USP<797> COMPLIANCE IN NUCLEAR MEDICINE – PART 2

INTRODUCTION

The previous lesson in this continuing education series, “USP<797> Compliance in Nuclear Medicine – Part 1”, familiarized nuclear medicine technologists with the United States Pharmacopeial Convention and its publication – the USP-NF and Chapter<797> Pharmaceutical Compounding – Sterile Preparations. The learner was also introduced to the various councils and committees within the organization, and the impact of the USP compendium upon the practice of healthcare professionals.

This lesson will further examine USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations, with a focus on the chapter’s relevance to nuclear medicine technologists.

PROGRAM OBJECTIVES

Upon completion of this lesson, the learner will be able to accomplish the tasks listed here:

• Define the criteria to be met when utilizing the immediate-use exemption for compounding a radiopharmaceutical.

• Differentiate the various risk levels of compounded sterile preparations: low-risk, medium-risk, and high-risk.

• List the minimum cleaning and maintenance frequencies for three components of the compounding area.

• Compare and contrast the characteristics of a sterile product and a sterile preparation.

BACKGROUND

As previously noted, the first lesson within the series discussed the United States Pharmacopeial Convention and the USP-NF compendium. The intent of this lesson is to provide the learner with an overview of Chapter <797> Pharmaceutical Compounding – Sterile Preparations, beginning with the organization of the chapter sections and definitions of terms. The lesson will conclude with discussions of the various sections of Chapter <797>, providing the learner with the standards established to achieve compliance.
The Sterile Compounding Committee (SCC) elected to organize USP Chapter <797> into sections, with the intent to ease comprehension of the information contained within the chapter. The sections appear in the list below in the same order as presented in the compendium. Each section will be discussed briefly in this lesson, with the focus towards how each section impacts the preparation of radiopharmaceuticals in a nuclear medicine department.

All personnel preparing compounded sterile preparations (CSPs) are responsible for understanding the fundamental practices in the chapter. Proper procedures must be developed and implemented to prevent harm to patients.

- Definitions
- Responsibility of Compounding Personnel
- Risk Levels
- Personnel Training and Evaluation of Aseptic Technique
- Immediate-Use CSPs
- Single-Dose and Multiple-Dose Containers
- Radiopharmaceuticals as CSPs
- Verification of Compounding Accuracy and Sterility
- Environmental Quality and Control
- Suggested Standard Operating Procedures (SOPs)
- Elements of Quality Control
- Finished Preparation Release Checks and Tests
- Storage and Beyond-Use Dating
- Maintaining Sterility, Purity, Stability of Dispensed and Distributed CSPs
- Adverse Events Reporting
- Quality Assurance Program

The definitions section deals mainly with environmental terminology. The full set of terms included in the Definitions area of the Chapter is not included in this unit and the learner is referred to the USP website for a review of the complete listing. Some of the specific terms that are more pertinent to the compounding of radiopharmaceuticals as CSPs, are shown here. Click each term to learn it’s definition.
**Aseptic Processing** – A mode of processing pharmaceuticals ... under at least ISO Class 5 conditions. All radiopharmaceuticals for parenteral administration must be prepared using aseptic technique.

**Beyond-Use Date (BUD)** – The date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded. The BUD of Tc-99m radiopharmaceuticals is usually based upon radiochemical purity. The BUD may be established to be greater than what is listed in the manufacturer’s product package insert. A reassigned beyond-use date or time may be established if the CSP is proven to meet purity requirements and retains clinical performance.

**Critical Site** – A location that includes any component or fluid pathway surfaces or openings exposed and at risk of direct contact with air, moisture, or touch contamination. The risk of microbial particulate contamination of the critical site increases with the size of the opening and exposure time. The critical site for most Tc-99m radiopharmaceutical kits is the vial stopper which is penetrated by the needle affixed to the syringe. The critical site for radiopharmaceuticals is shielded during storage and the syringe is also shielded. The shielding complicates the manipulation of radiopharmaceuticals.

**Direct Compounding Area (DCA)** – A critical area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional High Efficiency Particulate Air (HEPA) filtered air, also known as “first air.”

**First Air** – The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free. The SCC requires the use of a Primary Engineering Control (PEC) that includes a laminar airflow workbench. Radiopharmaceuticals, when not being prepared under the Immediate-Use Exemption, are to be compounded and dispensed in a PEC. Manipulations are best performed in the first air of the PEC.

**Preparation** – A CSP that is a sterile drug...compounded in a pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber(a Tc-99m radiopharmaceutical is classified as a preparation according to Chapter <797>).

**Product** – A commercially manufactured sterile drug ... that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information ...commonly known as the product package insert(Tl–201 Thallous Chloride would be classified as a product according to Chapter <797>).

**Segregated Compounding Area** – Designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such an area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding. Radiopharmaceuticals that are classified as low-risk level could be prepared in a PEC within a segregated compounding area.

**RESPONSIBILITY OF COMPOUNDING PERSONNEL**

Compounding personnel are expected to maintain the high standards for quality, control of processes, components, and environments and for workers’ competence, skills, and knowledge. Their responsibilities include assurances that the integrity and the quality of radiopharmaceuticals are maintained in regard to: identity of ingredients and accuracy of measurements, correct mixing and dilution, and appropriate storage and dispensing of radiopharmaceuticals as CSPs.
Training:

Requirements include proper training of compounding personnel in the areas of preparation of personnel to compound radiopharmaceuticals that includes proper hand cleansing and donning of garb, as well as cleansing and disinfecting of the nonsterile compounding surfaces. When radiopharmaceuticals are handled, personnel must be trained in proper shielding to keep radiation exposures as low as reasonably achievable (ALARA) as well as procedures to reduce potential for contamination of radioactivity and methods to contain and clean any radioactive spills.

Ingredient Integrity:

There are several responsibilities that deal with product integrity. The quality and purity of CSPs must be assured. Compounded sterile products are all expected to be maintained as sterile and pyrogen free. Radiopharmaceuticals as CSPs have other requirements including radiochemical and radionuclidic purity standards. The integrity of a radiopharmaceutical as a CSP must be maintained in the dispensed package until the assigned BUD. The BUD is based on direct testing or extrapolation from reliable literature sources.

CSP Quality:

Quality assurance and quality control processes are an important component of the compounding responsibilities. The extent of the quality program is dependent upon the potential hazard of the CSP.

RISK LEVELS

Immediate-Use Exemption:

The revision of Chapter<797> established an immediate-use category for CSPs. This category is intended for situations where there is a need for immediate patient administration and emergencies. Any immediate-use CSPs are exempted from the Low Risk Level requirements of Chapter <797> when the following criteria are met:

1. The process involves simple transfer of not more than three commercially manufactured packages of radiopharmaceutical products from the manufacturers’ original containers with not more than two entries into any one container.

2. The continuous compounding process does not exceed 1 hour.

3. Aseptic technique is followed in the preparation of the CSP.

4. The administration of the CSP is begun within 1 hour following the start of the preparation.
5. The CSP must be labeled with patient identification information and the initials of the preparer unless the CSP is immediately and completely administered as witnessed by the preparer.

6. If the radiopharmaceutical as a CSP is not administered within 1 hour following the start of its preparation, the CSP must be “promptly, properly and safely discarded”.

The preparation of Tc-99m MAA for immediate use in one patient to assess a pulmonary embolism would be considered exempt from Chapter <797> requirements because of this category. The remaining activity of Tc-99m sodium pertechnetate in the “bulk” vial used to compound the Tc-99m MAA would also have to be discarded within 1 hour following needle penetration outside an ISO 5 environment.

Chapter <797> establishes three contamination risk categories based on potential for microbial contamination during the preparation of the CSP.

**Low-Risk Level CSPs:**

Low-risk level CSPs start with all sterile ingredients and the compounding of low-risk CSPs involves minimal manipulations such as aseptically penetrating disinfected stoppers with sterile needles and syringes. The process of preparing a radiopharmaceutical kit with Tc-99m sodium pertechnetate eluted from a generator system is an example of a low-risk level procedure. Low-risk level CSPs may fall into the subcategory of Low-Risk Level CSPs with 12-hour or Less BUD. If radiopharmaceuticals are established to be used within 12 hours, CSPs may be prepared in a segregated compounding area PEC (LAFW). The chapter classifies radiopharmaceuticals prepared from Tc-99m sodium pertechnetate in the low-risk level category.

**Medium-Risk Level CSPs:**

Medium-risk level CSPs includes the low-risk level manipulations but adds other conditions which involve complex manipulations of long duration. CSPs that are prepared for administration to multiple patients are placed in this category.

**High-Risk Level CSPs:**

With regard to high-risk level CSPs the potential for contamination of the CSP is highest when nonsterile ingredients are incorporated into the preparation.

Beyond-Use Dates for CSPs are established in each of the risk categories and quality assurance procedures (media-fill tests) maybe used to verify the skills of the compounders.
PERSONNEL TRAINING

Chapter <797> requires that compounders be trained in theoretical principles and practical skills of aseptic manipulations by experts using a variety of training resources prior to preparing CSPs. Didactic reviews, achievement of passing scores on written examinations, and media-fill testing to determine aseptic manipulative skills are to be administered to compounders before initial activities are begun. Repeated evaluations are conducted minimally at annual intervals thereafter for low- and medium-risk level skills and semiannually for personnel involved in high-risk level activities. Any failures of these tests require personnel to undergo immediate re-instruction and re-testing.

RADIOPHARMACEUTICALS AS COMPOUNDED STERILE PRODUCTS

The Radiopharmaceuticals as CSPs section addresses issues specific to radiopharmaceuticals routinely used in practice.

The production of PET radiopharmaceuticals is subject to USP Chapter <823> Radiopharmaceuticals for Positron Emission Tomography-Compounding which supersedes Chapter <797>. Upon release from the production facility, Chapter <797> becomes applicable for these radiopharmaceuticals.

Radiopharmaceuticals that are compounded from sterile components in closed sterile containers with volumes of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container are designated as Low-Risk Level CSPs by this section of Chapter <797>. This allows Tc-99m kit preparations to be considered the lowest risk classification.

Environmental considerations are relaxed for radiopharmaceuticals as CSPs allowing ISO Class 5 PEC to be located in an ISO Class 8 environment. This is to accommodate special circumstances and legal requirements for radioactive material licensing like shielding and negative air flow. Storage conditions for shielded radiopharmaceuticals can occur in limited access ambient environments. Storage and elution of molybdenum-99/technetium-99m generator systems is allowed in ISO Class 8 or cleaner air environments. Direct visual inspection of radiopharmaceuticals is not required, but should be conducted in accordance with ALARA principles.

If radiopharmaceuticals are prepared with a 12-hour or less BUD, materials and garb exposed in patient care areas shall not be allowed in the segregated compounding area. This requires nuclear medicine technologists to consider the means of preparing doses of radiopharmaceuticals in a manner to limit any exposure to material that may have been in contact with a patient care area. Specific operating procedures must be in place to prevent any cross-contamination of radiopharmaceuticals, especially when autologous or donor blood specimens are labeled by the nuclear pharmacy or nuclear medicine department, such as leukocyte labeling or labeling of RBCs with UltraTag®.
Facilities and Equipment – Engineering Controls:

Chapter 797 has extensive requirements for environmental quality and control. These are certain to cause concern for all locations where CSPs are prepared, especially when considering radiopharmaceutical preparation. Protecting the sterility and cleanliness of critical sites is the paramount reason for controlling the environment. Conceptually, all manipulations in the direct compounding area (DCA), the area within the PEC where critical sites are routinely exposed, should occur in an ISO Class 5 environment. The air quality of the compounding environment should increase as you progress from the outer boundary to the DCA. Therefore, if radiopharmaceuticals are classified as CSPs with 12-hour or less BUD, they should be prepared in a DCA located in an ISO Class 5 primary engineering control (e.g., a laminar airflow workbench) within a segregated compounding area.

If radiopharmaceuticals are considered to be in the other risk level classification of higher concern, another level of environmental control is required. In this case, the DCA is located in an ISO Class 5 PEC inside of a buffer area of ISO Class 8 which is adjacent to an ante area. Chapter 797 considers placement of devices and objects that are not essential to the compounding procedures should be situated based on their effect on the required environmental quality.

Radiopharmaceuticals as CSPs have the specialized requirements for shielding and remote handling. This complicates the design of a centralized nuclear pharmacy or an in-house hot lab. Each patient dose has to be assayed in a dose calibrator. This requires the dose calibrator to be located in or near the DCA and special considerations for maintaining the environment have to be made. The legal requirements for negative pressure are a part of the exemption of radiopharmaceuticals as CSPs.

Environmental Sampling:

The program for environmental sampling is required to determine if the PEC is maintaining an environment with acceptable viable and nonviable particle levels. The sampling program is required at a minimum under any of the conditions listed here:

- When new facilities and equipment are commissioned and certified
- Following servicing of facilities and equipment
- Every 6 months in the recertification process of facilities and equipment
- When problems are identified
- When CSPs are being considered as a potential source of infection

Impaction is the preferred method of volumetric air sampling for evaluation of airborne microorganism in the compounding environment. Determining locations for sampling are based on areas that are considered to be prone to contamination during compounding activities and other routine activities that occur in the DCA. Chapter 797 recommends a sampling plan, the growth medium to be used, instrumentation that should be considered for
sampling, the sampling frequency and process, incubation period for the samples, action levels depending on contamination levels, documentation of testing and data evaluation. Recommended action levels for 3 environmental classifications are listed as colony forming units (cfu) per 1000 liters of air per plate (ISO Class 5 > 1 cfu, ISO Class 7 > 10 cfu, ISO Class > 100 cfu).

Cleaning and Maintenance:

Chapter 797 requires compounding personnel to be responsible for cleaning and disinfecting the compounding area either directly or via supervision of housekeeping personnel. Minimum frequencies for cleaning/disinfecting compounding areas are specified here, in Table 1.

Further details are given by Chapter 797. These should be reviewed and special considerations should be made for specialty equipment like shielding and remote handling equipment used in nuclear pharmacy and nuclear medicine.

Table 1. Cleaning and Maintenance Minimum Frequencies

<table>
<thead>
<tr>
<th>Compounding Area</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5 PEC</td>
<td>Beginning of each shift, before each batch, not longer than 30 minutes following previous surface disinfection when ongoing compounding activities are occurring, after spills, or when surface contamination is known or suspected</td>
</tr>
<tr>
<td>Counters and easily cleanable work surfaces</td>
<td>Daily</td>
</tr>
<tr>
<td>Floors</td>
<td>Daily</td>
</tr>
<tr>
<td>Walls</td>
<td>Monthly</td>
</tr>
<tr>
<td>Ceilings</td>
<td>Monthly</td>
</tr>
<tr>
<td>Storage shelves</td>
<td>Monthly</td>
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</tbody>
</table>
PERSONNEL REQUIREMENTS

Garb – Personnel Protective Equipment:

There are several controversial aspects posed by this section that compounders, especially nuclear medicine personnel, including technologists and pharmacists, will contend. Touch contamination is of greatest concern when contamination of CSPs is considered. Chapter <797> addresses careful cleansing of hands and arms and the use of personnel protective equipment in order to prevent microbial contamination. Personnel are required to remove outer garments, cosmetics, jewelry, and artificial nails and maintain nails in trimmed condition without polish while working in the compounding environment.

Workers are also required to don garb worn in the compounding area in a specific order. The sequence follows covering the dirtiest areas first and finishing with the cleanest areas. Dedicated shoes or shoe covers, head and facial covers would be worn first and a hand cleansing procedure would be performed using warm running water. Hands and forearms are to be washed to the elbows for a minimum of 30 seconds. After drying, by using a lint-free disposable towel or electronic hand dryer, a nonshedd ing gown with sleeves snugly fitting around the wrists and having an enclosed neck is to be worn. Another hand washing is required before entering the buffer area or segregated compounding area. Sterile gloves are the last item donned. The SCC approved the requirement for sterile gloves to reduce initial bioburden, understanding that gloves can easily become contaminated and should be disinfected frequently in processing radiopharmaceuticals by applying sterile 70% isopropyl alcohol (IPA).

When personnel exit the compounding area, the gown may be removed and retained in the compounding area, if the gown is not contaminated or soiled. The gown may be reused during the same work shift only. Shoe covers, hair and facial hair covers and gloves must be replaced before re-entry and hand hygiene must be performed.

Evaluation of Aseptic Work Practice:

Because touch contamination poses the greatest risk for compromising CSPs, Chapter <797> requires glove finger tip sampling. Assessment procedures given in this section are very specific. Sterile contact agar plates are used by an evaluator to collect gloved fingertip and thumb samples from both hands by lightly pressing each tip into the sterile agar plates. Plates are to be incubated at 30° to 35°C for 48 to 72 hours. When initiating an individual to proper aseptic technique, this testing is to be performed immediately after complete hand hygiene and garbing procedures. Re-evaluation is to occur at least annually for personnel compounding low- and medium-risk level CSPs and semi-annually for those involved with high-risk level CSPs.

Aseptic Manipulations Assessment:

Compounders are required to perform Media-Fill Test Procedures. These are used to verify the manual capability of compounders, the integrity of the compounding environment, and the processes used to produce CSPs. The tests mimic normal processing steps and should be administered during the normal working periods in order to represent the most challenging or stressful conditions that are actually encountered by personnel. The challenge test uses sterile fluid culture media (Soybean-Casein Digest Medium) that promotes exponential colonization of bacteria that
may be introduced to CSPs. Specific incubation periods and temperatures are given in the chapter. Turbidity is the indicator of test failure.

**Visual Assessment of Personnel Performance:**

Chapter 797 provides sample assessment forms for hand hygiene and garbing practices, cleaning and disinfection procedures, and aseptic technique and related practices. These are to be applied on a routine basis. The completed forms are to be maintained to provide a record of long-term assessment of personnel competency (refer to the appendices of Chapter 797 to review the sample assessment forms).

Corrective actions will be dictated by various things including, but not limited to, the number of cfu and the type of microorganisms recovered from cultures. Growth of highly pathogenic microorganisms will be cause for immediate investigation of the causal activities and institution of remedial actions.

**STANDARD OPERATING PROCEDURES (SOPS)**

Compounding facilities are to have written SOPs for environmental quality. Procedures provided in the chapter address the items listed here:

- Access to the restricted compounding area
- Introduction of supplies in the restricted area
- Preparation of personnel allowed in the compounding area
- Restriction of materials and activities in the compounding area
- Operation of PECs
- Preparation of the DCA
- Compounding procedures in the DCA
- Inspection of finished CSPs
- Removal of used supplies and equipment from the DCA
Other sections of the chapter address tests and release checks for finished preparations. The physical inspection of the CSPs includes a visual examination for particulate matter. In the case of radiopharmaceuticals as CSPs, this inspection should be performed using ALARA exposure techniques.

Written procedures for double-checking compounding accuracy are recommended for every CSP during preparation and immediately prior to their release. Accuracy measurements of radiopharmaceuticals should include measurement of the concentration of radioactivity using a dose calibrator.

Sterility testing and bacterial endotoxin testing is not required for radiopharmaceuticals that are routinely compounded using sterile components.

Identity and Strength Verification:

Written procedures should be followed for verifying the correct identity and quantity of the CSPs prior to dispensing and administration. The areas identified for this verification include those listed here:

- Labeling:
  - Correct names and amounts of ingredients
  - Total volume
  - BUD
  - Route of administration
  - Storage conditions
  - Other information for safe use

- Methods for comparing original written orders with compounding records

- Confirmation of amounts by required methods, such as correct volumes and quantities
DETERMINING BEYOND-USE DATES

Note that BUDs and expiration dates are not the same. Expiration dates are established by pharmaceutical manufacturers based on their testing. The chapter requires that BUDs for CSPs prepared strictly in accordance with the manufacturer’s product labeling shall be:

- Those specified in that labeling
- From appropriate literature sources
- From direct testing

Compounding personnel may refer to applicable publications to obtain relevant stability, compatibility, and degradation information regarding the drug. In those cases, the chapter allows compounders to consult and apply drug-specific and general stability documentation and literature when available. Several considerations must be addressed when extending the BUD. Radiopharmaceutical considerations include those listed here:

- The nature of the radiopharmaceutical
- The mechanism of degradation
- The packaging or containment
- Expected storage conditions
- The intended time of its administration

Therefore, radiopharmaceuticals as CSPs may have BUDs that deviate from the manufacturer’s product labeling if reproducible proof of the radiopharmaceutical’s radiochemical stability, sterility, and apyrogenicity through the time of use. A common example of a BUD that deviates from a product package insert is Technetium Tc-99m Sestamibi. In many instances, radiopharmacies and nuclear medicine departments have established longer BUDs stated in the product package insert based on sources such as scientific literature, internal testing with strict interpretation of actual compounding, and conditions for the preparation's storage and use.

Chapter <797> cautions practitioners regarding extrapolation of theoretically predicted beyond-use dating from literature sources. The general guidance provided is “the greater the doubt of the accuracy of theoretically predicted beyond-use dating, the greater the need to determine dating periods experimentally.”
IMPACT ON THE PRACTICE OF NUCLEAR PHARMACY AND NUCLEAR MEDICINE

Technologies, techniques, materials, and procedures used in the preparation, storage, and delivery of radiopharmaceuticals are affected by the establishment and revision of USP Chapter <797> Compounding – Sterile Preparations. Pharmacists and technologists working in radiopharmacies and nuclear medicine departments will have to evaluate their work environments for generator operation and radiopharmaceutical kit preparation. Minimally, compounding processes that are currently in use will have to be assessed to prove that they are equivalent to those described in the Chapter. In doing so, administrators and supervisors will have to review and/or establish compounding environments, equipment needs, personnel training for garbing and performance, and departmental standard operating procedures.

Personnel training activities will have to be reviewed and specific training for aseptic processing will have to be developed when necessary. Assessment techniques for sterile compounding will need to be instituted along with methods for documentation procedures and recording keeping. The fiscal impact of the added expense for supplies, equipment, and personnel time will also have to be evaluated with a perspective on legal and accreditation implications.

CONCLUSION

Nuclear medicine and nuclear pharmacy are among the most regulated specialties in health care. The objective of Chapter <797> is to “prevent harm, including death, to patients” and adds to those regulations. The SCC has struggled with whether the Chapter is too lenient or too strict. The Committee has considered the fiscal impact of providing CSPs and concluded that patient safety and the right to compound specific formulations for specific patients must be maintained in spite of the added expenses.

QUIZ

QUESTION #1

According to the section, “Environmental Quality and Control, “ monthly cleaning and disinfection applies to all of the following compounding areas except:

- floors.
- ceilings.
- counters.
- walls.
QUESTION #2
A commercially manufactured sterile drug that is accompanied by a product package insert is the definition of:

- sterile preparation.
- sterile product.
- Tc-99m sestamibi.
- Tc-99m macro aggregated albumin.

QUESTION #3
A zone within a primary engineering control and exposed to a “first air” environment is the definition of:

- critical site.
- critical area.
- segregated compounding area.
- direct compounding area.

QUESTION #4
A vial of Tc-99m macro aggregated albumin prepared for emergency patient administration and injected within one hour of the start of the compounding process may be classified as:

- immediate-use.
- high-risk level.
- medium-risk level.
- low-risk level.

QUESTION #5
A vial of Tc-99m macro aggregated albumin prepared with a segregated compounding area within a primary engineering control may be classified as:

- immediate-use.
- high-risk level.
- medium-risk level.
- low-risk level.
**QUESTION #6**

The preparation of a radiopharmaceutical using nonsterile products with the greatest potential for microbial contamination is:

- immediate-use.
- high-risk level.
- medium-risk level.
- low-risk level.

**QUESTION #7**

Radiopharmaceutical compounded from sterile components in closed sterile containers with volumes less than 100 mL for a single-dose injection may be classified as:

- immediate-use.
- high-risk level.
- medium-risk level.
- low-risk level.

**QUESTION #8**

A radiopharmaceutical compounded as a sterile preparation may have a BUD that deviates from the manufacturer’s product labeling, if reproducible evidence is established, based on stability, sterility, and apyrogenicity.

- true.
- false.

**QUESTION #9**

The method to provide evidence of quality in a preparation or process best describes:

- quality control.
- quality assurance.
- quality process.
- standard operating procedure.
QUESTION #10

For additional information regarding PET radiopharmaceuticals, a nuclear medicine technologists may consult:

- USP Chapter <797>.
- USP Chapter <823>.
- USP Chapter <1206>.
- USP Chapter <1222>.

GLOSSARY

*Aseptic Manipulations* – Handling sterile materials in a manner to maintain their sterility.

*BUD or Beyond-Use-Date* – This differs from the expiration date since BUD indicates the time beyond which a CSP (compounded sterile preparation) can be administered.

*CFU or Colony-Forming-Unit(s)* – A measure of viable bacterial numbers.

*CSP or Compounded Sterile Preparations* – These are preparations that must be sterile when administered to a patient. CSPs differ from manufactured sterile products because they are manipulated for constitution or transferred to an administration device.

*DCA or Direct Compounding Area* – This is the critical area within the ISO class 5 primary engineering control. This area is where the critical sites are exposed to cleanest air, such as the first air in a laminar airflow workbench.

*HEPA or High Efficiency Particulate Air* – This classification describes the high efficiency filter that is used to remove particles from air in order to improved the quality of an environment.

*IP or Isopropyl Alcohol* – This is a common alcohol used to disinfect surfaces.

*ISO or International Organization for Standardization* – A standard setting body that uses experts and specialists from other standard setting bodies from various countries to prepare internationally recognized standards for various industries.

*PEC or Primary Engineering Control* – This is a system that maintains the air quality (usually an ISO Class 5 or better) of an environment as defined within the context of this program. A PEC can be a laminar airflow workbench or a compounding aseptic containment isolator.

*QA or Quality Assurance* – This is a method to provide evidence of quality in a preparation or process.

*SOP or Standard Operation Procedure* – This includes the guides, procedures, or methods to perform a given operation consistently.
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DISCLAIMER

Although Dr. Augustine is a member of the USP Sterile Compounding Expert Committee, this CE Unit is presented in his individual capacity and not as a member of the Committee or as a USP representative. The views and opinions presented are entirely his own. They do not necessarily reflect the views of USP, nor should they be construed as an official explanation or interpretation of <797>.

REFERENCES
