Development of a Strategic Relationship with Facilities-Maintenance/ Outside Contractors for Interaction with Controlled Environments

ControlledEnvironmentConsulting

The following report is to discuss the concerns and complications along with the actions to take when dealing with controlled environment facility-related issues. Pharmacy is responsible to demonstrate a continuous "State of Control" over their sterile compounding facility.

General:

Facility/maintenance staff must not work on, adjust, enter, or remove any items that are associated with pharmacy without the consent from pharmacy. This includes but is not limited to:

- **Air Handler Unit** – Prefilters, HEPA filters, belts, sheaves, bearings, speed controllers, variable frequency drives, communication panels, control panels, breakers, ductwork, diffusers, dampers (supply, return or exhaust), chillers (temperature controls) or humidification (humidity controls).
- **Exhaust Fan** - Belts, sheaves, bearings, speed controllers, variable frequency drives, communication panels, control panels, breakers, ductwork, diffusers or dampers.
- **Pharmacy Area** – Painting, plumbing, electrical and or calibration.

Signage:

Signs posted must advise staff to stop and notify pharmacy prior to proceeding. Authority from pharmacy must be given prior to advancing with maintenance. Signs must be placed on any items that could potentially affect the pharmacy if any adjustments or changes were made to it. Such items may include but are not limited to:

- Air Handler doors (all doors that can be opened), air handler control panels or communication panels, manual dampers (supply, return and exhaust), breaker panels, exhaust fans, roof access hatches, chiller valves and entrance doors to pharmacy areas.

Training:

Aseptic processing / technique training should be given to all facility / maintenance staff which will give them knowledge of what takes place within a pharmacy. It should stress the critical nature of aseptic processing and that people's lives are at stake. An aseptic expert should conduct the training. The training should be reoccurring and placed on a set schedule no less than once per 12 months for all facility staff that will service pharmacy equipment. Examples of the items to be covered in this training include but are not limited to:

- Gowning training
- Sterile facility hand-washing training
- Specific training for the hazards in these rooms
    - Hazardous Drugs when applicable

- Implications of specific facililty requirements
    - Air Change rates
    - Room Pressures
    - HEPA filter integrity

Job Plans:

- **Routine** – It is recommended that the facilities preventive maintenance system be adjusted so that whenever a job plan is generated for a pharmacy area that the first sheet it prints out states "This is a controlled environment for pharmacy – please proceed accordingly".
    - Facility/ maintenance staff should have the job plan with them when performing the job at hand. The job plan should be followed step by step and in the order it is listed on the plan. This is critical for controlled environments like those in pharmacies and if the job plan is not followed exactly it could jeopardize the product being made within the pharmacy which could affect lives.
- **Emergency** – Details must be worked out with pharmacy on how to handle the emergency jobs that arise. It is recommended that there is a mechanism in place to require pharmacy to authorize the work prior to beginning any work that involves pharmacy.

HEPA Filters:

If the current practice is to change some of the HEPA filters on a routine basis, it is costly and of little benefit. It is recommended that the facility work with their certifier to develop a plan to have the certifier notify them when a HEPA filter is required to be changed. HEPA filters may last up to 15 years and in some cases, even longer depending on the environment it is installed in and how much HEPA filtered airflow it is recirculated within the space. The certifier should be instructed to document the clean (New) HEPA filter differential pressure and the airflow at that time so they can track the filter airflow versus pressure over time. This data can be used by the facilities team to determine when the filter is loaded and anticipate filter changes. The HEPA filters are considered loaded when the filter reaches approximately 2x the initial static pressure. New filters should be ordered, and a filter change scheduled when the static pressure reaches approximately 1.8x initial.

It is recommended that only properly trained individuals such as the certification professionals handle HEPA filters. Consideration should be given to contracting with the certifier or another outside vendor to stock all HEPA filters that are deemed as critical. The certifier should be able to help in determining what filters and how many of each should be stocked.

Miscellaneous:

Repairs within the compounding facility – these areas are considered controlled areas and are required to be kept clean. When repairs are made, the facility / maintenance staff must understand that they need to do their work in a way that will minimize any impact to the pharmacy (clean). It must be done in a professional manner in respect to the aesthetics. For example, the paint must be smooth, and any sealant must be smooth for

cleanability purposes. Some repairs may require hiring outside vendors that have the expertise in that particular field and can deliver an end product that the regulator (FDA, BOP, TJC, DPH, etc.) approves.

SOP's / Protocols:

It is critical that facilities and pharmacy work as a team to achieve the objective of supplying a safe and effective product to the patients. Pharmacy should have an SOP for their end when repairs and or emergencies arise. Facilities should develop an SOP for handling their end of repairs and maintenance as well. Both departments should review and advise on the development of each other's SOPs.

Summary:

The pharmacy is a critical element of the Healthcare facility's effort to provide optimal patient care. The sterile compounding facilities present higher than normal risk of infection when the cleanroom areas are not operating appropriately or when contamination is dragged into the room as part of the maintenance operation. These simple suggestions are intended to increase the cooperation between pharmacy and facilities to support creation of sterile preparations for patients. It is imperative that all pharmacy and facility staff understand the importance of working together to enable the facility to supply patients with a superior product.