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APF Temperature and Humidity, Chilled Water and Supplementary Chiller Requirements

Introduction

APF (Aseptic Processing Facilities) must be appropriately designed to maintain space temperature at lower conditions than laboratories and animal facilities and humidity must not exceed a certain lower value in summer. The chilled water coils must also be appropriately sized to achieve these conditions. The following is an elaboration of APF requirements from Chapter 13.8 of the DRM.

Temperature and Humidity

According to DRM section 13.8.3, "APF room temperature and humidity requirements depend on process, equipment, material and product requirements, and operator comfort. Personnel in the space produce fewer particles when comfortable. Also, high humidity increases microbial and mold growth on surfaces." Lower temperature and moderate humidity levels also reduce sweating and help in drying out the top layer of skin.

The DRM states that "The compounding pharmacy USP (US Pharmacopeia) regulations, require room temperature to not exceed 20°C (68°F) and room humidity to not exceed 60% RH." There is no such prescriptive requirement for GMP facilities, but significant gowning requirements and the concern for mold growth dictate cooler conditions and low humidity (in summer) in these rooms. There is no such concern for humidity during winter except as required for human comfort; the minimum humidity is typically 25% RH.

At NIH, the DRM specifies that APFs shall be designed to 19°C (66°F) for classified rooms with room temperature not to exceed 20°C [68°F]), which is also the temperature alarm limit for all APFs. It also specifies that room humidity shall be designed to 55% RH for the classified areas during summer months, so room humidity does not exceed 60% RH, which is the humidity alarm limit for all APFs.

Chilled Water and Primary Cooling Coil Row Depth

Chilled water to APF AHUs shall be provided from central utility plant (CUP). In DRM section 13.8.14, the specification is that "The main AHU's chilled water coil dew point temperature shall be designed at a maximum of 8.9 °C (48°F), to allow the necessary dehumidification and cooling needed to maintain these room conditions." The minimum number of rows for the primary cooling coil shall be 10-rows to improve such coil performance.

Supplemental Chiller

DRM section 13.8.18 states that "To help mitigate discharge air temperature and dew point fluctuations of AHUs due to varying chilled water temperatures from the CUP and extreme outdoor air conditions, supplemental air-cooled chiller shall be provided. N+1 redundancy of this supplemental chiller is not required; however, pumps shall be redundant. Typically, designs provide supplemental chiller and AHU trim coil to allow the supplemental chilled water system to respond quickly to sudden changes in CUP supply chilled water temperature. The supplemental chiller design shall be based on CUP supply temperature rising 2°F (from 44°F to 46°F) and extreme outdoor conditions of 97°F DB/84°F WB. The chiller shall be piped to the AHU trim coil. AHU trim coils may also be piped to the plant chilled water loop but would remain isolated closed during normal operation when the supplemental chiller is operational."

The supplementary chiller is generally air-cooled (See Figure 1) but may also be water-cooled if there is adequate plant chilled water available in close proximity. Either the CUP supply or return chilled water may be used on the heat rejection side of the heat exchanger for the water-cooled chiller. Water cooled chillers are compact in size but require indoor space. If an air-cooled chiller is used the fluid medium is glycol for freeze protection.

Figure 1 – Air Cooled Chiller

Section 13.8.18 also states that "For small APFs such as modular trailers where CUP chilled water is not available in proximity, N+1 redundant air-cooled chiller shall be provided."

Where existing base building AHUs are being utilized as the main source of air, booster coils in the supply duct serving the APF spaces are required to lower the dewpoint temperature of the supply air from the base building AHUs to 8.9 °C (48°F). The booster coil may use plant chilled water or even a trim chiller. If a trim chiller is used, the chiller would need to have N+1 redundancy, since the chillers would be expected to run a lot longer.

The two-cooling coil in series with the supplementary chiller shall be controlled to maintain design of maximum 8.9 °C (48°F) dewpoint temperature of the secondary coil. If the primary coil cannot maintain this temperature, the secondary coil and the chiller will be activated.