GOTCHA! MEDICAL GAS SYSTEMS
COMPLIANCE & SAFETY

Steve Bradshaw   |   ASSE 6050   |   Medical Gas Instructor
Steve.Bradshaw@evergreenmedical.com  |   800-872-8992

WWW.EVERGREENMEDICAL.COM
Component “Inventory” should include the manufacturer, model, & gas system ... not just an outlet count

Inspecting, testing, & maintaining (EC.02.05.09) medical gas components (time frame defined by hospital)

• Annual =12 months +/- 30 days

Corrections to deficiencies cited by TJC or CMS must be done in 60 days

If “self found” there is no time frame

Mapping (EC.02.05.01) of the distribution & labeling of shutoffs for partial & complete emergency shutdowns (CGA E.10-2013 specifies “Riser Diagram” with very specific guidelines)
TJC defines a medical gas failure that causes a minor injury as a Category 1 system.

Per NFPA it would be Category 2.

NFPA 99, 2012

4.1.1* Category 1. Facility systems in which failure of such equipment or system is likely to cause major injury or death of patients or caregivers shall be designed to meet system Category 1 requirements as defined in this code.

TJC - EC.02.05.09: The hospital inspects, tests, and maintains medical gas and vacuum systems.

- Elements of Performance

Medical gas, medical air, surgical vacuum, waste anesthetic gas disposal (WAGD), and air supply systems in which failure is likely to cause major injury or death are designated as follows:

- Category 1: Systems in which failure is likely to cause minor injury to patients
Facility’s governing body establishes the “category” of the system or space as well as the level of anesthesia by a documented risk assessment procedure.

A Risk Assessment is still required for category 1 spaces until CMS & TJC adopt 2015 or more recent editions of NFPA 99.

How is the patient, visitor or staff likely impacted in the event of a medical gas or vacuum system failure.

- **CATEGORY 1 :: MAJOR INJURY OR DEATH**
- **CATEGORY 2 :: MINOR INJURY (NO MECHANICAL VENTILATION, GENERAL ANESTHESIA)**
- **CATEGORY 3 :: DISCOMFORT**
NFPA REQUIRED TESTING per 5.1.14

Central Supply Systems (e.g. Oxygen Bulk, Medical Air Compressors, Manifolds, Vacuum System):
- INSPECTED ANNUALLY, MAINTAINED BY A QUALIFIED REPRESENTATIVE, & RECORD KEPT FOR THE AHJ

The Oxygen Supplier (Airgas, Linde, Air Products) performs an Oxygen Bulk Equipment Inspection

Periodic/Routine Testing & Inspections of Medical Gas & Vacuum Systems
- ALARM TESTING - AUDIBLE & VISUAL INDICATOR FUNCTION
- OUTLETS & INLET PERFORMANCE (INCLUDE FLOW & PRESSURE)

Medical Air, Vacuum, & WAGD Source Equipment
- PM’s PER MANUFACTURER’S RECOMMENDATIONS
- ANNUAL CALIBRATION OF CARBON MONOXIDE MONITOR
NFPA CODES THAT APPLY TO EXISTING SYSTEMS

- Potential fire/explosion hazards
- Labeling of Tanks & Manifold Rooms
- Cylinder & Container Handling & Locations
- Manifold Room Ventilation & Temperatures
- Medical Air Usage – no Endoscopy scope cleaning or SPD (Air or Vac!)
- Equipment Maintenance, Labeling, Inspections, personnel qualifications

5.1.14.1.4* The medical–surgical vacuum and WAGD systems shall not be used for nonmedical applications (e.g., vacuum steam condensate return).
Labels must be visible from outside of the zone valve enclosure

Examples:
- OUTSIDE OF THE ASSEMBLY
- INSIDE THE ASSEMBLY BUT VISIBLE FROM OUTSIDE
- BOTH INSIDE & OUTSIDE OF THE ASSEMBLY

May not be affixed to the removable cover

Per the NFPA 99, Handbook (since 2012) every individual room number is not required on the zone valve label. Example: continuous rooms may be labeled “301-330”.
LABELING APPLIES TO NEW & EXISTING

- Valves in the ceiling
- Pipe labels
  - Proper CGA colors
  - Every 20 feet
  - Both sides of walls & floors
  - Do not paint
- Source Labeling
- Manifold Entry Labels
- Gas or Vacuum Hoses – new to NFPA 99, 2018
  - Proper CGA colors (no clear hoses)
  - Installation Date
Outlets & Inlets that are facing downward must be DISS.

It would be inconvenient to have DISS on columns & quick connect outlets on walls.

It would be better to use DISS throughout the OR suite.
USP 93 OXYGEN SUPPLIES APPROVED

- 93% Oxygen or 99% Oxygen approved

- These supply sources have been included in ISO & Canadian standards for several years.

- NFPA needed to address concentrators since NFPA is the preferred code for many countries & regions where these systems are an important option.

- Pressure swing adsorption (PSA) & vacuum swing adsorption (VSA).

- It takes 0.8 kWh per m$^3$ of O$_2$ by using VSA.

- VSA can produce the equivalent of 100 gal of liquid oxygen per day for a year with an energy cost of ~$10,000.

- 3 producers - each providing peak flow (not average flow)
DON’T CALL IT INSTRUMENT AIR!

Instrument Air or Nitrogen is required for surgical instruments.

“Nonmedical Air,” per chapter 8, is a less expensive option for 60 psi Boom Brakes, SPD, or Endoscopy Scope Room - does not require B819 piping, -40°F dewpoint, 0.01μm filtration, zone valves, area alarms, master alarms, installation by an ASSE 6010 installer, verification by ASSE 6030 verifier, & duplex compressors & dryers.

8.3.5.2
Nonmedical compressed air shall not be used for powering medical instruments or for human respiration.
Outlet Leaks

- **O-Ring Age & Wear**
  Exposure to dry medical gases (especially Oxygen & Ntirous Oxide) reduces the life

- **Weak Springs**

- **Debris (copper burrs, copper oxide, or vacuum debris)**

- **Excessive weight connected to outlets**

- **Use only Oxygen Safe Lubricants**

Use only Oxygen Safe Lubricants
VACUUM INLET BLOCKAGE

- Clogging of inlets with lint, debris, or dried body fluids reduces flow
- Enzyme Flushing
  - Inject 50 ccs of protease enzyme & wait 15 min
  - Open inlet, test, & repeat if necessary
- Vacuum systems should be considered contaminated
Medical vacuum source supply systems now require inlet filtration.

- **Efficient to 0.3 \( \mu m \) & 99.97 % HEPA or Better (Mistake by editing that shows 0.03 \( \mu \))
- **Means to observe accumulation of liquids (clear housing) & vacuum relief petcock.**

International standards have required bacteria filtration for years.

Only informal studies have been completed to test viable bacteria levels inside medical vacuum systems. Vacuum systems may not be a good vehicle for transmission of viable bacteria due to its lack of oxygen, moisture, copper, pump heat, & vacuum expansion.
Hoses inside movable booms & columns (not headwalls) must be checked every 18 months including:

Inspect hose condition, fittings/DISS connections

5.1.14.2.3.2 Non-stationary booms and articulating assemblies, other than head walls utilizing flexible connectors, shall be tested for leaks, per manufacturer’s recommendations, every 18 months or at a duration as determined by a risk assessment.
Corrugated Medical Tubing (CMT)

ASTM B103/B103M is permitted for field installed medical gas, vacuum, & WAGD tubing.

The installer of a CMT distribution system must be qualified as an ASSE 6010 Medical Gas Installer only.

- BRAZING QUALIFICATION NOT REQUIRED

T-Drills are not permitted with CMT systems.

Turns, offsets, & other changes in directions for a CMT made by bending up to the minimum bend radius.

CMT was demonstrated that it could meet the necessary fire resistance, burst pressure & cleanliness, & thus has been added to the code as an acceptable material within the limits specified.

Semi-rigid, copper alloy tubing, continuous length rolls, fire retardant jacket, & axial swaged brass end fittings.
Axially swaged fitting with extension for brazing to hard drawn copper tubing

Distance between supports are same as hard drawn copper tubing

½” to 2” tubing

Operating pressure of 185 psig with a safety factor of 3.5 (647.5 psig)

Plenum (fire retardant) rated jacket

Why will you see it installed: saves installation time, reduces hot work, fewer brazed joints and 90s, no drawing lubricants or degreasing inside tubing, long lengths on reel,
System inspections shall be performed by a(n) ASSE 6020 Medical Gas Systems Inspector or ASSE 6030 Medical Gas Systems Verifiers (independent of installation company) prior to concealing piping distribution systems in walls, ceilings, chases, trenches, underground, or otherwise hidden from view.

Per NFPA, Medical Gas Inspections include:

- WITNESSING THE INITIAL PRESSURE TESTS (MAY BE DONE BY 6020, 6030, AHJ, OR AHJ DESIGNEE)
- LABELING & VALVE TAGGING THAT WILL BE CONCEALED (MAY BE DONE BY ASSE 6020 OR 6030)
ASSE 6020 INSPECTIONS

DOCUMENTATION:

- BUILDING PERMIT
- MANUFACTURER'S LITERATURE AND DATA
- COPPER TUBING CLEANED FOR OXYGEN SERVICE
- COPPER FITTINGSS CLEANED FOR OXYGEN SERVICE (PACKING SLIPS & DATES)
- MANUFACTURED ASSEMBLIES CLEANED FOR OXYGEN SERVICE (MANUFACTURER(S))
- PROPER BRAZING ALLOY
- CERTIFICATES OF EACH MEDICAL GAS INSTALLER & BRAZER
- BRAZER PROCEDURE PERFORMANCE QUALIFICATIONS RECORD
- PRE-CONSTRUCTION INSTALLER MEETING
ASSE 6020 INSPECTIONS

**INSTALLATION INSPECTIONS**

- Use of proper materials
- Supports (hanger spacing 5-10') & penetrations sealed
- Proper handling of materials in work area
- Visual spot check of brazed joints
- Witness razing process (cutting, deburring, cleaning, assembly, \( N_2 \) purge, fill, cap, & cooling)
- Pipeline capped or plugged with nitrogen NF during installation process
- Pipeline labeled
- Proper installation equipment used (e.g. fire extinguisher, torches, hose, abrasive pads, lint free white cloths, purge regulator, \( O_2 \) analyzer, pressure gauge, vacuum gauge, \( N_2 \) purge alarm)
- Proper installation of alarms, manufactured assemblies, & source equipment
Enforceable when 2012 edition of NFPA 99 was adopted by CMS & TJC

Persons maintaining systems shall be qualified per one of the 3 options:

1) TRAINING PROGRAM FOR EACH FACILITY'S SPECIFIC MEDICAL GAS EQUIPMENT

2) ASSE 6040 32-HR MEDICAL GAS MAINTENANCE CLASS AND SPECIFIC EQUIPMENT TRAINING

3) ASSE 6030 32-HR MEDICAL GAS VERIFIER CLASS AND SPECIFIC EQUIPMENT TRAINING

* New code will require “specific equipment training” alone or with 6030 or 6040 – someone devalued the 6040 credential

5.1.14.2.2.5 — Qualifications

a) Persons maintaining these systems shall be qualified to perform these operations.

b) Appropriate qualification shall be demonstrated by any of the following:

1. A documented training program acceptable to the health care facility by which such persons are employed or contracted to work with specific equipment as installed in that facility.

2. Credentialing to the requirements of ASSE 6040, & technically competent on the specific equipment as installed in that facility.

3. Credentialing to the requirement of ASSE 6030, & technically competent on the specific equipment as installed in that facility.
Vacuum pumps with oil used for WAGD need to be tested for Oxygen + Nitrous Oxide % to verify that oxidizers are <23.6%.

... or use pump technologies where these gases do not come in contact with oil – e.g. claw, water sealed, dry vane pumps.

Use the exhaust or pump discharge drip leg valve to test during peak anesthesia levels (busy surgery day morning – every 5 min an hour).
At least one WAGD inlet is required where anesthesia is administered (even if Nitrous Oxide not piped in through outlets)

Vacuum inlets must be 5 ft from tee connection to WAGD inlets
VACUUM & WAGD PUMP TECHNOLOGIES

Oil Lubed Rotary Vane
- **PROS** - Deep Vacuum, Long Vane Life, & Low Noise
- **CONS** - Oil incompatible with oxidizers, can't ingest liquids & oil/filter changes

Dry Vane
- **PROS** - No oil anywhere
- **CONS** - Must change vanes ~4-5000 HRS & less flow per HP

Claw
- **PROS** - No air-end oil & little maintenance
- **CONS** - Initial cost & heat

Liquid Ring – Water
- **PROS** - Little maintenance & low temps
- **CONS** - Water usage, water quality & lower flow per HP

Liquid Ring – Oil
- **PROS** - Reliable, quiet & low cost
- **CONS** - Oil & maintenance

Oil Screw
- **PROS** - Larger machines available
- **CONS** - Oil, maintenance, noise & energy waste
MEDICAL AIR COMPRESSOR TECHNOLOGIES

**Scroll**
- **PROS** – EFFICIENT, LOW MAINTENANCE, QUIET
- **CONS** – MAX SIZE IS 10 HP (TWO COMPRESSORS MAY BE POWERD BY 20 HP MOTOR)

**Oil-Less Reciprocating**
- **PROS** – EFFICIENT
- **CONS** – MAINTENANCE, NOISE, & VIBRATION

**Liquid Ring - Water**
- **PROS** – MAINTENANCE & LONGEVITY
- **CONS** – WATER QUALITY, RELIANCE ON WATER, HIGH SEPARATOR WATER ALARM, HIGH RECEIVER WATER ALARM

**Oil-Free Rotary Screw or Rotary Tooth**
- **PROS** – LARGE SIZES
- **CONS** – ENERGY CONSUMPTION, MAINTENANCE, MAY BE WATER COOLED, CHANCE FOR OIL CONTAMINATION QUARTERLY HYDROCARBON TESTING HYDROCARBON FILTERS

**Quarterly Hydrocarbon Testing**

**Hydrocarbon Filters**
FINAL LINE TIE-IN

“DIRTY BURN”

- An outlet in the immediate downstream zone of the affected area (Both new and existing) shall be tested

It is not safe to use Nitrogen for pressure testing after the tie in is made to the existing system! The valve may leak or be accidentally be opened allowing Nitrogen to enter the existing oxygen system.
3 OF THE HIGHEST MEDICAL GAS SAFETY RISKS

- Cross Connections between different gas systems (Tested by installer, verifier & hospital).
- Unintended Shutdowns — caused by mislabeled valves & poor valve/piping diagrams.
- Particulate Matter — Copper Oxide caused by improper Nitrogen Purge during brazing, hydrocarbons, or chemicals.
Follow ASSE 6000 "Annex J" Standards for Medical Gas Shutdown & Backfilling

Connect regulators to "H" cylinders (~7000 Liters per cylinder) & hose adapter to wall outlet downstream isolation valve

At least 2 cylinders should be connected during a back fill (more if higher patient flow is required)

One cylinder valve is opened & reserve cylinder valve is left closed

Hospital representative shuts appropriate isolation valve & monitors cylinder & line pressure continuously during backfill

When the in-use cylinder(s) falls to 200 psi open reserve cylinder(s) & exchange empty cylinder(s) with full one

- Pre-Set Regulators - static pressure is 60 psi and dynamic is 45-50 psi with a max flow of 100 LPM
VENTILATION TESTING

» FGI 2014 recommends that positive pressure for ORs be tested semi-annually
» CDC recommends routine air exchange rates and negative pressure measurements
» Nuclear Medicine rooms must be tested semi-annually where xenon gas is used
» Evergreen recommends semi-annual testing, in part, to account for seasonal HVAC differences

References:
FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014
A1.1 Operating Rooms. Each operating room should be tested for positive pressure semi-annually or on an effective preventative maintenance schedule.

CDC Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005
Performance monitoring should be conducted to verify that environmental controls are operating as designed. Performance monitoring can include 1) directional airflow assessments using smoke tubes and use of pressure monitoring devices that are sensitive to pressures as low as approximately 0.005 inch of water gauge and 2) measurement of supply and exhaust airflows to compare with recommended air change rates for the respective areas of the setting.

RPR 27 Nuclear Medicine 12/2006
Air Exchange Rates for Nuclear Medicine must be checked semi-annually

References:
QUESTIONS?

Steve Bradshaw

steve.bradshaw@evergreenmedical.com | work 800-872-8992 | cell 828-423-3982