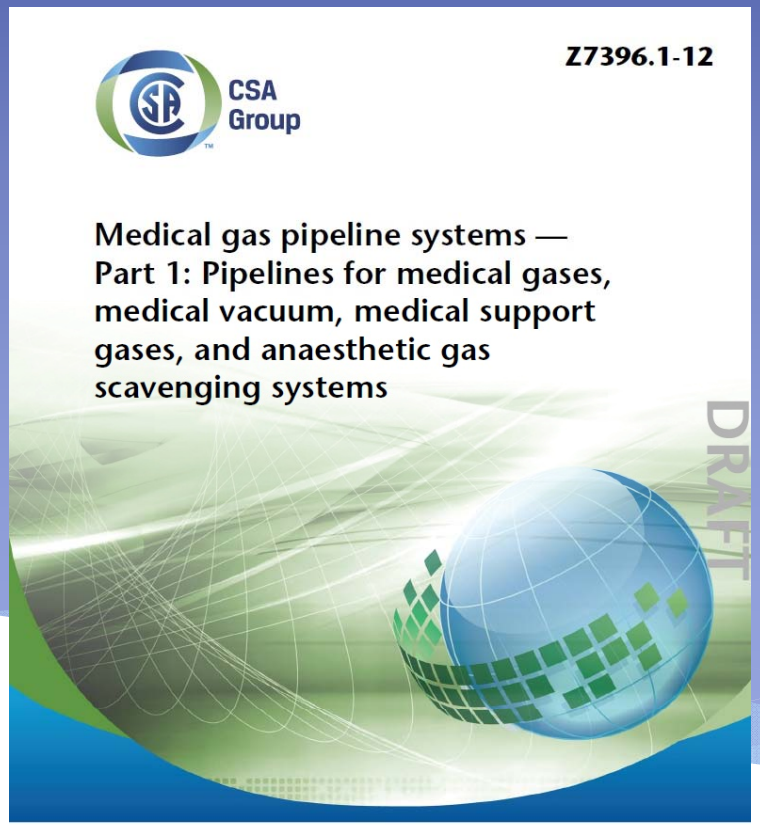
Protecting Patients from Bad Gas, Wrong Gas, No Gas Situations

CSA Z7396.1 2012

Barry Hunt

CLASS 1 INC.
Building Better Healthcare™



Jeff Smith

ENGINEERING HEMISPHERE

CSA Strategic Steering Committee On Healthcare

- 129 CSA Healthcare Standards
  - Products
  - Standards of Practice
  - Environmental
  - Guidance documents
- Training Programs
- Accreditation

- Regulation
  - Medical Device Act
  - Building Code
    - Z8000 - HCF Design
    - Z317 Series - HVAC, Commissioning
    - Z32 - Electrical
    - Z7396.1 – Med Gas

CSA Medical Gas TSC

- Develop Med Gas Pipeline & related Standards
- Provide input into ISO Standards
- Provide interpretations of the current Standards

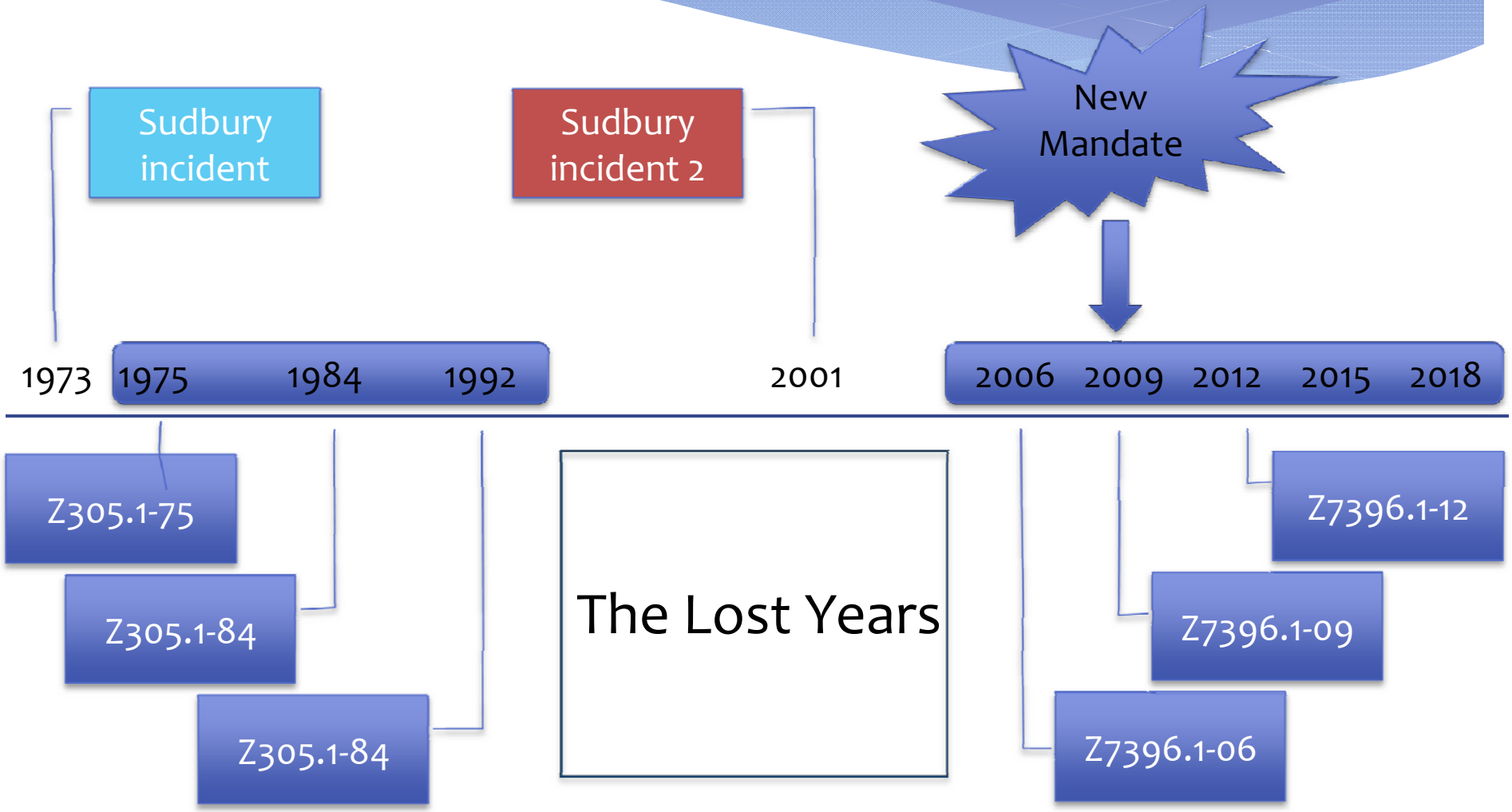
CSA Med Gas Membership

- Voluntary
- Interest, capability and funding
- Experience in Medical Gases
- Regional representation
- East, West, Central Canada & US
- Balance of stakeholders
- Producer, User, Regulatory

CSA Med Gas Member Interests

Users	HCF Maintenance / Engineering HCF Respiratory HCF Anesthesia HCF Med Gas Tech
Regulatory	Inspectors
Producers	Med Gas Suppliers Med Gas Equipment Suppliers Installers Maintenance Contractors Testing Laboratories Consulting Engineers

Evolution of the CSA Med Gas Pipeline Standard



Committee Focus

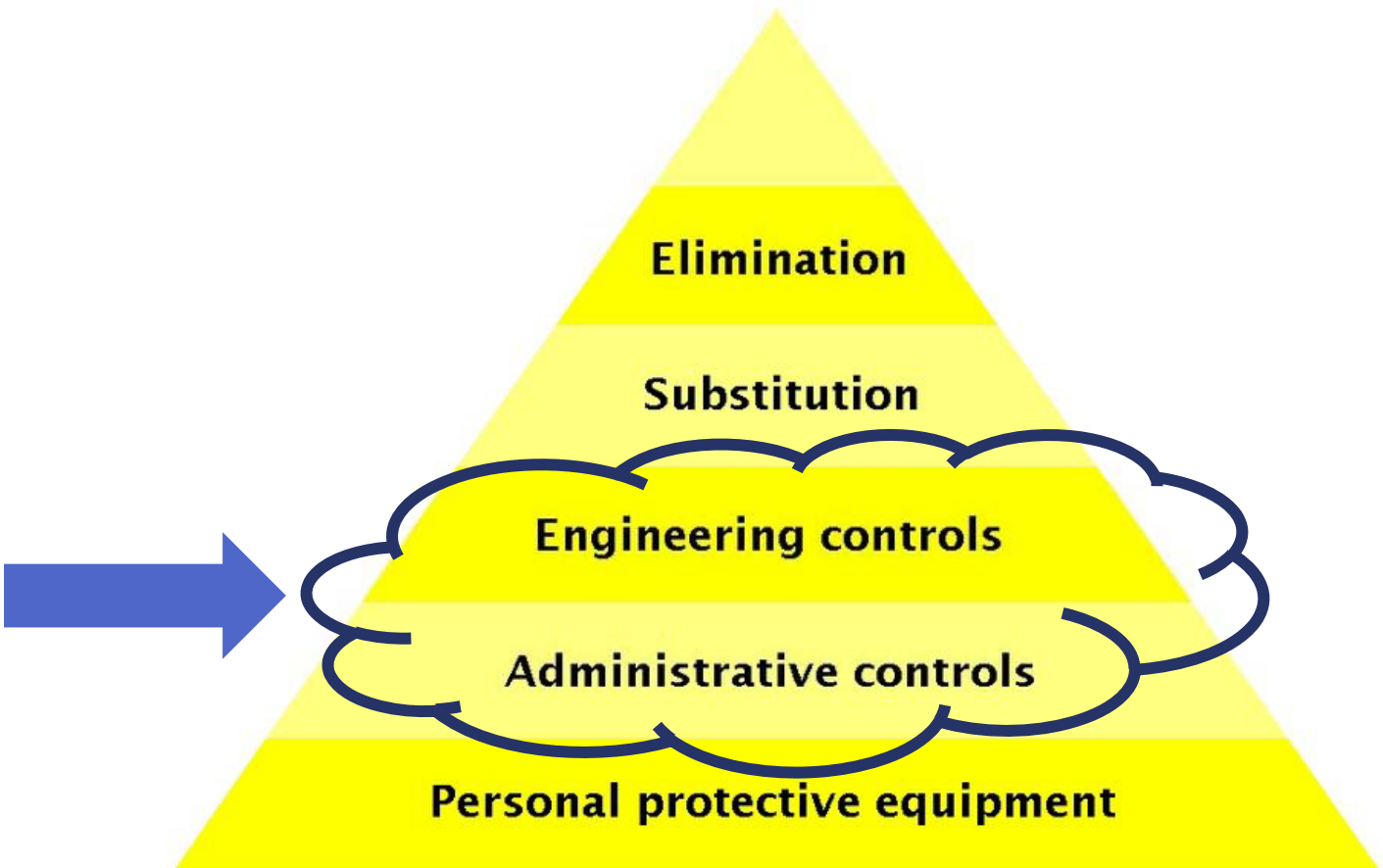
Patient safety

Bad Gas, Wrong Gas, No Gas

Occupational Safety

Fire, Explosion, Cryo, Bio, Asphyxiation

Hazard Control



Prescriptive vs Performance

Prescriptive = recipe for safety

Performance allows for best practice to evolve and encourage development and innovation

Balanced approach – prescriptive where applicable for safety, clarity, consistency; otherwise performance

2009

A mix of both Prescriptive and Performance clauses.

Maintenance added.

A Rationale Annex added.

Medical Air dewpoint changed to -32 deg. C @ 50 PSI

Instrument Air added.

2009 Guidance to Future CSA Standard Format

Use performance language where practical but maintain prescriptive style where prudent based on risk analysis, user interest, clarity and testing

Continue to add context and guidance to Annex A rationale

Develop and add safety objectives for each prescriptive clause

Will result in recipe for success with flexibility for innovation

Evidence-Based Standards

Incident Reports

Anonymous but verifiable, collected by committee members

Root cause determinations

- Don't know
- Don't care

Top 2 areas of concern

- Installation
- Maintenance

Example Incident Reports

No	Year	Prov	Reporter	Incident Near Miss RFI or Grey area	Description	Hazard(s) RFI Type	Risk (L,M,H)	Severity (L,M,H)	Causes	Solutions, Input	Impact to Standard(s)	WG(s)
1	1995	ON	Barry		desiccant dryer tower corroded completely through	No Gas; Explosion	H	H	High chlorine level in water supply to liquid-ring compressors produced high level of chlorine in med air stream...filters, piping, dryer vessels severely corroded	filter chlorine out of water supply with activated carbon filters; use oilless compressors	Z7396-1	Supply Systems (Z7396-1 Clause 5)
2	1999	ON	Barry		New med air system supplied for NICU undersized	No Gas	M	M	1) Guidance from Z305.1 flawed; 2) application of Z305.1 guidance for entire acute care facility, including flow rates and diversity factor, inappropriately applied to ultra-high usage area	size according to usage, not # of outlets; take into account appropriate duty factors for pump technologies, esp. oilless recip	Z7396-1	
3	2001	PE	Peter Emch via Barry		Odour detected in ICU from ventilators	Bad Gas	M	H	Refrigerant contamination in medical air line from defective refrigerant dryer	do not use refigerant dryers	Z7396-1	Supply Systems (Z7396-1 Clause 5)
4	2001	NS	Peter Emch via Barry		Med Air sample failed on chloroform	Bad Gas	M	M	Chlorophyll-loving bacteria in surface water supply to liquid-ring compressors produced chloroform which entered the medical air stream	use chlorinated water sources for liquid-ring compressors; use oilless compressors	Z7396-1	Supply Systems (Z7396-1 Clause 5)
5	2003	US	Paul		Oxygen cylinder became projectile in MR field	Blunt force trauma	L	H	lack of knowledge or experience with magnetic field environments	use pipeline source of oxygen and MR compliant materials within the magnetic field	Z7396.1	pipeline
6	2003	MB	Barry		dryer prefilters corroded through	Explosion	H	H	High chlorine level in water supply to liquid-ring compressors produced high level of chlorine in med air stream...filters, piping, dryer vessels severly corroded	filter chlorine out of water supply with activated carbon filters; use oilless compressors	Z7396-1	Supply Systems (Z7396-1 Clause 5)
7	2004	ON	Barry		Cross-connect in MSU's shipped to site - Oxy & Air; found by contractor after MSU installation	Wrong Gas	M	H	manufacturer - poor quality control	Always test at user connection; advice (in rationale) - check MSU's before installation	Z7396.1; Z305.8	Testing; Installation; MSU's
8	2005	ON	Barry		Infant died in LBRP when the suction failed and the nurse	No Gas	M	H	Old-style quick-connect Vac outlet had a broken internal	Use DISS outlets; test outlets regularly (pressure drop test is a	Z7396-1	Maintenanc e &

3-Pronged Solution for 2012

Standards	**CSA**
Training	**CSA + CHES ; CSA + UA**
Accreditation	**CSA + UA**

2012 Plan

1. HCF Responsibilities defined
2. Policies & Procedures
    - Shutdowns
    - Alterations
    - Maintenance
3. Training & Education Requirements
4. Expanded explanatory Rationale annex

2012 Actual

1. AGSS
2. Installer training, qualification and license
3. Risk analysis in accordance with CAN/CSA Z1000
4. Provisional inspections – 90 days
5. Hyperbaric demarcation point
6. Shop drawings and as-builts required for certification
7. Table D.4 contaminant testing changes
8. Exemption criteria changes for small systems
9. Policies and procedures
10. "Qualified Person" to supervise shutdowns, etc.
11. Expanded explanatory Rationale annex
12. New pipe sizing charts (first in 40 years)
13. New guidance for Additions, Modifications and Repairs.

Original Six

Oxygen, USP

Nitrous Oxide, USP

Carbon Dioxide, USP

Nitrogen, NF

Medical Air, USP

Medical Vacuum

Expansion

Laboratory Air (2006)

Laboratory Vacuum (2006)

Instrument Air (2009)

Anesthetic Gas Scavenging (2012)

Oxygen Concentrators (2015)

Plume Scavenging (2015?)

Facility Risk Assessments

- Is an important addition to the responsibilities of Healthcare Facilities
- Uses CSA Z1000-06 as the basis to to assess acceptable risks and means to manage them
- Allows involvement of HCF in decision making process

Changes to Instrument Air

- Recognition 09 requirements were too restrictive
- Classified as a utility gas and not for patient care
- Purity and quality is maintained
- Dewpoint is -40° C (Med Air is was adjusted to -5° C)

Hyperbaric Demarcation Point

- Hyperbarics – different application but need for safety exists
- Guidance from the governing body was requested
- Recognition gases are medical even though pressures and equipment are different

“Small Systems” become an exception…

- Recognition outpatient settings are different but not when it comes to safety
- Maintain no gas, wrong gas, bad gas focus
- Provides scalability based on clinic type and size

Scavenging Systems – the new Section

- Scavenging systems were in "no mans land" – the previous "ISO" AGSS Standard was withdrawn in 2010
- Active systems only
- Separate from med vac
- May use slightly lower vac level

AGSS "Air Break"

New Maintenance Requirements

- Largely based on incident reporting data
- "Qualified Person"

  one with professional training and/or extensive knowledge and experience in the subject field who is capable of analyzing performance and specifications in the subject work, project, or product.

- 3 year audit

Annex J – Maintenance Audits

Audit/Verification of compliance with Clause 15 — Maintenance and ongoing verification

J.1 General*

In accordance with Clause 15.1.6, an audit/verification of the health care facility maintenance program shall be completed every 3 years by a qualified person or organization

A. Annex J, J.1

Failure to comply may affect liability and heighten risk. Lack of maintenance has been identified as a significant root cause of medical gas incidents or failures.

Training for Operators

A joint venture between CHES and CSA

2010 - Med Gas 101

- online course and exam
- For everyone involved in Medical Gases

2012 - Med Gas Advanced

- 2-day hands-on course
- For "Qualified Persons" (1 – 2 per facility)

Installer Qualifications & Certification

Response to: Don't Know or Don't Care Incidents

11.4.1.1
An installer shall meet the requirements of CSA *Medical Gas Piping & Systems Installation Personnel Certification Program* or equivalent.

11.4.1.2
Prior to any installation, with the exception of stationary liquid supply systems, installers shall submit evidence of qualification to install medical gas systems to the health care facility for insertion into its permanent records.
Note: *In Canada evidence of qualification to install medical gas systems consists of a valid medical gas license meeting the requirements of CSA* Medical Gas Piping & Systems Installation Personnel Certification Program *or equivalent.*

11.4.1.3*
If applicable, prior to any installation, installers shall submit a valid brazing licence, as issued by an authority having jurisdiction in accordance with CSA B51, to the health care facility for insertion into its permanent records.

Training & Accreditation for Installers

1984 - Brazing Certificate Required – Provincial

Provincial Accreditation (Liscence) required for NB & NF

2012 – Pipeline Standard Requires Accreditation

2013 – National Installer Accreditation Program

- A joint venture between UA and CSA
- 40h course
- Supervised exam
- Revocable license

Roles and Responsibilities

Installer

Brazing certification
Med gas training
Med gas license
Install systems
Commission systems
Test systems
Provide test confirmation
Provide as-built drawings
Witness inspection

Health Care Facility

Employ or contract a "qualified person"
Operate & Maintain systems
Maintain as-built drawings
Maintain Certification Reports
Hire licensed installers
Witness inspections
Risk Assessments

Inspector

Quality Management System
Accreditation by SCC
Inspect new installations
Confirm Installer qualifications
Confirm as-built drawings maintained
Provide Certification Reports
Provide Provisional Certification Reports

Qualified Person

Professional training, knowledge, experience in med gas
Authorize shutdowns, repairs, return to service
Audit Maintenance records (3 y)

Provisional Reports

12.5.5

The health care facility shall obtain documented evidence from the inspection body that the system is in compliance with this Standard, as determined by the tests in Annex C or D, as applicable. The inspection shall be witnessed by the installer and the health care facility representative. The health care facility may elect to accept a **provisional report** on a temporary basis as defined in Clause 12.6.1.4. See Annex K.

12.6.1.4

When the results of the inspection fail to meet the requirements of this Standard, the inspection body shall issue a **provisional report** detailing the results of the test completed to date together with a list of system non-compliances. The provisional report's non-compliance items shall be addressed and be re-inspected by an inspection body within 90 days; otherwise the inspection report shall become null and void. Once non-compliance items are corrected and inspected by an inspection body and found to be in compliance, the inspection body shall issue a certification report.

Medical gas piping system provisional inspection report

Annex K
Provisional Inspection

Note: *This Annex is an informative (non-mandatory) part of this Standard.*

Date: _____

Health care facility: _____

Project scope: _____

Provisional inspection report of test results to date includes project compliance to Clauses 12.6.2 and/or 12.6.3 with the following exceptions:

Project non-compliant to the following clauses: _____ _____

_____ _____

Health care facility* shall complete risk assessment as per CAN/CSA-Z1000 for the non-compliant components listed above.

**It is recommended that the health care facility consult with experts in the field that may include clinical staff, suppliers, installers, inspection bodies, and consultants.*

Upon completion of risk assessment, the health care facility shall determine whether or not to accept the system for patient care use as is.

Signature of health care facility representative _____

Re-inspection date to be completed by: _____

Non compliant components shall be corrected within a 90-day period. Non-compliant components shall be retested to confirm compliance after which a certification report for project will be issued. Failing to address non-compliant components within 90 days will render the Provisional Inspection report null and void.

Witness: Health care facility _____

Installer _____

Inspection body _____

Pipe Sizing Charts – updated and verified

- Pipe sizing charts had not been validated since 1980's
- Charts provide and information source but good engineering and fact finding is still key
- E.3

  There are several ways to use the charts. The most usual is to group the load in a branch as if that load was all at the farthest point of a branch, then use the figures to determine the pipe size for that branch.

  Where branches join, the summed load of the branches is assessed at that point and the figures used to determine a size for the common line. Pipe sizes always increase as one moves from the farthest terminal toward the source.

Annex A – Practical explanations

- 2009 - 6 pages; 2012 – 19 pages
- Provides context, design & implementation guidance, education
- Organized numerically and clause specific
- Example:

  A.5.6.1.4

  Some incidents have occurred where liquid has been drawn into the medical vacuum piping system. In a recent incident a large volume of fluid entered the vacuum supply system causing all pumps to fail, leading to a complete loss of vacuum throughout the facility. The facility installed a liquid interceptor to prevent a future catastrophic failure. A risk assessment in accordance with CAN/CSA-Z1000 should be completed to determine if a liquid interceptor should be installed or other means should be applied to monitor or control the unintended ingress of liquids.

Annex H - Suggested Protocols

Shutdowns

H.1.1*

Procedures shall be in place to provide alternate medical gas and/or vacuum prior to shutting down any portion of a pipeline.

H.1.2*

The health care facility shall ensure, in conjunction with contractors, gas suppliers, consultants, and staff that a risk assessment is conducted in accordance with CAN/CSA-Z1000 to ensure risk to patients and facility is minimized.

H.1.3*

The health care facility shall develop a working plan prior to each scheduled shutdown.

H.1.4*

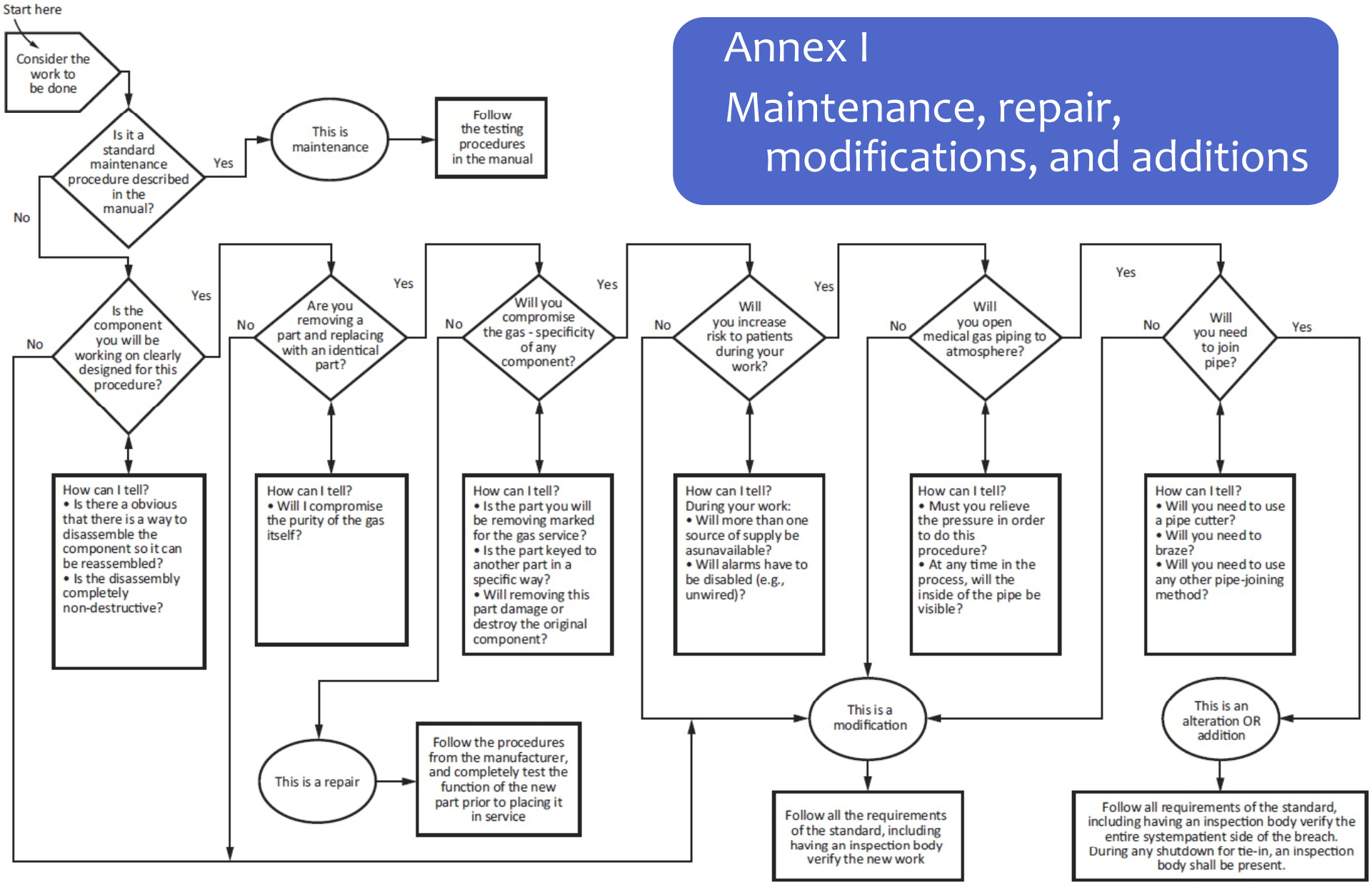
The health care facility shall conduct preliminary test(s) to determine suitability and functionality of backup equipment.

H.1.5

An inspection body shall be present during any shutdown where modifications or additions are made, and shall otherwise be consulted prior to shutdowns to ensure compliance with this Standard is maintained and risk is mitigated.

Annex I

Maintenance, repair, modifications, and additions



2015 Plan Ideas

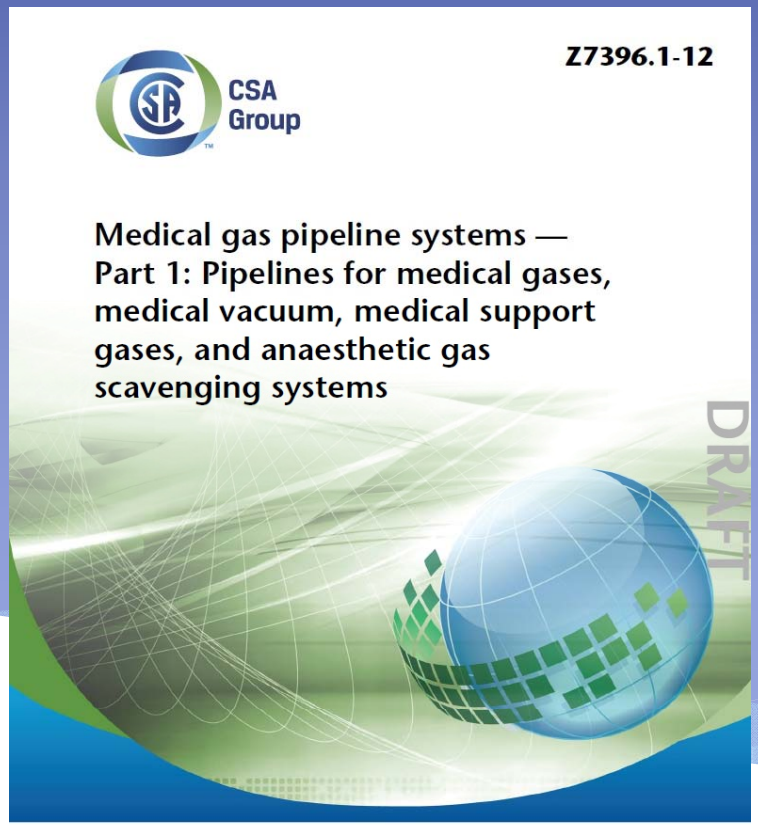
1. Plume Scavenging
2. Oxygen Concentrators
3. Inspection of Maintenance Audits
4. Accredited “Qualified Person”
5. “Qualified Person” Responsibilities
    - Manage shutdowns
    - Respond to Med Gas Emergencies
    - Fire response team
    - Verify fire control
6. Additions to Policies & Procedures
7. Permanent certification exceptions allowed based on risk analysis
8. Technology friendly
9. Environmental
    - Energy
    - N_2O

2018

TBD :)

Any Questions?

CSA Z7396.1 2012



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