



RADIOPHARMACEUTICAL  
VENDOR

QUALIFICATION  
CHECKLIST



APhA-APPMSIG

NUCLEAR PHARMACY PRACTICE

# OVERVIEW

Nuclear pharmacies play an essential role in the preparation and distribution of radiopharmaceuticals for use in nuclear medicine departments and outpatient clinics. Upon receipt of a prescription from an Authorized User physician, radioactive legend drugs are dispensed to nuclear medicine departments and outpatient centers for diagnostic imaging and therapeutic applications. Each patient-specific unit dose is calibrated to time of administration and delivered by nuclear pharmacy personnel.

Nuclear pharmacies function as pharmacies under applicable state laws and therefore must comply with the pharmacy regulations of the state in which they are registered. Nuclear pharmacies must also comply with the requirements of USP <797> when compounding sterile preparations and USP <795> as appropriate. The majority of nuclear pharmacy activity consists of mixing, reconstituting, eluting, radio-labeling, or otherwise manipulating FDA approved radiopharmaceuticals in a manner that is not considered to be compounding by the FDA.

Nuclear pharmacies dispense to institutions with Radioactive Materials Licenses that specify the Authorized User physicians and the conditions under which radiopharmaceuticals must be received, handled, and used. Nuclear pharmacy services when offered within the scope of state and federal regulations do not constitute “outsourcing” as defined by Drug Quality and Safety Act.

A detailed overview of the Radiopharmaceutical Vendor Qualification Checklist can be found in Appendix A.

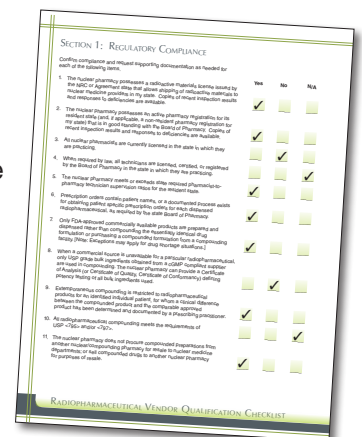
## PRINCIPLES OF USE

- When selecting a vendor to supply radiopharmaceuticals as compounded sterile preparations, each institutional department of pharmacy should take a comprehensive and organized approach to vendor selection.
- Departments of pharmacy are strongly encouraged to engage the nuclear medicine department in the vendor selection process.
- While this tool is intended to be useful for all institutional departments of pharmacy, its use will vary based upon the institutional size, geographic location, services needed, and available resources.
- The institution is encouraged to use this tool along with site visits to ensure a comprehensive review of potential nuclear pharmacy service.

## DIRECTIONS FOR USE

This document provides a checklist of relevant items to be assessed when evaluating potential nuclear pharmacy vendors for the provision of radiopharmaceuticals. Note that the items may not address all areas of concern for a given institution, but are intended to serve as a basic screening tool only. Appropriate compliance is noted by marking “Yes”. A response of “No” warrants additional investigation.

The institution is encouraged to request supporting documentation as appropriate to substantiate compliance. A site visit may provide additional information confirmation of appropriate operational procedures.



## SECTION 1: REGULATORY COMPLIANCE

Confirm compliance and request supporting documentation as needed for each of the following items.

	Yes	No	N/A
1. The nuclear pharmacy possesses a radioactive materials license issued by the NRC or Agreement state that allows shipping of radioactive materials to nuclear medicine providers in my state. Copies of recent inspection results and responses to deficiencies are available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The nuclear pharmacy possesses an active pharmacy registration for its resident state (and, if applicable, a non-resident pharmacy registration for my state) that is in good standing with the Board of Pharmacy. Copies of recent inspection results and responses to deficiencies are available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All nuclear pharmacists are currently licensed in the state in which they are practicing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. When required by law, all technicians are licensed, certified, or registered by the Board of Pharmacy in the state in which they are practicing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The nuclear pharmacy meets or exceeds state required pharmacist-to-pharmacy technician supervision ratios for the resident state.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Prescription orders contain patient names, or a documented process exists for obtaining patient specific prescription orders for each dispensed radiopharmaceutical, as required by the state Board of Pharmacy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Only FDA-approved commercially available products are prepared and dispensed rather than compounding the essentially identical drug formulation or purchasing a compounded formulation from a compounding facility. [Note: Exceptions may apply for drug shortage situations.]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. When a commercial source is unavailable for a particular radiopharmaceutical, only USP grade bulk ingredients obtained from a cGMP compliant supplier are used in compounding. The nuclear pharmacy can provide a Certificate of Analysis (or Certificate of Quality, Certificate of Conformancy) defining potency testing of all bulk ingredients used.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Extemporaneous compounding is restricted to radiopharmaceutical products for an identified individual patient, for whom a clinical difference between the compounded product and the comparable approved product has been determined and documented by a prescribing practitioner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. All radiopharmaceutical compounding meets the requirements of USP <795> and/or <797>.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. The nuclear pharmacy does not procure compounded preparations from another nuclear/compounding pharmacy for resale to nuclear medicine departments; or sell compounded drugs to another nuclear pharmacy for purposes of resale.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## SECTION 1: REGULATORY COMPLIANCE

Confirm compliance and request supporting documentation as needed for each of the following items.

	Yes	No	N/A
12. Radiopharmaceutical prescription distribution is restricted to nuclear medicine departments within the nuclear pharmacy resident state or immediately contiguous state(s). If no, what percentage of prescriptions is dispensed to users beyond immediately contiguous states? _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. The nuclear pharmacy maintains the required minimum amount of liability insurance as outlined by my institution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Patient records are maintained in accordance with the privacy and security standards of HIPAA and other applicable state laws.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## SECTION 2: QUALITY AND PATIENT SAFETY MEASURES

Confirm compliance and request supporting documentation as needed for each of the following items.

	Yes	No	N/A
15. Compounding staff competency (garbing and hand hygiene, aseptic technique and related practices, and cleaning and disinfection procedures) are evaluated prior to actual radiopharmaceutical preparation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Compounding staff are pre-qualified to perform aseptic manipulations by documenting successful completion of media fill simulations per USP <797> standards.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Beyond Use Dates are determined using evidence-based and validated stability testing procedures for compounded sterile preparations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Nonviable and viable particle testing of primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and clean room/areas are performed in accordance with to USP <797> standards.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Action and alert limits for routine surface microbiological and fungal environmental monitoring are established to minimize contamination.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Comprehensive investigations of out-of-limit findings are conducted, to determine root cause as recommended by USP <797> and are followed by corrective and preventative actions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. The physical facilities and equipment meet USP <797> requirements for compounding sterile preparations (buffer area, segregated compounding area, primary engineering controls, HEPA air filtration) including testing and certification.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Risk from contamination is minimized through hand hygiene (pharmacy and courier staff) and adequate sanitation of reusable unit dose shields.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## SECTION 2: QUALITY AND PATIENT SAFETY MEASURES

Confirm compliance and request supporting documentation as needed for each of the following items.

	Yes	No	N/A
23. Quality systems are in place to document deviations, failures, and corrective & preventative actions for performance improvement.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. A documented policy on white blood cell labeling describes the nuclear pharmacy process and engineering controls used to mitigate risk of medication errors involving radiolabeled blood products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## SECTION 3: MEDICATION ADMINISTRATION SAFETY

Confirm compliance and request supporting documentation as needed for each of the following items.

	Yes	No	N/A
25. Information regarding reactive substances (latex, DEHP, preservatives) found in dispensed prescriptions is readily accessible.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. All prescription labels include the calibration date/time, lot number, and expiration date/time (BUD) as part of machine-readable bar coding.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Prescription labels are compliant with Board of Pharmacy regulations, easy to read, and contain patient name when applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Additional precautions are used in blood labeling procedures to ensure that the right blood is returned to the right patient (i.e., barcoding, auxiliary and coded labels, etc.).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. The prescription label distinguishes between diagnostic and therapeutic radiopharmaceutical indications or procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. The prescription label contains necessary special administration, storage, or precaution instructions (e.g., SQ, oral, use of in-line filter).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Procedures in the nuclear pharmacy are available to prevent errors from "look-alike/sound-alike" medications (stored & dispensed).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Risk mitigation procedures are available to prevent patient harm from drugs/radiopharmaceuticals that require special handling (e.g., beta emitters, alpha emitters, I-131 therapy, labeled blood products).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. A plan for the communication of medication shortages and outages to customers is available.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Tamper-evident options are routinely used (e.g., overwrap, shrink wrap, tamper-evident foil, and/or tamper-evident seals).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. Radiochemical purity testing is performed on each prepared product prior to release with results readily available for review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## SECTION 3: MEDICATION ADMINISTRATION SAFETY

Confirm compliance and request supporting documentation as needed for each of the following items.

	Yes	No	N/A
36. Written protocols are available addressing the use of investigational medications that includes review, approval, supervision, monitoring, storage, dispensing, labeling, and distribution, when applicable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Medications are stored according to the manufacturer's recommendations or, in the absence of such recommendation, according to a pharmacist's instruction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. All medication storage areas are monitored & evaluated for temperature and humidity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## SECTION 4: SERVICE EXCELLENCE: CRITICAL AND ESSENTIAL BUSINESS PRACTICES

Confirm compliance and request supporting documentation as needed for each of the following items.

	Yes	No	N/A
39. Products are dispensed in container types (e.g. syringes, vials, needles) that meet the needs of my institution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. Secure delivery of radiopharmaceuticals is provided to my institution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. Delivery personnel background checks meet my institutional requirements.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Delivery personnel training includes Hazmat and Security training that meets the requirements of 49 CFR 172 for transportation of radioactive materials.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Business continuity plans in event of natural or man-made disaster or public health emergency are available and tested for effectiveness on a set schedule.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44. The nuclear pharmacy maintains a current, physician-approved, listing of radiopharmaceutical and dose activity used for specific procedures for my institution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45. A written policy is available for the retrieval and handling of medications that are recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46. A written process is available for response to actual or potential adverse drug events, significant adverse drug reactions, altered biodistribution, or formulation errors including prescriber notification.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47. Staff members with clinical expertise are available to assist with clinical questions, formulary review, or other informational requirements needed by my institution.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# APPENDIX A

## OVERVIEW OF RADIOPHARMACEUTICAL VENDOR CHECKLIST

Radiopharmaceuticals are legend drugs approved by the FDA for use in diagnostic imaging or therapeutic applications. A tracer amount of a radioactive isotope is affixed to a chemical or biological substance, providing a radiolabeled entity. Upon patient administration, the labeled substance will follow physiological pathways to provide diagnostic information about patient conditions. For example, a technetium radiolabeled phosphonate will provide information about blood flow to the bone and identify areas of rapidly growing bone (e.g., metastatic disease). Radioactive isotopes are also used therapeutically to target abnormal pathophysiology. For example, radioactive iodine can be used to ablate hyperfunctioning thyroid cells in thyroid disease.

### HISTORY

The development of radiopharmaceuticals began in the 1960s. The primary source of diagnostic radioactivity, the technetium/molybdenum generator, received FDA approval in the early 1970s. The generator is eluted with normal saline to remove the technetium. The radioactive technetium solution is then aseptically added to FDA-approved lyophilized reagents (kits) to prepare a specific radiopharmaceutical. The radiopharmaceutical is then tested to assure standards of purity are met prior to patient administration. The preparation of radiopharmaceuticals must be done under the direction of a physician or a pharmacist who has received special training in handling radioactive materials for human use and under conditions specified by regulations<sup>1</sup>.

In the past, hospital nuclear medicine departments purchased generators and reagent kits and prepared radiopharmaceuticals in-house. Pharmacists were

not routinely involved until the appearance of commercial nuclear pharmacies in the mid-1970s. Pharmacists specifically trained in preparation of radiopharmaceuticals brought a standard of quality and uniformity to radiopharmaceuticals used in diagnostic imaging. Nuclear pharmacies provided an alternative to in-house preparations allowing hospitals to purchase patient-specific doses as needed. This reduced hospital needs for space, personnel, and other resources effecting a more cost-effective provision of radiopharmaceuticals for imaging needs. Use of a commercial nuclear pharmacy also minimizes hospital requirements for regulatory compliance in the handling of radioactive materials. While many large institutions currently maintain an in-house nuclear pharmacy, it is estimated that more than 80% of radiopharmaceuticals are purchased from a commercial nuclear pharmacy<sup>2</sup>.

### PRESENT

The nuclear medicine department is usually part of hospital radiology services. Radiologists and other physicians performing medical imaging have a long history of autonomy, operating outside standard medication use systems. Direct purchase of imaging drugs without pharmacy oversight has been routine. Historically, the hospital pharmacy has not been involved with medical imaging other than to perhaps supply adjunct medications (e.g., adenosine, morphine, aminophylline, enalaprilat). Nuclear medicine is no exception, routinely purchasing radiopharmaceuticals directly from a commercial radiopharmacy and bypassing any institutional pharmacy oversight.

This autonomous function of radiology continued until 2004 when all CMS deemed accreditation organizations (The Joint Commission, DNV Healthcare and American Osteopathic Association Healthcare Facilities Accreditation Program) defined radiopharmaceuticals as medications. This recognition of radiopharmaceuticals as medications places the responsibility for medication management of radiopharmaceuticals and any other drugs used in nuclear medicine on the institutional pharmacy. The issue is additionally complicated by additional requirements specific to the use of radioactivity from both the accreditation organization(s) and the Nuclear Regulatory Commission or Agreement State radiation control agency.

# NEED FOR A VENDOR ASSESSMENT TOOL FOR NUCLEAR PHARMACY

Directors of pharmacy are faced with multiple challenges in providing oversight. Many have little, if any, working knowledge of radioactive drugs, their use and handling, and the additional regulatory requirements for safely managing radioactive materials. The majority of radiopharmaceutical purchases are outside the normal channels of procurement. Many nuclear medicine management systems are not linked to hospital electronic records making patient monitoring difficult. Nuclear medicine departments have long operated independently and may be reluctant to accept and make changes to work within the pharmacy-driven medication system. In order to effectively manage all medications used in diagnostic imaging, pharmacy directors needed information and direction.

Information on best practices for incorporation of radiopharmaceuticals into hospital medication management practices is limited. A single peer-reviewed publication<sup>3</sup> and presentations in trade journals<sup>4-7</sup> and professional newsletters<sup>8,9</sup> provide some direction. Pharmacy management guidelines<sup>9,10</sup> published by the American Society of Health-System Pharmacists do not distinctly address radiopharmaceutical services. Pharmacy directors have used the contractor assessment tool from ASHP<sup>11</sup> as guidance for the evaluation of vendors contracting compounded sterile products and the tool specifically excludes radiopharmaceutical vendors. Thus, there is no standardized way to evaluate vendors offering radiopharmacy services.

The radioactive component of radiopharmaceuticals presents specific challenges to management by hospital pharmacy departments. These include:

- Time critical preparation and use due to short lived radioactive components
- Regulation of preparation, dispensing, storage and

use of radioactive materials for human use

- Regulation of packaging, transporting and delivery of radiopharmaceuticals
- Federal and state statutes that supersede institutional policies and procedures

Pharmacy directors turned to radiopharmacists to learn more about radiopharmaceuticals and nuclear medicine. Commercial nuclear pharmacies received numerous requests for information. For example, at the request of Novation, a healthcare supply cost management group, nuclear pharmacy provided a webinar addressing the unique characteristics of radiopharmaceuticals; the foundational principles of radiopharmaceutical preparation; specific issues challenging management oversight of medication use; resources available for pharmacy directors; and internal processes for monitoring radiopharmaceuticals to comply with accreditation requirements. A common request was for a document similar to the ASHP sterile products contractor assessment tool structures specifically oriented to contracting for nuclear pharmacy services.

In March of 2013, The APhA-APPM Nuclear Pharmacy Practice SIG Professional Practices Committee was charged with developing a tool for use by hospital pharmacists in the evaluation of contractors of nuclear pharmacy services. A task force of nuclear pharmacists including two who practice within hospital settings, developed a vendor assessment tool. This was presented at the 2014 business meeting of the SIG for review by members and followed by close editing and comments by members of the committee. The tool is designed to assist hospital pharmacists in evaluating relevant regulatory and practice standards in selecting a commercial nuclear pharmacy to supply radiopharmaceuticals to institutional nuclear medicine departments.



The final document consists of four sections:

## Section 1: Regulatory Compliance

The section essentially lists the regulatory requirements with which nuclear pharmacies must comply. The majority of the section addresses state Board of Pharmacy requirements for the practice of pharmacy addressing issues of licensure; compliance with USP <795> and <797>; and extemporaneous compounding requirements as specified by the FDA. The handling of radioactive materials as specified by the Nuclear Regulatory Commission or Agreement State agency is also defined. The section essentially lists the requirements pertinent to nuclear pharmacy.

### References:

- USP <795>, <797>, <823> and others
- State Board of Pharmacy regulations
- Nuclear Regulatory Commission (or Agreement State agencies) (10 CFR)
- Federal Food, Drug and Cosmetic Act
- Nuclear Pharmacy Guideline: Criteria for Determining When to Register as a Drug Establishment. Division of Drug Labeling Compliance, Center for Drugs and Biologics, Food and Drug Administration. May 1984
- Drug Quality Security Act- Title I: Drug Compounding – Compounding Quality Act (Sec.102). November 2013.

## Section 2: Quality and Patient Safety Measures

The section parallels a similar section in the ASHP tool listing key tests and documentation required by USP <797> in the compounding of sterile preparations. A unique item is process and engineering controls to prevent medication errors by the nuclear pharmacy when radiolabeling of patient white blood cells.

### References:

- USP <797>
- The Joint Commission. Medication Management Chapter. Effective January 2012

## Section 3: Medication Administration and Safety

The section addresses issues of proper radiopharmaceutical labeling, highlighting compliance with Board of Pharmacy regulations. Recommendations for medication management as recommended by accreditation agencies such as storage, 'look-alike/sound-alike' medications, and risk mitigation procedures to prevent patient harm are listed. Nuclear pharmacy standards of practice including radiochemical purity testing; white blood cell labeling precautions; and differentiation of diagnostic and therapeutic uses are presented. The purpose of the section is to emphasize patient safety issues with which a non-nuclear pharmacist may not be knowledgeable.

### References:

- State Board of Pharmacy regulations
- The Joint Commission. Medication Management Chapter. Effective January 2012
- USP <797>
- Procedure Guidelines for the Use of Radiopharmaceuticals (Callahan, 2007)
- Model Rules for Nuclear/Radiologic Pharmacy in Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. August 2013.

## Section 4: Service Excellence: Critical and Essential Business Procedures

This section includes items presented in the ASHP document but additionally addresses issues unique to radiopharmaceuticals. Accreditation agencies specify procedures for secure and safe control of all medications. Items are included that address the federal requirements of delivery and delivery personnel for the transportation of radioactive materials.

### References:

- The Joint Commission. Environment of Care Chapter. Effective January 2012.
  - Department of Transportation ( 49 CFR)
  - State Board of Pharmacy regulations
  - Board of Pharmacy Specialties, Nuclear Pharmacy Certification Content Outline/Classification System. Domain 4: Health and Safety. Domain 5: Drug Information and Professional Consultation. 2013
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  2. Ponto JA, Hung JC. Nuclear pharmacy, Part II: Nuclear pharmacy practice today. Journal of Nuclear Medicine Technology. 2000; 28:76-81.
  3. Beach TA, Griffith K, Dam HQ, Manzone TA. Ensuring safe and quality medication use in nuclear medicine: collaborative team achieves compliance with medication management standards. Journal of Nuclear Medicine Technology. 2012; 40:1-10.
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  7. Kienle PC, Green RL. Tips for managing radiopharmaceuticals. Pharmacy Purchasing & Products. 2013; 10(3): 30.
  8. Mehlberg LM. What does medication management mean for nuclear medicine?. Uptake The SNMTS Newsletter. 2007; 13(2):1, 3.
  9. Mills, G. Ensuring safety and security of radiopharmaceuticals. Joint Commission Perspectives. 2012; 32(7):8-10.
  10. ASHP Guidelines on outsourcing pharmaceutical services. American Journal of Health-System Pharmacy. 1998;55:1611-1617.
  11. ASHP Guidelines on outsourcing sterile compounding services. American Journal of Health-System Pharmacy. 2010; 67:757-765.
  12. Outsourcing sterile products preparation contractor assessment tool. 2011. American Society of Health-System Pharmacists Research and Education Foundation. Bethesda, MD. Available at: <http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool/SterileProductsAssessmentTool.aspx>. Accessed September 10, 2014.