THE FUTURE OF MEDICAL GAS

A Z7396.1-2012 Roundtable
INTRODUCTION

• George Pankiw, Director of Facilities Planning & Redevelopment Brant Community Healthcare System,
  • Member of CSA Medical Gas Technical Subcommittee

• Barry Hunt, President & CEO Class 1 Inc,
  • Chair of CSA Medical Gas Technical Subcommittee
  • Member CSA Technical Committee on Perioperative Healthcare
  • Member CSA Strategic Steering Committee for Healthcare
  • Standards Council of Canada representative to ISO for Medical Gases

• Paul Edwards, Vice-President VitalAire
  • Member of CSA Medical Gas Technical Subcommittee

• Jeff Smith, Business Development, Hemisphere Engineering,
  • Member of CSA Medical Gas Technical Subcommittee
TOPICS

• Background to Development of Standard
• Example Incidents
• New for 2012
• Questions from Audience
PUBLICATION TIMELINES

• 1975  Z305.1
• 1984  Z305.1-84
• 1992  Z305.1-92

The Great Struggle re: Harmonization with ISO

• 2006  Z7396.1-06
• 2009  Z7396.1-09
• 2012  Z7396.1-12
• 2015  Z7396.1-15

NEW
Amendments
2012 DEVELOPMENT PRINCIPLES

• Evidence-based approach

• Root Causes:
  • Lack of education
  • Lack of Professionalism
  • Lack of maintenance

• Solutions:
  • Combination of Performance text & Prescriptive text
  • Frequent updates – 3 y publication cycle for Standard
  • Med Gas Advanced Training program – CHES & CSA - 2012
  • Certification program(s) – CSA & UA – Installers 2012
**PRESCRIPTIVE NUMBERS**

- **1992**  50 ppm x 2 = 100 ppm
- **2006**  25 ppm  Samples were being failed as low as 25.7 ppm
- **2009**  100 ppm
- **2012**  100 ppm

**1992 - (3) Methane is a nontoxic substance and is classified only as a simple asphyxiant. Excursions up to twice the allowable limits shown in the table may be considered to be within acceptable limits, however, the source of the elevated level should warrant investigation.**

**2012 Solution**
  - Risk assessment
  - 90 Day provisional certification
NON-METHANE HYDROCARBONS IN BULK N2O

- Production method #1 - below limits of detection
- Production method #2 - 2 to 20 ppm ethane, propane, butane. Samples were being failed at 10 ppm

- 2009 – Table D.4 based on rationale of 1/10 TLV but non-methane hydrocarbon investigation trigger – 10 ppm
- Non-methane hydrocarbon TLV’s range from 800 ppm to 2700 ppm
- 1992 - (4) Nonmethane hydrocarbons are permissible at concentrations not exceeding 1/2 of the TLV.

- 2012 Solution:
  - Guidance that Table D.4 applies to pipeline contribution only, even though a single test is initially performed; 10 ppm is a trigger point only for investigation and a second test yields a delta value if required.
Example

CROSS-CONNECTION TEST FAILURE

• Cross-connect test signed off on by Inspection Body but not actually performed; oxygen and air cross-connected in one section of an Emergency Department for a year before cross-connect was discovered; Inspection Body lost SCC accreditation to certify medical gas systems.

• 2012 Solution
  • Installer performs 1\textsuperscript{st} cross-connect test
  • Installer signs off to HCF 1\textsuperscript{st} tests have been performed
  • Inspection Body is called in and performs 2\textsuperscript{nd} cross-connect test
Example

POORLY MANAGED O2 SHUTDOWN

• Oxygen shutdown on ward, filled line with Nitrogen, nurse hooked up flowmeter to patient, patient blue in chair

• 2012 Solution
  • Protocol Annex, including guidance for medical gas shutdowns, added to Standard
Example

VACUUM PUMPS SUCK 😊

• New vacuum pumps installed can’t meet hospital demand; isolation valve missing between source and distribution piping; interconnecting pipe from new pumps not full-size; vacuum exhaust pipe blocked; HCF forced to go back to old vacuum system until new replacement system installed.

• 2012 Solution
  
  • Commissioning Annex added
ARC FLASH EXPLOSIONS

- 600V arc flash explosion, created during supply system alarm simulation testing of a med vacuum system, narrowly misses service technician and hospital personnel

- 600V arc flash explosion occurs when panel door of ancient medical vacuum system is opened to investigate a chattering contactor

- 2012 Solution

  - Rationale Annex provides warning and guidance regarding arc flash and recommends only trained personnel using PPE service panels
Example

MED AIR FAILURE IN MAJOR HCF

- During generator testing, hospital electrician cut power to one of 2 feeds supplying 2 of 3 compressors; remaining compressor went out on high temperature; 32 cylinder reserve bank was emptied; security did not page engineering because they had been getting almost daily high temp alarms for years because system is undersized; medical air pressure dropped to 30 psi throughout building and shut down ventilators; pressure continued to drop to 17 psi because of consumption of oxy/air blenders in NICU.

- 2012 Solution
  - Single fault paradigm; commissioning; maintenance audits
Example

MED AIR DEWPOINT IGNORED

• New med air outlets fail certification on dewpoint; liquid-ring compressors with single dryer; dewpoint monitor not working and disconnected; 32 ventilators in HCF, 24 typically in use on any given day; Respiratory dept. worried about H1N1 pandemic in fall of 2009; Engineering dept. says “medical air isn’t needed, only 1 patient uses it”...does not want to repair or upgrade non-compliant source; HCF asks service company to take lab sample from reserve cylinders to pass dewpoint test.

• 2012 Solution
  • 3 y maintenance audits; single fault paradigm
MEDICAL GAS ALARMS TURNED OFF

- During CT scan renovations, electrical contractor turned off breaker to the CT alarm panel as well as 3 others he did not know about; alarms were off for a week.

- 2012 Solution
  - Alarm breaker labeling
  - Zone alarm systems shall each...be on a dedicated circuit for Medical Gas alarms. The circuit breaker shall be labeled with a control label, generally as follows, “Medical Gas Zone Alarm Panel(s). Do not turn off except in emergency. This breaker controls alarm panels monitoring _______________” (list specific zones).
Example

UNPROFESSIONAL INSTALLER

- One installer is repeatedly found to have cross-connects; four in one hospital; 7 in total in one city in 1 year.

- 2012 Solution:
  - Installer must take training courses in medical gas, available through CHES / CSA, UA, trade colleges
  - Installer must have completed new CSA Medical Gas Piping & Systems Installation Personnel Certification Program to earn a Medical Gas ticket; ticket is revocable.
INEXPERIENCED INSTALLER

• Installer purges final joint in main oxygen line with Nitrogen and reduces the Oxygen concentration throughout the entire hospital

• 2012 Solution:
  • Instructions not to purge final joint
  • Must have Inspection Body present for additions and modifications when brazing to existing lines
  • Installer must take training courses in medical gas, available through CHES / CSA, UA, trade colleges
  • Installer must have completed new CSA Medical Gas Piping & Systems Installation Personnel Certification Program to earn a Medical Gas ticket; ticket is revocable.
NEW!

AGSS

- AGSS now included in pipeline Standard
  - Active scavenging only
  - Closer harmony to US NFPA and ISO global approach
  - Applies to new projects only
  - Duplex pumps for small systems; triplex for large
  - Piped, valved, and alarmed just like med vac
RISK ASSESSMENT

• Many clauses now require the HCF to perform a risk assessment in accordance with CSA Z1000 – e.g. – locations of alarms and terminal units; capacity of supply systems; and repairs.

• Offers the HCF more flexibility in design and operation
COMMISSIONING

• New pipeline work now requires:

  • Testing by the installer – pipeline leak test; terminal unit pressure-drops; particulate test; cross-connect

  • Commissioning by the designer or designate to ensure performance compliance – pipe sizes, valve placement, supply system pressure and flow performance

  • Inspection to ensure conformance to CSA Z7396.1 – same as installer tests plus gas identity and minor component gas sampling
NEW!

PROVISIONAL CERTIFICATION

• If a non-compliance is found by the Inspection Body, the HCF may request a 90 day provisional Certification

• Provisional Certification requires the HCF perform a risk assessment in accordance with CSA Z1000 and complete a form found in the Annex of the Standard

• Upon correction of the non-conformance within 90 days, the Inspection Body shall provide a Certificate of Compliance
MAINTENANCE AUDIT

• Medical gas pipelines shall be serviced and maintained in accordance with Chapter 15

• Defective components shall be repaired or replaced immediately, or tagged out following a risk assessment by a qualified person

• The administrator is responsible for the maintenance program

• A record of maintenance of all medical gas pipeline components shall be kept for the life of the pipeline

• The maintenance record shall be subject to audit every 3 years

• Lack of maintenance is one of the 3 leading causes of medical gas incidents reported in the last 3 years
ANNEX A - RATIONALE

• Newly expanded rationale providing more context and education to facilitate HCF risk assessment, improvements and / or flexibility in design, interpretations of the Standard, and general safety tips

• e.g. - A.5.3.2.2 Carbon dioxide manifolds are designed for use with gaseous carbon dioxide only and are supplied with a CGA 320 connector. Siphon carbon dioxide cylinders, with the same CGA 320 connectors, are designed for liquid carbon dioxide service only and withdraw cold liquid carbon dioxide through an abductor tube from the bottom of the cylinder. The cold liquid can and will freeze and plug manifold components, especially small orifices in the primary regulators. This creates two simultaneously dangerous conditions:
  (a) it stops the flow of gas from the manifold into the pipeline and can therefore endanger the patient by causing an immediate cessation of laparoscopic surgery; an
  (b) trapped cryogenic liquid will warm to room temperature, converting to a gaseous state in the process and expanding greatly in volume, and ultimately lead to dangerous and possibly life-threatening over-pressurization.

• e.g. - A.5.6.3.7.1 The −32 °C minimum dew point level was chosen for consistency with ISO 7396.1 (water vapour content of 67 mL/m3 = −45 °C, atmospheric dew point = −32 °C, pressure dew point at 350 kPa).
NEW!

PROTOCOL ANNEX - SHUTDOWNS

- Informative only

- Working plans shall be in place prior to any med gas shutdown and shall include contractor, designer, gas supplier, and Qualified Person from HCF

- Elements of a Working Plan are included

- Backup supplies shall be in place

- Contingency plan shall be in place

- Inspection Body shall be consulted and shall be present during shutdowns for additions and modifications
TABLES AND FIGURES UPDATED

• Gas flow charts finally updated after 35 years

• Supply system figures updated for clarity and consistency
  
  • e.g. – new “Hyperbaric Chamber Demarcation Point” identified as one of three possible terminations of the pipeline (along with a terminal unit and junction point for MSU’s)
NEW!

ADDITIONS, MODIFICATIONS & REPAIR

- New definitions for these terms
- New flow chart identifies how to classify proposed work and whether or not Inspection is required
Q. STANDARDS

- Which Standard do I use?
Q. MEDICAL AIR DEWPOINT

• Why did dewpoint change in 2006 and again in 2009?

• My Medical Air system was installed and inspected to 1992. I have not modified it. Now the Inspection Body is failing my annual lab sample based on dewpoint. Is this right?
Q. BULK OXYGEN

- We changed gas suppliers. Which Standard should the new system be
  Inspected to? The gas supplier says the latest edition mandated by the
  Provincial Building Code. The Inspection Body says whatever edition
  they are SCC accredited to. The Healthcare Facility would prefer the
  latest published Standard. Who is right?
Q. AGSS

• Can I use my Medical Vacuum system?

• Can I still use my old Passive Scavenging system?
Q. ITEMS NOT ADDRESSED IN STANDARD

- The standard makes no mention of special conditions such as the use of wave guides for MRI suites and as a result we have failed our inspection?

- I want to pipe Argon into my OR. Does Z305.1-92 or Z7396.1 (any edition) apply?
Q. INSPECTION REQUIRED?

- I’m changing a few outlets from quick connect to DISS. Do I need to get re-inspected?
Q. CERTIFICATION OF TECHNICIAN DOING TESTING?

- what will the testing frequency be and what will the certification required for technicians doing the testing?
Q. FIGURE 9

- Please see attached Fig 9 from prevailing CSA Code. Please note that this new code requires a pressure switch on each header bar to indicate BANK LOW PRESSURE. This now means that each manifold for all gases requires 5 alarm conditions as per following example:

  1. Oxygen Left Bank Low Pressure
  2. Oxygen Right Bank Low Pressure
  3. Oxygen Reserve in Use
  4. Oxygen High Line Pressure
  5. Oxygen Low Line Pressure

- Has anyone questioned this code requirement at the committee level?
- At what pressure would you or could you activate N20 or CO2 which maintain a constant pressure until all liquid has vaporized
ANY MORE QUESTIONS?
SUMMARY

• Evidence Based Design / Patient Safety

• New clauses for 2012

• Risk assessment by HCF to help

• Maintenance Audit

• Period of public review
  • Get involved by reviewing and commenting
  • It’s your standard too
  • Some of these changes may cost HCF more

• Coordinated CHES response