Dr. Becker's Sterile Modular Cleanroom

F23toSp24_02

ISO 7 Cleanroom maintenance for various use cases

By
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Introduction

The cleanroom being designed for this project is large enough that more than one operation can take place within it at once, the goal of this analysis is to determine what operations an ISO 7 cleanroom can be used for, how many simultaneous operations can be reasonably done within the 12'x16' floor area, and what sort of maintenance will be required for those different use cases to keep the cleanroom uncontaminated and certified. There is significant overlap in the maintenance procedures, so a standard cleaning procedure will be outlined as well as several special cases.

This analysis will not feature a comprehensive list of possible operations, therefore any operation not listed below should be researched to ensure the cleanroom remains within the standards of an ISO 7 cleanroom.

Standard use case

To maintain a cleanliness standard certain cleaning procedures should be done regardless of the operation taking place. Surfaces need to be regularly wiped with an antiseptic agent, proper gowning procedure must be followed, all materials brough in should be sterile, and the fan filters need to be regularly changed.

A solution of 70% ethanol will be used to wipe all surfaces within the cleanroom [1]. This team is responsible for the cleanroom itself, which is made from aluminum tubing, polycarbonate sheets, and zinc-plated steel bolts, all of which can be safely cleaned with the solution of 70% ethanol, any additional surfaces added after manufacturing, such as benches, machinery, or glassware, will need to be confirmed safe with said solution. So long as proper gowning procedure and regular filter replacements are made, the room will only need this level of sterilization once a year. However, all surfaces should be wiped down with water or an ethanol solution immediately after use, the floors should be mopped and walls should be wiped with distilled water, then vacuumed dry weekly [2].

To properly gown, a worker should remove all extraneous clothing such as jackets should be removed first and placed on a rack. The gowning room will be split into a clean side and a dirty side, you enter on the dirty side and don gloves first, then a facemask which should be held snuggly against your chin and nose, if the worker has facial hair an addition beard cover is put on after the facemask, safety glasses are put on, followed by the sterile gown which should not reach the floor when worn, finally the gloves should be sterilized with an ethanol solution and allowed to air dry. Finally, shoe coverings are put on, being sure to never step to the "clean" side of the room until that shoe is covered, and the worker is permitted to enter the cleanroom. For each procedure working with separate materials a new sterile gown should be used, with the previous gown being disposed of [3].

Finally, for regular indoor use, the FFU top filters need to be changed every 4 months, or if fan performance drops. This filter is not secured with anything beside a pressure differential, to replace it, the used filter is removed, and a new MERV 7 filter [4] is placed in the now open slot.

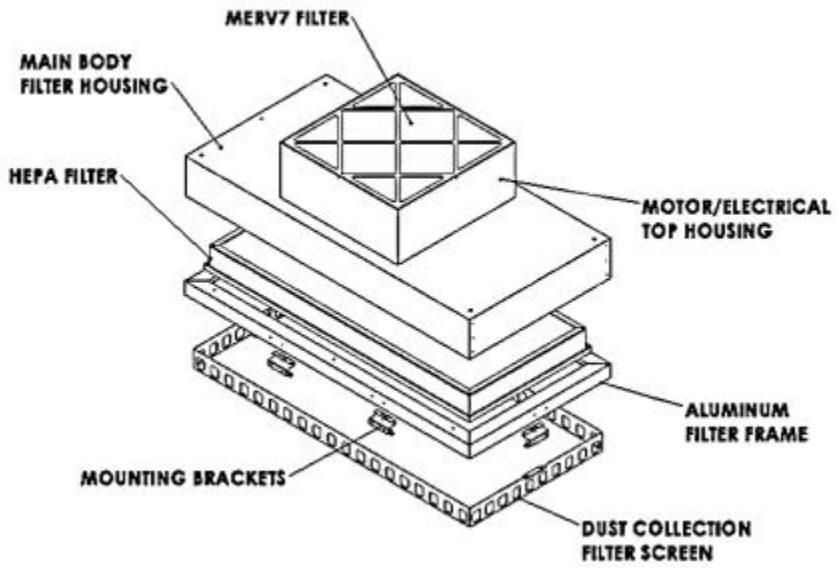

Figure 2: FFU exploded view, showing MERV 7 filter [4]

The above procedure encompasses nearly all the cleaning procedures required for any operation performed within the cleanroom, and anything else is dependent on the type of operation being performed.

Manufacturing medical devices

Any device that is going to be used in a medical setting must be manufactured and packaged in a sterile environment to avoid infection or contamination. Anuevas, the primary stakeholder in the cleanroom, specializes in stents used in blood vessels in the brain, and this is the primary use case for the cleanroom.

In addition to the standard procedures detailed above, after gowning has concluded, the gloves used in during gowning should be disposed of and new, sterile, and non-powdered, gloves stored within the cleanroom should be donned on dry hands and sterilized. Tools need to be sterilized or disposed of between every batch of materials used in the manufacturing process [5].

Chemical manufacturing

When working with chemicals, it is important to maintain the safety of the workers as well as the cleanliness of the product. A fume hood (figure 2) will be placed in the cleanroom, and all reactions that produce irritant or dangerous gases should take place under the fume hood, with the door closed. Any spills need to be immediately cleaned safely, with distilled water and a safe detergent before being vacuumed dry.

Figure 2: Fume hood and current cleanroom to be converted to gowning room [6]

It's assumed any workers working with dangerous chemicals will understand the chemicals they are working with, and how to safely dispose of them. If chemical manufacturing is taking place concurrently with another operation, the team should ensure that all chemical materials remain safely contained and stored within a cabinet when not in use.

Pharmaceuticals

As with chemical manufacturing, the safety of the workers is important when working with pharmaceuticals. The danger in pharmaceutical manufacturing is in solid or liquid contaminants, rather than gaseous or liquid. The procedure is the same for liquid spills, however with a solid powder spill, great care needs to be taken to not allow the powder to be blown or brushed into the air. For this reason any powder spill should be first carefully vacuumed up into a HEPA vacuum, and the waste removed. Once this is done the location of the spill still needs to be wiped down with distilled water and vacuumed dry. All the waste needs to be contained in a biohazard container. Syringes and packaging need to be sterilized before final packaging and removal from the cleanroom. [6]

Conclusion

No matter the operation occurring inside the cleanroom, standard gowning and cleaning procedure must be followed. This means surfaces regularly cleaned with distilled water, regular replacement of the top MERV 7 filter, proper gowning procedure, and ensuring all equipment and materials are brought in sterile. If this procedure is maintained, certification of the cleanroom will last several years.

Certain operations require additional cleaning and maintenance, detailed above is the additional procedures associated with medical, chemical, and pharmaceutical manufacturing. This is not a comprehensive list of the possible operations within the cleanroom, but the 3 most common for an ISO 7 cleanroom. If 2 or more operations are taking place concurrently, great care needs to be taken to ensure there is no cross contamination.

References

[1] T. Becker, *MG:008.00 Aseptic Processing*. Anuevas, Flagstaff, Arizona, 2019

[2] E.- Hunter, "Cleanroom Cleaning: How often should it be cleaned?: Angstrom," Angstrom Technology, https://angstromtechnology.com/cleaning-your-cleanroom/#:~:text=Weekly%20Cleanroom%20Cleaning%3A,distilled%20water%2C%20then%20vacuum%20dry. (accessed Feb. 2, 2024).

[3] T. Alshammari, Z. Bell, S. Hatcher, and B. Davis, "NAU ME Capstone - Fume Hood," Nau Fume Hood Capstone, https://www.ceias.nau.edu/capstone/projects/ME/2020/20Spr5_FumeHood/index.html (accessed Feb. 1, 2024).

[4] Terra Universal, *Terra Universal Product Manual: WhisperFlow Fan Filter Units*. Fullerton, CA: Terra Universal Critical Environment Solutions.

[5] M. Walleser, "Cleanroom Cleaning and gowning protocol guide - ISO 14644," Technical Articles by Production Automation Corporation, https://blog.gotopac.com/2018/01/26/cleanroom-cleaning-procedure-contamination-control-iso-14644-1-protocol/ (accessed Feb. 2, 2024).

[6] T. Alshammari, Z. Bell, S. Hatcher, and B. Davis, "NAU ME Capstone - Fume Hood," Nau Fume Hood Capstone, https://www.ceias.nau.edu/capstone/projects/ME/2020/20Spr5_FumeHood/index.html (accessed Feb. 1, 2024).

[7] E.- Jeralin, "Pharmaceutical cleanroom maintenance tips," Angstrom Technology, https://angstromtechnology.com/pharmaceutical-cleanroom-maintenance-tips/ (accessed Feb. 2, 2024).