

Consultants Update

COVID-19

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Discussion Topics

- CGA SA-36 and GAWDA Safety Alert
 - FDA Guidance
- FDA Portal for submissions
- New Posters

CGA Safety Alert – SA 36

Temporary measures to consider to meet high demand during the COVID-19 crisis

- **Change of grade** – converting high pressure and cryogenic cylinders into medical gas service
- **DOT SP 21025** – temporary extension of requalification period
- **Colors** – considerations for color coding options
- **“Top-fill”** – vent and evacuation considerations
- **SB-26** – tamper-resistant connection considerations

CGA Safety Alert – SA-36

- The adoption of temporary measures should be formalized with:
 - A written “deviation” - approved by your Quality Control Unit
 - Documented personnel training
- When the temporary measures are retired, the process should be formalized with:
 - Closure of the “deviation” by your Quality Control Unit
 - Documented personnel training detailing the retirement of the temporary measures and restoration of your SOPs, FDA CGMP and CGA standards
- Contact tom@asteriskllc.com for the sample templates – Two versions

Alternative FDA Document Portal

- FDA staffers are working remotely – mail delays
- CDER NextGen Portal, Designated Medical Gas submissions

New Free CGA Posters

- Three critical steps that healthcare providers can take to support the medical oxygen supply chain:
 1. Understand their medical gas supply system needs and capabilities
 2. Manage medical gas container inventory
 3. Clean their medical gas containers
- Add your contact information
- Link to CGA P-83, *Guidelines for Cleaning Externally Contaminated Medical Gas Containers*.
- Wall Connection Poster
 - [https://www.cganet.com/wp-content/uploads/CGA Medical Oxygen Wall-Connection Poster 8.5x11 QRCode.pdf](https://www.cganet.com/wp-content/uploads/CGA_Medical_Oxygen_Wall-Connection_Poster_8.5x11_QRCode.pdf)
 - [https://www.cganet.com/wp-content/uploads/CGA Medical Oxygen Wall-Connection Poster 11x17 QRCode.pdf](https://www.cganet.com/wp-content/uploads/CGA_Medical_Oxygen_Wall-Connection_Poster_11x17_QRCode.pdf)
- Cylinder Poster
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 - [https://www.cganet.com/wp-content/uploads/CGA Medical Oxygen Cylinder Poster 11x17 Link.pdf](https://www.cganet.com/wp-content/uploads/CGA_Medical_Oxygen_Cylinder_Poster_11x17_Link.pdf)
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WE'RE HERE AND READY TO MEET YOUR COVID-19 MEDICAL OXYGEN NEEDS.



HERE ARE 3 CRITICAL STEPS THAT HEALTH CARE PROVIDERS CAN TAKE TO SUPPORT THE MEDICAL OXYGEN SUPPLY CHAIN:

Our members continue to produce and deliver essential products, particularly oxygen and other medical gases. They have ramped up production in preparation for anticipated demand related to COVID-19, drawing on experience from seasonal demand surges, natural disaster response, and lessons learned from their global COVID-19 response teams. The extensive network of oxygen production and fill plants in North America provides redundancies to support continued production and delivery of medical oxygen. Throughout this crisis, medical oxygen suppliers will be closely communicating with their customers to monitor the situation and reallocate resources as necessary to respond to high demand situations.



UNDERSTAND YOUR MEDICAL GAS SUPPLY SYSTEM NEEDS & CAPABILITIES



UNDERSTAND YOUR FACILITY'S OXYGEN SUPPLY SYSTEM MAXIMUM OPERATING CAPACITY (I.E., TANK VOLUME, VAPORIZER CAPACITY, IN HOUSE PIPING FLOW LIMITS).



COMMUNICATE ANTICIPATED CHANGES TO YOUR MEDICAL OXYGEN DEMAND AND SUPPLY NEEDS AS EARLY AS POSSIBLE TO YOUR SUPPLIER TO ALLOW ADEQUATE TIME FOR DELIVERY RESPONSE.



MONITOR YOUR MEDICAL GAS SUPPLY SYSTEMS FOR EXCESSIVE ICE BUILDUP OR FALLING SUPPLY PRESSURE. CONTACT YOUR SUPPLIER IMMEDIATELY WITH ANY CONCERNS.



WORK WITH YOUR MEDICAL GAS SUPPLIER TO IDENTIFY THE BEST SUPPLY SOLUTION FOR YOUR FACILITY NEEDS.



MANAGE MEDICAL GAS CONTAINER INVENTORY



ORDER AND RETAIN ONLY THE OXYGEN CYLINDERS NEEDED FOR YOUR IMMEDIATE PATIENT NEEDS.

CREATE AND IMPLEMENT A RECOVERY PLAN FOR MEDICAL OXYGEN CYLINDERS PRESCRIBED FOR HOME USE.



CLEAN YOUR MEDICAL GAS CONTAINERS



MEDICAL GAS CONTAINERS MUST BE RETURNED TO YOUR GAS SUPPLIER FREE FROM CONTAMINATION

SCAN HERE FOR CGA P-83, GUIDELINES FOR CLEANING EXTERNALLY CONTAMINATED MEDICAL GAS CONTAINERS

SUPPLIER INFORMATION

THE MEDICAL GASES INDUSTRY IS FULLY COMMITTED TO MAKING SURE THAT YOUR OXYGEN NEEDS ARE MET TODAY AND THROUGHOUT THE DURATION OF THE COVID-19 PANDEMIC. TOGETHER, WE CAN WEATHER THIS CRISIS.

Contact Info

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