

Better Regulation Division
NSW Department of Customer Service
4 Parramatta Square
PARRAMATTA NSW 2150
By email to: medicalgas@customerservice.nsw.gov.au

RE: Regulation amendments for medical gas work consultation

25 September 2020

Thank you for the opportunity to provide comment on the proposed Gas and Electricity (Consumer Safety) Amendment (Medical Gas Work) Regulation (No 2) 2020 and participation in the round of consultation teleconferences held over the last fortnight.

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. You have requested responses to a series of questions proposed in the associated consultation paper. Our responses are provided below.

1. Do you have any comments on the definitions in the regulations ?

Definition of 'Medical Facility'

We note the proposal to exclude premises used for residential purposes and pathology laboratories from the scope of this regulatory framework with the justifying statement "...there is no risk to patients.' It is apparent that the driver for introduction of this framework to regulate medical gas system installation work and the systems themselves is, primarily, the risk to the recipient of the gas(es) delivered by the system.

It should be noted, however, that incorrect delivery of gas(es) is only one element of risk associated with a medical gas system. There is also a potential safety risk presented by the system if not built to an appropriate standard such as AS 2896 if poor quality materials, components or installation practices are used.

It allows for circumstances where there are several installations of systems delivering medical gases where some are regulated and some are not depending on the activities undertaken in the facility, resulting in potential confusion when undertaking installation or maintenance of these systems.

Engineers Australia believes all installations delivering medical gas(es) should be within the scope of these regulations, with the aim not only of ensuring appropriate delivery of the correct gas, but also the integrity and overall safety of the system infrastructure.

Definition of 'Medical Gas'

It is unfortunate that the definition of a medical gas is written in terms of it being a '*substance*' because suction is also an important element of a medical gas installation. Suction is provided by developing a vacuum using a vacuum pump or pumps and these are installed as an integral element of the medical gas system. Suction is, in fact, the '*absence of a substance*' rather than a substance within the intent of this definition of medical gas.

It is important that suction is included within the scope of this regulatory framework. To not do so would result in part of the installation being regulated and part of it not regulated leading to potential confusion and increase the potential of risk, not only to the system but to the user and the patient.

Last week during the video conference we explored and discussed defining '*air held at a negative pressure*' as a medical gas (satisfying the requirement for it to be considered a '*substance*') and including a note to clarify that '*air held at a negative pressure*' is also referred to as suction. Engineers Australia believes it is imperative that suction is also included in the scope of this regulatory framework and encourages incorporation of suction into the definition of a medical gas.

2. *Should veterinary hospitals also be captured under the law?*

For the same reasons outlined above as to why residential and pathology laboratories should be within the scope of this law, Engineers Australia recommends that veterinary hospitals should also be included.

3. *Are there any other standards that are relevant and should be listed to be complied with? If yes, please provide the standards and the reasons why.*

Engineers Australia does not believe there is a need for any further standards to be cited in the regulations.

We do however strongly recommend several standards currently cited in the draft regulation be removed because they are un-necessary or inappropriate.

The proposed clause 69A (1) of the G & E Regulations cite the following standards:

- **AS2030 - Gas Cylinders General requirements**
- **AS 2473.1 Valves for compressed gas cylinders Part 1: Specifications, type testing, and manufacturing tests and inspections**
- **AS 2473.2 Valves for compressed gas cylinders Part 2: Outlet (threaded) and stem (inlet) threads**
- **AS 2473.3 Valves for compressed gas cylinders Part 3: Outlet connections for medical gases (including pin-indexed yoke connections)**
- **AS 2568 Medical gases—Purity of compressed medical breathing air**
- AS 2896 Medical gas systems—Installation and testing of non-flammable medical gas pipeline systems, and
- **AS 2902 Medical gas systems—Low pressure flexible hose assemblies.***

They are also proposed to be cited in Schedule 4 of the HBA Regulation to define the work of mechanical services and medical gas work and medical gas fitting.

*We recommend removal of the standards in bold above from the regulations for two reasons:

1. They are not a part of the work of a medical gas fitter or medical gas technician who will have no control over their application within a medical gas system. These standards are used by the manufacturer of the devices which are subject to these standards, not the medical gas fitter or medical gas technician.
2. By mandating that the medical gas installation be compliant with *AS 2896 – Medical gas systems – Installation and testing of non-flammable medical gas pipeline systems*, automatic compliance with these standards, along with twenty seven other AS NZS standards, five ISO standards, one ANSI standard and one National Transport Commission Code, all of which are normatively referenced in Appendix A of AS 2896, and compliance with is required for the installation.

The proposed clause 69A (2) of the G & E Regulations cites *ISO 7396-1:2007 Medical gas pipeline systems- Part 1: Pipeline systems for compressed medical gases and vacuum* as an acceptable international standard to which a compliant medical gas system could be constructed.

In citing the ISO standard in this way, the proposed regulations completely bypass the standards development or adoption of international standards processes Standards Australia has in place, and supported by all State and Territory government and the Commonwealth government to ensure standards published in Australia delivery safe products and processes for use by our community.

Standards Australia has a process whereby international standards (ISO and others) are reviewed by their expert committees and, where appropriate, may be adopted as an 'AS ISO' standard in lieu of developing a unique AS. ISO 7396-1 has been considered by the expert committee responsible for development and maintenance of AS 2896, and it cites the following differences and reasons in the preface of AS 2896 for not adopting the ISO document as an Australian Standard –

- *Testing procedures in this edition [AS 2896 – Ed] are more in keeping with Australian industry practice;*
- *Performance criteria vary substantially;*
- *Copper piping specification differ;*
- *Medical participation in commissioning is required by AS 2896.*

One of the fundamental advantages we have in Australia is the longstanding history of AS 2896 as a standard for medical gas systems which allows interoperability and interchangeability of medical gas equipment within an institution and between institutions because of the universal adoption of gas specific terminal outlets as specified by AS 2896.

Allowing an alternative such as ISO 7396-1 would compromise this interoperability and interchangeability and allow the potential for installation of 'orphan' installations built to a different standard, or worse, an installation which has been modified/repaired/expanded having segments built to conflicting standards.

By way of comparison, it would be the equivalent of introducing an alternative to the ubiquitous three pin plug on electrical appliances and wall outlet we are all familiar with for electricity distribution with an alternative without any formal process of risk/hazard assessment or consideration of the consequences.

Engineers Australia Strongly recommends that any reference to the ISO 7396-1 standard as an acceptable alternative to AS 2896 be removed from the draft.

4. *Is there any more information that should be included in the safety and compliance test notice?*

Engineers Australia wishes to express its concern that it would appear from the consultation document that it is acceptable for a medical gas fitter to undertake both performance and compliance testing of a medical gas installation.

While we consider it acceptable for a medical gas fitter to undertake performance testing of an installation, it should not be acceptable for them to undertake compliance and commissioning testing. To do so raises the potential for them to carry out performance and commissioning of a medical gas system they have also installed, and thus remove the safety net of independent testing by a second competent person. This is the very set of circumstances this regulatory framework should be designed to prohibit.

5. *Are there enough reporting requirements to the Secretary on the testing, and are they suitable?*

Engineers Australia believes these requirements are practical and adequate and has no further comment to offer.

6. *Are the requirements in relation to reporting defective medical gas installation work appropriate? If not, what further directions could be placed on a 'responsible person'.*

By and large, Engineers Australia considers the reporting requirement adequate, with one exception. It appears there no defined timeframe or time limit by which a report of non-compliant work must be issued or in which the non-compliance must be corrected.

Engineers Australia recommends specific timeframes be set for both circumstances. These may vary depending on the nature of the non-compliance, with non-compliances rated as minor or significant and appropriate rectification time limits set for both.

7. Do you think the compliance provisions are adequate and fit for purpose? If not, explain why.

As written, the reporting requirement appears to be focusing on a pre-compliance inspection/review scenario and does not consider reporting requirements surrounding defective work found post-commissioning which may render an installation unsafe.

Further, as written, it appears that the report is made only to the '*...responsible person for the non-compliant work.*' There is no provision for reporting the non-compliance to the responsible person from the facility or, in the case of non-compliant work found post commissioning, reporting the non-compliance to the Secretary. Time frames should be established for both circumstances with penalties for non-compliance.

A provision for reporting of non-compliances found post commissioning to the Secretary is particularly important in that 'repeat offences' by the same individual may be cause to withdraw a licence to undertake work on medical gas systems for reasons of lack of adequate competence.

8. Are there any factors that should be considered with licencing mechanical services in NSW?

Engineers Australia has no comments on this question.

9. Are there any other government departments that should be included in the information sharing arrangements?

Engineers Australia is not familiar with the structural or governance arrangements between the Ministry of Health and Health Infrastructure, but recommends that Health Infrastructure, as the government infrastructure procurement body for health care institutions and utilities such as medical gas installations embodied in those institutions, should be in the information sharing loop.

Thank you once again for providing the opportunity to comment on the draft regulations. Should you have any further queries in relation to our responses, please do not hesitate to contact Michael Flood at mike@locusconsulting.net.au

Yours Sincerely

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