Environmental Monitoring
Capturing, Cultivating & Collating Viable Data

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Caution: EM is Primitive!

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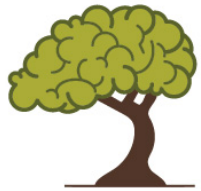
Early microbiologists

Current Guidelines for Viable Monitoring (2019)



United States

- United States Pharmacopeia 41 - <1116> Microbiological Control and Monitoring of Aseptic Processing Environments (February 2018)
- FDA Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice (September 2004)

Europe

- EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use - Annex 1, Manufacture of Sterile Medicinal Products (November 2008) (DRAFT REVISION - December 2017)

Japan

- Japanese Pharmacopoeia 17th Edition (April 2016) - Microbiological Environmental Monitoring Methods of Processing Areas for Sterile Pharmaceutical Products
- PDMA - Guidance on the Manufacture of Sterile Pharmaceutical Products by Aseptic Processing (July 2006)

World Health Organization

- Technical Report 961, Annex 6: WHO good manufacturing practices for sterile pharmaceutical products (2011)

PIC/S

- PE 009-14: Guide to Good Manufacturing Practice for Medicinal Products, Annex 1 - Manufacture of sterile medicinal products (July 2018)

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Types of Viable Monitoring

Air Sampling

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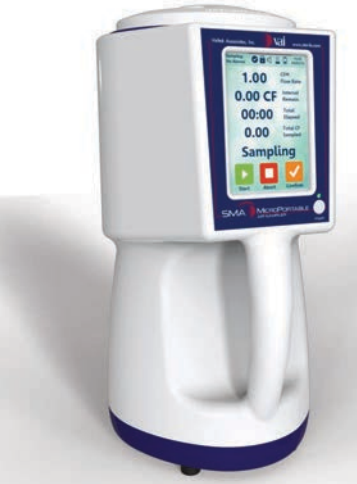
- Passive/Settle Plates
- Sieve Impaction (many devices)
- Surface Air Sampler (SAS)
- Centrifugal Air Sampler (RCS)
- Slit to Agar Sampler (many devices)
- Sterilizable Microbial Atrium (SMA)
- Gelatin Filter Air Sampler (MD-80)
  - What makes them all different?



Compressed Gasses

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Regulation	Specification
WHO & PIC/S	Not Specified
FDA Guidance	A compressed gas should be of appropriate purity (e.g., free from oil) and its microbiological and particle quality after filtration should be equal to or better than that of the air in the environment into which the gas is introduced.
USP	Microbial monitoring of manufacturing clean rooms, RABS, and isolators should include compressed gases, surfaces, room or enclosure air, and any other materials and equipment that might produce a risk of contamination.
Japanese Guidance	• Environmental monitoring targets should also include … compressed air or gas that comes in contact with the environment and equipment. • The monitoring frequency of compressed air and gas necessary for manufacturing equipment or used during manufacturing processes may be separately set, provided the cleanliness level can be maintained by integrity test for filters for sterile liquid filtration or other tests.
Japanese Pharmacopoeia	Not Specified
EU Annex 1 – Draft 2019 Revision	Compressed gases that come in direct contact with the product/container primary surfaces should be of appropriate chemical, particulate and microbiological purity.

Surface Sampling (Depends on Surface)

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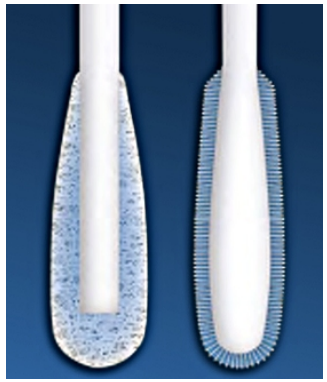
- Contact plates (RODAC) and swabs (regular or irregular surfaces).
- Contact Plate and Swab recovery studies
- Contact plates can offer “better recovery” than swabs and utilized more often (where surface and location permits)
- Flocked swabs offer “better recovery” than spun/cotton swabs due to physical composition
- Rinse samples can be performed on interior surfaces of kettles and tanks using membrane filtration and sterile water (or ringer’s, etc.).
- Sampling done on equipment, work surfaces, floors, walls and product contact surfaces **after production is complete**



How Dirty are We?

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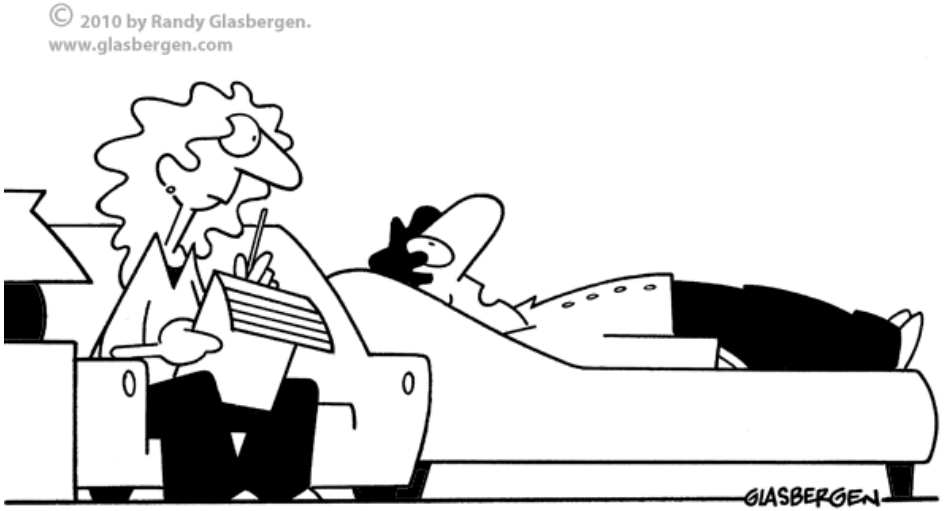

"There are billions of germs, bacteria, and microbes living on my body...but I still get lonely sometimes."

AREA	NUMBER OF MICROORGANISMS/cm^2
Scalp	1 million
Saliva and nasal fluid	10 million/gram
Back	100
Groin	1 – 20 million
Forehead	100 – 1000
Hand	10,000 – 100,000
Armpit	1 – 10 million
Feet	1 million

Source: Clean Room Primer, 1985, J.J. Nappi Jr. Liberty Industries Inc. USA.

Gross! What Happens When We….?

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Activity	Number of particles generated (0.5 micron and larger per minute)
Sitting or standing still	100,000
Sitting, small movement of arms or head	500,000
Sitting, moving arms, legs or head	1,000,000
Standing Up	2,500,000
Walking slowly	5,000,000
Walking normally	7,500,000
Walking ~ 5.5 MPH	10,000,000
Performing a workout	15,000,000 - 30,000,000

Source: Encyclopedia of Cleanrooms, Bio-Cleanrooms, and Aseptic Areas, July 2000, Philip R. Austin

Personnel Monitoring

- **Personnel Monitoring:**
- Routine during production
  - Gloved fingers: underside where contaminants are most likely
  - Critical gown sites for aseptic operations
  - Contact plate testing of people leaving/exiting area
  - Routine failures on a person requires a corrective action (re-training and/or re-qualification)

Gown Training Certification

- Surface sampling of gown at key garment locations
- Personnel MUST participate in a media challenge at least once annually if they will be filling aseptic product

Gowning Qualification & Testing

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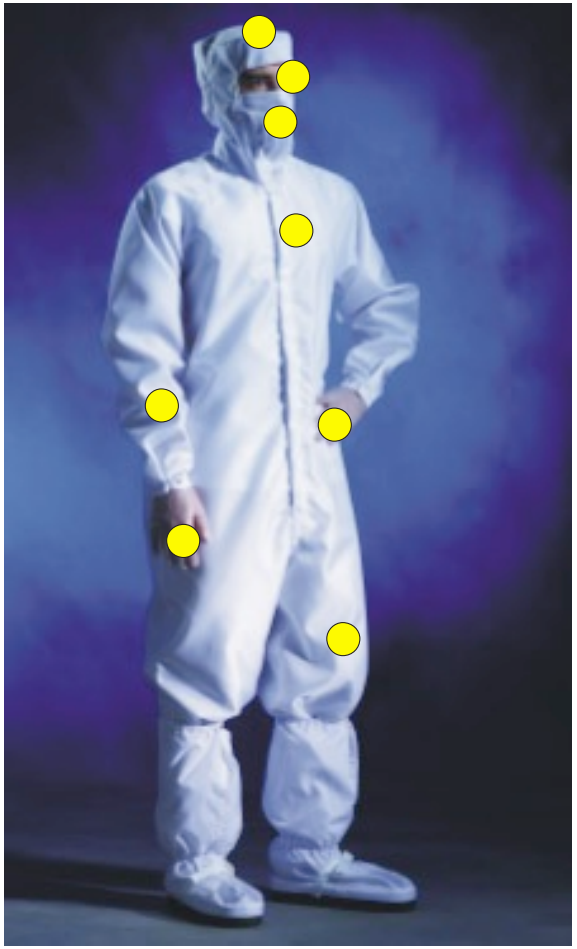
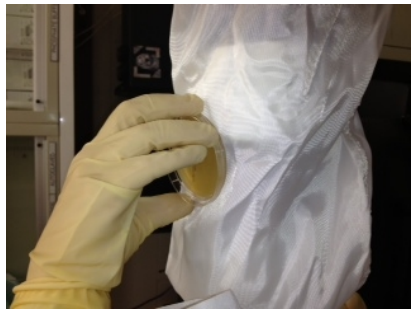
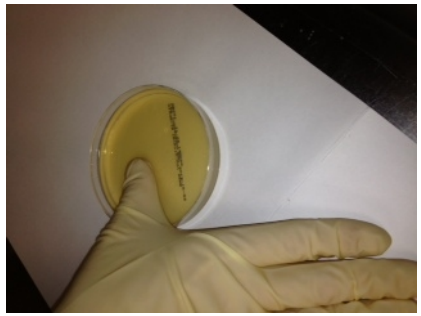
- Set strict limits (< 1 CFU) for qualification
- Remove those who fail and retrain them
- Operators should not qualify or sample/evaluate themselves
- Determine Qualification Test locations
  - **Examples: Hood, goggles, mask, zipper, sleeves, hands (both), thighs, fingers**
- Re-qualify on an every 6 month or annual basis







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Sampling Frequency

Do I Take Enough Samples?

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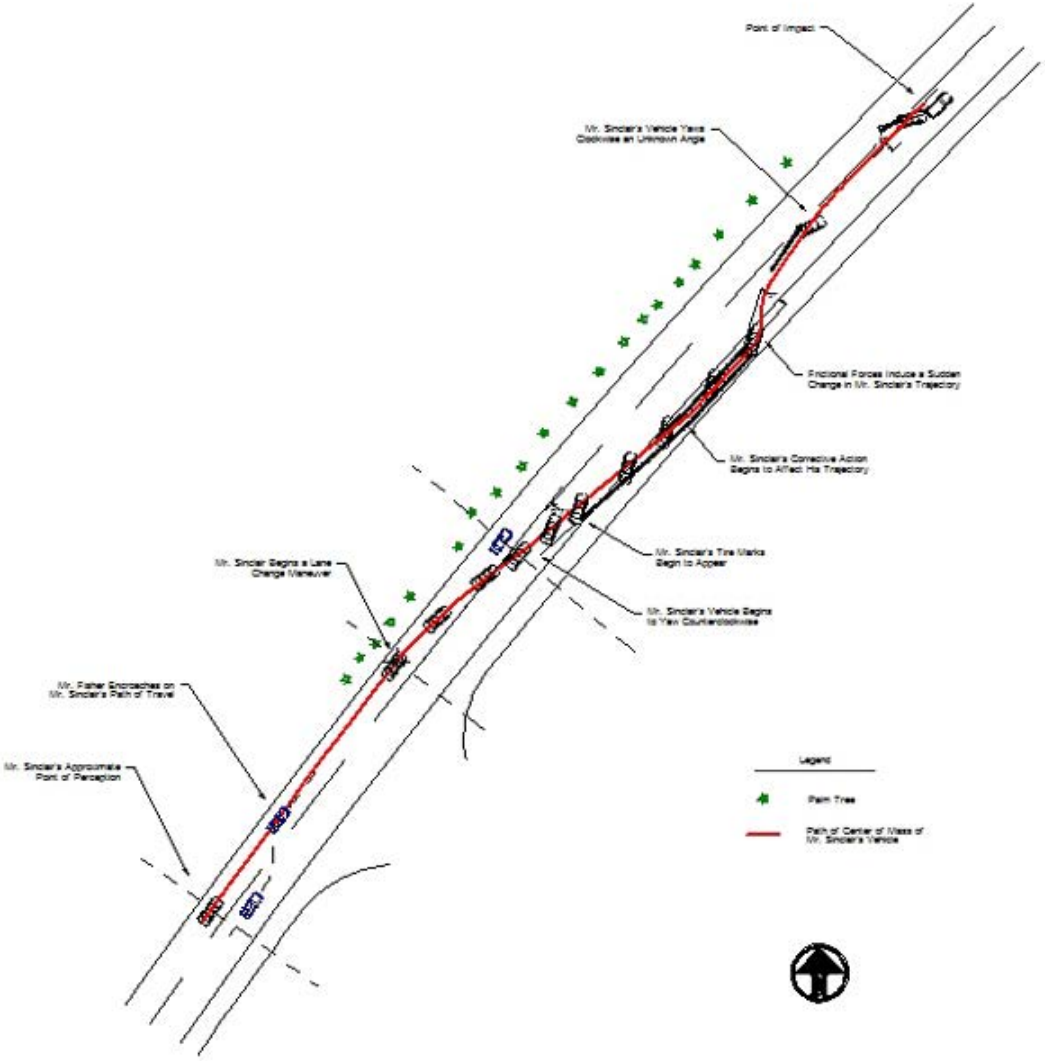
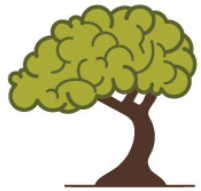
- Once is chance
- Twice is coincidence
- Third time is a pattern



Sampling Frequency



Regulation	Frequency
EU (2008), WHO & PIC/S	• The Grade A zone should be monitored at a frequency and sample size such that all interventions, transient events and any system deterioration would be captured and alarms triggered if alert limits are exceeded. • The Grade B zone should be monitored at a frequency and with a sample size such that changes in levels of contamination and any deterioration of the system would be captured and alarms triggered if alert limits are exceeded. • The monitoring of Grade C and D areas in operation should be performed in accordance with the principles of quality risk management.
FDA Guidance	Based upon the relationship to the operation performed… Sample sizes should be sufficient to optimize detection of environmental contaminants at levels that might be expected in a given clean area.

Sampling Frequency (*cont.*)

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Regulation	Frequency
USP	• The frequency of sampling depends on the manufacturing process conducted within an environment. Classified environments that are used only to provide a lower overall level of bioburden in nonsterile product manufacturing areas require relatively infrequent environmental monitoring. • Classified environments in which closed manufacturing operations are conducted, including fermentation, sterile API processing, and chemical processes, require fewer monitoring sites and less frequent monitoring because the risk of microbial contamination from the surrounding environment is comparatively low. • Microbiological monitoring of environments in which products are filled before terminal sterilization is generally less critical than the monitoring of aseptic processing areas.

Suggested Frequency of Sampling for Aseptic Processing Areas	
Sampling Area/Location	**Frequency of Sampling**
Clean Room/RABS	
Critical zone (ISO 5 or better)	
Active air sampling	Each operational shift
Surface monitoring	At the end of the operation
Aseptic area adjacent critical zone	
All sampling	Each operating shift
Other nonadjacent aseptic areas	
All sampling	Once per day
Isolators	
Critical zone (ISO 5 or better)	
Active air sampling	Once per day
Surface monitoring	At the end of the campaign
Non-aseptic areas surrounding the isolator	
All sampling	Once per month

Sampling Frequency (*cont.*)

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Regulation	Frequency
Japanese Guidance	• The frequency of microbiological monitoring may be increased or decreased depending on the type and time of processing activities; however, the frequency needs to be adequate for effective monitoring of potential microbiological contamination of pharmaceutical products. • The frequency of microbiological sampling from the surface of personnel gown and other stuff should be commensurate with ability and experience of individual personnel. For example, sampling frequency should preferably be increased for operators with less aseptic processing experience. • The monitoring frequency for Grade C and D areas should be determined by the types of pharmaceutical products, processes, operations, etc. to be performed in the areas for appropriate quality control and risk management.

Grade	Airborne Microorganisms	Microorganisms on Surfaces	
		Instruments, walls, etc.	Gloves, gowns
A	Every working shift	After completion of processing	
B	Every working shift		
C, D - Areas in which products and containers are exposed to the environment	Twice a week	Twice a week	N/A
C, D - Other areas	Once a week	Once a week	N/A

Sampling Frequency (*cont.*)

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<table>
<tr><th>Regulation</th><th>Frequency</th></tr>
<tr><td>Japanese Pharmacopoeia</td><td>

The Grade A area, in which sterile products are in contact with environmental air, should be monitored during every operational shift.
In individual cases, appropriate monitoring frequency should be determined based on the results of risk assessment.
In contrast, in manufacturing operations in which isolator, RABS (Restricted Access Barrier System), or brow/ fill/seal units are used, monitoring frequency may be reduced due to lower contamination risks.

<table>
<tr><th rowspan="2">Grade</th><th rowspan="2">Airborne Microorganisms</th><th colspan="2">Microorganisms on Surfaces</th></tr>
<tr><th>Instruments, walls, etc.</th><th>Gloves, gowns</th></tr>
<tr><td>A</td><td>Every working shift</td><td colspan="2" rowspan="2">After completion of processing</td></tr>
<tr><td>B</td><td>Every working shift</td></tr>
<tr><td>C, D* - Areas in which products and containers are exposed to the environment</td><td>Twice a week</td><td>Twice a week</td><td>N/A</td></tr>
<tr><td>C, D* - Other areas</td><td>Once a week</td><td>Once a week</td><td>N/A</td></tr>
</table>
* When a contamination risk is low, for example, where products are not exposed to the surrounding environment, monitoring frequency may be reduced accordingly.
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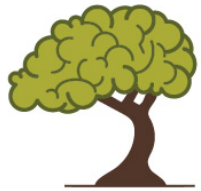
Sampling Frequency (*cont.*)



Regulation	Frequency
EU Annex 1 – Draft 2019 Revision	• Continuous monitoring in grade A and B areas should be undertaken for the full duration of critical processing, including equipment (aseptic set up) assembly and filling operations (i.e., an understanding of function and interactions of each clean area). • The monitoring should be performed in such a way that all interventions, transient events and any system deterioration would be captured and any risk caused by interventions of the monitoring operations is avoided. • Routine monitoring for clean rooms, clean air devices and personnel should be performed "in operation" throughout all critical stages, including equipment set up. • The locations, frequency, volume and duration of monitoring should be determined based on the risk assessment and the results obtained during the qualification. • Monitoring should also be performed outside of operations within the area, e.g. pre disinfection, post disinfection, prior to start of manufacturing and after a shutdown period etc., in order to detect potential incidents of contamination which may affect the controls within the areas. • The number of samples and frequency of monitoring should be considered in the context of the risk assessments and contamination control strategy.

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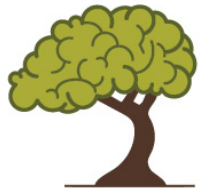
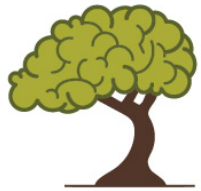
Media Selection & Incubation Scheme

Media Selection & Incubation



Regulation	Target Microorganism	Indicated Media for Use	Incubation Conditions
FDA Guidance	The goal of microbiological monitoring is to reproducibly detect microorganisms for purposes of monitoring the state of environmental control.	The microbiological culture media used in environmental monitoring should be validated as capable of detecting fungi (i.e., yeasts and molds) as well as bacteria.	TABC: 30 - 35°C for 48 - 72 Hours TCYM: 20 - 25°C for 5 – 7 Days
USP	Bacteria, yeast, and molds. Strict anaerobes not performed, but micro-aerophilic organisms may be sampled for, if warranted.	• A general microbiological growth medium such as soybean–casein digest medium (SCDM) is suitable for environmental monitoring in most cases because it supports the growth of a wide range of bacteria, yeast, and molds. • This medium can be supplemented with additives to overcome or to minimize the effects of sanitizing agents or of antibiotics. • Manufacturers should consider the specific detection of yeasts and molds. If necessary, general mycological media such as Sabouraud's, modified Sabouraud's, or inhibitory mold agar can be used.	• Time and incubation are set once appropriate media is selected. • SCDM (TSA): 20 - 35°C for not less than 72 hours (longer for slow growers)

Media Selection & Incubation *(cont.)*



Regulation	Target Microorganism	Indicated Media for Use	Incubation Conditions
Japanese Guidance	• Target microorganisms are bacteria and fungi. • Target microorganisms are airborne bacteria and microorganisms on the surface of walls, floors, fixtures, equipment, gowns, etc.	The culture medium used for the detection and enumeration of airborne and surface microorganisms should be suitable for the growth of target microorganisms such as aerobic bacteria, fungi (i.e. yeasts, molds), and anaerobic bacteria.	The incubation condition of the medium should be suitable for growth of the target microorganisms
Japanese Pharmacopoeia	Aerobes, Yeast and fungi	SCD (or L or LP) agar medium	25 – 30°C - More than 5 days
	Aerobes	SCD (or L or LP) agar medium	30 – 35°C - More than 5 days
	Yeast and fungi	SCD (or L or LP) agar medium Sabouraud glucose agar medium Potato dextrose agar medium Glucose peptone agar medium	20 – 25°C - More than 5 days
	Anaerobes	Reinforced clostridial agar medium SCD agar medium	30 – 35°C - More than 5 days (under an anaerobic culture condition)

Micro 101, GSK Study

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Does this look familiar?

- First incubate at 20-25°C temperature for 72 hours for fungal growth and then same plates transferred to 30-35°C for further 48 hours for bacterial growth. – Favors Fungi & *Bacilli* (Environmental Contamination)
- First incubate at 30-35°C temperature for 48 hours for bacterial growth and then same plates transferred to 20-25°C for further 72 hours for fungal growth. – Favors Gram Positive *Cocci* (People Contamination)

GSK, Barnard Castle, UK Study (Symonds, Davies, Martin)

Results (*spoiler alert!!!!!* It depends):

- In Grades A & B (it is recognized that operators and their garments present the greatest contamination threat. Therefore TSA medium incubated at 30-35° C is recommended.\
- However, initial qualification of the aseptic area should be conducted using duplicate TSA sampling media with one set incubated at 20-25°C and at 30-35° C. This should also be carried out following both planned and unplanned shutdowns where the classified area may have been exposed to environmental contaminants.
- Dual temperature incubation (one temp followed by another) provided the lowest recovery and is not recommended.

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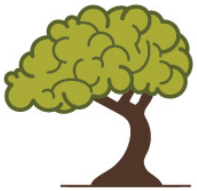
Identification of Microorganisms

Identification of Microorganisms



Regulation	Microorganism
EU Annex 1 – Draft 2019 Revision	• If microorganisms are detected in a grade A or B zone, they should be identified to species level and the impact of such microorganisms on product quality (for each batch implicated) and state of control should be evaluated. • Consideration may also be given to the identification of grade C and D contaminants and the requirements should be defined in the contamination control strategy.
FDA Guidance	• Monitoring of critical and immediately surrounding clean areas as well as personnel should include routine identification of microorganisms to the species (or, where appropriate, genus) level • Establishing an adequate program for differentiating microorganisms in the lesser-controlled environments, such as Class 100,000 (ISO 8), can often be instrumental in detecting such trends (migration of microorganisms into clean areas)
USP	• A successful environmental control program includes an appropriate level of identification of the flora obtained by sampling. • A knowledge of the flora in controlled environments aids in determining the usual microbial flora anticipated for the facility and in evaluating the effectiveness of the cleaning and sanitization procedures, methods, agents and recovery methods. • The information gathered by an identification program can be useful in the investigation of the source of contamination, especially when recommended detection frequencies are exceeded.
Japanese Pharmacopoeia	• Identification of microorganisms detected in Grade A and B areas to the species level is recommended. Genotypic methods are more accurate and precise than traditional biochemical and phenotypic techniques. • These results can be used for investigations into contaminants found in sterility tests or process simulations.

What your Contract Lab Uses (or you, with funds)

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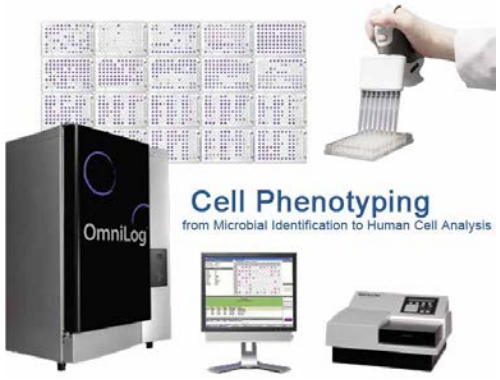
Phenotypic Identification



Biolog GEN III OmniLog ID® System

BioMerieux Vitek® 2 System

Genotypic Identification

DuPont RiboPrinter®

Thermo Fisher Scientific MicroSeq®

Proteotypic Identification

BioMerieux Vitek® MS System

Bruker MALDI Biotyper

Identification Results

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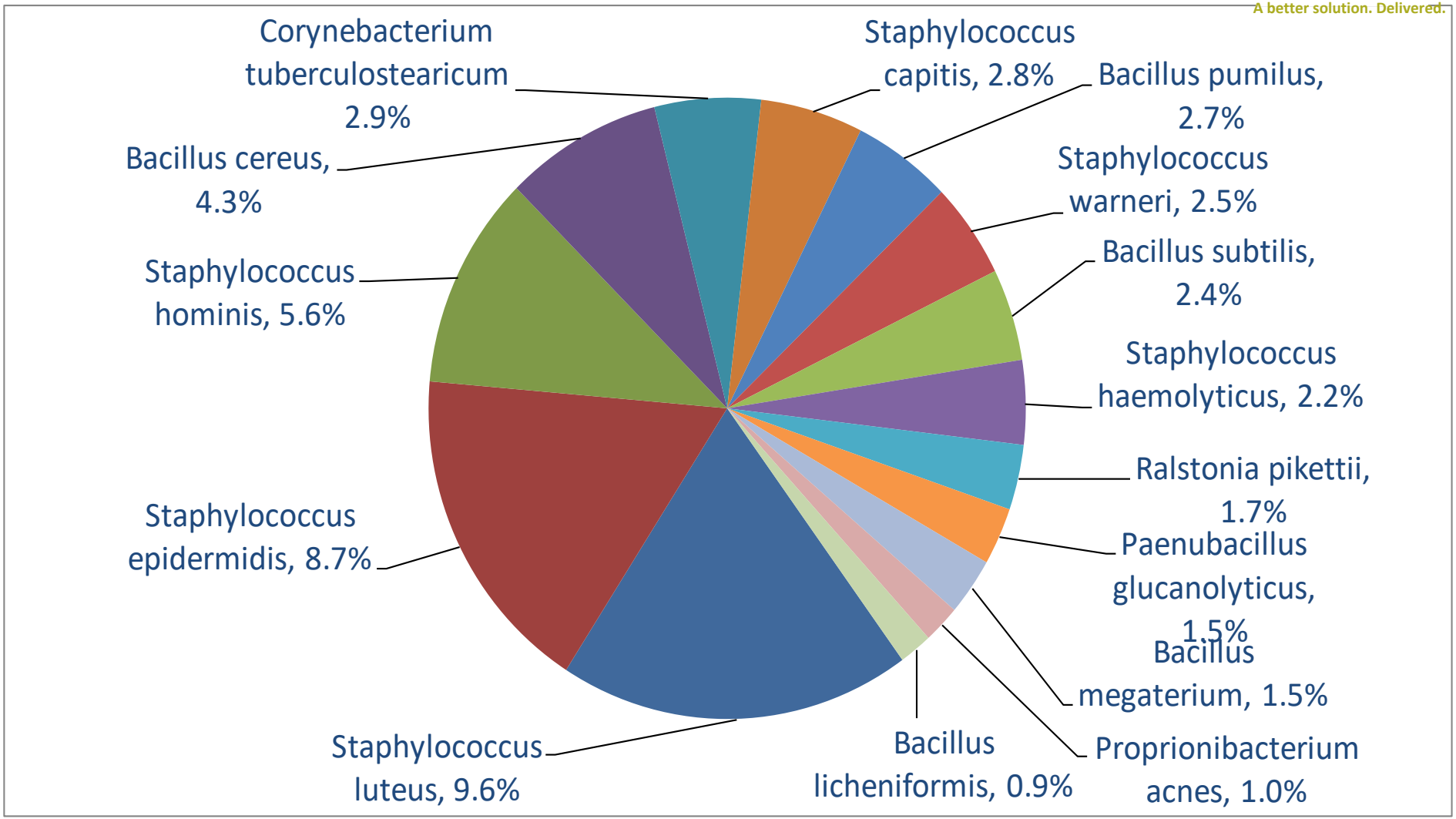

Source: Bacteria Most Often Submitted for Identification Testing During 2010, Barry A. Friedman, posted May 17, 2011

Distribution/Source of Microorganisms

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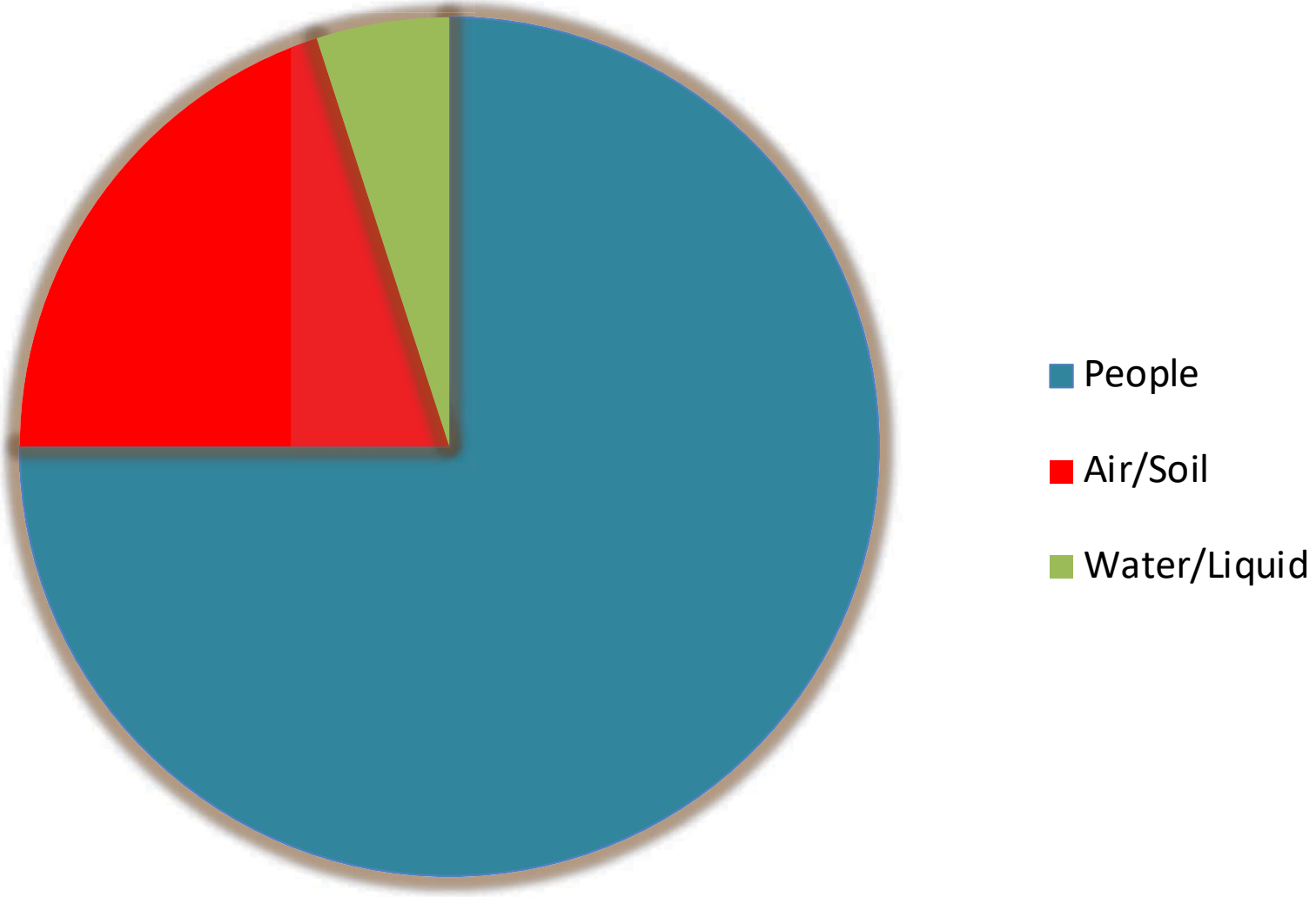

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Viable Action Limits

Viable Limits – EU (2008), WHO & PIC/S

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Recommended Limits for Microbial Contamination [a]				
Grade	**Air Sample - CFU/m³**	**Settle Plates (diam. 90mm) CFU/4 Hours [b]**	**Contact Plates (diam. 55mm) CFU/Plate**	**Glove Print 5 Fingers CFU/Glove**
A	< 1	< 1	< 1	< 1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

a. These are average values.
b. Individual settle plates may be exposed for less than 4 hours.

Viable Limits – EU Annex 1 (2019 DRAFT)

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Recommended Maximum Limits for Microbial Contamination				
Grade	**Air Sample - CFU/m³**	**Settle Plates (diam. 90mm) CFU/4 Hours [a]**	**Contact Plates (diam. 55mm) CFU/Plate**	**Glove Print 5 Fingers on Both Hands CFU/Glove**
A[b]	1	1	1	1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

(a) Individual settle plates may be exposed for less than 4 hours. Where settle plates are exposed for less than 4 hours the limits in the table should still be used. Settle plates should be exposed for the duration of critical operations and changed as required after 4 hours.

(b) It should be noted that for grade A the expected result should be 0 CFU recovered; any recovery of 1 CFU or greater should result in an investigation.

Viable Limits – FDA GMP (2004)

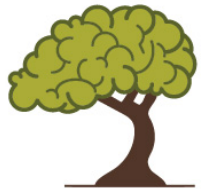


TABLE 1 - Air Classifications [a]				
Clean Area Classification (0.5 µm particles/ft³)	ISO Designation [b]	> 0.5 µm particles/m³	Microbiological Active Air Action Levels [c] (CFU/m³)	Microbiological Settling Plates Action Levels [c, d] (diam. 90mm; CFU/4 hours)
100	**5**	3,520	1 [e]	1 [e]
1,000	**6**	35,200	7	3
10,000	**7**	352,000	10	5
100,000	**8**	3,520,000	100	50

a. All classifications based on data measured in the vicinity of exposed materials/articles during periods of activity.

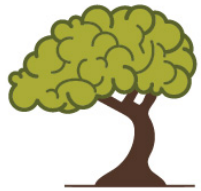
b. ISO 14644-1 designations provide uniform particle concentration values for cleanrooms in multiple industries. An ISO 5 particle concentration is equal to Class 100 and approximately equals EU Grade A.

c. Values represent recommended levels of environmental quality. You may find it appropriate to establish alternate microbiological action levels due to the nature of the operation or method of analysis.

d. The additional use of settling plates is optional.

e. Samples from Class 100 (ISO 5) environments should normally yield no microbiological contaminants.

Viable Limits – Japanese GMP & Pharmacopoeia



Acceptance Criteria for Environmental Microorganism Count (during Operations) *Note [1]*				
Cleanliness Grade	Airborne microorganisms		Surface microorganisms	
	Air (CFU/m³)	Settle Plate [Note 2] (CFU/Plate)	Contact Plate (CFU/24-30 cm²)	Gloves (CFU/5 Fingers)
A	< 1	< 1	< 1	< 1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

Note 1) Acceptance criteria are expressed as mean values. – *GMP*

*1 These are average values. – *Pharmacopoeia*

Note 2) Measurement time per plate is 4 hours at maximum and the measurement is performed during processing operation. – *GMP*

*2 The exposure time of each plate should be less than four hours. Monitoring should be performed throughout operations. – *Pharmacopoeia*

Viable Limits – USP

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Suggested Initial Contamination Recovery Rates in Aseptic Environments*				
Room Classification	**Active Air Sample (%)**	**Settle Plate (9 cm) 4 h Exposure (%)**	**Contact Plate or Swab (%)**	**Glove or Garment (%)**
Isolator/Closed RABS (ISO 5 or better)	<0.1	<0.1	<0.1	<0.1
ISO 5	<1	<1	<1	<1
ISO 6	<3	<3	<3	<3
ISO 7	<5	<5	<5	<5
ISO 8	<10	<10	<10	<10

* All operators are aseptically gowned in these environments (with the exception of background environments for isolators). These recommendations do not apply to production areas for non-sterile products or other classified environments in which fully aseptic gowns are not donned.

- Detection frequency should be based on actual monitoring data and should be re-tabulated monthly.

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Establishing Alert Limits & Trending

Responding to Events

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- **Regulations require:**
  - **Immediate follow-up**
  - **Identification of microorganisms**
  - **Corrective actions/preventive actions (CAPAS) if appropriate**

- **Indicates potential deviation from normal operational conditions**
- **Document and follow-up**
- **Additional or modified sample plan**
- **Designed to allow appropriate capability of reaction before reaching Action level**

- **No actions required**

Regulatory Expectations

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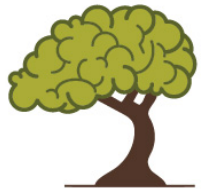
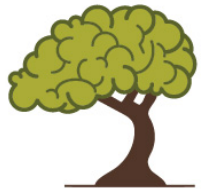
Document	Setting Levels & Trending
EU, WHO & PIC/S	• Levels of detection of microbial contamination should be established for the purpose of setting alert and action limits and for monitoring the trends in environmental cleanliness in the facility. Limits expressed in colony-forming units (CFU) for the microbiological monitoring of clean areas in operation are given in the [Limits Table]. • Appropriate alert and action limits should be set for the results of particulate and microbiological monitoring. If the action limits are exceeded or a trend is identified in the alert limits, investigation should be initiated and the appropriate corrective actions should be taken, as prescribed in the operating procedures.
FDA Guidance	Based on : • The relationship of the sampled location to the operation • The need to maintain adequate microbiological control throughout the entire sterile manufacturing facility • Historical databases, media fills, cleanroom qualification and sanitization studies
Japanese Guidance	• Action level by referring to data contained in monitoring frequency table. • Alert level specifications should be established based on results of PQ tests. • … data obtained from routine monitoring should be analyzed to detect any trends in changes in the environment and establish monitoring limits for trend analysis. • … any trends suggesting variations from normal conditions (trend analysis level) should be predicted and the cause(s) investigated to maintain the quality of the environment at an appropriate level.

Regulatory Expectations



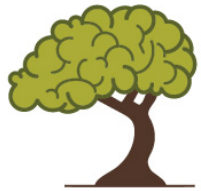
Document	How to Determine Locations
Japanese Pharmacopoeia	• Environmental monitoring data should be evaluated both in the short-term and the long-term. The following items should be included in the evaluation: (i) Changes in numbers of microorganisms and airborne particulates over a period of time (ii) Changes in detected species of microorganisms (iii) Changes of monitoring points (iv) Review of the validity of alert and action levels (v) Review of frequency of positive results from each operator (vi) Changes that may impact the monitoring results during the monitoring periods • Trend analysis of environmental monitoring data will provide information required to predict potential deterioration of the manufacturing environment before it occurs and to determine its probable causes. Information that may impact the environment, such as monitoring location, date and time, product manufactured during the monitoring period, batch number, personnel in operation, is also important. • In the event of any deviation found in the environmental monitoring data, actions to be taken for the products manufactured and measures to be taken to recover the required cleanliness of the environment should be determined with consideration of the nature of activities performed at the time, distance between the product and the site where the deviation was found, and the severity of the deviation.

Regulatory Expectations



Document	How to Determine Locations
EU Annex 1 – Draft 2019 Revision	• Appropriate alert and action limits should be set for the results of particulate and microbiological monitoring. Alert levels should be established based on results of Performance Qualification (PQ) tests or trend data and should be subject to periodic review. • The alert limits for grade B, C and D should be set based on the area performance, with the aim to have limits lower than those specified as action limits, in order to minimize risks associated and identify potential changes that may be detrimental to the process. • If action limits are exceeded operating procedures should prescribe a root-cause investigation followed by corrective and preventive action. If alert limits are exceeded, operating procedures should prescribe scrutiny and follow-up, which might include investigation and corrective action. • The monitoring of grade C and D areas in operation should be performed in accordance with the principles of QRM to provide sufficient data to allow effective trend analysis. The requirements and alert/action limits will depend on the nature of the operations carried out. • Monitoring procedures should define the approach to trending. Trends can include but are not limited to: a) Increasing numbers of action or alert limit breaches. b) Consecutive breaches or alert limits. c) Regular but isolated breaches of limits that may have a common cause, for example single excursions that always follow planned preventative maintenance. d) Changes in flora type and numbers.

Calculating Alert & Action Limits



- **Normal Distribution Approach**
- The mean and standard deviation of the data are calculated and the alert and action levels are set a the mean plus two (2) and three (3) times the standard deviation.
- This is best used for high counts and when the data is normally distributed only.
  - A Poisson distribution is used for low counts.

- **Cut-Off Value Approach**
  - The mean All the test data are arranged in a histogram and the alert and action levels are set at values whose monitoring results are 5% and 1% higher than the level selected.
  - A variation is to take the last 100 monitoring results and use the 95th and 99th percentile values as the alert levels.

- **Use Software (← pick this option)**

What Does Trending Look Like?

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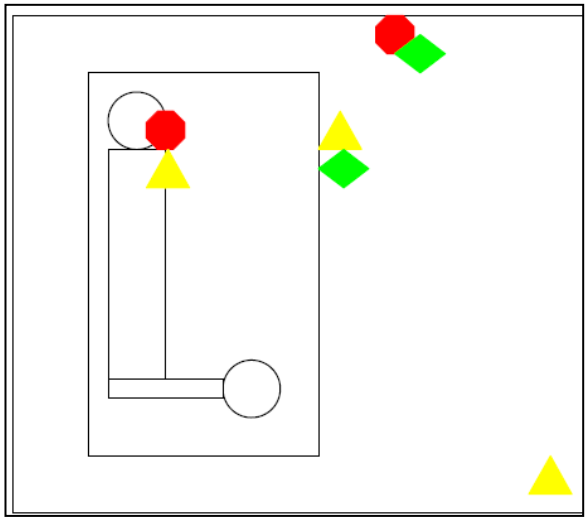
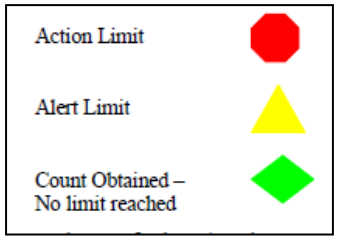
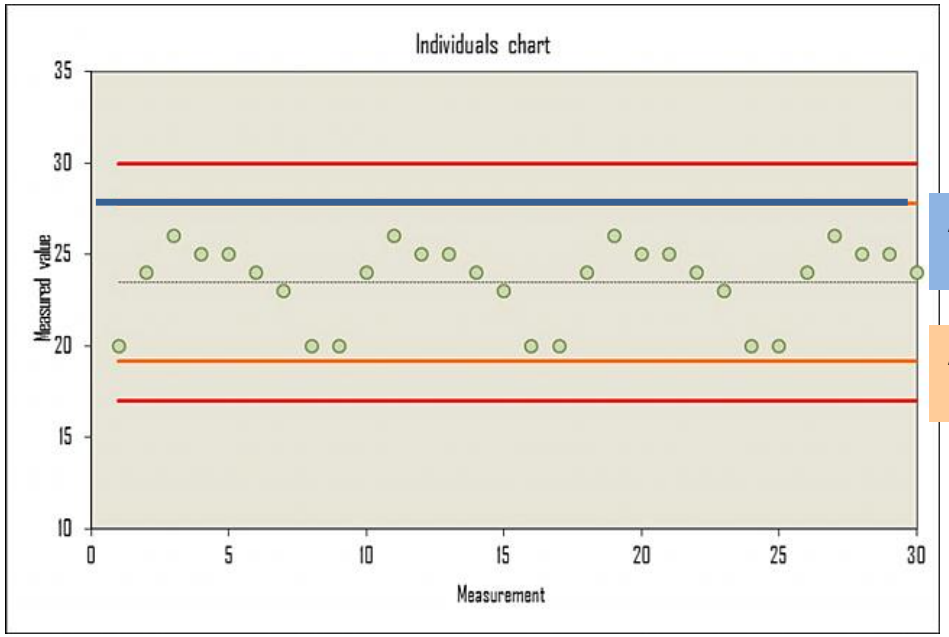
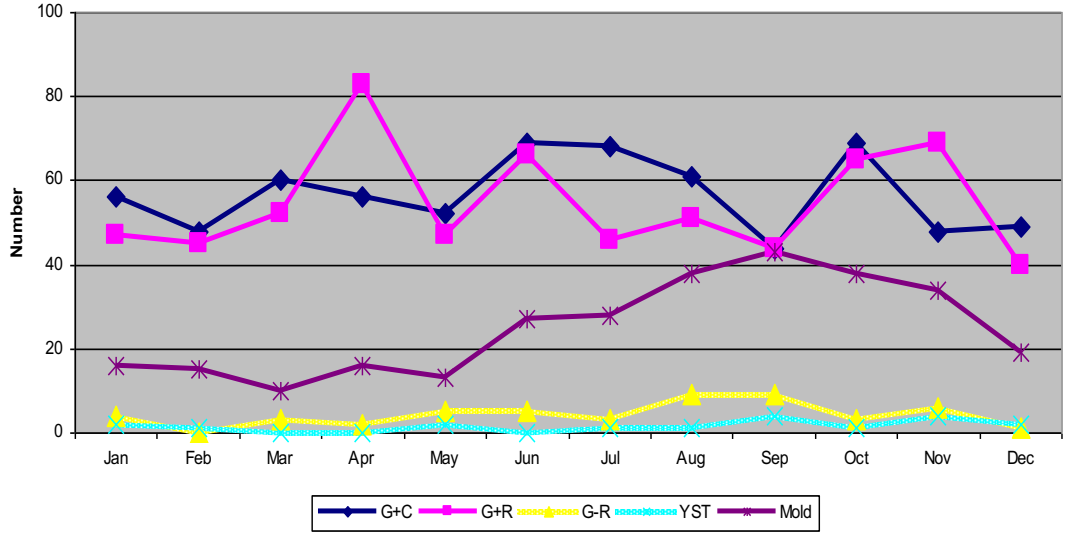






Action level

Alert level



Putting it all Together

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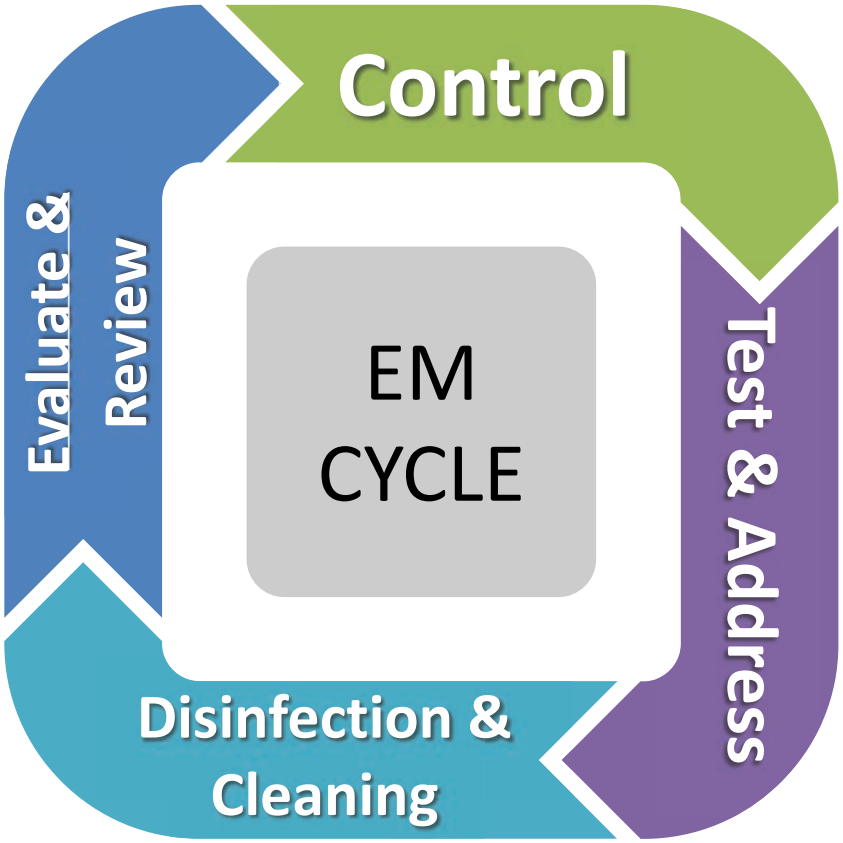
Evaluate & Review

Periodic trend review with multiple disciplines and departments.

Ensure appropriateness of current EM program, make changes and continue with EM cycle.

Cleaning & Disinfection

Application of qualified disinfectants. Routine cleaning & sporicide rotation should be part of the disinfection system.



Control

Control what enters the Environment. Can be done with airlocks, HVAC, gowning, facility design, etc.

Test & Address

Perform sampling, evaluate data and address concerns

Questions?

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