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The Original Compressed Air Testing Laboratory

Validating a Compressed Air System for a Food or Beverage Production Facility

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This presentation is the product of TRI Air Testing's 41-years of industry knowledge

We pioneered the science of compressed air testing

Awarded the Navy and Coast Guard contract for the past 20 years

This presentation will detail:

- analytes that we **typically** test for
- regulations and spec limits of these analytes
- why we test for these particular analytes

This list makes up the the majority the spectrum of analytes that need to be TRI test for in compressed air or purity gas (items in bold relate most to the food industry) :

- **Oxygen (O₂)**
- **Nitrogen (N₂)**
- **Carbon Monoxide (CO)**
- **Carbon Dioxide (CO₂)**
- **Methane (CH₄)**
- **Total Hydrocarbons (THC) minus Methane (CH₄)**
- **Oil Mist and Particulates (condensed hydrocarbons)**
- **Mold and Bacteria**
- **Water Vapor (moisture content)**
- **Dew Point Pressure Dew Point**

This presentation will facilitate dialogue and hopefully help educate food production professionals on the importance of facility compressed air testing for

Compressed Air



Compressed air is the most commonly used form of pressured gas in a food production facility (consist of):

- 21% O₂
- 78% N₂
- 1% trace elements (mostly Ar)

Common uses of compressed air:

- Breathing air (SCBA, SCUBA, Umbilical)
- Pneumatic tool operation
- Drying
- Cooling
- Bottling
- Mixing
- Packaging
- Molding
- Blending
- Cleaning

Two Types of Air Compressors:

1. High pressure (350psi and above)
2. Low Pressure (under 350psi and most commonly used in the food industry)

Air Quality Testing



- Quality of compressed air being used is of the utmost importance for the end user's safety and product quality
- This is where a testing facility such as TRI Air Testing, Inc. is needed
- TRI will send out air testing kits with sampling media for onsite sampling performed by the customer
- The customer sends back the sampling media to our air testing laboratory for analysis
- The air testing kits contain an air sampler
- This air sampler, along with pressure fittings, attaches directly to air compressor systems or the gas source being tested
- The sampling media is contained within or attached to the air sampler and collects all the important material based on volume of air passed through the media

CHAMPION 35 TEST KIT



KIT WITH
INSTRUCTIONS



BOTTLE AND FILTER



DRÄGER TUBES

TRI Analysis of Components



- All gaseous analytes tested by TRI are done with highly customized gas chromatograph (GC) instruments
- All gaseous analytes are detected and quantified using a Flame Ion Detector (FID), a Thermal Conductivity Detector (TCD), and an Electron Capture Detector (ECD)
- All condensable analytes and biological material are allowed to collect on filter media and analyzed gravimetrically and/or by colony counting and species identification
- Moisture and Dew Point are determined with the use of Drager tubes and calculated based on a specific volume of air and vapor pressure

Oil Mist and Particulates



- Condensed hydrocarbons (oil mist) and particulates are typically the most critical component that needs to be tested for food and beverage customers
- A properly working compressed gas system should generate no detectable amount of oil mist and particulate
- Compressed gas/air systems will have particulate filtration mechanisms in place to filter out particles of anything above very small micron sizes
- Micron sized particulate matter can build up over time and diminish the functionality of the equipment and affect in process and final product quality if not properly maintained
- It should be noted that TRI's standard oil mist and particulate gravimetric analysis does not include particle counting or sizing as required by the ISO 8573, however if this analysis is needed TRI can contract a 3rd party vendor to perform this analysis or rent to the customer a laser particle counter

Mold and Bacteria



- Mold and bacteria typically require moisture to grow and thrive, so if the compressed air or gas system has proper moisture reducing filters in place then this should not pose a threat
- TRI suggests that if any unidentifiable odor is ever detected in the compressed air system, that a mold and bacteria analysis be performed
- TRI collects the mold and bacteria sample very similar to the oil mist and particulate sample (collected on a filter)
- A minimum five-day culture growth is required for colony counting and identification
- If mold and bacteria is found to be present it is important to fix the issue immediately as certain species of both can cause serious systemic health issues in the human body

TRI Air Testing, Inc. Analytical Methods, Accuracy, and Reporting Limit Chart

<i>Analyte</i>	<i>Analysis Method</i>	<i>TRI's Level/Accuracy</i>	<i>TRI's Detection/Reporting Limits</i>	<i>TRI's Recommended Maximum Allowable Level for Compressed Breathing Air</i>
Oxygen and Nitrogen	Gas chromatography with thermal conductivity detector	+/- 0.4% absolute or +/- 2% of concentration	0.5%	19-22% O ₂ and 77-80% N ₂ (for non blended gases)
Carbon monoxide	Gas chromatography with catalytic converter followed by flame ionization detector	+/- 5% of reported value or 1 ppm whichever is greater	0.5 ppmv	10 ppmv
Carbon dioxide	Gas chromatography with catalytic converter followed by flame ionization detector	+/- 5% of reported value or 20 ppm whichever is greater	20 ppmv	1000 ppmv
Total gaseous hydrocarbons (methane)	Gas chromatography with direct flame ionization detector	+/- 5% of reported value or 1 ppm whichever is greater	1 ppmv	5 ppmv
Condensed Hydrocarbons (Oil Mist and Particulate)	Standard gravimetric, with hexane extraction for oil mist if results are with 90% of the specification	+/- 0.1 mg/m ³ or 10%, whichever is greater	0.1 mg/m ³ (can be as low as 0.01 mg/m ³ based on volume)	0.1 mg/m ³
Moisture Test	Color indicator tube with critical orifice size to measure air flow (test performed on site)	+/-30% or 1 ppm whichever is greater	2 ppmv	25 ppmv

Common Food Industry Specifications



SPECIFICATIONS FOR COMPRESSED AIR

INDUSTRY SPECIFICATION NAME	SQF Code 8th Ed. Food Safety Fund 11.5,12.5,13.5 and various other sections	BRC Issue 7 4.5.4	FSMA 21CFR117.40(g), Response comments 19 and 310	TRI Indirect Product Contact	TRI Direct Product Contact	Average Limits Requested for Food and Beverage Industry
TRI's Air Standard Code	BLI/BLD/C23/A3/MI	BLI/BLD/C23/A3/MI	BLI/BLD/C23/A3/MI	BLI/B1	BLD/C23/A82	various
LIMITING CHARACTERISTICS						
Dew point (°F)	Based on Risk Analysis	Based on Risk Analysis	Based on Risk Analysis	Product and Dryer Dependent 0°F for Refrigerent -50°F for Desiccant	Product and Dryer Dependent 0°F for Refrigerent -50°F for Desiccant	Ranges from 95°F to 37°F
Water, ppm (v/v)	Not Specified	Not Specified	Not Specified	67-1267ppmv	67-1267ppmv	Ranges from 2-1267ppmv
Recommended Filtration	0.1 micron point of use	Not Specified	Not Specified	NA	NA	NA
Oil (condensed) and Particulate (mg/m3)	The Quality of Air and Other Gases. Compressed air or other gasses (e.g. nitrogen, carbon dioxide) that contacts food or food contact surfaces shall be clean and present no risk to food safety. Compressed air systems, and systems used to store or dispense other gasses used in the storage and distribution process shall be maintained and regularly monitored for quality and microbiological purity and completed annually, at minimum.	Air, other gases and steam used directly in contact with, or as an ingredient in, products shall be monitored to ensure this does not represent a contamination risk. Compressed air used directly in contact with the product shall be filtered.	(g)Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives. (310)...As written, the provision provides flexibility for an establishment to determine the appropriate treatment for compressed air or other gases in a manner that works best for its plant. (19)...If a facility believes that its use of compressed air should be addressed in its food safety plan, then it should do so.	1	0.1	0.01-5
Particulates (mg/m3)				part of above	part of above	part of above
Microbiological Contaminants (cfu's/m3)				50	50	10-100
Chemical Contaminants				See Below	See Below	See Below
Total Volatile Hydrocarbons (as methane in ppm)				5	2	<1-10
Halogenated Hydrocarbons (ppm)				5	1	<1-5
Frequency Required (Testing per year)	Minimum of Annually	Minimum of Annually	Not Specified	Per Specification, Food Safety Plan or Minimum of Annually	Per Specification, Food Safety Plan or Minimum of Annually	Quarterly - Annually

Facility Validation Project Plan



- The validation project plan is the most critical step in setting up any critical system in a regulated facility including the compressed gas
- A properly executed validation project plan must be concise and direct to the point and must define three clear objectives:
 - 1) The plan should provide for a complete and detailed description of the entire system and the usage of the compressed gas
 - 2) The plan should define the Installation Qualification (IQ), Operational Qualification (OQ), and the Performance Qualification (PQ)
 - 3) The plan should assign all relevant responsibilities for vendors and team members that are associated with the compressed gas system

Installation Qualification (IQ)



- **The organization's responsible team members should work very closely with compressed gas supply vendors and facility engineers to install the compressed gas system appropriately within the scope of the intended usage**
- **When installing compressed gas or gasses that are under pressure in one or multiple points of usage within a facility, safety of the user and others nearby the point of usage should always be paramount**
- **Correct installation of piping and proper accountability of utilities/power supplies for the individual pieces of the equipment, then testing for leaks within the entire system should all be taken into consideration to ensure proper functionality and safety**

Operational Qualification (OQ)



➤ The OQ has three main sub functions:

1. The system, once installed properly, operates as intended and that it is supplying the required cubic feet per minute (CFM) volume at the intended working pressure
2. The quality of the compressed gas must be tested
 - a. All critical components of the gas must be baseline tested after installation (critical components example would be oil mist and particulate and mold and bacteria)
 - b. A second baseline test should be taken one week following installation
3. OQ should conclude with establishing and verifying that the operation and maintenance procedures are in place and approved by the supply vendor and that all responsible team members are fully trained

Performance Qualification (PQ)



➤ The PQ consist of two phases:

1. The critical components should be tested 3-4 weeks after the second baseline test is performed and this is where control limits of these components are established based on the quality standards of the product and/or a specific accreditation organization or regulatory agency if applicable
2. **Routine monitoring** of critical components and the compressed gas system air volume delivery should be tested over the course of six months to ensure the system is consistently delivering quality gas

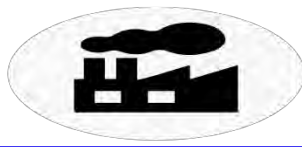
➤ If the compressed gas *Validation Project Plan* is drafted properly, it will serve as a living document and will provide a roadmap for implementation for a proper working system for the life of the system usage following the PQ

HVAC System




- A properly functioning HVAC system is typically very critical in the overall functionality of the compressed gas system
- In itself, the HVAC system is just as important as any other system within a regulated facility and may very well be the most important, especially in critical situations where a GMP or clean room environment must be maintained
- The HVAC directly controls laminar air flow, controls temperature and humidity, circulates out toxic gases such as carbon monoxide and carbon dioxide, and controls particulate levels with HEPA filtration
- For systems that are closed looped (draws intake from an indoor pure gas generator or cascade source) or a compressed air system that intakes indoor air from within the facility are very HVAC dependent
- HVAC and/or facility engineers should always consult with the compressed gas supply vendor to determine the proper HVAC installation and performance requirements in closed loop situations

Conclusions



- Equipment must function at peak operating capabilities for safety and quality
- Regulatory agencies require that the compressed air or gas being used in this industry is of the highest quality
- It is important that the rules and regulations surrounding food and beverage quality be taken very seriously and adhered to
- Please visit www.airtesting.com for further information about TRI and air quality testing



TRI strives to be a reliable partner with all customers to help them maintain high levels of quality in their processes.

TRI Air Testing, Inc. is here to help all of our diving customers to be in compliance and we are dedicated to the highest standards of scientific analysis

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At TRI we know air testing so you don't
have to!

