Subpart C: Meeting GMP Requirements For Buildings and Facilities

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This article serves as a reference manual for interpreting and successfully complying with this regulation. Critical areas of this regulation are reviewed, including design and construction features, lighting, air: ventilation, filtration, heating and cooling; plumbing, sewage and refuse, washing and toilet facilities, clean, and sanitation. There is a special section on Auditing Applications of these critical areas.

ARTICLE EXCERPT BEGINS

Soap and Detergent

"...In addition to the requirement for hot or cold water, 21 CFR 211.52 also requires that soap or detergent be available in these facilities. Soaps and detergents are of a substance group called surfactants. Surfactants work with water to aid in the removal of microorganisms or dirt and grease from the skin. They help to break the adhesion of such contaminants to the skin. In addition to soap and detergents, a sanitizing agent may also be used. The purpose of a sanitizing agent is to kill microorganisms on the skin. These agents help control microbiological contamination. Sanitizing agents are antibacterial and specifically target common microorganisms. An example would be a foam cleanser containing alcohol. During an inspection, it is not uncommon for an FDA investigator to check that detergent and soap is available in restrooms.

Air Dryers or Single-use Towels

The requirement in regulation 21 CFR 211.52 for the presence of air dryers or single use towels is aimed at preventing the spread of contaminates from one individual to another. If a multi-use towel is used, there can be no guarantee that dirt or microorganisms will not be passed from previous individuals to the one currently using the towel. This is the reason that single use towels are required. Air dryers do not pose any problem of transfer of contamination, because there is no direct contact with the individual. As one can see, this part of the regulation is focused on preventing the spread of contamination.

Clean and Easily Accessible

The final requirement 21 CFR 211.52 for washing and toilet facilities contained in this GMP regulation states that facilities be clean and easily accessible to personnel.

Clean

Maintaining the cleanliness of washing and toilet facilities requires a program or written procedures that will assure proper and complete cleaning of these facilities. This program or written procedure must include the following information:

- **Frequency of cleaning procedures** - This appears most often in the form of schedules for performing cleaning activities, such as, the start or end of each production shift, daily, weekly, etc. The schedule should be based on activity, and should include all such facilities in manufacturing areas.
- **Assignment of responsibilities** – This is a list of those individuals responsible for cleaning the washing and toilet facilities. This provides accountability for following schedules, and ensures that proper cleaning is being done.

- **Approved cleaning agents** – There should be a list that identifies what cleaning agents are approved for use in specific cleaning tasks, and which items can be cleaned with them.
- **Methods** – These are detailed instructions about what has to be cleaned and how to perform each cleaning task. An example might be mop the floor twice with a wet mop using brand X floor cleaner.
- **Documentation** – Cleaning procedures must include a requirement to document the cleaning of washing and toilet facilities. This documentation would include identification of the facility that was cleaned, individuals that cleaned the facility, date and time it was cleaned, and any inspection notes or observations by another individual. Periodic review of these records will indicate whether procedures and schedules are being followed…"

ARTICLE EXCERPT ENDS

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