Impact of the Changes to ISO 14644-1 & 2

The Long Awaited Changes Are Here – Are You Ready to Comply?

Marsha Steed (Hardiman)

ValSource

Presenter

Marsha Steed (Hardiman)

- Over 20 years experience in the Pharmaceutical and Medical Device industries
- Microbiologist
- PDA Scientific Advisory Board - SAB
- Senior Consultant, ValSource

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Presentation Overview

- Changes to ISO 14644 Part 2
- Impact and How to Prepare in Your Company
- New Risk Assessment Requirements

ISO 14644-2 Changes

- Emphasizes the need to consider a monitoring strategy in addition to the execution of the classification of a cleanroom or clean zone
- As you collect more data after initial classification, your on-going monitoring will help you better assess how your cleanroom operates
- Principal – gain assurance your cleanroom performs as expected after classification

14644-2:2015 Highlights

- Title Change
- Monitoring Plan
- Risk Assessment
- Periodic Classification
- Alarms

Title Change

- ISO 14644-2 1999 Specifications for testing and monitoring to prove continued compliance with 14644 -1

- ISO14644-2 2015 Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

Risk Assessment

- ISO 14644-2 specifies the requirements of a monitoring plan, **based on a risk assessment of the intended use**
- A risk assessment shall be undertaken to
  - Develop a monitoring plan by determining what factors may your ability to maintain your classification air cleanliness levels
  - Determine the monitoring requirements to provide evidence of performance

Monitoring Plan

Guidance given for:

- Creation of the Plan
- Use of Risk Assessment
- Review and approval of your monitoring plan
- Implementing
- Data analysis
- Review the monitoring plan periodically

The plan should reflect the level of air cleanliness required, critical locations and performance attributes of the cleanroom

Monitoring Plan

- List and justify parameters to be monitored
  - Including those that may affect the airborne particle concentration
- Describe and justify measuring methods
- Identify and justify sample locations
- Establish alarms and/or alert/action levels
  - Explain what will be done if out of limits data found
- Establish the need and frequency of periodic cleanroom classification
- The format for recording data
- Trending methods
- Reporting requirements
- Frequency of review of the monitoring plan

Periodic Classification

- Periodic classification shall be undertaken annually
- The frequency can be extended based on risk assessment, the extent of the monitoring system, and data that are consistently in compliance with acceptance limits or levels defined in the monitoring plan
- What about ISO 14644-3 ancillary tests?

Annexes

- Annex A – Matters to consider when developing a monitoring plan
  - Select a risk assessment tool
  - Pressure differential monitoring
  - Airborne particle monitoring system
  - Airflow velocity and volume monitoring
- Annex B – Setting Alert and Action Levels

- *Both are informative annexes*

Impact of ISO 14644-2 Changes

- Perform a risk assessment based on your HVAC and cleanroom performance
- Create a monitoring plan based on results of the risk assessment – **what might contaminate my cleanroom and how/when will I monitor this?**
- Determine and justify your periodic classification testing frequency based on the risk assessment results
- Determine and justify other testing (recovery, leak test, etc.)
- HUGE opportunity to leverage your day to day data to support your testing frequencies

Monitoring Plan Development – Risk Assessment

- Select and appropriate tool
  - HACCP, FMEA, PHA, FTA, HAZOP, etc

Monitoring Plan Development – Risk Assessment

- Define required performance and operating conditions that may need to be monitored
  - Factors such as
    - Understand contamination sources and their impact on the activity in the cleanroom
    - Performance of HVAC that may affect cleanliness levels – pressure differentials, airflow uniformity, airflow volume, ventilation effectiveness, temperature, RH

Monitoring Plan Development – Risk Assessment

- Normal and energy-saving set-back mode
- At rest or operational states
- Occupancy and level of activity – including change of shift

Monitoring Plan Development – General Consideration

- Measuring system being used
  - Accuracy, calibration
- Measuring technique
  - Manual or automated
- Location of monitoring system components
  - Access for PM and Calibration
- Instrument/sample probe location, configuration and orientation
- Frequency of sampling to detect excursions

Monitoring Plan Development – General Consideration

- Factors that can impact the monitoring system
  - Cleaning procedures/agents, fumigation, temperature, humidity, product or material hazards
- Any potential adverse impact of the sampling system on the process or environment
  - Pulling too much volume from an air sampler in a small space
- Smoke study results
- Ventilation effectiveness in the rooms
  - Air change rates, room recovery, clean-up times

Monitoring Plan Development – General Consideration

- Impact of extent/frequency of cleaning on particle levels
  - During cleaning, immediately after cleaning
- Process activities that may impact the environment (setup)
  - Recovery time after activity?
- Personnel positions and movements during production
- Number and role of personnel in the cleanrooms
- Impact of equipment generated particles
  - Conveyor belt abrasion, sealing glass ampules, welding of tubing

Monitoring Plan Development – General Consideration

- Data Management
  - Includes data integrity, storage and retrieval
- Establishing techniques to assess and evaluate data
  - Trending, creating trend reports
- Development of alert and action levels
- Requirements for commissioning and testing the monitoring system(s)
- Requirements for PM of the monitoring system(s)

Monitoring Plan Development – General Consideration

- Pressure Differential Monitoring
  - Managing fluctuations caused by door openings or use of local exhaust
  - Establishing alert and action levels that are sensitive to normal pressure fluctuations (door openings/closings)
  - Manual or automated monitoring of pressure diffs?

Monitoring Plan Development – General Consideration

Airborne Particle Monitoring System

- Determining the system configuration needed for real-time systems
  - *Do I need multiple point of use units or single system with manifold and transport tubing (could impact 5 micron particles)*
  - Collection efficiency
  - Suitability to monitor selected sizes
  - Accessibility for PM, calibration, repair
  - Manual or automated monitoring of pressure diffs?
  - Air sample flow rates and volumes
  - Frequency and duration of sample collection
  - Sample probe orientation

Monitoring Plan Development – General Consideration

Airflow Velocity and Volume Monitoring

- Determining the airflow velocity or volume measurement technique
- Determining the location of the measurement device so it is representative of the system being monitored
  - You may have to evaluate multiple locations to prove measurements are representative

THANK YOU

Marsha Steed (Hardiman)

ValSource

mstabler@concordiavalsource.com