ENVIRONMENTAL MONITORING 22

(See Sections 6 and 17 in <800>.)

APIs of any HD and antineoplastics (except those that require only counting or packaging) must comply with all containment listed in <800>, which allows the entity to perform an Assessment of Risk to evaluate exempting specific dosage forms of HDs from the containment strategies and/or work practices. Antineoplastics that require only counting or packaging, non-antineoplastic agents, and reproductive hazards may be considered for the entity's Assessment of Risk if alternative containment strategies and/or work practices are identified and implemented.

22.1 What types of quality assurance and quality control activities are required or recommended in USP <800>?

USP <795> (for nonsterile compounding) and USP <797> (for sterile compounding) contain information on general compounding quality control and quality assurance expectations. The environmental monitoring in USP <797> deals with monitoring of microbial (bacterial and fungal) contamination; this is still required for compounding sterile hazardous drug (HD) preparations.

In addition, USP <800> recommends—but does not require—environmental monitoring for HD contamination. This type of environmental monitoring is accomplished by taking surface wipe samples of areas where HDs are handled.

22.2 USP <795> doesn't include a requirement for microbial monitoring for nonsterile compounding areas. Should this be considered?

It is not required but should be considered. If there is a contamination of the containment ventilated enclosure (CVE) or nonsterile compounding room, the quality of the nonsterile compound will be affected.

22.3 Is surface sampling the only quality point that needs to be considered?

No.

USP <795>,[21] <797>,[18] <800>,[8] and the other USP general chapters that support compounding activities require or recommend other quality elements, including:

- Personnel training
- Personnel monitoring
- Microbial environmental monitoring
- Certification of the primary engineering controls (PECs) and secondary engineering controls (SECs)
- Documentation

22.4 Are wipe samples required?

No, but they are recommended.

22.5 Are there different requirements if we are using an isolator instead of a BSC?

USP <800> does not differentiate based on the type of C-PEC used. The requirements and recommendations are the same.

22.6 How often should wipe samples be collected?

USP <800> recommends—but does not require—collection of benchmark samples and then repeated samples at least every 6 months to verify that HDs are contained.

22.7 Where should wipe samples be collected?

Suggested areas include inside the biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI), pass-through chambers, surfaces near the BSC or CACI, the floor underneath the front of the C-PEC, areas immediately outside the negative pressure room, and areas where patients are administered antineoplastics.

22.8 Are we likely to find contamination?

Yes. You will likely find measurable levels of the antineoplastics that you handle.

22.9 What drugs are commonly assayed?

Common drugs that most companies evaluate are cyclophosphamide, ifosfamide, methotrexate, fluorouracil, and platinum-based agents. Detection of other agents may be available from the companies.

22.10 How many surface samples are usually taken?

Most companies provide six wipes with instructions for use. The wipes are returned to the company for analysis, and you receive a report with the results.

22.11 What action do we need to take if antineoplastic contamination is found? How can we get the level to zero?

It is unlikely that repeat sampling will reveal zero contamination, but changes in your practice should reduce the levels.

Practice changes to consider include: re-training personnel; changes in work practices; comprehensive decontamination, cleaning, and disinfecting HD areas; and improving engineering controls.

22.12 What is the responsibility of the *designated person* regarding surface sampling results?

The *designated person* needs to identify, document, and implement processes to improve the results.