

Bringing Cleanroom Online



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

PDA Technical Report No. 70 “Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities” (2015)

Cleanrooms Shutdown

- Planned shutdown
 - Maintenance work
 - Construction work
 - Equipment repair / installation
 - Extended holidays / Non-use
- Unplanned shutdown
 - Power outage
 - AHU breakdown
 - Natural disaster

- 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

- 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

- 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

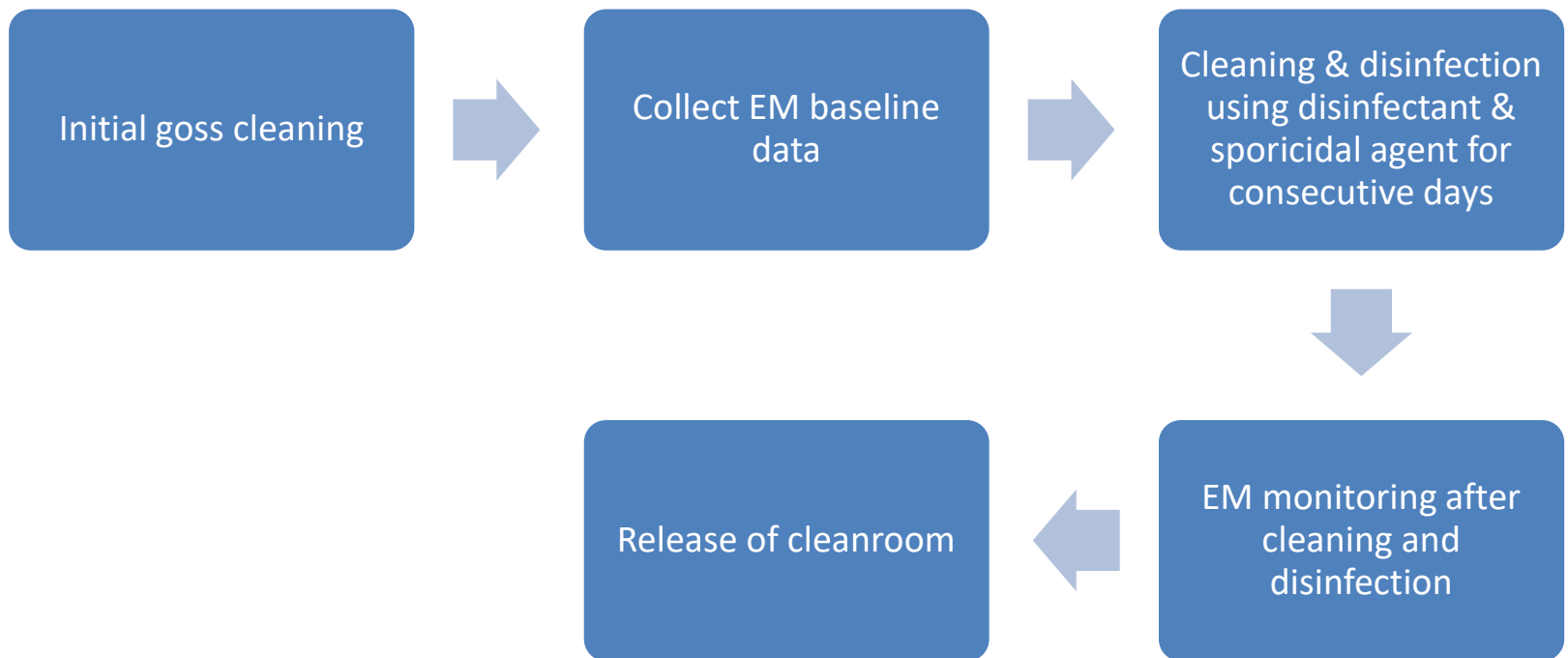
Typical Restoration Activities (Cont)

- 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]

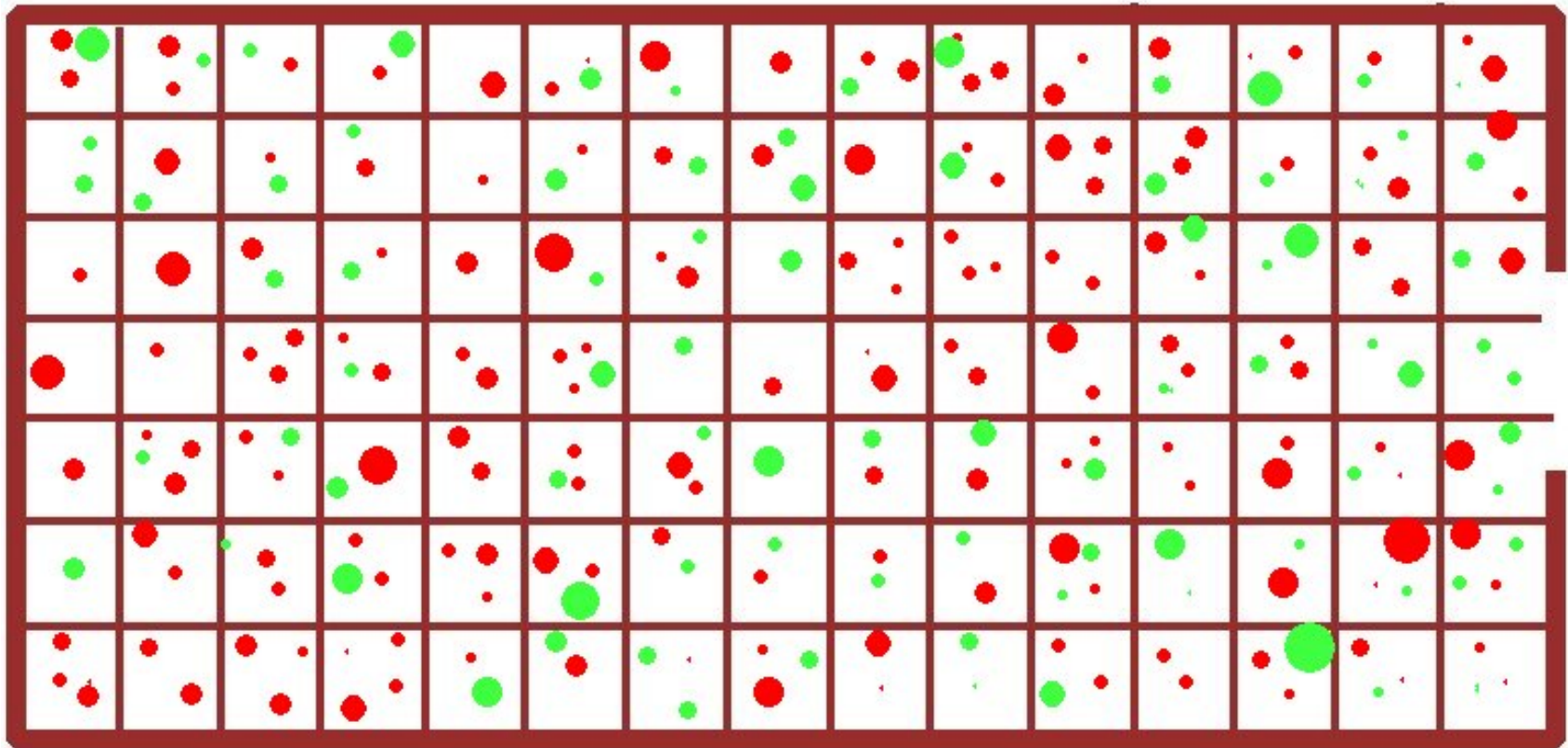
Summary of Restoration Activities



Time 0

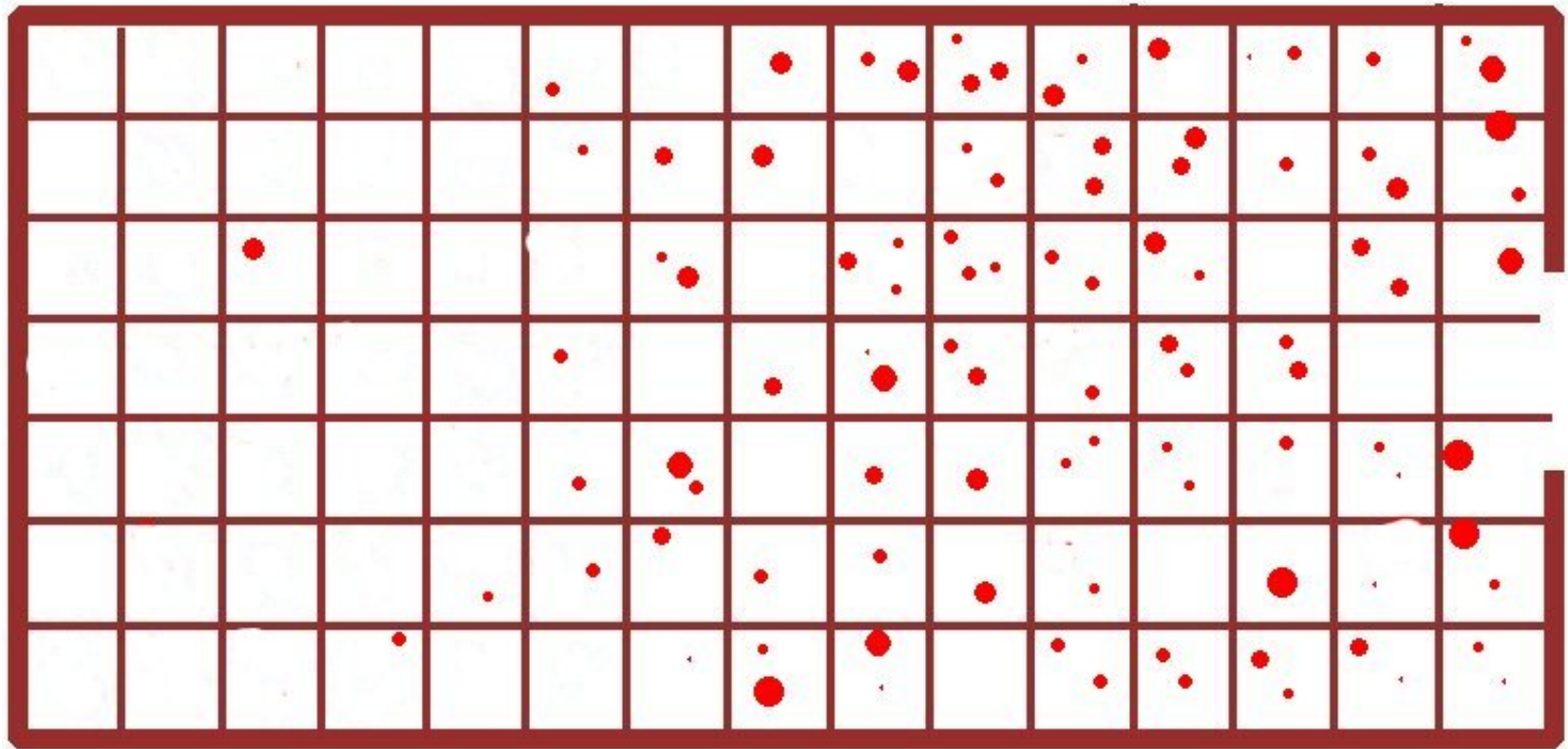
Red = Spore formers

Green = Other



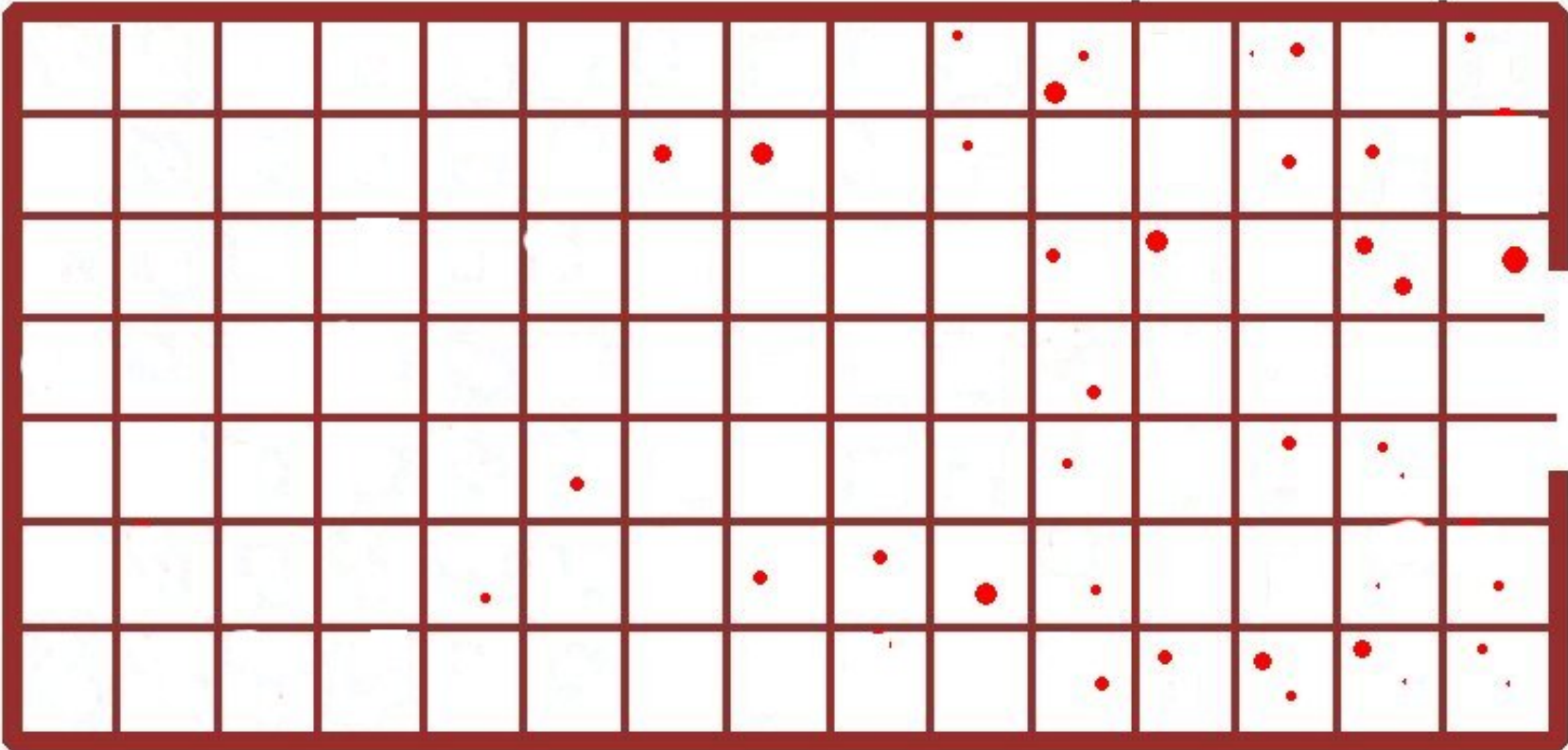
After 1X Cleaning - No Sporicide

Red = Spore formers



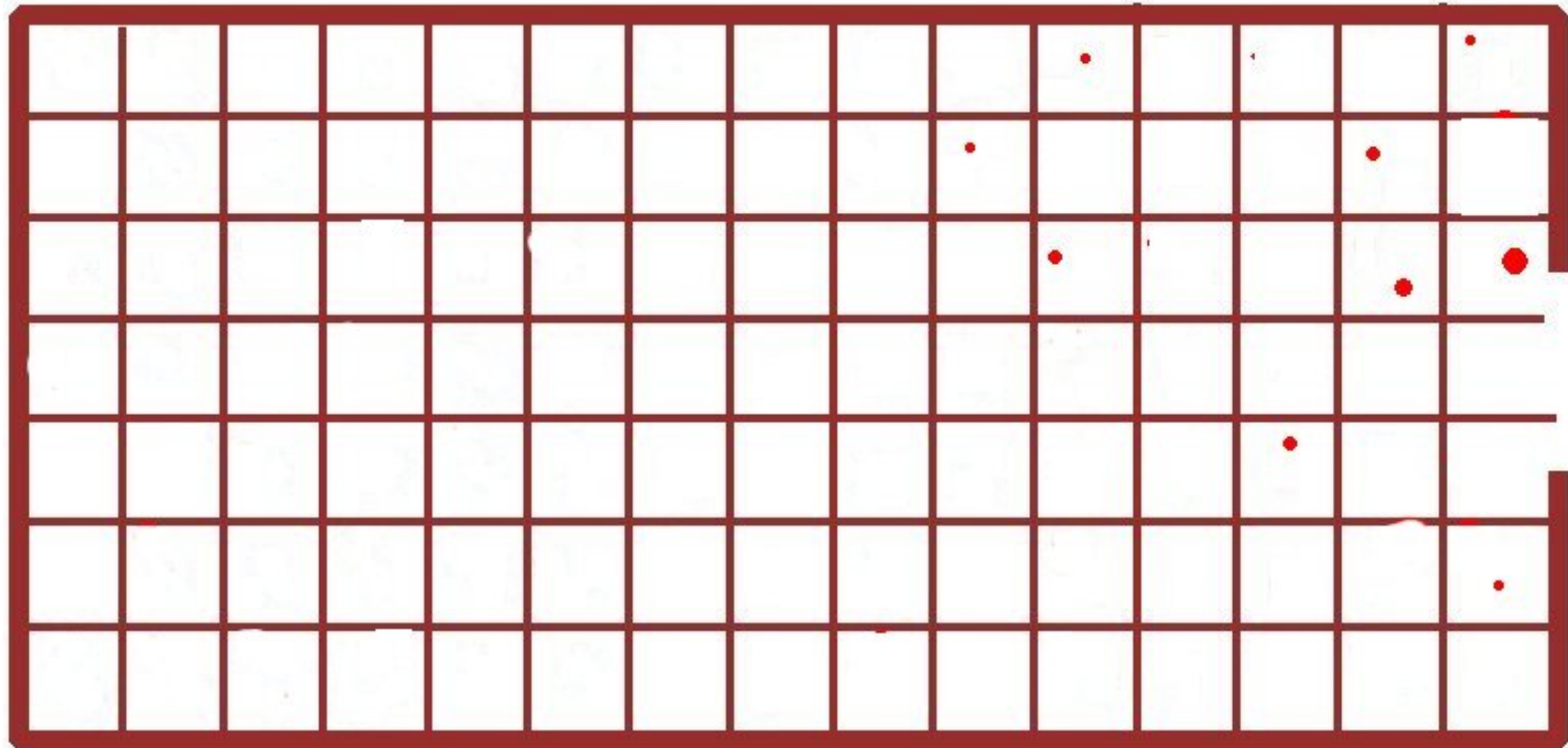
After 2X Cleaning - No Sporicide

Red = Spore formers



After 3X Cleaning - No Sporicide

Red = Spore formers



After Sporicide

