USP <797> and <825> -- Current and Future Standards for Sterile Preparation and Compounding of Radiopharmaceuticals

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Target Audience: Pharmacists
ACPE#: 0202-0000-18-075-L03-P
Activity Type: Knowledge-based
Disclosures

Mr. Ponto is a volunteer member on USP Chemical Medicines Monographs 4 Expert Committee and chair of USP Radiopharmaceutical Compounding Expert Panel

This presentation is not endorsed by the USP, nor does it represent the views or opinions of the USP

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Learning Objectives

1. Describe the development of USP General Chapter <797>.
2. Describe recent problems involving sterile compounding and responses to those problems.
3. Describe special issues related to compounding of radiopharmaceuticals.
4. Describe focus of forthcoming USP <825>.
1. Standards for radiopharmaceutical compounding were FIRST EXPLICITLY INCLUDED in which USP General Chapter?

D. <800> Hazardous Drugs – Handling in Healthcare Settings (2016)
2. Assessment Question

2. In the near future, compounding standards for radiopharmaceuticals will be found in USP General Chapter:
A. <797>, 2nd revision
B. <800>
C. <821>
D. <825>
Outline

- Overview of USP
- Development of USP <797>
- Subsequent Events and Responses
- Special Issues Related to Compounding of Radiopharmaceuticals
- Development of USP <825>
United States Pharmacopeia (USP)

- USP is a non-governmental agency that provides standards of identity, strength, quality, purity, and labeling of medications, excipients, and dietary supplements.
- Originally formed by 11 physicians in 1820 to create a compendium of established medicines, give them useful names, and provide recipes for their preparation.
- Evolved over time from a compendium of recipes to a compendium of documentary standards for identity and quality that typically involve reference material standards in specified tests and assays.
United States Pharmacopeia (USP) (cont’d)

- Was recognized in the Federal Food and Drugs Act of 1906 and again in the Federal Food, Drug, and Cosmetic Act of 1938 (esp. related to adulteration, misbranding)

- Contains monographs for official drug substances (i.e., active ingredients) and for official drug preparations (i.e., final drug products)

- Monographs typically include: name, definition, packaging, storage, universal tests (description, identity, impurities, assay), specific tests, analytical procedures for each test, acceptance criteria, and other requirements.
United States Pharmacopeia (USP) (cont’d)

- General Chapters may contain the following:
  - Descriptions of tests and procedures cited by monographs
  - **Descriptions and specifications of conditions and practices for pharmaceutical compounding**
  - General information for interpretation of compendial requirements
  - Descriptions of general pharmaceutical storage, dispensing, and packaging practices
  - General guidance to manufacturers of official substances or official products

- General Chapters numbered <1000 are enforceable
- General Chapters numbered >1000 are informational
USP General Chapter <1206>

- Development was prompted by problems encountered in the preparation of home parenteral therapy products
- Provide information and recommendations to promote good sterile compounding practices for parenteral preparations in home health care
- 1995: <1206> Sterile Products for Home Use
- 1996: revised to clarify various sections
- 2000: revised <1206> Sterile Preparations – Pharmacy Practices, which broadened its scope to include sections on “Sterile Drug Products for Institutional Use” and “Off-site Compounding Pharmacies”
- Radiopharmaceuticals were not specifically mentioned
USP General Chapter <797>

- Adoption of <1206> recommendations were less than hoped for based on surveys of practitioners
- FDA study Jun-Dec 2001 found 34% of compounded sterile preparations failed one or more standard quality tests
- Because voluntary compliance was deemed inadequate to protect the public, USP set forward in the development of standards that could be enforced by state boards of pharmacy, accreditation organizations, etc.
- 2004: <797> Pharmaceutical Compounding - Sterile Preparations
- Radiopharmaceuticals were not specifically mentioned
USP General Chapter <797> (cont’d)

- 2008: First revision <797>
  - Added a short section on "Radiopharmaceuticals as CSPs"
  - e.g., Tc 99m generators can be eluted in ISO Class 8 room

- 2015: Proposed revision <797> published in *Pharmaceutical Forum* (PF) for public comment
  - "Radiopharmaceuticals as CSPs" section slightly expanded
  - >8000 comments received from >2500 stakeholders
  - A modified proposed revision is anticipated to be published in *PF 44(5) Sept-Oct 2018* for an additional round of public comment, with proposed implementation date of Dec 1, 2019
Subsequent Events and Responses

- **2012**: New England Compounding Center (NECC)
  - Distributed 17,000 vials of fungal-contaminated methyl prednisolone injection to 23 states
  - This contaminated epidural steroid injection used to treat back pain caused fungal meningitis in > 800 people, 76 died
  - Owner Barry Cadden was acquitted on 25 counts of second-degree murder, but convicted on >50 counts of racketeering, mail fraud, and interstate commerce of misbranded drugs, and sentenced to 9 years in prison and $ 7.5 million
  - Pharmacist-in-charge Glenn Chin was acquitted of second murder charges, but convicted of mail fraud and racketeering
Subsequent Events and Responses

- Several other, smaller outbreaks of infection
  - 2011: Alabama, contaminated IV bags of parenteral nutrients caused infections in 19 patients, 9 died
  - 2011: Florida, contaminated injections for treating macular degeneration caused eye infections in 17 patients, 11 blindness
  - 2013: Texas, contaminated calcium gluconate injection caused bloodstream infections in 15 patients, 2 died
Drug Quality and Security Act (DQSA)

- **2013:** in response to NECC and other problems with compounded preparations, Congress enacted DQSA
- **Section 503A:** describes safe harbors for traditional pharmacy compounding
  - regulation by state law and state boards of pharmacy
  - traditional, individualized prescriptions
  - requires compliance with USP chapters on compounding
- **Section 503B:** create a new entity, Outsourcing Facilities
  - FDA registration and inspection
  - allows interstate distribution of larger quantities of compounded preparations
  - requires compliance with cGMPs
DQSA (cont’d)

- Section 503A safe harbors for traditional pharmacy compounding explicitly do not apply to radiopharmaceuticals and PET drugs
- Radiopharmaceuticals may be compounded by Section 503B Outsourcing Facilities (none are registered at this time)
- Regulation of and safe harbors for radiopharmaceutical compounding remain undefined and controversial
- Desire by industry and the profession to obtain guidance
FDA Listening Session

- September 2014: FDA held a listening session to begin gathering stakeholder input regarding radiopharmaceutical compounding.
- Of special interest was differentiating preparation vs. compounding, and preparation with minor deviations.
CORAR Response

- November 2014: The Council on Radionuclides and Radiopharmaceuticals (CORAR), with support from groups listed below, responded to FDA with proposed definitions and descriptions of preparation, minor deviations, and compounding:
  - American Pharmacists Association (APhA)
  - National Association of Nuclear Pharmacies (NANP)
  - Society of Nuclear Medicine and Molecular Imaging (SNMMI)
  - United Pharmacy Partners (UPPI)
CORAR Response (cont’d)

- February 2015: CORAR, et al. provided FDA with a draft Compliance Policy Guide for Radiopharmaceutical Compounding developed by these stakeholders
- Essentially, this draft guide described safe harbors for radiopharmaceutical compounding analogous to those described in 503A of DQSA
  - licensed pharmacist or physician
  - valid prescription or order
  - follow USP compounding chapters
  - prohibit compounding copies of approved products except if a clinical difference for the patient or in times of shortages
  - interstate distribution
2nd FDA Listening Session

- April 2016: more discussion of preparation vs. compounding and examples of activities that would be considered minor deviations
Draft Guidance: Insanitary Conditions

- August 2016: FDA released “Insanitary Conditions at Compounding Facilities – Guidance for Industry” as Draft Guidance for comment purposes only
  - applies to entities that compound or repackage drugs under 503A or 503B
  - explicitly includes radiopharmaceuticals
  - describes examples of conditions that would be considered insanitary conditions under section 501(a)(2)(A) of the FD&C Act and thus cause the drug to be adulterated
    - aseptic practices
    - equipment/facilities
    - cleaning and disinfecting

- describes conditions under which the Agency does not intend to take action for violations of Sections 505 [new drugs], 502(f)(1) [directions for use], and 501(a)(2)(b) [cGMP requirements]
- describes terminology for compounding, minor deviation, and repackaging and conditions for applicability
3rd FDA Listening Session

- June 2017: more discussion of various items described in the Draft Guidance for Compounding and Repackaging of Radiopharmaceuticals
Centers for Medicare and Medicaid Services (CMS)

- “Conditions of Participation” are health and safety requirements that healthcare organizations must meet in order to participate in Medicare and Medicaid programs (i.e., to receive payments for medical care provided, physician fees, and costs for graduate medical education)

- 2015: CMS revised portions of the Pharmaceutical Services Condition of Participation to require compliance with current accepted standards of practice for compounding sterile preparations, specifically USP <797>

- This revision will trickle down to healthcare accreditation organizations with “deemed status”
Compounding Certification

- National Association of Boards of Pharmacy (NABP): Verified Pharmacy Program (VPP)
  - has been ongoing for many years
  - assists State Boards in ensuring compliance by non-resident pharmacy licensees
  - assists pharmacies licensed in multiple states who otherwise may require multiple inspections
  - independent inspection for compliance with USP General Chapters <795> and <797>
Compounding Certification (cont’d)

- Pharmacy Compounding Accreditation Board (PCAB): Compounding Pharmacy Accreditation
  - established in 2007 by 8 pharmacy organizations
  - voluntary program for hospital, retail, mail order pharmacies
  - became a service of Accreditation Commission for Health Care (ACHC) in 2014
  - independent expert verification of compliance with USP General Chapters <795> and <797>
Compounding Certification (cont’d)

- The Joint Commission (TJC): Medication Compounding Certification
  - initiated January 2017
  - voluntary program for hospitals and home health agencies
  - independent evaluation and recognition of compliance with USP General Chapters <795> and <797>

- Michigan was the first state to require compounding certification by NABP VPP, ACHC/PCAB, or TJC
Special Issues Related to Compounding of Radiopharmaceuticals

- <795> Pharmaceutical Compounding – Nonsterile Preparations
  - “Specialty areas such as radiopharmaceuticals require special training and are beyond the scope of this chapter.”

- <797> Pharmaceutical Compounding – Sterile Preparations
  - contains a short section on radiopharmaceuticals but lacks sufficient details to fully elucidate important differences for radiopharmaceuticals
Compounding of Radiopharmaceuticals

- Similar to sterile compounding of conventional drugs e.g., aseptic practices, environmental facilities

- Also similar to hazardous drug compounding e.g., prevention and control of contamination

- Unique aspects
  - radiation protection practices (time, distance, shielding)
  - supplies: lead shields, absorbent contamination pads
  - equipment: radioactivity/radiation instruments/monitors
  - often involves chemical reactions to create radiolabeled compounds
Manufactured Radiopharmaceuticals

- Some radiopharmaceuticals are manufactured in single- or multiple-dose vials ready for use
- Simply withdraw contents into a syringe for administration = “DISPENSING” (although falls under ‘sterile compounding’ in <797>, and in part under ‘repackaging’ in FDA draft guidance)
- Comply with aseptic handling, “use by” dating, etc.
PREPARATION of Radiopharmaceuticals Using FDA-Approved Kits

- Majority of commonly-used radiopharmaceuticals e.g., Tc 99m medronate, In 111 pentetreotide
- Preparation instructions are described in the package insert
- Most often, lyophilized powder in a vial and may include other components/ingredients
Preparation of Radiopharmaceuticals Using FDA-Approved Kits (cont’d)

- Similar to reconstitution of drugs for injection
- However, chemical reactions take place (e.g., reduction, chelation) so quality control testing of the reconstituted product is a standard of practice

\[
\text{Tc(II)O}_4^- + \text{Sn}^{+2} + \text{gluconate} \rightarrow \text{Tc(V)-gluconate}
\]
\[
\text{Tc(V)-gluconate} + \text{tetrofosmin} \rightarrow \text{Tc(V)O}_2(\text{tetrofosmin})_{2}^+
\]
Preparation with Minor Deviations

- Package insert instructions are often deficient*:
  - ambiguous/vague (e.g., may, should, recommend)
  - restrictive (e.g., specific gauge needle)

- Package insert instructions are often outdated:
  - new clinical indications which may require somewhat different activity, concentration, etc.
  - changes in technology (e.g., heat block vs. water bath)
  - radiation protection practices (e.g., add Tc 99m to vial and then dilute with normal saline vs. dilute Tc 99m in syringe and then add to vial)

Extension of Beyond Use Dates (BUDs)

- Package inserts state or suggest ‘use-by’ times
  - e.g.: “use within ___ hours”, “should be discarded after ___ hours”
  - primarily based on stability; very conservative

- Extension of BUD is necessary for supplying radiopharmaceutical doses to hospitals/clinics at some geographic distance
  - professional practice guidelines support extension of BUD if analytical studies show continued compliance with USP specifications

- SNMNI Recommendations for Beyond-Use Dates (BUD) for Tc-99m Radiopharmaceuticals [2011]
  - comply with <797> BUD based on risk level (i.e., sterility)
  - comply with clinical use requirements (e.g., # particles/dose)
  - comply with USP monograph specifications (e.g., purity at time of use)

http://snmmi.files.cms-plus.com/docs/BUDs_for_Tc99m_radiopharmaceuticals_1382109507530_1.pdf
COMPOUNDING of Radiopharmaceuticals

- Admixing with other drugs (e.g., lidocaine, ascorbic acid)
- Converting one dosage form into a different dosage form
  - dissolving capsules to prepare an oral liquid
- Preparation using raw materials or radiochemicals
  - rare, usually done during times of product shortages or for radiopharmaceuticals no longer marketed for economic reasons (e.g., P 32 chromic phosphate)
  - may require extensive sterility testing, stability testing, etc
Problems

- Several different definitions of “compounding”
  - traditional pharmacy extemporaneous compounding
  - State boards of pharmacy
  - FDA
  - USP
  - professional organizations, standards of practice
  - accreditation organizations
Problems (cont’d)

- 503A safe harbors for pharmacy compounding “do not apply to ... radiopharmaceuticals.” [DQSA 2013]
  - FDA draft guidance document for radiopharmaceutical compounding (12/29/2016) is still undergoing public comment
  - currently, different interpretations by different inspectors

- Related issues
  - nearly 90% radiopharmaceutical doses are prepared in commercial nuclear pharmacies and transported to hospitals and clinics
  - crossing state lines (e.g., New York City, Washington D.C.)
  - patient name on each dose (e.g., cardiac doses for ER)
Problems (cont’d)

- Immediate Use
  - prime example: Tc-99m autologous red blood cells for localization of GI bleeds
  - Tc-99m sodium pertechnetate is delivered from a commercial nuclear pharmacy but the RBC labeling is performed in the clinic using an FDA-approved kit; but it requires >2 entries into the vial, so it is non-compliant with <797> immediate use
  - SNM submitted a petition to USP in 2008
  - proposed revision of <797> in PF 36-3 to allow this, but was never adopted
Problems (cont’d)

  - the descriptive list of *Insanitary Conditions in a Sterile Operation* includes several items that may be problematic for radiopharmaceuticals
Insanitary Conditions

- “Performing aseptic manipulations outside of an International Organization for Standardization Class 5 (ISO 5) area.”

- Mo-99/Tc-99m generators, with auxiliary lead shielding, may be too large and too heavy to place inside ISO 5 hoods. Hence, <797> allows generator elution in ISO 8 or cleaner areas.
Insanitary Conditions (cont’d)

- “Moving quickly in the vicinity of open containers or instruments (e.g., needles).... Quick movement of personnel disrupts the airflow and increase the risk of bringing lesser quality air into the ISO 5 area.”
- compliance with principles of radiation protection (viz., time, distance, and shielding) may require relatively quick movements
Insanitary Conditions (cont’d)

- “Conducting aseptic manipulations or placing equipment/supplies in an area that blocks the movement of first pass air around an open container…”
  
  - compliance with radiation protection practice requires use of leaded-glass L blocks, vial shields, etc. which may block first pass air
Insanitary Conditions (cont’d)

- “Touching equipment or other surfaces (e.g., walls, telephone, floors) located outside of the ISO 5 area with gloved hands and then proceeding with aseptic manipulations without changing or sanitizing gloves.”
  - frequent and necessary touching of lead syringe shields/carriers, labels for vials and syringes, etc.
New USP Chapter on Radiopharmaceutical Compounding

- April 2016: Jim Ponto and Steve Zigler (members of USP Chemical Medicine Monographs 4 Expert Committee) met with USP staff and discussed the need for a new separate chapter for compounding radiopharmaceuticals

  - precedent for a separate chapter: <800> Hazardous Drugs – Handling in Healthcare Settings
  - precedent for radiopharmaceutical chapter: <823> Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses
  - other general chapters dedicated to radioactivity/radiopharmaceuticals:
    - <821> Radioactivity
    - <1821> Radioactivity – Theory and Practice
    - <1823> Positron Emission Tomography Drugs - Information
Proposed Revision <797>

- In response to the 2015 proposed revision of <797>, >8000 comments were received by early 2016

- About 100 of these comments addressed Section 17 Radiopharmaceuticals as CSPs -- all indicated inadequacy of this section
SNMMI White Paper

- Fall 2016 – SNMMI COR developed a white paper entitled *USP Public Standards for Compounded Sterile Radiopharmaceuticals: Recommendations from SNMMI*

- Three recommendations from the white paper:
  - delineate common practices that are defined as sterile compounding within the practice of nuclear pharmacy
  - create a public standard for the preparation, compounding, and dispensing of sterile radiopharmaceuticals with the practice of nuclear pharmacy [i.e., create a new general chapter]
  - reinstate an expert committee dedicated to all standards for radiopharmaceuticals [i.e., chapters and monographs]

General Consensus of the Nuclear Medicine and Nuclear Pharmacy Community

- Preparation, compounding, and dispensing of sterile radiopharmaceuticals involves unique safety considerations (radiation protection practices) and involves special equipment (lead shielding, radiation detectors) that may necessitate some compromises in aseptic handling practices.

- A separate USP chapter on Preparation, Compounding, and Dispensing of Sterile Radiopharmaceuticals would serve the profession well in defining and describing standards for these activities, especially in relationship with the FDA Draft Guidance on Compounding and Repackaging of Radiopharmaceuticals.
Previous Related Work by USP

- 2000-2005 Radiopharmaceuticals and Medical Imaging Drugs (RMI) Expert Committee proposed, and created a draft of, a new general chapter: <1017> Radiopharmaceutical Quality Assurance and Compounding.

- But: it was never published in PF; Frank Barletta retired in 2003, the committee turned its focus to PET, and chapter <1206> Sterile Preparations – Pharmacy Practices was on its way to becoming <797>.
USP Stakeholders Workshop on Radiopharmaceutical Compounding

- Held at USP HQ on Feb 1, 2017

- Invited participants included representatives from:
  - Chemical Medicines Monographs 4 Expert Committee
  - Compounding Expert Committee
  - nuclear pharmacists in hospital, commercial, and academic settings
  - FDA
  - SNMMI COR
  - USP staff

- Practitioner stakeholders were strongly in favor of developing a separate chapter for radiopharmaceutical compounding
Proposed New General Chapter
<825> Compounding - Radiopharmaceuticals

- After serious discussion and deliberation, in May 2017 the Compounding Expert Committee and USP staff agreed that creation of a new chapter was appropriate.

- Scope and Rationale (posted June 1, 2017):
  “The objective of the new General Chapter <825> Compounding—Radiopharmaceuticals is to provide clear and effective USP public standards that meet patient and practitioner needs for compounded sterile radiopharmaceuticals today and in the future. The proposed new general chapter will delineate compounding activities for radiopharmaceuticals and provide standards associated with these activities.”

http://www.usp.org/usp-nf/notices/825-compounding-radiopharmaceuticals
Formation of Expert Panel

- Call for candidates for an Expert Panel (posted June 1, 2017 with deadline of July 9, 2017): [http://callforcandidates.usp.org/node/4636](http://callforcandidates.usp.org/node/4636)

- More than 60 applications received

- Desire for a diverse group of experts from various settings that represent the profession/industry

- Input from CHM4 EC and Compounding EC representatives, but final selection was made by USP staff in August 2017
Formation of Expert Panel (cont’d)

- Preferred candidate characteristics:
  - nuclear pharmacy experience in a commercial setting
  - nuclear pharmacy experience in a hospital setting
  - experience teaching nuclear pharmacy (academic setting)
  - experience interacting with State Boards of Pharmacy
  - hold board certification in nuclear pharmacy
  - participant at USP Stakeholders Roundtable meeting
  - participant at FDA listening sessions
  - members of CHM4 EC and Compounding EC
  - work for regulatory agency
Formation of Expert Panel (cont’d)

- Members (total = 14)
  - CHM₄ EC - 2
  - Compounding EC - 2
  - commercial nuclear pharmacies - 4
  - university-based nuclear pharmacy - 1
  - hospital - 1
  - academic – 1
  - regulatory - 3
# Expert Panel Membership

<table>
<thead>
<tr>
<th>David Barnes</th>
<th>Brenda Jensen*</th>
<th>James Ponto †</th>
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<tr>
<td>Allegra DePietro</td>
<td>Ravi Kasliwal #</td>
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<td>Wendy Galbraith</td>
<td>Patricia Kienle*</td>
<td>Vivian Loveless</td>
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<td>Fred Gattas</td>
<td>Paul Mahan</td>
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<tr>
<td>Richard Green</td>
<td>Rezaul Mannon</td>
<td>Steve Zigler †</td>
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USP staff: Domenick Vicchio, Ravi Ravichandran, Gerald Hsu, James Austgen

† member, Chemical Medicines Monographs 4 Expert Committee
* member, Compounding Expert Committee
# FDA representative
First Meeting of Expert Panel

- September 28, 2017 at USP HQ
- Shared perspectives from different practice settings
- Discussed the scope of, and an outline for, the chapter
- Agreed on shared assignments and responsibilities
- Tentative planning of subsequent tele-conferences and face-to-face meetings
- Very aggressive timeline – draft chapter hoped to be published in the Nov-Dec 2018 *PF* for public comment
Public Comment

- When proposed <825> is published in PF for public comment, please review and submit comments
- Positive comments of agreement and support are as important (possibly more important) as negative comments
- Remember, you are the public
- Key Issues page for Radioactive Articles, including <825>
1. Assessment Question

1. Standards for radiopharmaceutical compounding were FIRST EXPLICITLY INCLUDED in which USP General Chapter?
   D. <800> Hazardous Drugs – Handling in Healthcare Settings (2016)
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THANK YOU
Target Audience: Pharmacists
ACPE#: 0202-0000-18-075-L03-P
Activity Type: Knowledge-based
Disclosures

No disclosures

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Learning Objectives

1. Understand the statutory framework for compounded and repackaged radiopharmaceuticals.
2. Understand FDA’s policy objectives.
3. Understand the conditions described in FDA’s draft guidances.
4. Understand FDA’s process for evaluating comments and issuing final guidance.
1. Assessment Question

1. Are compounded radiopharmaceuticals eligible for the exemptions in section 503A of the Federal Food, Drug, and Cosmetic Act, concerning compounded drugs?

A. Yes
B. No

Target Audience:

ACPE#: 

Activity Type:
2. Assessment Question

2. Can radiopharmaceuticals be compounded by outsourcing facilities?
A. Yes
B. No
3. Assessment Question

3. Which of the following is true?
   A. Pharmacies that compound radiopharmaceuticals are only subject to state and NRC oversight.
   B. Under FDA draft guidance, compounding using bulk drug substances can constitute a “minor deviation.”
   C. FDA’s draft guidance describes different policies depending on whether or not the compounding constitutes “minor deviations.”
   D. Compounding and repackaging have the same meaning.
4. Assessment Question

4. Which is a condition addressed in the draft guidances?
   A. Compounded radiopharmaceuticals are not essentially copies of approved radiopharmaceuticals.
   B. Compounding of radiopharmaceuticals occurs only during drug shortage situations.
   C. All compounding of radiopharmaceuticals complies with current good manufacturing practice standards.
   D. All compounding of radiopharmaceuticals complies with United States Pharmacopeia <797> standards.
Policy Objectives

FDA’s policies on compounding of radiopharmaceuticals aim to:

- Preserve access to compounded and repackaged radiopharmaceuticals for patients whose medical needs cannot be met by an FDA-approved radiopharmaceutical.

- Reduce the risks of safety and quality concerns associated with these products.

- Prevent inappropriate compounding of radiopharmaceuticals that undermines the drug approval process.
Background—Statutory Framework

- Under the FD&C Act, radiopharmaceuticals, including compounded and repackaged radiopharmaceuticals, are generally subject to all requirements of the Act related to the production of drugs, including:
  - New drug approval requirements (section 505)
  - Labeling with adequate directions for use (section 502(f)(1))
  - Current good manufacturing practice (CGMP) requirements (section 501(a)(2)(B))

- Note, however, exemptions available to radiopharmaceuticals compounded by outsourcing facilities.
Background—Statutory Framework

- Section 503A
  - While section 503A of the FD&C Act exempts certain compounded drugs from those requirements, the exemptions do not apply to compounded radiopharmaceuticals:
    - “This section shall not apply to . . . radiopharmaceuticals.” Section 503A(d) of the FD&C Act.
Background—Statutory Framework

- Section 503B
  - Section 503B does not contain similar language excluding radiopharmaceuticals from its scope.
  - FDA has determined that compounded radiopharmaceuticals can qualify for the exemptions described in section 503B if its conditions are met.
  - Specifically, a radiopharmaceutical compounded by an outsourcing facility in accordance with the conditions in section 503B is exempt from:
    - New drug approval requirements (section 505)
    - Labeling with adequate directions for use (section 502(f)(1))
  - Radiopharmaceuticals compounded by outsourcing facilities remain subject to CGMP requirements in section 501(a)(2)(B) of the FD&C Act.
Policy Objectives—Access

- FDA recognizes that entities, including nuclear pharmacies, sometimes compound radiopharmaceuticals using bulk drug substances or FDA-approved drugs, to meet patients’ medical needs.

- For example:
  - Compounding from bulk in drug shortage situations.
  - Manipulating an FDA-approved drug using step-by-step instructions that differ from those of the approved drug to accommodate advances in technology.
  - Increasing the radioactivity of an approved radiopharmaceutical to accommodate a patient who lives farther away.
Policy Objectives—Safety and Quality

- Under certain circumstances, such compounding can serve an important need for patients.

- However, it is also higher risk. For example:
  - No premarket review of the compounded drug is conducted to ensure that the formulation being administered is safe and effective.
  - Lack of CGMP compliance can increase the potential for quality concerns, such as inadvertent contamination.

- It is important that such compounding be done under appropriate conditions that balance patient access with patient safety protections.
Policy Objectives—Integrity of the Drug Approval Process

- Stakeholders have advised FDA of certain compounders that may have been compounding from bulk drug substances radiopharmaceuticals that were similar to FDA-approved radiopharmaceuticals for patients whose needs may have been met by the approved products.

- Such compounding both undermines the drug approval process and unnecessarily exposes patients to the risks associated with unapproved drugs.

- It is important that any policy that provides for compounding of radiopharmaceuticals, particularly from bulk drug substances, limit such compounding to circumstances in which the approved product does not meet patients’ medical needs.
Draft Guidance for Entities other than Outsourcing Facilities
Terminology

- What is compounding?
  - No statutory definition of “compounding” of radiopharmaceuticals because they are excluded from section 503A.
  - For purposes of this draft guidance: “FDA regards compounding as the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.”

- Draft guidance describes two types of compounding:
  - Compounding that involves manipulations other than “minor deviations”
  - Compounding that is limited to “minor deviations”
Terminology

- Repackaging
  - “FDA regards repackaging as the act of removing an FDA-approved radiopharmaceutical from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product.”
Policy

- Draft guidance describes the conditions under which FDA would not intend to take action for violations of:
  - New drug approval requirements (section 505),
  - Labeling with adequate directions for use (section 502(f)(1)), and
  - CGMP requirements (section 501(a)(2)(B)).

When a state-licensed nuclear pharmacy or federal facility compounds or repackages radiopharmaceuticals.
Conditions

- Two sets of conditions:
  - Compounding that involves manipulations other than minor deviations.
  - Compounding that constitutes minor deviations, and repackaging.
Conditions—Other than Minor Deviations

- Pharmacist supervision and state or NRC license
- Receipt of valid prescriptions for individually identified patients
  - Compounding (but not distribution) before the receipt of a prescription.
  - Compounding after the receipt of a prescription.
- Bulk drug substances used in compounding
  - Complying with a United States Pharmacopeia (USP) or National Formulary monograph.
  - Source of bulk drug substances and certificate of analysis.
- Inactive ingredients
Conditions—Other than Minor Deviations

- Compliance with USP chapter on pharmacy compounding.
- List of drugs that have been withdrawn or removed from the market for reasons of safety or effectiveness.
- Compounded radiopharmaceuticals that are essentially copies of an approved radiopharmaceutical.
- List of drugs that present demonstrable difficulties for compounding.
- Wholesaling.
- Compliance with state requirements.
- Compliance with NRC requirements.
Conditions—Minor Deviations and Repackaging

- Compounding or repackaging using only an FDA-approved drug product (and not a bulk drug substance).
- Pharmacist supervision and facility has a state or NRC license.
- Compliance with USP chapter on pharmacy compounding.
- Compliance with state requirements.
- Compliance with NRC requirements.
- Wholesaling.
Draft Guidance for Outsourcing Facilities
Terminology

- **Compounding**—statutory definition in section 503B:
  - “The combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.”

- **Repackaging**
  - “Act of taking a finished drug product, including a radiopharmaceutical, from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.”
Terminology

- Outsourcing facility—statutory definition in section 503B:
  - Facility at one geographic location or address that is engaged in the compounding of sterile drugs;
  - Has elected to register as an outsourcing facility;
  - Complies with all of the requirements of section 503B;
  - Is not required to be a licensed pharmacy; and
  - May or may not obtain prescriptions for identified individual patients.
Policy—Compounding

- A radiopharmaceutical compounded by an outsourcing facility is exempt from new drug approval and labeling with adequate directions for use requirements if all of the conditions of section 503B are met.

- Draft guidance describes specific policies applicable only to the compounding of radiopharmaceuticals, with respect to:
  - Bulk drug substances used in compounding, and
  - Compounding radiopharmaceuticals that are essentially copies of approved radiopharmaceuticals.
Compounding—Bulk Drug Substances

- Bulk drug substances used in compounding under section 503B must either be (1) used to compound a drug that appears on FDA's drug shortage list at the time of compounding, distribution, and dispensing, or (2) appear on a list developed by FDA of bulk drug substances that can be used in compounding because there is a clinical need ("bulks list").

- Compounders should refer to FDA's guidance, *Interim Policy for Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, for FDA's policy regarding the use of bulk drug substances in compounding while the bulks list is being developed.
Compounding—Essentially A Copy

- Under section 503B, a drug cannot qualify for the exemptions under 503B is essentially a copy of one or more approved drugs.

- A compounded radiopharmaceutical prepared with only minor deviations may meet the definition of essentially a copy because the differences from the approved drug are minimal. However, these differences may be clinically important.

- Therefore, the draft guidance describes conditions under which the Agency would not intend to take action with respect to the copies provision of section 503B in the context of minor deviations.
Policy—Repackaging

- The exemptions in section 503B are available to compounded drugs, but not to repackaged drugs.

- Repackaged radiopharmaceuticals are generally subject to all requirements of the Act applicable to the production of drugs.

- The draft guidance describes the conditions under which FDA would not intend to take action for violations of the following sections of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals:
  - New drug approval requirements (section 505).
  - Labeling with adequate directions for use (section 502(f)(1)).
Conditions—Repackaging

- Product being repackaged is an FDA-approved drug.
- Pharmacist supervision and facility has state or NRC licensure.
- Compliance with CGMP requirements.
- List of drugs that have been withdrawn or removed from the market for reasons of safety or effectiveness.
- Wholesaling.
- Compliance with state requirements.
- Compliance with NRC requirements.
- Labeling.
- Drug product reporting.
- Adverse event reporting.
Examples of Comments on the Draft Guidances

- Commenters requested clarification on:
  - Applicability of the draft guidance to certain settings and entities, including:
    - Nuclear medicine physicians/supervised designees;
    - Hospital-based nuclear medicine departments; and
    - Nuclear medicine clinics.
  - Beyond-use-dates applicable to compounded radiopharmaceuticals.
  - “Essentially a copy” condition.
  - “Minor deviations.”
1. Assessment Question

1. Are compounded radiopharmaceuticals eligible for the exemptions in section 503A of the Federal Food, Drug, and Cosmetic Act, concerning compounded drugs?
   A. Yes
   B. No
2. Assessment Question

2. Can radiopharmaceuticals be compounded by outsourcing facilities?
A. Yes
B. No
3. Assessment Question

3. Which of the following is true?
   A. Pharmacies that compound radiopharmaceuticals are only subject to state and NRC oversight.
   B. Under FDA draft guidance, compounding using bulk drug substances can constitute a “minor deviation.”
   C. FDA’s draft guidance describes different policies depending on whether or not the compounding constitutes “minor deviations.”
   D. Compounding and repackaging have the same meaning.
4. Assessment Question

4. Which is a condition addressed in the draft guidances?
   A. Compounded radiopharmaceuticals are not essentially copies of approved radiopharmaceuticals.
   B. Compounding of radiopharmaceuticals occurs only during drug shortage situations.
   C. All compounding of radiopharmaceuticals complies with current good manufacturing practice standards.
   D. All compounding of radiopharmaceuticals complies with United States Pharmacopeia <797> standards.
Accreditation Standards Impacting Nuclear Medicine

Cindi Luckett-Gilbert
Regulatory Compliance
Shertech Pharmacy
Target Audience: Pharmacists
ACPE#: 0202-0000-18-075-L03-P
Activity Type: Knowledge-based
Disclosures

No commercial or financial interests

Target Audience:

ACPE#:

Activity Type:

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Learning Objectives

1. Explain how to integrate basic quality and safety concepts into nuclear medicine
2. Discuss current nuclear medicine practices impacted by TJC
3. List QAPI ideas for nuclear medicine
4. Recognize risk and establish actions to mitigate risk
1. Assessment Question

1. Which of the following can be used as a patient identifier for radiopharmaceutical white blood cell labeling?
   A. Wristband provided by the nuclear pharmacy
   B. Blood collection worksheet for nuclear medicine technologists
   C. Color labels provided by the nuclear pharmacy
   D. Name or birthdate on patient identification label
2. Assessment Question

1. What does NPSG stand for
   A. New Patient Security Group
   B. National Patient Safety Goal
   C. National Patient Safety Guideline
   D. New Product Safety Group
3. Assessment Question

3. What medical equipment in nuclear pharmacy carries infection out of the pharmacy?
A. Bore of scanner
B. Straps
C. Lead pigs
D. Wheelchairs
4. Assessment Question

1. What does QAPI stand for
   A. Quality Action Plan for Improvement
   B. Quantification of Assessment and Investigation
   C. Quality Assessment and Performance Improvement
   D. Quantification of Action and Performance Improvement
“Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective, and potentially dangerous”

Chanter, 1999
Defining Medication

Prescription and sample medications, herbal remedies, vitamins, OTC, nutraceuticals, vaccines, diagnostic contrast agents, IV solutions, radiopharmaceuticals/radionuclides, blood derivatives

- Includes:
  - All contrast media (oral, rectal, IV, intracavitary, intrathecal, intravesical, intrauterine, etc)
  - Echo “Bubbles” contrast
  - Radiolabeled blood products
  - Imaging adjunctive medications
Why survey and compliance are necessary

- Hospitals are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment
- Goal of survey is to determine if the hospital is in compliance with the CoP set forth at 42 CFR Part 482
- Certification of hospital compliance is accomplished through observations, interviews, and document/record reviews
Quality and Patient Safety Initiatives

- TJC National Patient Safety Goals
- Solutions for Patient Safety (SPS)
- Institute for Healthcare Improvement (IHI)
- National Quality Forum (NQF)
- National Association for Healthcare Quality (NAHQ)
- Institute for Safe Medication Practices (ISMP)
- National Patient Safety Foundation (NPSF)
- US Pharmacopeia (USP)
Medical Legal Considerations

- Medical Malpractice Concerns
- Professional Liability
  - Must follow the hospital driven policies in order to be covered under the hospital liability insurance. **Staff that willingly disregards policy may be excluded from coverage in the event of a serious safety event**
- State informed consent and documentation laws
Each of these documents and initiatives are meant to shape the work we do by:

- Providing guidance and best practice recommendations
- Driving standardization

All in an effort to

Provide the best care and eliminate harm
HOW TO PRIORITIZE?

Start with Compliance

CoPs (CMS)

MUST FOLLOW or risk non-compliance with

Immediate jeopardy

Condition-level findings

Standard-level findings
42 CFR 482.53 - Condition of participation: Nuclear medicine services

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

- (a) **Standard: Organization and staffing.** The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.
  
  - (1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

  - (2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.
42 CFR 482.53 - Condition of participation: Nuclear medicine services

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42 CFR 482.53 - Condition of participation: Nuclear medicine services

- (b) **Standard:** *Delivery of service.* Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

- (1) In-house preparation of radiopharmaceuticals is by, or under, the **direct** supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

- (2) There is proper storage and disposal of radioactive material.

- (3) If laboratory tests are performed in the nuclear medicine service, the service **must meet** the applicable requirement for laboratory services specified in §482.27.
UPDATE on § 482.53(b)(1)


- This new rule finalized the previously proposed change of removing the term “direct” from the current requirement at § 482.53(b)(1).
  - Removing requirement of having provider in the suite at time of preparation, per “Supervision” rules interpretation.

42 CFR 482.53 - Condition of participation: Nuclear medicine services

- (c) **Standard: Facilities.** Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—
  - (1) Maintained in safe operating condition; and
  - (2) Inspected, tested, and calibrated at least annually by qualified personnel.
42 CFR 482.53 - Condition of participation: Nuclear medicine services

- (d) **Standard: Records.** The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

- (1) The hospital must maintain copies of NM reports for at least 5 years.

- (2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.
42 CFR 482.53 - Condition of participation: Nuclear medicine services

- (3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

- (4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

[51 FR 22042, June 17, 1986, as amended at 57 FR 7136, Feb. 28, 1992]
Why survey and compliance are necessary

- The survey process focuses on a hospital’s performance of patient-focused and organization functions and processes
- The survey is the means to assess compliance with federal health, safety and quality standards
- Insures the beneficiary receives safe, quality care and services
Who surveys for Compliance and Accreditation?

Accreditation by an approved national accreditation organization demonstrates that all applicable conditions are met or exceeded

- The Joint Commission (TJC)
- Det Norske Veritas (DNV)
- Healthcare Facilities Accreditation Program
- Center for Improvement and Healthcare Quality
Hospital Rules / Governing Documents

- Medical Staff Bylaws, Rules and Regulations, Policies
- Hospital Policies, Procedures, Standard Operating Procedures (SOPs)
- Department Policies and Procedures
- Department Protocols
- Standard Work
PROFESSIONAL GUIDELINES / Practice Standards

• ACR Appropriateness Criteria
• Image Gently, Image Wisely, Choosing Wisely
• Professional Practice Standards
  ▪ SNMMI Procedure Standards
  ▪ SNMMI-TS NMT Scope of Practice and Performance Standards
  ▪ ACR Practice Parameters & Technical Standards
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CMS Interpretive Guidelines

- Revised Hospital Radiologic and Nuclear Medicine Services Interpretive Guidelines – State Operations Manual (SOM) Appendix A
- Revised Nov 20, 2015
- 42 CFR 482.53 – Nuc Med Services

SOMA

• the type of radiopharmaceutical;
• the location in the hospital where it was received, stored and dispensed;
• the amount received or dispensed at each location;
• the staff member receiving or dispensing; and
• when applicable, how/when it is disposed of and by whom. This would also include, when applicable, the type and amount of any radiopharmaceuticals returned to the source vendor.
Medication Management in Medical Imaging

- TJC has established numerous patient safety initiatives for general pharmacy:
  - Some, which may be directly applied to medical imaging and nuclear pharmacy
  - Other initiatives must be adopted for medical imaging and nuclear pharmacy practice
  - Medical imaging and nuclear pharmacy practice must be adapted to incorporate these medication management standards
2018 Joint Commission National Patient Safety Goals

- Focused safety goals each year
- TJC accreditation is one way to demonstrate quality and participate in Federal Medicare and State Medicaid Programs
- TJC goals were written and interpreted with surgery or nursing in mind and needs to be translated for medical imaging
- Goals are not open for debate
Goal 1: Improve the accuracy of patient identification

NPSG.01.01.01 Elements of Performance

1. Use at least two ways to identify patients. For example, use the patient’s name and date of birth. This is done to make sure that each patient gets the correct medicine, blood, collecting blood samples and other specimens and treatment.

Most hospitals use name and date of birth and compare information to hospital issued identification bracelet

Room number or physical location is not an identifier
Goal 1: Improve the accuracy of patient identification

NPSG.01.01.01   Elements of Performance

2. Label containers used for blood and other specimens in the presence of the patient

Identification of patient
Must be hospital generated information
This means nuclear pharmacy color alphanumeric bands are not acceptable as identification
The bands are not hospital generated
Hospital produced labels are affixed to the syringe before leaving the patient on the syringe (for WBC, RBC)
Goal 1: Improve the accuracy of patient identification

NPSG.01.03.01  Elements of Performance

Eliminate transfusion errors related to patient misidentification

- Go back to correct patient identifier NPSG – name, date of birth
- Some surveyors call labeled white blood cells and red cells blood transfusions
Goal 1: Improve the accuracy of patient identification

NPSG.01.03.01 Elements of Performance

Eliminate transfusion errors related to patient misidentification

Drawing blood

- Match the patient to the order
- Label patient blood in presence of patient with hospital stickers
- Some hospital protocols include sending row of patient stickers to nuclear pharmacy for use in the labeling process
- New software being written for nuclear pharmacies to bar code labels
Goal 1: Improve the accuracy of patient identification

NPSG.01.03.01 Elements of Performance

Eliminate transfusion errors related to patient misidentification

**Reinjecting blood**

- Match the blood or blood component to the order
- Match the patient to the blood or blood component
- Use a two person verification process or a one-person verification accompanied by an automated identification technology such as bar coding
Goal 1: Improve the accuracy of patient identification

NPSG.01.03.01 Elements of Performance

Eliminate transfusion errors related to patient misidentification

Reinjecting blood

- Two person verification:
  - One person conducting identification verification is the qualified transfusionist who will administer the blood or blood component to the patient
  - Persons verifying patient must be qualified
  - Technologist injecting must have blood transfusion reaction training documented
Goal 2: Improve the effectiveness of communication among caregivers

NPSG.02.03.01
Report critical results of critical tests and diagnostic procedures on a timely basis – hospitals define immediate action

Elements of Performance
1. Develop written procedures for managing critical results and diagnostic procedures;
   1. By whom and to whom the results are reported to
      1. Includes PET/SPECT CT, identification of pneumothorax, etc.
2. The acceptable length of time between availability and reporting of critical results
   1. Check the clocks against each other
Quality Assessment and Performance Improvement

- Quality Assessment and Performance Improvement (QAPI)
- Hospital-wide program
- Required by 482.21
- The hospital must monitor the quality and safety of nuclear medicine services
- All CMS chapters state areas must participate: NM participating in 80% already established processes
QAPI for nuclear medicine

Examples include:
Issues with radiopharmaceutical dose; bad tag, wrong dose,
Incidents of wrong radiopharmaceutical being used
Incidents of improper patient preparation
Repeats of same diagnostic studies within a short time span
Diagnostic studies or therapeutic procedures performed in a manner inconsistent with applicable hospital written protocol
Where pharmacy has oversite, not just RSO and Medical Director – track through pharmacy and P + T Committee
QAPI for nuclear medicine

The hospital is required under the QAPI CoP:
Track medical errors
Track adverse events related to nuclear medicine
must be analyzed for cause
preventative actions must be undertaken

Deficiencies identified related to tracking, analyzing and addressing adverse event and quality indicator data and performance activities must be cited under applicable QAPI standards
EXISTING Nuclear Medicine Safety CONSIDERATIONS Are only the Tip of the Iceberg
Risk Points in Nuclear Medicine

- Communication - Critical Results
- 2 Person verification required for blood administration
- Time Out and Universal Standards for Invasive or High Risk Procedures
  - Procedures with laterality
  - Cisternogram/LPs – MUST wear a mask
  - Intra-abdominal injections
  - Therapy
Risk Points in Nuclear Medicine

- **Hand Hygiene** - CDC estimates 50-60% of healthcare associated infections CAN be prevented with proper hand hygiene.

- **Infection transmission risk from equipment.**
  - Bore of scanner, scanner beds
  - Straps, positioning blocks
  - Lead pigs, carry cases, syringe shields
  - Carts, wheelchairs
Risk Points in Nuclear Medicine

- Spinal Injections - Due to outbreaks of bacterial meningitis among patients who’ve undergone spinal injections, facemasks should always be worn by healthcare providers when performing these spinal injection procedures.
  - Inpatient as well as outpatient
  - Epidural or Spinal anesthesia
  - Myelogram
  - Cisternogram

Risk Points in Nuclear Medicine

- Labeling - Every medication and solution must be labeled with 5 components when transferred from original package or container
  - Drug Name
  - Strength
  - Amount (if not apparent from packaging)
  - Expiration date (when not used within 24 hours)
  - Expiration time (when expiration occurs within 24 hours)

- Exception: The medication will be immediately administered. If it leaves your hands, it must be labeled

- Any product found unlabeled must be immediately discarded
Risk Points in Nuclear Medicine  Healthcare Associated Conditions (HACs)

- **Blood Incompatibility and Reactions**
  - RBC and WBCs- monitoring for autologous transfusion reaction, estimated at 2.1 percent of all reactions

- **Falls and Trauma**
  - Fractures, Dislocations, Intracranial Injuries, Crushing Injuries, Burn, Other Injuries

- **Catheter-Associated Urinary Tract Infection (CAUTI)**

- **Central Line (Vascular Catheter)-Associated Blood Stream Infection (CLABSI)**
Administration

MM.06.01.01 - The hospital safely administers medications. COP 485.635(a)(3)(v) and (d)(3)

Key Elements of Performance

- Defines in writing, LIPs and clinical staff disciplines that are authorized to administer medications, with or without supervision, in accordance with law and regulation.

- Consider adding to hospital bylaws that NMTs can prepare and administer radiopharmaceuticals and adjunctive pharmaceuticals, as defined in the NMT Scope of Practice.
Current discussions with TJC

Overnight activity for hot labs

- Bulk vials of tc99m are questioned
- Syringes with 25 mCi, 50 mCi, send instead and questioned
- Calling tc99m floor stock alleviated the issue

Gastric emptying

- Picking up eggs from cafeteria results in nuclear medicine technologists having to participate in food safety training
- Washing out pan egg cooked with cannot be in same sink to wash hands
- Fork used to scramble eggs cannot be same fork given to patient
Contracted services

TJC wants a list of all contracted services only those with direct patient care: ex. nuclear pharmacy

CMS definition is different: wants master list, blood bank, eye and tissue

Annual assessment of every single contract services

Some objective way of determining of continuing contract, not ‘just because they want to’

Goals, specific measures in contracts, 90% dose on time, bi-annual or quarterly on survey
1. Assessment Question

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Appreciation and thanks to Lyn Mehlberg

- References
  - CMS
  - Joint Commission