Facilities should strongly consider having special start-up cleaning and disinfection programs in place following shutdowns or when significant construction has been performed.

Cleanrooms Shutdown

• Planned shutdown
  • Maintenance work
  • Construction work
  • Equipment repair / installation
  • Extended holidays / Non-use

• Unplanned shutdown
  • Power outage
  • AHU breakdown
  • Natural disaster
 Restoration of Cleanroom

• Type of restoration activities depends on:
  • Length of shutdown
    • Less than 24 hours vs weeks
  • Type of activities during shutdown
    • Extensive renovation work - Heavily soiled
    • Non use or extended holiday – relatively clean
Restoration of Cleanroom

• For restoration of cleanroom following a planned or unplanned shutdown:

• A plan or procedure stating:
  • Initial gross cleaning
  • Baseline environmental monitoring
  • Cleaning and disinfection strategy
  • Environmental monitoring
  • Criteria of handing over for production
Typical Restoration Activities

• Initial gross cleaning
  • Removal of soil & other contaminants
    Heavily soiled: broom clean / vacuum, mop with water / detergent

• Collect EM baseline data

• Perform cleaning & disinfection using disinfectants and sporicidal agents on all room surfaces
Typical Restoration Activities (Cont)

• Ceiling, walls, floors
• Equipment surfaces, cleanroom furniture
• Collect EM data (both viable & non-viable) after cleaning and disinfection
• Release of cleanroom
Triple Clean

• Triple Clean in One Day
  • Disinfectant A (low pH phenolic)
  • Disinfectant B (high pH phenolic)
  • Sporicidal agent

• 9X Clean
  • Perform triple clean each day on 3 consecutive days
  • [2X Phenolic disinfectants + 1X Sporicidal agent repeated on days 1,2,3]
Summary of Restoration Activities

1. Initial goss cleaning
2. Collect EM baseline data
3. Cleaning & disinfection using disinfectant & sporicidal agent for consecutive days
4. Release of cleanroom
5. EM monitoring after cleaning and disinfection
Time 0

Red = Spore formers     Green = Other
After 1X Cleaning - No Sporicide

Red = Spore formers
After 2X Cleaning - No Sporicide

Red = Spore formers
After 3X Cleaning - No Sporicide

Red = Spore formers
After Sporicide