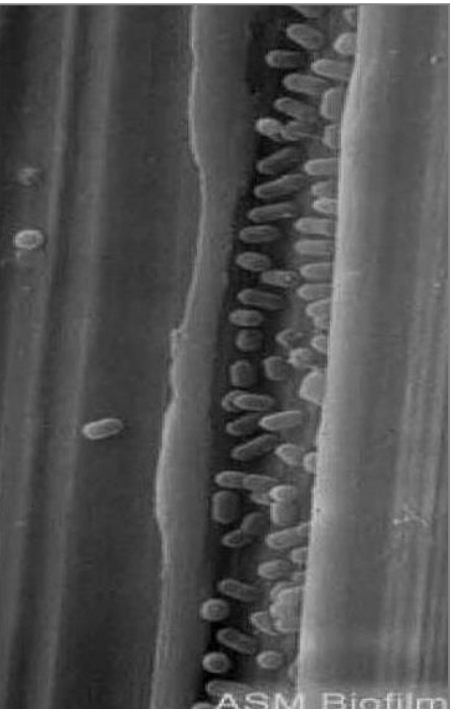
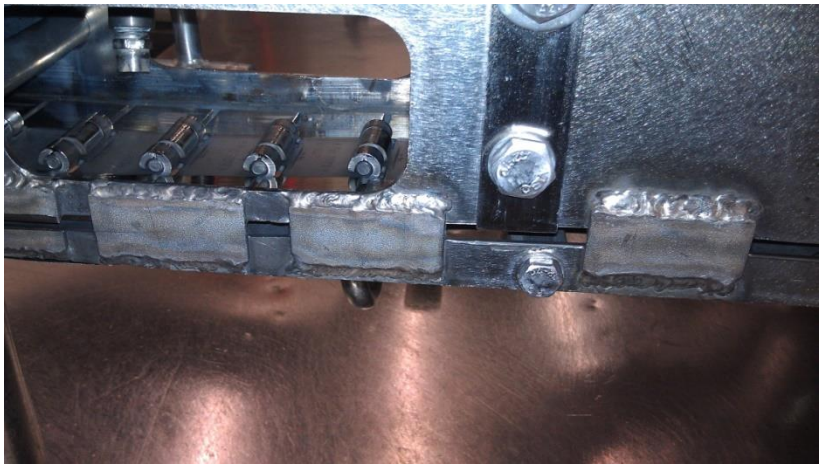
Contamination Control and Decontamination of Low Moisture Food Processing Facilities Using Chlorine Dioxide Gas





Kevin Lorcheim
Sr. Manager

ClorDiSys

Low Water Activity

Low water activity (a_w)foods are those with a water activity less than 0.7.
Common low water activity foods are:

Food	Water activity
Peanut Butter	0.7
Dried Fruit, honey	0.6
Pasta Noodles (~12 moisture) spices (~10% moisture)	0.5
Whole Egg Powder (~5% moisture)	0.4
Cookies, Crackers, Bread crusts	0.3
Instant Coffee	0.2
Whole Milk Powder, Dried Vegetables, Corn Flakes, Dehydrated soups	0.03

7 Steps of Effective Dry Sanitation

1. Pre-sanitation preparation
2. Securing and disassembling
3. Dry cleaning
4. Detail cleaning
5. Self-inspection
6. Final Inspection
7. Final sanitizing and assembling

7 Steps of Effective Dry Sanitation

1. Pre-sanitation preparation
2. Securing and disassembling
3. Dry cleaning
4. Detail cleaning
5. Self-inspection
6. Final Inspection
7. **Final sanitizing** and assembling

Chlorine dioxide gas fits in during Step 7
as a final decontamination step

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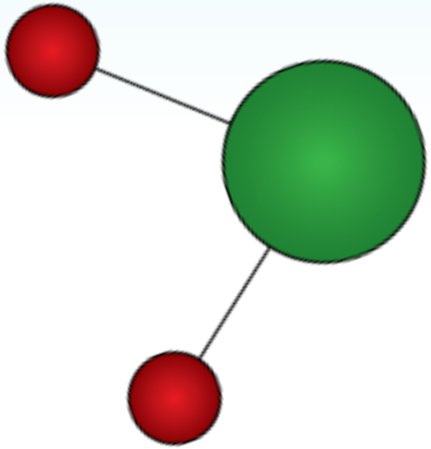
Chlorine Dioxide Gas

Chlorine dioxide gas is an EPA registered sterilant, capable of eliminating all viruses, bacteria, molds, and spores.



Chemical Properties:

- Yellow-Green Gas
- Water Soluble
- Boiling Point 51^{o}F

Types of Antimicrobial Pesticides

Sterilizers (Sporicides): Used to destroy or eliminate all forms of microbial life including fungi, viruses, and all forms of bacteria and their spores. Spores are considered to be the most difficult form of microorganism to destroy. Therefore, EPA considers the term Sporicide to be synonymous with "Sterilizer."

Disinfectants: Used on hard inanimate surfaces and objects to destroy or irreversibly inactivate infectious fungi and bacteria but NOT necessarily their spores. Disinfectant products are divided into two major types: hospital and general use.

Sanitizers: Used to reduce, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.

Antiseptics and Germicides: Used to prevent infection and decay by inhibiting the growth of microorganisms. Because these products are used in or on living humans or animals, they are considered drugs and are thus approved and regulated by the Food and Drug Administration (FDA).

http://www.epa.gov/oppad001/ad_info.htm

Keys of Effective Decontamination

There are four keys to achieving an effective decontamination

The decontamination method must:

- ✓ **Be able to kill the organism in question**
- ✓ **Achieve good and complete distribution**
- ✓ **Achieve thorough and total penetration**
- ✓ **Achieve sufficient contact time at the correct concentration**

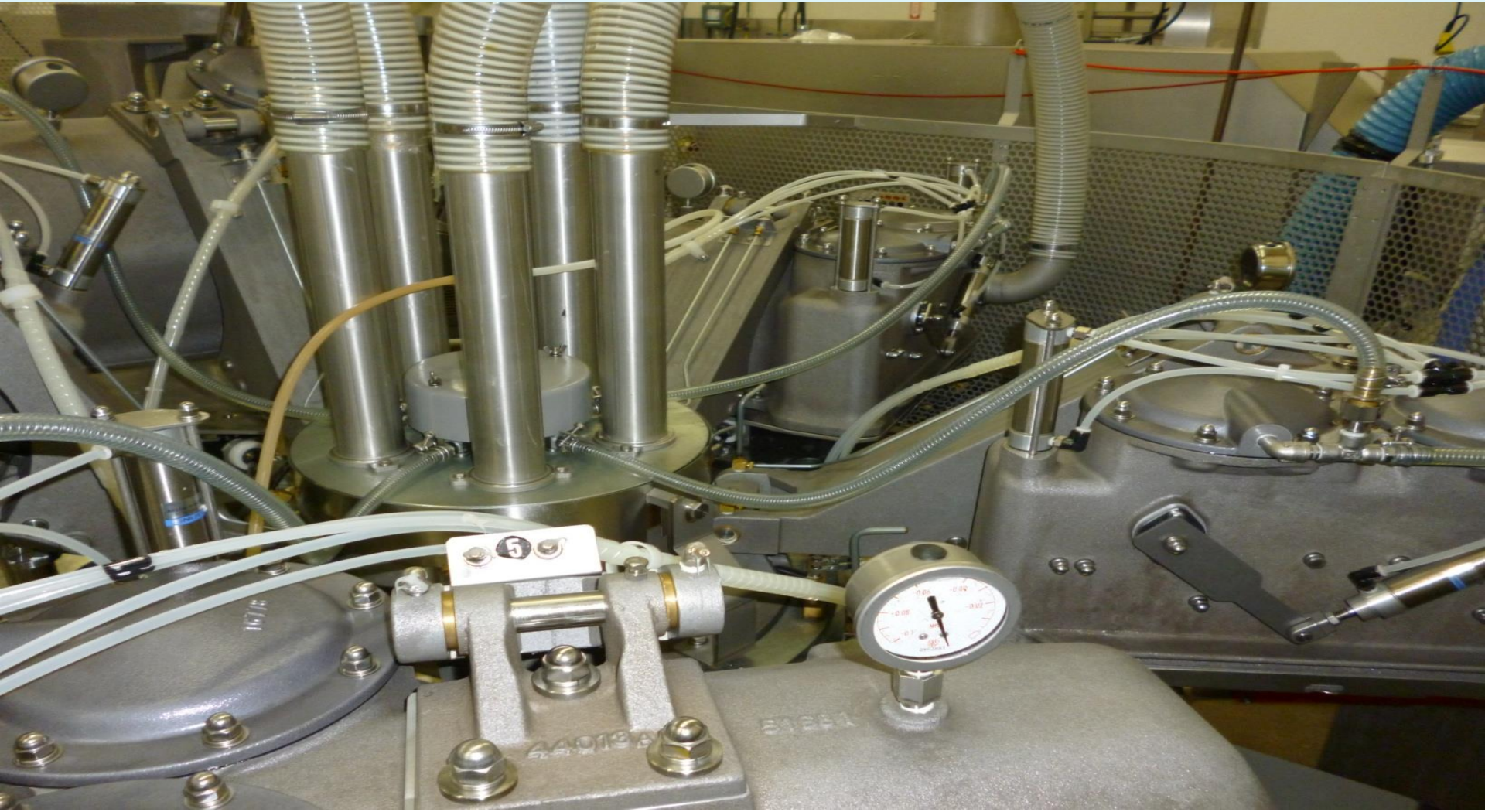
Keys of Effective Decontamination

Traditional sanitation methods can have difficulty guaranteeing that all organisms have been contacted / contacted with the proper dosage

The decontamination method must:

- ✓ **Be able to kill the organism in question**
- ? **Achieve good and complete distribution**
- ? **Achieve thorough and total penetration**
- ? **Achieve sufficient contact time at the correct concentration**

Niches



Niches

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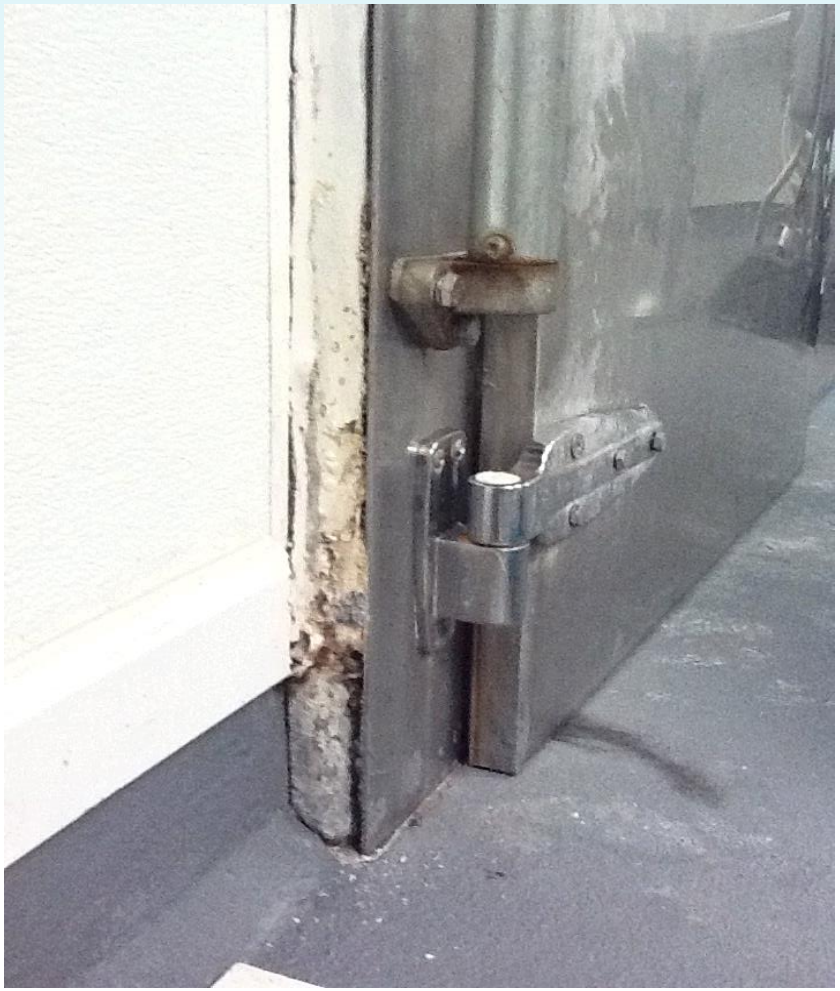
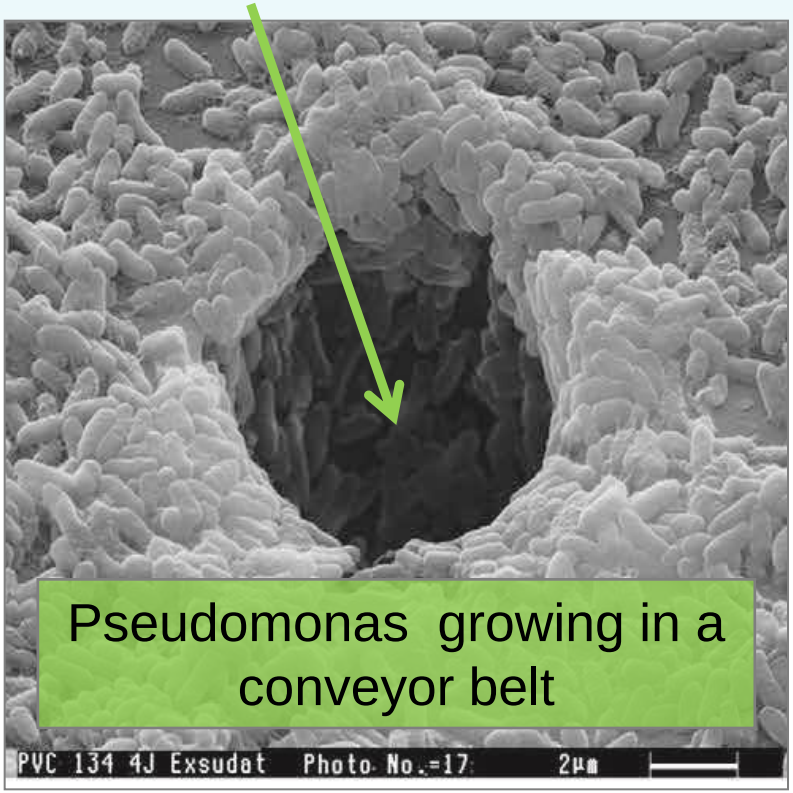
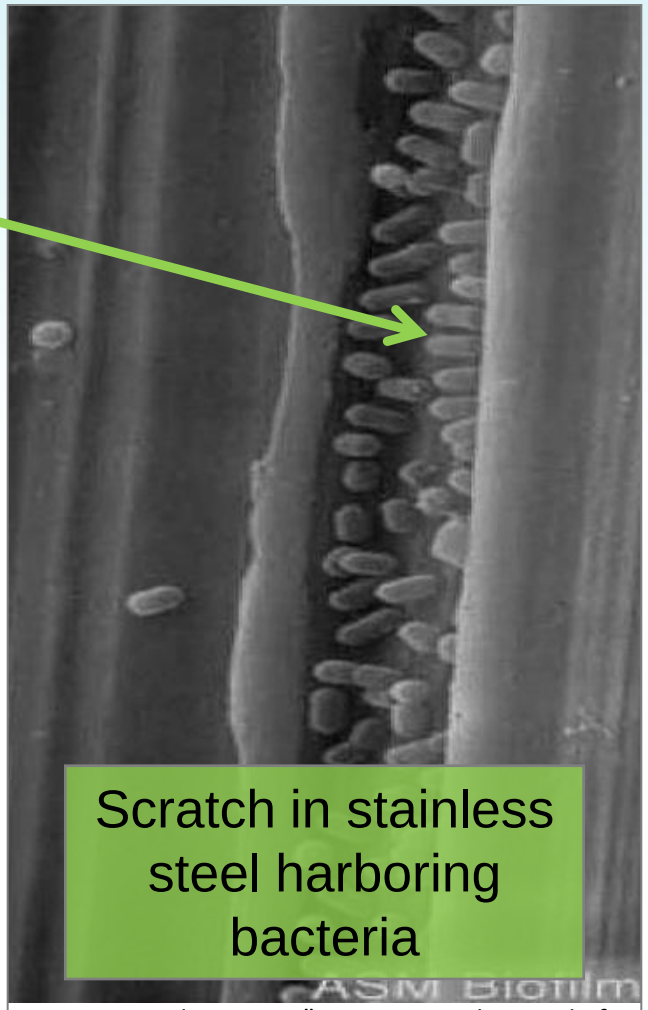


Niches

Scratches[2,3] - Crevices - Punctures[1]



Pseudomonas growing in a conveyor belt



Scratch in stainless steel harboring bacteria

1. Carpentier B., Cerf O. "Review — Persistence of Listeria monocytogenes in food industry equipment and premises", International Journal of Food Microbiology 145 (2011) 1–8.
2. JENNY SCOTT, U.S. Food and Drug Administration-CFSAN, Washington, D.C., USA, "The Significance of Persistent Bacterial Strains in the Food Processing Environment", Presented at IAFP Session 21 (8-2-2011) Milwaukee.
3. Solioz, M, Biochimica - Copper kills bacteria: end of hospital-acquired infections? Scienza in rete, 18 April, 2011, Accessed on 6-26-2013 http://www.scienzainrete.it/en/content/article/copper-kills-bacteria-end-hospital-acquired-infections

Traditional Sanitation

With the difficulty that traditional sanitation can have in reaching ALL of the organisms including the niches and harbor locations, you're left playing microbial whack-a-mole with persistent contaminations that keep popping back up.

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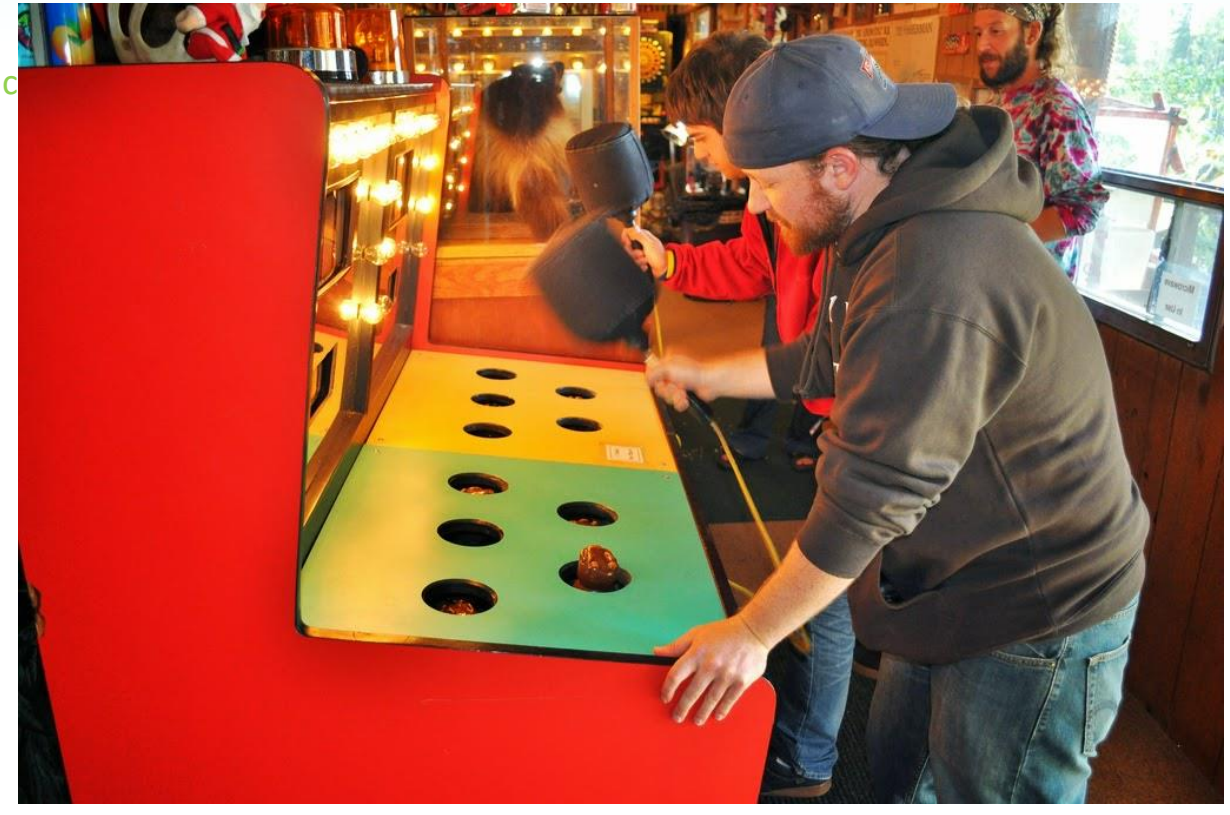


Distribution

A chemical can't kill what it can't reach.

	Chlorine Dioxide Gas
Boiling Point	**51°F**
Natural State at Room Temperature	**Gas**

Gasses fill the space they are contained within evenly and completely.

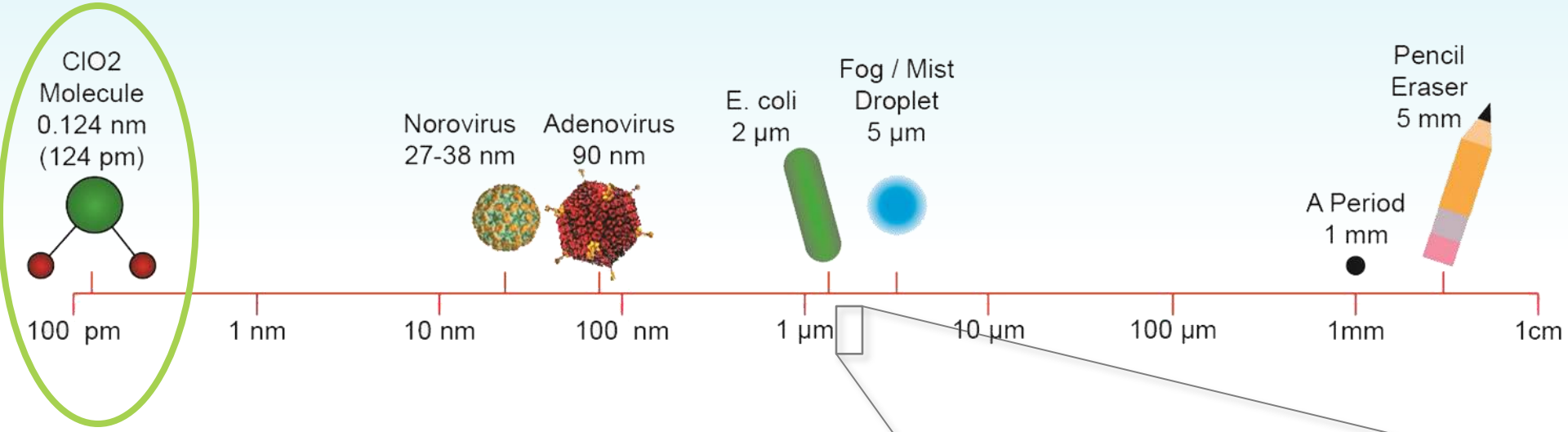
Chlorine Dioxide Gas is able to evenly fill the area it is decontaminating, no matter how large, tall or filled with equipment.

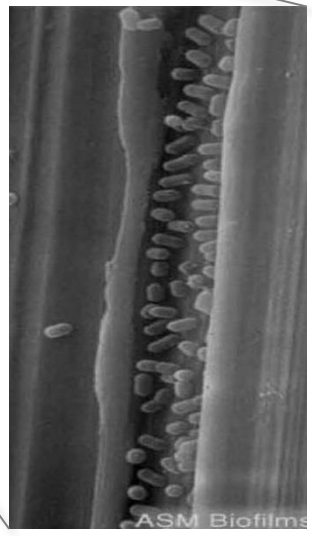
Distribution

Distribution

Penetration into Crevices

Organisms sizes vs ClO_2 molecule





Magnified scratch in stainless steel harboring bacteria

Process Verification

QA Method	Description
Concentration Monitor	Verifies the concentration of CD gas during a decontamination and overall cycle dosage
Biological Indicators	Verifies that the decontamination cycle achieved 6-log sporicidal reduction
Swab Testing	Verifies that the organism itself is no longer present

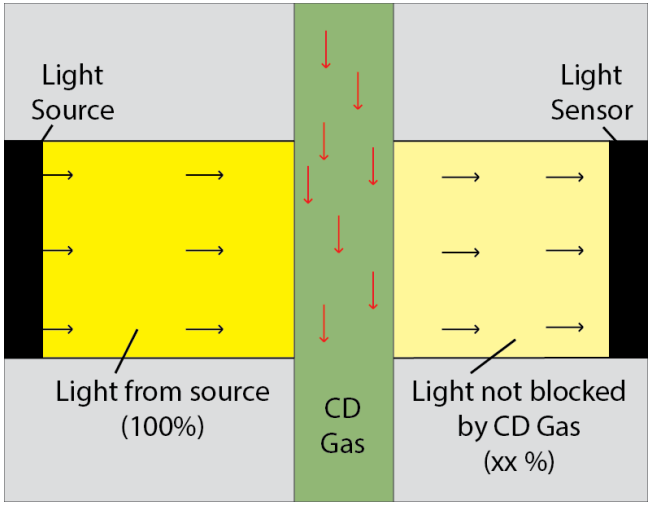
Concentration Monitoring

The concentration of chlorine dioxide gas can be monitored and logged during a decontamination.

2 main methods:

Chemical Sensor

uv-vis spectrophotometer



Concentration Monitoring

Chemical Sensor:

Advantages:

- Relatively Inexpensive

Disadvantages:

- Difficult to monitor multiple points within environment
- Less accurate due to saturation issues

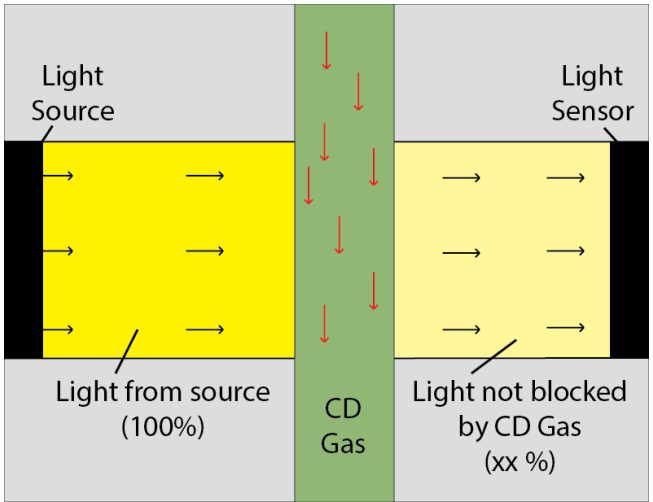
Uv-vis spectrophotometer:

Advantages:

- Highly accurate
- Able to monitor multiple points within environment

Disadvantages:

- More expensive

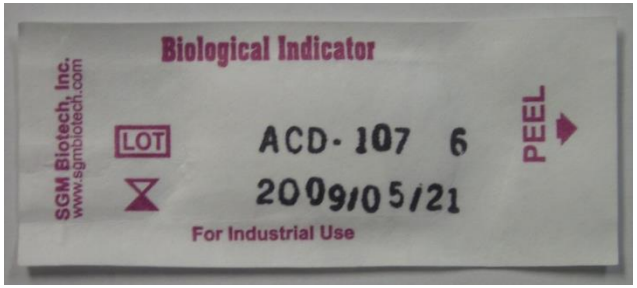


Decontamination Dosage

Ref. Mark A. Czarneski. *Microbial Decontamination of a New 65-Room Pharmaceutical Research Facility*. Applied Biosafety, Vol 13. No. 4, 2008

Biological Indicators

Biological indicators consist of a semi-permeable outer packaging and a interior carrier impregnated with bacterial spores. For sterilization, BI's contain over 1 million bacterial spores, providing the ability to prove a 6-log (99.9999%) sporicidal reduction.



Biological Indicators for chlorine dioxide gas use either *bacillus atrophaeus* or *geobacillus stearothermophilus* spores.

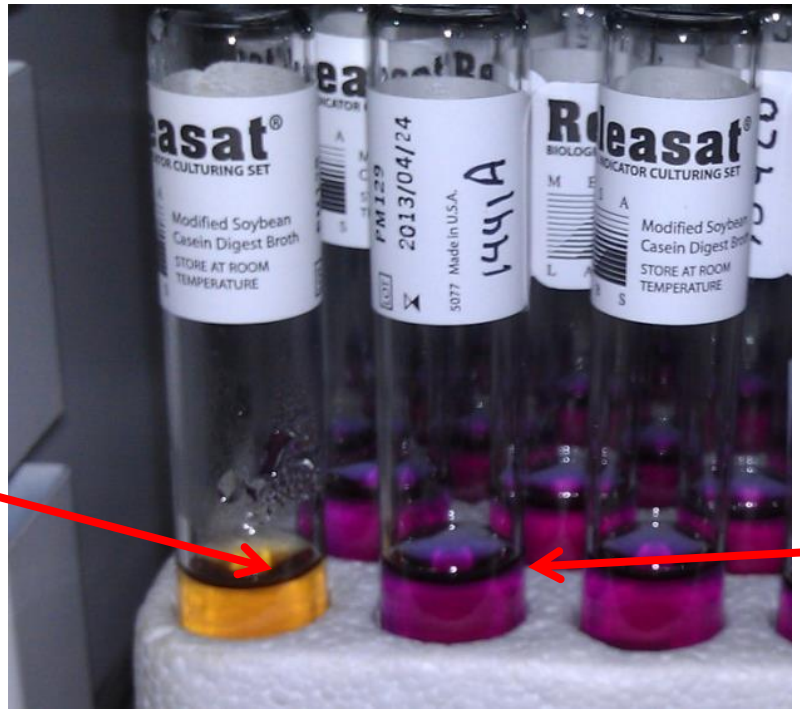
BI Analysis

After the decontamination process is complete, BI's are collected and aseptically dropped into growth media tubes and incubated. If even one spore was not killed, they will grow and the bacteria will multiply causing turbidity (cloudiness) or a color change within the media tube.

CD gas has a 36-48 hr incubation time depending on BI manufacturer.

Positive for growth

(Decon unsuccessful)



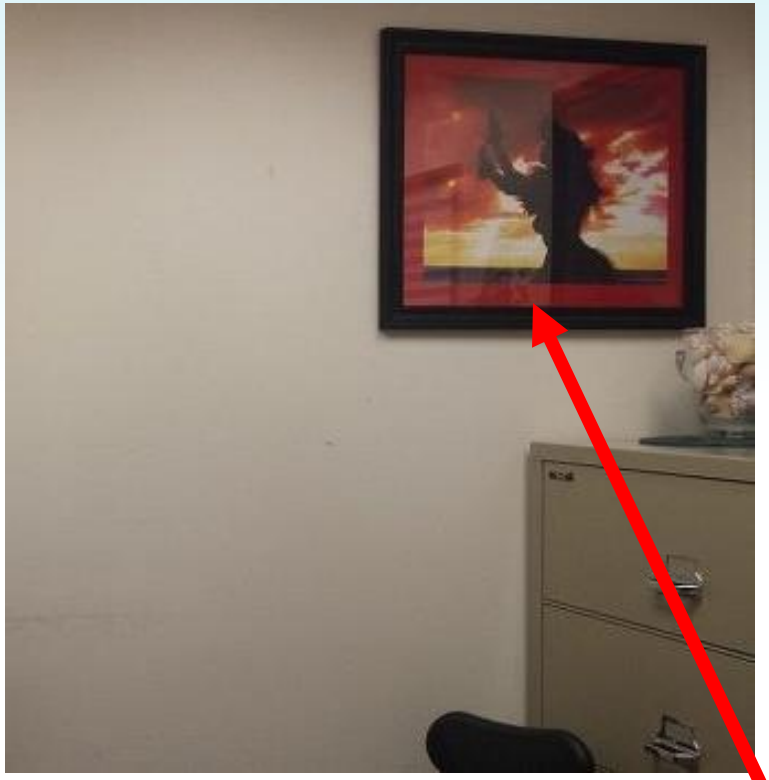
Negative for growth

(Decon successful)

Penetration into Open and Closed Cabinets

Penetration Under Forklift Tire

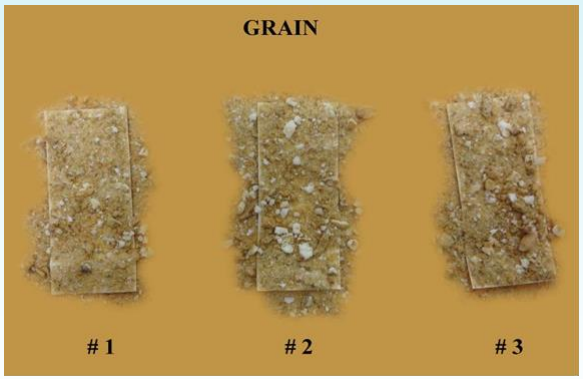
Penetration Behind Objects

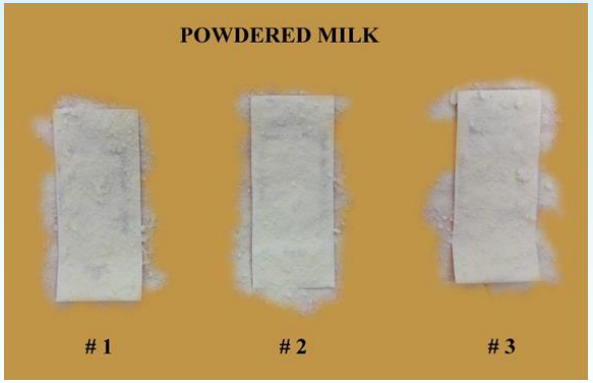


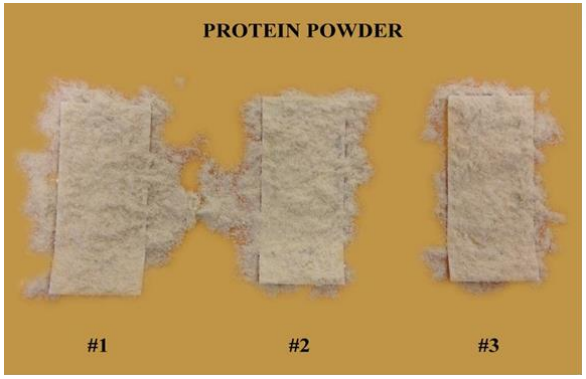
BIs Killed

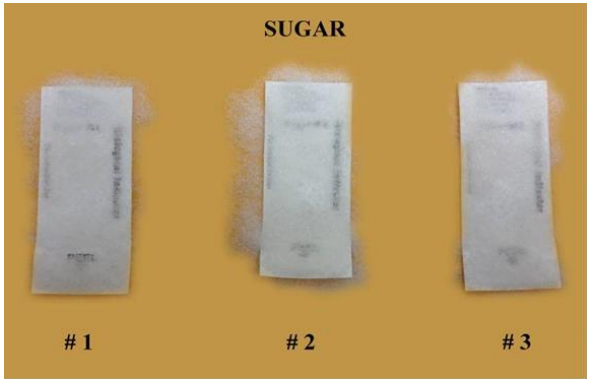
Penetration into Grain, Powdered Milk, Protein Powder, Sugar, Flour, Baby Formula

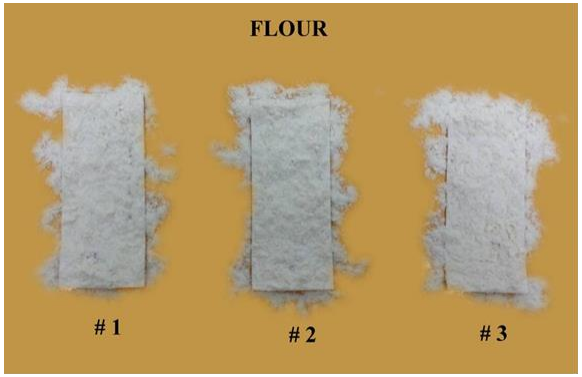
ALL BIs Killed

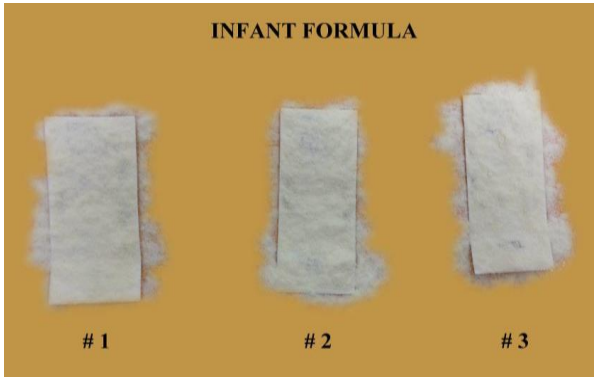








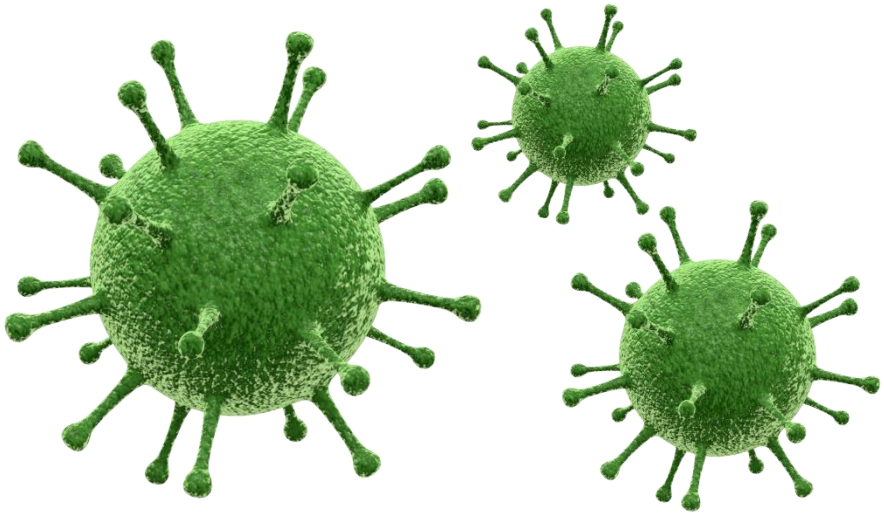


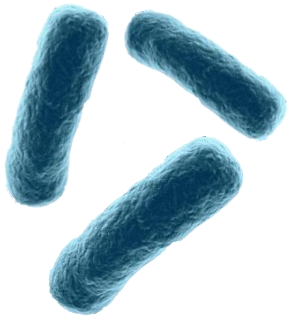


Biocidal Effectiveness

	Chlorine Dioxide Gas
Registration	Sterilant

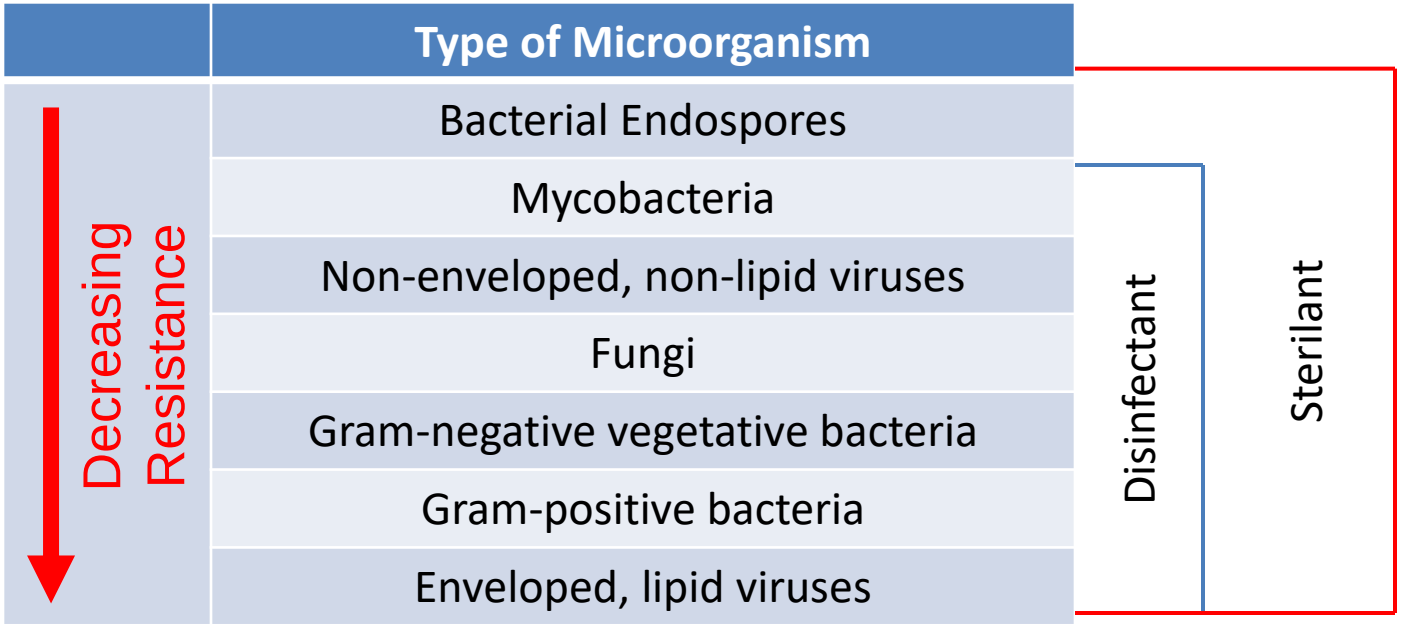
Certain chlorine dioxide gas products are registered as sterilants, which means they are capable of eliminating all viruses, bacteria, molds (fungi) and spores.





Spore Reduction

Spores are the most resistant microbial organisms. Spore reduction is aided by increased humidity (~65% RH) which causes spores to swell and crack, allowing the chemical to enter and inactivate the spore



Spore Forming Bacteria

Some organisms which form spores include:

Organism	Associated Foods
Bacillus cereus	Rice, Grains, Cereals
Clostridium botulinum	Home-canned foods, honey, baked potatoes
Clostridium perfringens	Meats, Stews, Gravies
Molds	Cheese, Meats, Grain, Flour, Nuts, Apples

Antimicrobial Efficacy

Target Organism	Dosage Required using CD Gas
Spores	~600 ppm-hrs for 6-log kill
Listeria	~300 ppm-hrs for a 5-log kill
Salmonella	~100 ppm-hrs for 6-log kill

Dosage measured in ppm-hours

600 ppm-hours can be attained by holding a:

300 ppm concentration for **2 hours** (300 x 2 = 600)

or

100 ppm concentration for **6 hour** (100 x 6 = 600)

or

Any equivalent combination of concentration and time*

*Ref. Kevin Lorcheim and Erik Melgaard. *Linearity of the Relationship Between Concentration and Contact Time for Sterilization with Chlorine Dioxide Gas*. ABSA 58th Annual Biological Safety Conference, 2015.

Efficacy and Humidity - Spores

Chlorine dioxide has been validated to be effective at lower relative humidity, but requires a higher dosage

RH	Dosage Required for 6-log Spore Reduction
65%	~600 ppm-hrs
55%	~1000 ppm-hrs
45%	~1550 ppm-hrs

*Ref. Mark A Czarneski. *Effects of Relative Humidity, Concentration, and Exposure Time on Chlorine Dioxide Gas Decontamination*. ABSA 54th Annual Biological Safety Conference, 2011.

Is It OK to Humidify in a Dry Environment?

Raising the humidity levels within a dry environment goes against traditional thinking as it can promote microbial growth.

However, this is followed up with a gaseous sterilant which is capable of reaching and eliminating any microbes within the space.

As the gas is eliminated (typically through the air handling unit) the environment is brought back to its normal dry environment.

Efficacy and Humidity - Salmonella

A study was performed to demonstrate the effect of chlorine dioxide gas on *Salmonella typhimurium* (ATCC# 14028) at 25% RH

Sample	Treatment	CFU Recovered
Test 1 (5 glass slides)	720 ppm-hr	<10
Test 2 (5 glass slides)	720 ppm-hr	<10
Test 3 (5 glass slides)	720 ppm-hr	<10
Positive Control (5 glass slides)	N/A	3.2×10^7

Study performed at EMSL Analytical, Inc
Cinnaminson, NJ 9/12/2017

Cycle Flexibility

	Chlorine Dioxide Gas
Temperature	Not a factor above 52 F
Starting Relative Humidity	Not a factor
Equipment Within Space	Not a factor, gas gets everywhere
Room Shape / Size	Not a factor, gas gets everywhere

Principles of Decontamination

Chlorine Dioxide Gas is able to achieve these principles due to its chemical properties

The decontamination method must:

- ✓ **Be able to kill the organism in question (Sterilant)**
- ✓ **Achieve good and complete distribution (True Gas)**
- ✓ **Achieve thorough and total penetration (True Gas & Small Molecule)**
- ✓ **Achieve sufficient contact time at the correct concentration (Accurate Concentration Monitoring)**

Safety

How to Decontaminate Safely

The key component to decontaminating a space safely is to contain it within the area you are treating. This can be done through the following steps:

- Sealing all penetrations leading in / out of the space (such as pipes)
- Sealing off the HVAC system handling the space (where applicable)
- Sealing off the doors and entry points to the space

Chlorine Dioxide is Non-carcinogenic

Current Uses:

- Over 700 municipalities use chlorine dioxide to disinfect their public drinking water.
- Used in poultry processing rinse water
- Used in fruit and vegetable rinse water
- Listed as an allowed substance on its National Organic Program's National List of Allowed and Prohibited Substances

Chlorine Dioxide is not classified as a carcinogen by any health agency

Odor Threshold

	C D
OSHA 8 hr TWA	0.1 ppm
Typical Concentrations	360 ppm
Odor Detection	**YES** **At 8 hour safety level**

The smell of CD is distinguishable from, but similar to the smell of chlorine. This is beneficial as chlorine's odor is widely known and recognized, so there is no learning curve for personnel in recognizing when there is CD present. While one's nose is not meant to be used as a primary means of odor detection due to the variance in sensitivity to smell that personnel have, it provides an extra layer of personal protection.

Aeration

Chlorine dioxide gas is not an ozone-depleting chemical, and can be emitted to the atmosphere in most places*. This offers a quick method of aerating a space after a decontamination is complete.

- Chlorine dioxide gas rapidly dissipates and dilutes in the atmosphere to reduce the danger level
- Sunlight breaks down the gas as well to further reduce any danger

*Emissions are regulated at the state level. Most states do not limit the emission of chlorine dioxide gas.

Whey Powder Processing Facility

578,000 ft^3

~75ft Tall Main Floor

+ Production Floor

+ Bin Room

+ Packaging Room

1st Decon – Contamination Response

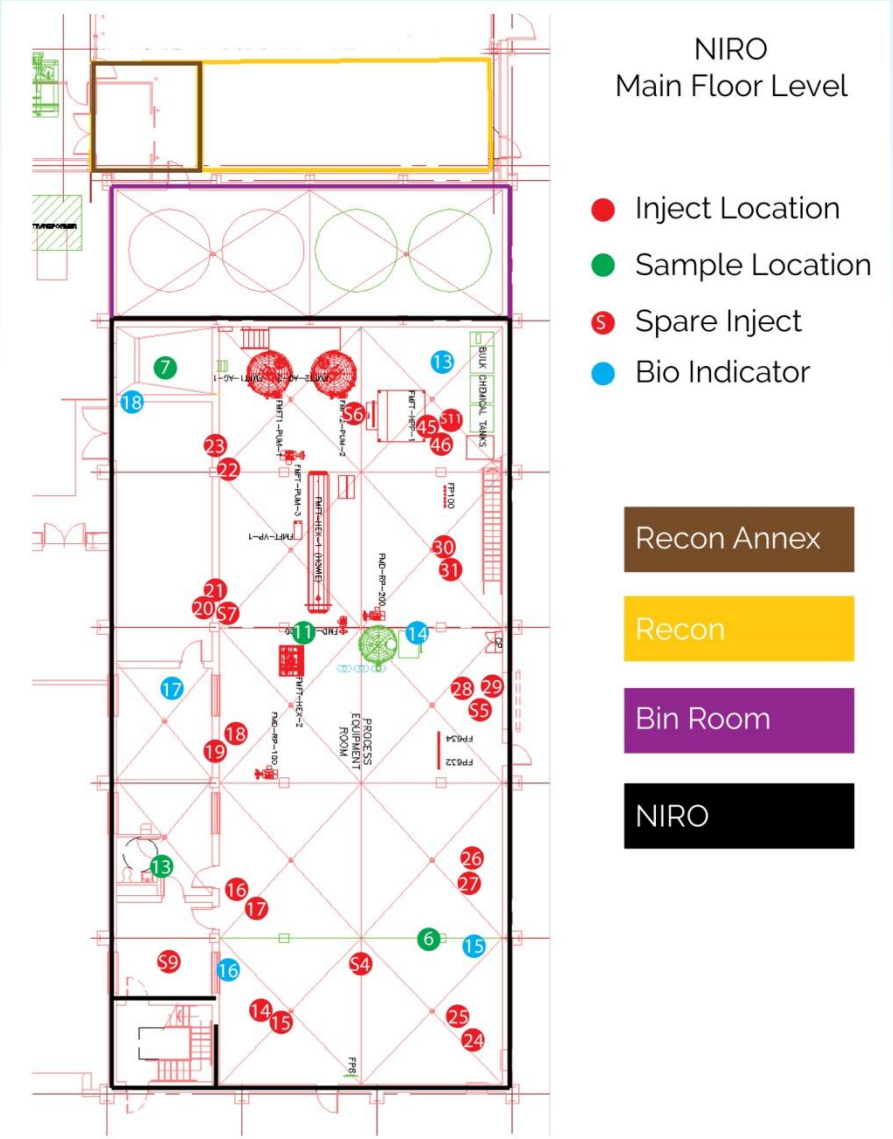
2nd Decon – Yearly Preventive Decon

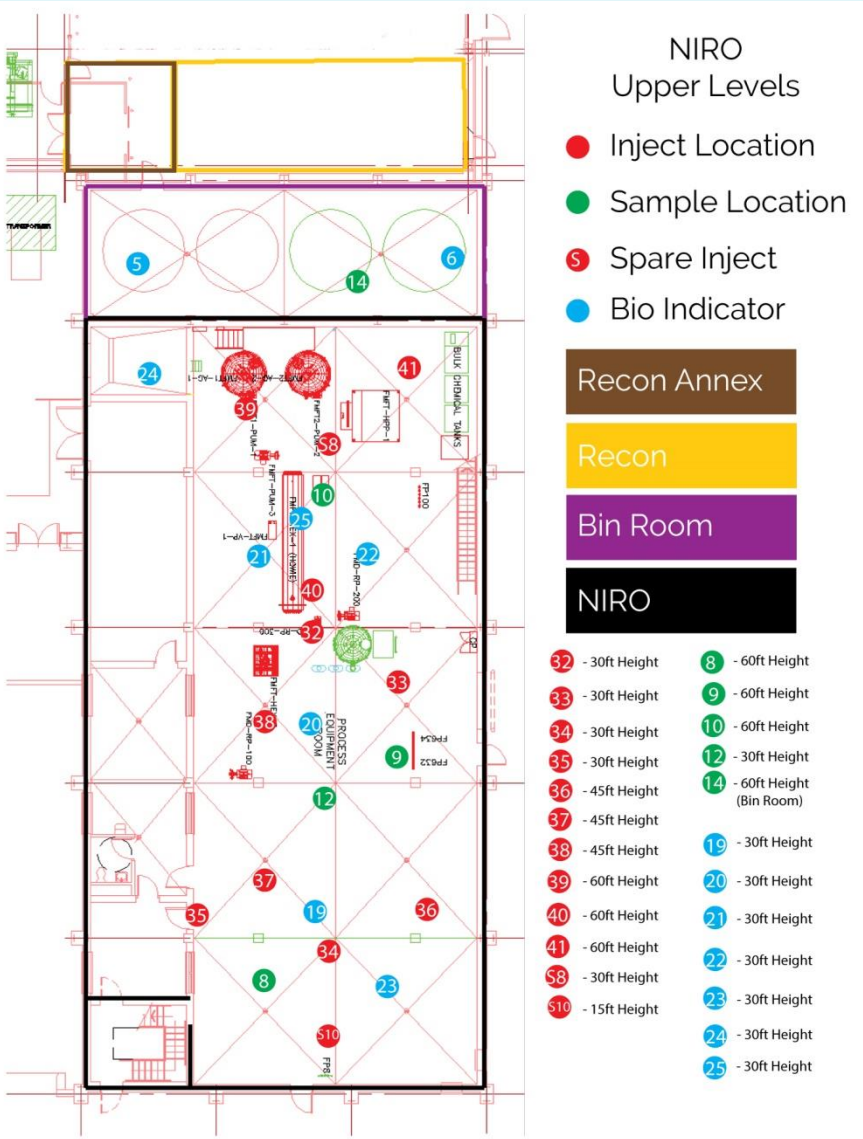
3rd Decon – Yearly Preventive Decon

4th Decon – Contamination Response

5th Decon – Yearly Preventive Decon

Whey Powder Processing Facility





Whey Powder Processing Facility

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Chlorine Dioxide Gas

Chlorine dioxide gas is able to achieve a complete 6-log sporicidal decontamination of all surfaces within a space, including hard-to-reach areas such as crevices.

This allows it to successfully treat large areas all at once without missing any organisms and without leaving a residue.

Questions?

Thank you

Kevin Lorcheim

ClorDiSys Solutions, Inc

kevinlorcheim@clordisys.com

908-236-4100