, or other misadventure except at the time of first commissioning.

Where pendants, booms or columns are part of the system reticulating medical gases, commissioning of the system should incorporate the need for all relevant operational testing to be undertaken at the outlet, on the pendant, boom or column.

Once commissioned, the gas delivery elements of these devices should not be considered part of the pipeline distribution system.

### 3.5 Medical gasfitting work

**Question 5 - Is the scope of *medical gasfitting work* appropriately defined? If no, please explain why and provide the proposed changes to the scope.**

The skill set required for medical gasfitting work is described in AS 2896:2011 and the proposal in the consultation paper is considered appropriate to ensure competency in installation activities.

## 3.6 Medical gasfitting technician

**Question 6 - Is the scope of *medical gasfitting technician* work appropriately defined? If no, please explain why and provide the proposed changes to the scope.**

The scope of work described in the consultation paper is appropriate, recognising the personnel competent to undertake this role are not only drawn from plumbing/gasfitting trades personnel but also professional clinical and biomedical engineering personnel to align with the requirements of AS 2986:2011, the medical gas installation standard.

## 3.7 Medical gas suctioning

**Question 7 - Should there be an additional category of specialist work that is restricted work on medical gas suctioning? Please explain your response.**

A separate licencing scheme for personnel working on healthcare facility suction systems is unnecessary. Suction systems and medical gas systems are typically installed in tandem using common installation techniques. The delivery of medical gases, and the provision of wall suction performance and testing for both are well documented and within the scope of AS 2896:2011, which is the foundational standard proposed.

Engineers Australia does not believe it is necessary to regulate dental suction systems, their installation or the competence of installing personnel. It should also be noted that paragraph 1.1 of the Standard, which outlines the reach of AS 2896:2011, specifically excludes dental suction from the scope of the standard.

The operational requirements for dental suction differ significantly from suction requirements in a medical facility. Dental suction is high flow and low vacuum, whereas medical facilities use a centralised vacuum suction pump with reticulated pipework. Dental suction systems are designed for use with wet extractants with short, often single pipe reticulation. Medical facility suction systems are designed for use with very low moisture extractants supported by lengthy suction systems.

## 3.8 Other categories of specialist work

**Question 8 - Are there any other categories of specialist work that should be included in the licensing framework in relation to medical gases? Please explain your response.**

It is critical to define four distinct areas relating to medical gas pipeline distribution systems which must be included in the licensing framework in relation to medical gases: engineering design; installation; commissioning; and servicing, inspection, testing and maintenance.

### 3.8.1 Engineering design

Engineering design is distinct from installation, commissioning and maintenance and incorporates specific client requirements, including potential maximum gas draw requirements, mode of incorporation into specific facility infrastructure, future serviceability and maintenance and consideration and risk analysis for the provision of emergency supply in the event of supply disruption.

### 3.8.2 Installation

Installation must be considered as entirely separate to commissioning. To include the role of commissioning in this phase presents a direct conflict of interest for the installation personnel in that they are commissioning their own installation without any external verification of safety or performance, and would be in conflict with the requirements of AS 2896:2011 clause 5.7 which requires the presence of '*.....a member of the healthcare facility experienced in administration of medical gases to patients and such other persons as are required by the administration of the healthcare facility, shall be present and witness the tests.*

Installation by appropriate trade qualified personnel in accordance with the documented design is critical. This also includes initial operational testing of a completed system to verify the installation work and performance of the installation but excludes formal commissioning and handover of the system to the facility manager.

### **3.8.3 Commissioning**

Ensuring that commissioning of the medical gas pipeline distribution system is completed by specialist personnel, independent of personnel responsible for installation eliminates any potential conflict of interest as outlined above and provides greater confidence in the safety and performance of the pipeline system, beyond operational testing.

The skill set required to competently test and commission a pipeline distribution system, and the definition of the scope of work, must be different from that of the gasfitter installing the system. While it is possible for the installing gasfitter to perform the operational testing, independent verification by a person described in clause 5.7 of the Standard and detailed in the italicised text in section 3.8.2 of this document, is essential.

Typically, this includes facility personnel, such as anaesthetic department clinical or technical staff, respiratory specialists such as specialist respiratory nursing personnel, biomedical technicians/engineers or facility technical staff competent in management of gas delivery systems, or external contractors demonstrating an ability to meet the Standard.

### **3.8.4 Servicing, inspection, testing and maintenance**

Post commissioning, on-going service and periodic inspection, testing and maintenance of the system must be conducted by suitably trained and qualified personnel.

The skill set required for these activities is different from those required for installation and maintenance of most of the medical gas pipeline system. Medical gas systems are complex networks that interact with gas pressure/flow failure alarm systems, and other facilities management systems and equipment used in patient care. Consideration and understanding are required to service, test and maintain isolated components of the system without compromising the safe operation and functionality of the entire clinical environment. Medical gasfitting skills are insufficient to equip a gasfitter to competently and safely maintain, program or repair systems installed and being installed today and into the future.

Engineers Australia encourages a degree of regulation at all levels described above commensurate with the risk presented at each level, from system design through to on-going maintenance. At each stage of the process, independent validation of the step prior is a critical consideration in introducing these regulations.

## **3.9 Medical gasfitting qualifications**

### **Question 9 - Are the qualifications outlined above for medical gasfitting work appropriate? Are there other qualifications that could be considered?**

The training prerequisites to qualify for licence to undertake medical gasfitting are appropriate. However, the introduction of regulation with strict formal qualification and experience requirements, into a previously unregulated environment, has the potential to seriously disrupt continuity of service provided.

Under Question 12 we make comment on the need for a transition period with provision for exemption from some of these requirements, for example the requirement to ...*complete an apprenticeship with at least two years combined industry experience*. Many competent, knowledgeable and experienced medical gas pipeline installers are currently employed, but despite vast practical experience in industry and specific knowledge of gasfitting for medical gas pipeline systems, may not have formal qualifications in plumbing, LPG or air-conditioning/refrigeration gasfitting.

Engineers Australia believes a transition period to allow these personnel to continue to install medical gas systems is an essential element of the proposed regulatory framework, noting that these individuals will leave the industry either through retirement, or career changes, and once this has occurred, the exemption would become redundant.

## 3.10 Medical gas technician qualifications

### **Question 10 - Are the qualifications outlined above for medical gas technician work appropriate? Are there other qualifications that could be considered?**

The proposed training prerequisites for qualification as a medical gas technician are insufficient and overly restrictive for a role proposed to be established to separate the function of commissioning from that of installation. Both are too restrictive and insufficient as proposed.

The material presented in the description of competency unit *CPCPMC3034A – Install medical gas systems* is enough to equip non-medically or non-clinically trained personnel with sufficient understanding of what a medical gas pipeline system is. But it fails to provide adequate understanding of what the system is required to deliver in terms of clinical requirements, rationale for commissioning test requirements, and performance.

Conversely, *CPCPMC3034A – Install medical gas systems* may be useful to medically or clinically trained personnel in providing background knowledge and understanding medical gas pipeline system infrastructure in the delivery of clinical requirement and overall performance.

In its current format, the proposed requirements will likely preclude personnel identified in AS 2896:2011 clause 5.7.1 as appropriate to undertake commissioning activities. Competent personnel experienced in administration of medical gases to patients such as anaesthetic technicians, respiratory technicians, biomedical engineers and technicians and anaesthetists, have an extensive understanding of what a medical gas pipeline system is expected to deliver, both in terms of gases delivered and system delivery performance, during routine use, use at full capacity and with regards to emergency reserves.

Engineers Australia does not believe it is necessary for such personnel to undertake the two prescribed units of competency.

Many of the elements of *CPCPMC3034A – Install medical gas systems* relate to directly preparing for and undertaking the activity of installation of the pipeline system, whereas commissioning relies on the system being installed and operationally tested by installation personnel. Commissioning does not include personnel involved in the separate activity of installation.

The unit descriptor for CPCPCM2043A states:

*This unit of competency supports safe work practices for the plumbing and services industry. Site location for work application may be either domestic or commercial and may be a new work site or an existing structure or fitting being renovated, extended, restored or maintained. It could also be conducted in an on or off-site workshop or at a customer's premises.*

Commissioning of a medical gas pipeline system is not a *plumbing activity*, and separation of responsibilities for installation and commissioning and the competencies of required, acceptable personnel to undertake or oversight a commissioning activity described in Section 5.7 of AS 2896:2011 must be emphasised.

Suitability and relevance of prescribed units of competency content, coupled with the competency of the listed Registered Training Organisations detailed as able to deliver these units of competency has not been considered in the consultation paper.

The website [www.training.gov.au](http://www.training.gov.au) lists 42 organisations registered to deliver *CPCPCM2043A – Install medical gas systems* and 89 organisations registered to deliver *CPCPCM2043A – Carry out WHS requirements*. Delivery appears to be incorporated in certificate III and IV courses for various building, construction or plumbing specialities.

Given the emphasis placed on the need to regulate activities surrounding medical gas pipeline systems in the proposed framework, when related specifically to medical gas systems it is vital that RTOs training personnel providing courses for medical gas system licencing are experienced in and can relate specifically to medical gas systems, and that such providers have been assessed as competent to deliver the appropriate and necessary

training required to install, commission and maintain medical gas pipeline systems. These requirements relate not only to the work practices of installation but to materials used in systems, assembly techniques and materials such as brazing materials, sealing materials and suitability of various components installed in the system, all of which are very different to those typically used in flammable gas, refrigerated gas or LPG systems for example.

One concerning example of an RTO delivering *CPCPCM2043A – Install medical gas systems* offers only a Certificate IV or Diploma in *Building and Construction (Building)*, and that the Certificate IV course is described on the RTO's website as follows:

*This course will assist you in developing skills in building regulations, project scope and planning, estimating, management, contracts and finances, and industry best practices. Designed for those seeking to become registered as a domestic builder in Victoria. Designed to meet the needs of builders and managers of small to medium-sized building businesses.*

Most other courses offered by the organisation relate to areas outside of building and construction, such as personal grooming and retail. There is no clear demonstration of competence in medical gas pipeline systems installation training, or whether such training is included in every course in the building and construction curriculum content.

The same organisation is also listed as an RTO for delivering *CPCPCM2043A – Carry out WHS requirements*.

There is little doubt that the organisation can deliver a generic training package relating to workplace health and safety in building and construction. However, Engineers Australia members are not confident that the organisation has the appropriate knowledge and experience to deliver WHS training specific to the installation, commissioning and maintenance of medical gas systems, where strong oxidisers and non-respirable gases may be present and potentially released into the work environment during installation, testing and commissioning.

A comprehensive regulatory framework surrounding the activities of design, installation, commissioning and maintenance of medical gas pipeline systems must also consider the competence of training organisations supporting training and licencing of personnel operating in the field.

Furthermore, training personnel in an RTO must be required to retain competence and knowledge in the area. The medical gas pipeline system installation industry is very small relative to the overall building/construction industry delivering and commissioning healthcare facilities. Therefore, demand for training will be small and infrequent for an RTO to deliver cost effectively. The small training demand spread over the large number of registered providers creates risks relating to cost effectiveness, and continued currency of trainer expertise in contemporary standards and practice, resulting in deficiencies in knowledge of graduating students.

## 3.11 Additional compliance and enforcement provisions

### **Question 11 - Should there be any additional compliance and enforcement provisions in addition to the existing provisions in the G&E Act and HB Act?**

Engineers Australia has identified additional compliance and licencing requirements relating to design of medical gas pipeline systems, and restricted licencing for specific maintenance requirements.

#### **3.11.1 Design of medical pipeline systems**

To ensure installations are compliant with AS2896:2011 whilst ensuring specific client clinical requirements are met, the design of medical gas pipeline systems must be completed by competent and qualified professional engineers, engineering technologists or engineering associates.

Furthermore, medical gas system design must be reviewed and signed off by a competent and suitably qualified person, just as is required for electrical installations in line with provisions in AS NZ 3003 – Electrical installations – Patient area, which extend to include AS NZS 3000 – general electrical wiring.

Critical to patient safety is the commissioning phase and it is therefore recommended that those responsible for the commissioning phases must be treated and licenced independently of design, installation and maintenance.

### 3.11.2 Maintenance

Maintenance of wall outlets, pendants, sources of supply, medical gas alarm systems and medical gas equipment from the wall outlet through to delivery to the patient are typically undertaken by specialist external contractors. These contractors may also engage in installation activities, in-house facilities engineering, or biomedical engineering.

Serious consideration should be given to introducing restricted or limited licences to ensure competence of personnel responsible for servicing of the wall outlet and replacement of aged seals but excluding replacement of the wall outlet involving breaking and replacing the connection to the gas pipeline system, and maintenance activities of medical gas related equipment connected to a point beyond where cross connection is possible. This point could be defined as either the gas specific wall outlet or the NIST gas specific connection for ceiling mounted booms or pendants.

## 3.12 Other issues and comments

### Question 12 - Are there any other issues or comments you would like to make?

### 3.12.1 Recognition of prior learning and experience

Engineers Australia recognises that introduction of licencing regulation to any previously unregulated sector will present short to medium term challenges. Licencing based on formal qualifications and specified coursework may preclude otherwise competent personnel with years of experience and knowledge.

To guard against skill shortages and mitigate risks to patient safety, a method of recognition of existing skills and experience in the provision of licenses must be provided. The suggested approach is to consider a grandfathering process for eligible personnel, similar in operation to the Tasmanian *Occupational Licencing (Medical Gas Exemption) Order 2012* issued under the *Occupational Licencing Act 2005* needs to be an essential and integral element of the regulatory framework proposed for NSW.

Another challenge which is likely to adversely impact the industry is that coursework must be developed for delivery, students must enrol, complete and be assessed for competency prior to issue of a licence. Scrutiny must be applied to ensure that RTOs can meet training objectives which are aligned with competency requirements. A grandfathering scheme allowing for recognition of prior learning and experience will assist in continuity of service during development, accreditation and delivery of courses are completed.

### 3.12.2 Clarification of proposed mandated standards

The consultation paper cites several standards at Section 1.1 but does not clarify anywhere which, if any, will be mandated under the proposed regulatory framework. Engineers Australia strongly recommends that any medical gas pipeline installed, and any work undertaken on such systems be installed and undertaken in accord with the requirements of and in compliance with the standard AS 2896:2011.

In mandating AS 2896:2011 under the regulatory framework, it is not necessary to mandate the other documents cited. They are normatively referenced in Appendix A of AS 2896:2011 and thus automatically mandated as a result.

### 3.12.3 Review of legacy systems

In 1998 it became mandatory for medical gas pipeline systems to which pendants, booms or columns are connected to incorporate NIST fittings at the wall/ceiling terminal outlet. Anecdotal advice from Engineers Australia members active in the medical gas industry suggests that some legacy systems installed prior to 1998 remain operational. These systems may have fittings which have not been incorporated and cross-connection of gas lines during removal and re-installation for maintenance pose a potential hazard risk. Requirements should be incorporated in the proposed regulatory framework to undertake a review of legacy systems to ensure they are brought up to full compliance with AS 2896:2011.



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