

NUCLEAR MEDICINE:

USP GENERAL Chapter <825> RADIOPHARMACEUTICALS PREPARATION, COMPOUNDING, DISPENSING, AND REPACKAGING

Negative pressure Room, with sterile supply & Neutralizing Carbon + HEPA Filtration exhaust air. USP General Chapter 825 is the USP standard that provides the minimum requirements for preparing, compounding, dispensing, and repackaging both sterile and nonsterile radiopharmaceutical drugs. It describes facilities and engineering controls, personnel training and qualifications, and procedural requirements for processing radiopharmaceuticals in various clinical settings. All of these requirements work together to ensure that workers are protected while handling these hazardous drugs and that patients are protected while consuming them.



Personnel

- Authorized nuclear pharmacists (ANPs)
- Authorized user (AU) physicians
- Individuals in training and under supervision, like students, technicians, and trainees

Environments

- State-licensed nuclear pharmacies.
- Federal-licensed nuclear pharmacies
- Nuclear medicine departments in hospitals and other specialized healthcare clinics



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Filtration

The latest edition of ASHRAE 170 was published in early 2021 and states that operating rooms require a minimum filter efficiency of MERV 16 (previously MERV 14), although HEPA filters are typically used in these spaces. HEPA filters shall be provided and located in the air terminal device.”



ISO Classification of Cleanrooms

Within the ISO standards, there are specific instructions for maintaining clean air. It must be so specific that pharmaceutical companies must measure the concentration of air particles and ensure they're within a given threshold.

Every ISO has a predetermined air concentration threshold depending on the class of the cleanroom. For example, a class 8 cleanroom provides air cleanliness levels of a maximum of 100,000 particles per cubic foot.

Although this may sound complex at first, it's important to know what class works best for a cleanroom in the pharmaceutical industry. A class 8 cleanroom is only one out of an entire ISO range.

ISO Classification Number	Maximum Concentration Limits (particles/m ³ of air) for Particles Equal to and Larger Than the Considered Sizes Shown Below					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1,000	237	102	35	8	
ISO Class 4	10,000	2,370	1,020	352	83	
ISO Class 5	100,000	23,700	10,200	3,520	832	29
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO Class 7				352,000	83,200	2,930
ISO Class 8				3,520,000	832,000	29,300
ISO Class 9				35,200,000	8,320,000	293,000

NOTE: Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level.



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