# Rapid decontamination, biological validation, HEPA and Pressure degradation testing to reduce shut-down time in a PC3/4 annual maintenance shutdown

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**ABSTRACT**

The maintainance of a PC3/4 facility is a challenging and complex task. The need for up-time, reliable containment, multiple stake holders and the inherent risks of these facilities, presents a very high level of difficulty for all involved.

A general part of the maintenance strategy is an annual shut down, where all major works are compressed into as narrow a window as possible. One of the more time consuming elements in this shut down is the steps involving decontamination, biological verification testing, thence HEPA testing and Pressure Degredation testing.

This poster outlines a number of novel steps that allow a compression of downtime of this process, without any compromise in the resulting safety or efficacy of the individual steps. Explanation of how a traditional 7-10 day decontamination/testing time can be compressed into a 4 day duration for this stage of the shutdown will be detailed, along with data to demonstrate efficacy of these processes.

## INTRODUCTION

For any Facility Manager, the annual shutdown of a High containment facility; PC3/PC4; requires precision planning, scheduling and execution to enable the facility to be up and running in the shortest time possible. The multitude of specialist and generalist trades that are involved, timing in terms of works scheduled and execution of said works followed by the required documentation and validation for Regulators (OGTR/DAWR) is a highly involved process requiring long term planning.

Any delay or issue encountered as part of the annual maintenance shutdown can result in length delays resulting in extended shut down of these much required facilities. Additional pressure is sometimes placed on an already highly sensitive environment, is when the facility is involved in clinical diagnostic work or critical timed research.

This poster looks at some novel approaches to reducing the amount of time the annual shut down is required by utilising available and approved methods especially in the preliminary decontamination and critical testing at the beginning of any High Containment shut down period.

A typical schedule for shutdown may look like Figure 1 indicating the major components of a shut down period.

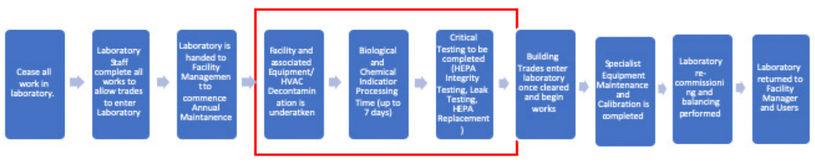


**Figure 1** - shows typical shutdown period of PC3/PC4 facility (not in detail). This poster concerns itself with the section highlighted in red whereby many days can be saved using a more rapid decontamination process, rapid biological efficacy validation and intelligent scheduling and testing.

A traditional approach to biological decontamination would typically require at least 12-24 hours aeration post decontamination (Formaldehyde, $H_2O_2$ etc) and would typically occurred on day 1 of the shutdown period. Please see Figure 2 that demonstrates, in principle, the first 12 days of a typical a) traditional method shutdown and b) a rapid method shutdown process outlined in this poster.

**Figure 2** - shows typical shutdown period in days activities of PC3/PC4 facility (not in detail).

| Traditional Method | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Shut down Days | | | | | | | | | | | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | ... |
| Decontaminate Lab & exhaust overnight | Return to wipe down & clear lab. Collect & Process BI's | Await BI Results | Await BI Results | Await BI Results | Await BI Results | Await BI Results | BI Results & Acceptable | Commence Leak Testing & Critical Testing | Facility Maintence | Facility Maintence | Facility Maintence | Facility Maintence |

| Rapid Method | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Shut down Days | | | | | | | | | | | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | ... |
| Decontaminate Lab & exhaust on same day. Collect BI's and Process | Await BI Results | BI Results & Acceptable (AM). Commence Leak Testing & Critical Testing (PM) | Facility Maintence | Facility Maintence | Facility Maintence | Facility Maintence | Facility Maintence | Facility Maintence | Facility Maintence | Facility Maintence | Facility Maintence | Facility Maintence |

Methodology:

By adopting the following principles and decontamination process, there can be up to a 6 day saving alone on the first step of the shut process.

Traditional biological indicator incubation times would be

1. Rapid Decontamination Process – Chlorine dioxide (as per AS/NZS 2243.3)
2. Rapid & Validated Biological Indicator Technologies and Incubation Times
3. Intelligent Scheduling and Planning to minimize downtime in Critical Testing (Pressure Degradation and HEPA Integrity Testing)
4. Rapid Reporting of Results and Quality Gates

### RAPID DECONTAMINATION PROCESS – Chlorine dioxide (as per AS/NZS 2243.3)

The use of more rapid biological decontamination methods (such as Chlorine dioxide in this case), can reduce the amount of time a facility is down in terms of time. Chlorine dioxide offers some unique chemical and physical characteristics that make it preferable in terms of cycle lengths. The fact that it is a true gas at room temperature means that it will quickly fill the target space. Given that it is a true gas, it will not condense out onto cold surfaces and therefore only requires minimal aeration times. Figure 3 indicates a typical cycle in a large space showing the charge, exposure and aeration back to below 0.1ppm in a little over 3 hours for the complete cycle. There is no need to leave aeration for 12-24 hours like other methods and therefore saving precious shutdown time.

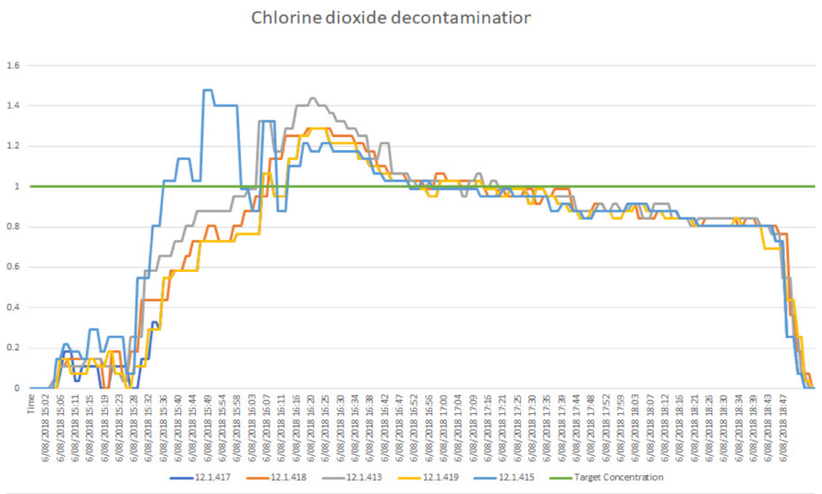


**Figure 3** - A typical biological decontamination cycle for a large space and cycle stages. Note cycle time is 3.5 hours.

It's gaseous properties also allow it to be mechanically moved in the space and therefore able to decontaminate air handling units such as BSC2 Cabinets, Laminar Flow Cabinets and HEPA Housings during the same cycle time eliminating the need to perform these decontamination cycles after the main target area. This can again save up to 24 hours by eliminating multiple decontamination cycles using traditional methods. This, of course, relies on the facility design allowing for such mechanical movement. Figure 4 shows a typical HEPA housing arrangement with the addition of side-channel blowers to assist the movement of the Chlorine dioxide through the HVAC ductwork and HEPA Housings during the main cycle. Scheduled intelligently, the Chlorine dioxide decontamination cycle allows for the retrieval of biological indicators on the same day as the cycle is performed and therefore able to be processed the same day eliminating unnecessary delays in the schedule.

**Figure 4** - A typical HEPA Housing and Side-Channel Blower set up in actual in-situ image.

### RAPID & VALIDATED BIOLOGICAL INDICATOR TECHNOLOGIES AND INCUBATION TIMES

There are many available and emerging rapid biological indicators (BI) that allow for rapid detection of biological decontamination efficacy. Many BI manufacturers have designed and validated rapid systems that will detect growth within as little as 3-4 hours (3M, Getinge etc) and where validated for the facility and process, can shave days off the shutdown period. For the sake of this paper, the use of Crosstex Medical Geobacillus stearothermophilus (Product Code TCDS-06) Tyvek spore strip enclosed in Tyvek pouches; Batch No. RU86, expiry 31/5/2020 – see Figure 4.5) were used which have been validated by the manufacturer to 36 hours. Used in conjunction with the manufacturers specified TSP Prepared Media allows the incubation times for the BI to be reduced from traditional 7 days to as little as 36 hours eliminating up to 4 days from the traditional shut down period. It can be seen in Figure 2 that the testing may be commenced as soon as day 3 using these methods rather than the traditional day 8 or 9.

Of course this requires intelligent scheduling and execution to allow BI to be removed from the facility and processed by the laboratory in potentially the same day. 24 hours laboratory inspections for positive growth of control samples and treated samples can indicate early alarms for positive growth and therefore scheduling of other trades based on these results. Previous papers by the authors suggest the use of paired samples to minimise confusion and build a more robust statistical interpretation when a single positive BI is discovered especially with accompanying chemical indicators/ data in support.

**Figure 4.5** – shows the Biological Indicators validated to 36 hour incubation and pairs of samples in each location (Luftmann et al, 2010)


### INTELLIGENT SCHEDULING AND PLANNING TO MINIMIZE DOWNTIME IN CRITICAL TESTING (Pressure Degradation and HEPA Integrity Testing).

Scheduling, planning, execution and Project Management is crucial to any maintenance shutdown period but much time can be saved by intelligent Management of the project.

Early engagement of the stake holders by the Project Manager is crucial to maintaining the project requirements, scheduling and execution and subsequent communication between each trade/service provider. Procurement of long lead-time parts and labour needs to be planned well in advance and be taken into consideration during the scheduling process. Of course, it is imperative that the Project Manager has a full and comprehensive knowledge of the r egulatory requirements of PC3/PC4 facilities, the required outcomes and regulatory responsibility the operator has to produce accurate records to Regulators. All this information can then be shared in a project schedule that is communicated to each stakeholder, their responsibilities and outcomes are and what communication is required back. Figure 5 shows a part of a typical shutdown schedule or Gannt chart.

Once the results of the biological decontamination have come back to confirm efficacy, the next testing phase of the facility/equipment can be commenced. Utilizing qualified and experienced Consultants for the scheduling and testing can lead to savings in time. The Consultant will make sure that all parts and staff are available and ready for the next phase of thae maintenance shutdown. Working with the decontamination service provider or internal staff in the case where this is done in house, not removing room selaing material after the decontamination cycle means this can be utilized for a secondary purpose of room/laboratory pressure degradation testing saving valuable time in terms of secondary set up processes. This requires trades to work closely together and communication through a series of predetermined quality gates to confirm readiness for the next phase of the shut down.

From Figure 2, Specialist Testing Consultants are able to move their equipment in and be ready to undertake testing as soon as the biological indicator results are available. Once received, consultants are able to immediately commence testing and this saves down time once again. With strategic planning and execution, much of this testing work can be carried out in unison and in one day saving several days on a typical schedule. This can involve leak testing of rooms and HEPA Housings (AS/NZS 2243.3, 2010) (See Figure 6) or HEPA Filter change over or Integrity Testing to AS1807. These results can be available immediately after testing is completed rather than waiting for days after the testing has been completed.

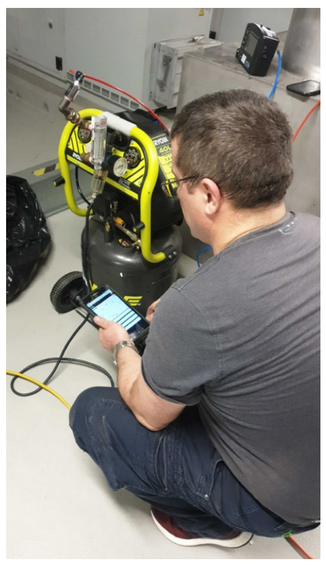

**Figure 6** - shows the pressure degradation testing being performed on a facility.

### RAPID REPORTING OF RESULTS AND QUALITY GATES

For any plan to come together, it requires prompt communication from stake holders on each stage of the shutdown period. This includes reporting from various trades and service providers on progress and outcomes at each stage of the project. To maintain the shortest possible downtime of the facility, the critical dates for each report/communication should be nominated by the Project Manager in consultation with each stakeholder and prescribed in the Project Schedule, similar to the one in Figure 5. Each stage of the project will require the report/results from the Service provider to be provided as this reporting can then trigger the next phase of the project, ie: Quality Gates. The Project Manager is then able to instigate the next phases of the project.

The need for rapid reporting needs to be discussed and confirmed prior to the project commencement as part of the Stakeholder engagement process. As the reporting can sometimes involve third-party laboratories and external processes, the need to have this communicated to said providers is required pre-process so that there can be no or minimal delays when executed. Providing a central communication and file sharing system will allow Service Providers to be able to upload their reports to the Project Manager whilst storing all Reulatory required documents in a central system. The Project Manager will have preliminary knowledge of the overall shutdown reporting requirements from the Facility Operator and by Service Providers providing these rapidly, the Project Manager can better control the schedule and compile the overall report during and not after the shutdown period has ended.

## CONCLUSION

It can be seen in Figure 2, that by following all or some of these methods/ processes, that many days can be saved in a traditional PC3/PC4 annual maintenance shut down period. Each step requires stakeholder engagement and outcome communication, intelligent scheduling and quality gates nominated and rapid communication down and upline between stakeholders at critical times during the project. The use of rapid decontamination processes like Chlorine dioxide and adoption of rapid and validated Biological indictators can vastly save many days from a traditional shutdown methodology.

Critical to all the above processes is Intelligent and experienced Project Management to bring together Facility Operators and Service Providers to clearly plan, communicate, execute and deliver a rapid and comprehensive shut down whilst providing prompt reporting of testing, maintenance and data to fulfill operator regulatory requirements.

## REFERENCES

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