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Andrew D. Watson

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CLEAN BUILD PROTOCOLS – CONCEPTS AND CONSIDERATIONS

Andrew D. Watson[a],

[a] CBE Pty Ltd
andrew.watson@cbe-ap.com.au, www.cbe-ap.com.au
Independent Chair ME-060 Committee – Controlled Atmospheres, Standards Australia

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Abstract. A clean build protocol (CBP) is an essential component of a cleanroom construction project. This paper provides guidance on how to develop and implement a CBP in order to deliver a cleanroom that can successfully achieve its designated ISO classification.

1 INTRODUCTION

A Clean Build Protocol (CBP) is a fundamental part of the construction quality documentation of any cleanroom build. It should be proportional in response to the specific cleanroom project and encompass all aspects that will influence the handover quality of the internal cleanroom surfaces. Stricter controls are often necessary if work is occurring in close proximity to an operational facility or if the finished cleanroom will be a sterile environment.

Construction is fundamentally a messy business. Contamination is inevitable and ultimately necessary if we want to deliver a cost-effective project. Ultimately, we want a series of protections and controls that will deliver a sufficiently clean facility that can be commissioned and classified in a predictable and timely manner.

The purpose of this document is not to envisage every scenario, but provide a broad approach that should help to facilitate an individual response to any cleanroom project.

2 CLEAN-AT-THE-END VS CLEAN-AS-YOU-GO

There are three main sources of contamination during construction:

- Construction related activities
- Material that enters the site from the outside environment
- Material that proliferates due to inadequate cleaning practices and waste removal

It is feasible that the main cleaning activity occurs at the end of the project just before commissioning. It is well acknowledged that the implementation of a CBP will add cost and time to a project (Whyte, [2010]), however the overall cost and time for a facility that fails the first round of testing due to residual contamination could end up being more expensive. For sterile facilities, colonies of micro-organisms can form that make an aseptic space very difficult to achieve. Also, irreparable damage to flooring, seals and even sensitive production equipment can occur.

Control of contamination during construction in accordance with specific procedures will reduce the risk to budget and program, particularly in the final stages of project completion.

3 REFERENCES IN ISO STANDARDS

There is limited reference to clean build (construction) protocols in the ISO 14644 suite of cleanroom standards:

- ISO 14644-4:2001 Design, construction and start up – There is a reference in the normative section (6.4) "A clean construction protocol and cleaning procedures shall be developed as part of the quality plan…"
  Further, in Annex E, Construction and Materials Section E.3.3 a CBP is outlined in four short paragraphs.
  ISO 14644-4 is currently being revised. More detail on CBPs have been proposed.
- ISO 14644-5:2004 Operations – In Annex F, Cleanroom Cleaning, there is a section on a Construction-related cleaning program (F.9). In this section a cleaning program, based on 10 separate project stages, is provided. It should be noted that this is quite a strict protocol, possibly best suited for construction that is occurring in close proximity to an operational area.

4 SETTING THINGS UP

Anyone involved in the delivery of a cleanroom project should have thought through their part in contamination control during their involvement. At the earliest stages of the project, consideration should be given to:

- Movement of staff, materials and waste through the site during each stage of the construction process – ensure that waste flows and personnel and material flows do not overlap and there is sufficient separation from any operational staff movements.
- Location of the setdown area – it should be adequately sized and well protected from the outside elements. There should be sufficient space for de-crating and decontamination, as well as locations for materials requiring inspection and rejected items.
- Construction staff amenity location – it should not present its own contamination hazard to the site, nor should it be too far removed to encourage construction staff to make "short cuts" or ignore other aspects of the CBP.
- Waste storage – should be removed from staff movements, compromise site containment or provide a contamination issue during removal.
- Methods and paths for installation of equipment – errors in equipment size versus doorway widths are common experiences in any industrial build. Any demolition activity that has to occur in the late stage of a cleanroom build can introduce a huge amount of contaminants you may have, up to this stage, successfully kept out.
- Any segregation requirements of adjacent operational areas – Operational staff flow paths should not cross with construction staff flow paths.
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5 A HOLISTIC APPROACH

With the design concept in place, and the above considered, a CBP should be developed and integrated into the overall Project Quality Plan.

Architectural and Engineering firms, construction companies, material suppliers, cleaning contractors and clients that regularly operate in the cleanroom space should at least have a list of common practices and at best a template to be offered to the project team for the preparation of the CBP.

The site induction and programs should integrate the CBP concepts and detail the personal responsibilities required of each project individual.

Suppliers should have contamination control activities in place before dispatch and strategies to ensure equipment / materials get to site in the best state possible.

6 A PROPORTIONAL RESPONSE

It is important, in the interests of delivering a cost-effective build, that the level of the CBP and the methods employed be proportional to the type of cleanroom to be buit and its classification. Similarly, the contamination control activities should also be proportional to the stage of build. Even though the CBP should be applied across the entire project, a pressurised site, with full gowning and regular wiping of every surface is probably not appropriate for all cleanrooms and throughout the project.

One of the first steps in the development of the CBP is to identify the key stages of the project where a change is contamination control is warranted. An example of stages could be as follows:

I. Shell enclosure – internal is no longer affected by the external weather conditions
II. Cleanroom shell complete – internal cleanroom space is separate from external building area
III. Services installation complete – all penetrations have been made
IV. "Air on" – air flow inside the facility commences operation, finishes and sealants are installed
V. Final interior sealing – controls in place to ensure a clean application of sealant
VI. Commissioning and certification – completed facility commissioning commences
VII. Handover – facility is handed over to client. Cleaning and monitoring commences

At the commencement of each stage a new set of controls can be implemented.

7 FORMAT

A CBP is often seen in two formats – a long form, Standard Operating Procedure (SOP)-like document or a matrix type document.

The long form SOP can be embedded permanently into a company's quality system and can contain sufficient information. However, it can difficult to integrate into a specific project.

A matrix type document that summarises each specific stage and the requirements, procedures, gowning and cleaning techniques for each stage can also be used. It needs to be project specific, but is particularly useful for clearly communicating the requirements to all staff. It should be included in the induction program. An example is provided in Figure 1.

Of course, a bespoke matrix document that is backed by a detailed SOP should provide the best outcomes for each project.

8 FUNDAMENTALS

The CBP should be part of your project quality plan and integrated into training documents and the induction program.

It is recommended that all CBPs include references to the following:

- Key quality system documents.
- Key safety system documents.
- Overall responsibility of the CBP across all contractors, both those under the main construction contract and those under control of other parties; for example, where the client is in control of equipment procurement and installation.
- Site layout – see Part 4.
- Stages of the project – see Part 6.
- Training and induction requirements for construction staff – expected staff conduct is key, restricted and no-go areas should be clearly defined.
- Setdown area layout – Location, zones and controls applied to this area.
- Cleaning responsibilities – clear demarcation of cleaning responsibilities should be made in the CBP. While everyone should be making a contribution to the cleaning effort, the responsibility of the overall condition of the facility during construction should reside with one party. At some point this responsibility will shift to the client, however it should not interfere with the cleanroom contractor's obligation to meet set as-built and at-rest cleanroom certification requirements. However, for any conducted "in operation" tests, it makes sense for the client to take on the cleaning process, as this will help to qualify their cleaning processes,

and the fact that their conduct in the cleanroom will impact "in operation" cleanroom compliance.

Clean Build Construction Protocol Matrix

PROTOCOL LEVEL	LEVEL I	LEVEL II	LEVEL III	LEVEL IV	LEVEL V
NAME	SHELL ENCLOSURE	PERIMETER ENCLOSURE	"AIR ON"	"AS BUILT" CERTIFICATION	HOOK UP / HAND OVER
OBJECTIVE	Create a weather proof building shell/enclosure	Provide a controlled entry and exit of people/materials	Complete cleanroom envelope and **HVAC** services to provide continuous room pressurisation to exclude ingress of debris	Achieve "As Built" Certification.	Installation of Equipment/Process tools Achieve "At Rest" / " Operational" Certification.
CLOTHING	* Site PPE (Personal Protective Equipment	* Site PPE.	* Site PPE * Badge/Permitry * Disposable Mop Caps, Suit & Shoes	* Site PPE * Badging/Permitry * Disposable Mop Caps, Beard Covers, Suits, Gloves & Shoe Covers	* Badging/Permitry * Client supplied disposable cleanroom clothing
PROTOCOL TRAINING	NONE	NONE	YES	YES	YES
CLEANING	**OUTDOOR** None	**BUILDERS CLEAN** * Broom Sweep	**PRE-CLEANROOM** * Broom Sweep * Standard Vacuum * Local Extract	**CLEANROOM CONSTRUCTION CLEAN** * HEPA Vacuum * Wet Mop Wipe Down * IPA Wipe Down	**CLEANROOM OPERATIONAL** * HEPA Vacuum * IPA Wipe Down
MONITORING AND MEASUREMENT	**None**	**Visual Inspection**	**Visual Inspection & Airborne Particle Count (5 Micron)**	**Particle Counts & " White Glove " Visual Inspection**	**Particle Counts & " White Glove Visual Inspection**
CONSTRUCTION ACTIVITIES	* General Civil Works * Erect Steelworks * Pour Floor * Perimeter Cladding * Fit Ext. Doors/Louvres	* All Dry Lining Walls * 1st Fix A, M&E, process * Base Build Services * Sealnig of all fibrous materials	* Fit out cleanroom * 2nd Fix A, M&E, process * Pre-Commissioning * Electrical Commissioning * Plant Commissioning (Final Steps of Level III Protocol Stage) * Wipe down * Silicone Sealing	* Clean down / Blow down * Superclean * GEL pour * Fit Final Filters * Fina Balance * Filter Scans * Room Integrity Tests * Environmental Tests * "As Built" Certification	* Hook Up Equipment * Hook Up Process Services & Tools. * "At Rest" Certification * Characterisation Tests
CLEAN BUILD PROTOCOL - DO'S	* Remove all waste & debris daily	* Use defined access and transport routes * Remove waste material daily * Carry out continuous rough cleaning/sweeping * Offload materials in designated areas * Remove/clean off surface dirt prior to entry to construction area	* Clean shoes at entrance. Staff or material must enter via designated access routes * Unpack material in designated areas only * Store WIP materials inside designated areas only * Remove packaging & left over material daily * Remove debris at place of work * Carry out all works in a controlled manner as per manufacturer's instructions * Use standard vacuum * Entry permit & badge for designated areas required	* Follow gowning procedure before entry * Remove packaging in staging area before entry * Wipe down tools before entry * Follow prior written work plan * Use HEPA vacuum * Use bubbles for penetration * Entry permit and badge required	* Follow prior written work plan * Use bubbles for tool hook up * Use HEPA vacuum * Entry permits and badge required
CLEAN BUILD PROTOCOL - DON'TS	* No smoking	* No eating and drinking in construction area * No smoking	* As per Protocol Level II * No cutting,grinding and welding. * No unpacking of materials inside area. * No unscheduled work or work without work plan and protocol requirements.	* As per Protocol Level III	* As per Prjtocol Level IV * As client requirements.
PROTOCOL CHANGE CONTROL	NONE	None	* Client acceptance and sign off * "Out of protocol" form * Isolation action plan	* Client acceptance and sign off * "Out of protocol" form * Isolation action plan * Special measurements	* Client acceptance and sign off * "Out of protocol" form * Isolation action plan * Special measurements

Figure 1 – Example of a CBP Matrix

- Cleaning processes to be applied at each stage – usually comprises of variations on sweeping, vacuuming and wiping. Cleaning equipment and chemicals may be specified. It is important to consider the residual contamination that each cleaning method may create, such as smaller dust generation through sweeping, and potential residual chemical contamination from cleaning chemicals.
- Protection of surfaces – damage to installed flooring, such as vinyl or epoxy, during construction can be difficult and costly to fix. Floor scratches become a cleaning issue in the long term. Floor protection using thin sheets of fibre board, either across the entire surface or common pathways should be used. Even with floor protection, the use of booties/overshoes will help to reduce the amount of outside contamination that is brought in which could damage surfaces.
- Sealing of duct and pipework – Ductwork and critical process or utility pipework should have the same status of contamination control as your internal cleanroom surfaces. As such they should be cleaned in an appropriate area (preferably off-site) and be capped and sealed for storage on site. The seal should only be broken at the time of connection. This should be extended to fans, filter boxes and air handling unit componentry.
- Storage of filters – The storage of HEPA filters and other fragile sensitive equipment needs to be considered. All instructions on the outer packaging should be strictly adhered to.
- Sealant application – Sealant should be applied in a clean environment with no other activity in the room, in order to get the best finish possible. Contamination that infiltrates silicone is there for the life of the facility. Activity in room where sealant has been applied should be restricted at least until a skin has formed on the sealant.
- Vermin control – Will vary according to season, climate and geographical location.

9 OTHER CONTAMINATION CONTROL CONSIDERATIONS

There are a range of other contamination control techniques that may be useful for specific facilities, particularly those that will operate aseptically, or to a very low (number) ISO classification.

- Specific cleanliness attributes – not all cleanrooms are focused solely on particle contamination. Chemical contamination, viable contamination, macro particle and nanoparticle contamination and these types of contamination on surfaces or in air, will all require specific considerations on cleaning materials, equipment and techniques.
- Pressurisation of the construction space – this is an expensive, but highly effective option for contamination control from an early stage. Pressurisation can be achieved with the proposed HVAC system, using sacrificial filters (changed over just before commissioning), or with portable units specifically for the build process. Note that this method is effective in keeping contamination out, but may not be as effective in containing contamination that is generated within. These systems can also be expensive to run, however, the better sealed the perimeter, the less air is required.
- Airlocks – an airlock can be used in conjunction with a pressurised space, or simply as a transition point between the outer and inner construction zones. They can be used as a gowning location and a decontamination location for equipment, materials and tools prior to entering the facility. Note that if the construction zone

is operated at an extremely clean levelk, a separate airlock for gowning should be considered.

- Gaseous decontamination – there are a range of different products and methods available to provide a final decontamination step, using materials in a gaseous or volatilized form. They should be considered for new sterile facilities, or non sterile healthcare facilities where contamination has perhaps got out of control. It should be considered for any healthcare facility built in a tropical or sub-tropical environment. It is critical that surface compatibility of any interior materials be tested prior to performing such a decontamination.

10 COMMON ISSUES

There are a range of issues that can occur during a project that CBPs may not necessarily cover, including:

- Gowning non-compliance – gowned staff who briefly leave the cleanroom site without changing can provide a significant contamination risk to the facility. If gowns and other protective clothing such as hairnets and overshoes, can be put on and removed easily and replacements are always available, then non-compliance will be reduced.
- Connection to sewers – connections into live sewers must be immediately sealed or trapped with water, particularly for sterile facilities. They will be a constant source of microbial contamination.
- Shipping conditions – often machinery must be shipped in from far flung corners of the world. During shipping, the interiors of containers can experience extremes of humidity, heat and cold. Condensation that forms inside the containers can occur early in what might be a six to eight week journey – longer if it gets held up at the border. As a result bacteria and mould can proliferate and cause quite a dilemma if it is discovered just prior to installation, or worse, post installation.
- Animals on site – in some countries it is common for workers to bring their pets onto site. This can cause serious contamination issues. What can be worse, is if the animals are left behind at the conclusion of the project.
- Stagnant water – Stagnant water is a major contamination risk. The cleanroom construction zone should be made weather-tight as soon as possible. Any pooling of water due to leaks or spills need to be cleaned up quickly.
- Broken glass – Broken glass on vinyl flooring can provide a long term hazard if it becomes embedded in the material. Often this hazard comes in the form of fluorescent lighting tubes. Although they are becoming rarer with the advent of LED, these tubes are still used and provide the added hazard of traces of mercury.
- Welding and grinding – Welding and grinding need to be performed in specific locations where the contamination can be contained. If it has to occur in the presence of final internal cleanroom surfaces, complete protection of the surfaces must be provided. Frequently metal particles become embedded in vinyl flooring, stainless steel benches and silicone sealants. These then react with cleaning chemicals and provide further contamination through oxidation.
- Separation of stainless steel and other steel materials – For the same reason as above, stainless steel can become contaminated with iron particles. Client complaints about their stainless steel rusting or being stained orange is usually due to this.

- Rogue contractors – occasionally, some contractors who might be under the control of the client rather than the head contractor can make their way onto site. The CBP must ensure that all on-site personnel adhere to the CBP.

11 OPERATIONAL SITES

Where construction is occurring on an operational site, whether it is for an extension or renovation, extra controls will be required for both sides of the containment barrier.

For the construction side there needs to be a clear demarcation of the no-go zones for construction staff. Entry and exit paths should not mix with operational staff. In addition service interruptions require careful planning and notification. An interruption to a cleanroom service can have serious ramifications to the product or the recipient of the product.

The construction barrier, the key transition between the operational and construction zones, requires careful design. It should be designed in conjunction with the client and their operational staff. The barrier should be regularly monitored for damage or deterioration.

There should be a direct line of communication between the construction team and the operational team. Project progress, changes and future schedule should be regularly communicated. In addition, production schedules, maintenance downtime and shift changes should also be communicated from the operational team.

The operational team should perform risk assessments on their facility and process to ascertain where problems from the construction zone could impact their product/patient. Extra monitoring should be performed throughout the entire project, particularly around the construction barrier.

12 COMMISSIONING AND CERTIFICATION

The final stages of the cleanroom construction phase prior to handover, the commissioning and certification phase, is usually time critical. The success of this phase relies in part in the quality of the design and the skill of the construction team, but also to the controls applied during the build. As such, from a client perspective, it makes sense to ensure that the commissioning process is thorough and robust enough to ensure that the facility is indeed fit for purpose, therefore ensuring that successful certification is assured.

For the commissioning process the following should be considered:

- Gowning – gowning should be specified for the initial "air on" processes of blow through and airflow balancing. Once filters are installed the gowning should be equivalent to the intended gowning regime of the operational facility.
- Use of an "as-built" particle count – ISO 14644-1:2015 specifies the "as-built" operational state as "condition where the cleanroom or clean zone is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present" (3.3.1). A suitable ISO classification should be able to be achieved before commencing the next steps of commissioning. It indicates the ability of the facility to achieve a certain level of cleanliness, but also that the room has been cleaned to an adequate level. Analysis of the ≥5.0 micron particle count will provide valuable information regarding the success of the cleaning effort.
- Cleaning responsibility transition – a time needs to be determined when the cleanroom cleaning becomes the responsibility of the client. This time should

balance confirmation of when the facility is fit for purpose with when development of a facility cleaning program should commence.

12 CONCLUSION

A clean build protocol is an essential element in the delivery of successful cleanroom projects. It controls the necessary elements to ensure a trouble-free cleanroom certification process.

There are a number of elements to the document and each must be addressed according to the stage of the project, the ultimate use of the cleanroom and eventual cleanroom classification.

It requires consideration from the earliest parts of the project and must be embraced by the entire project team to ensure its usefulness.

13 ACKNOWLEDGEMENTS

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