Model Rules for Nuclear/Radiologic Pharmacy

Terms/Definitions Used in This Article

"Board of Pharmacy" or "Board" means the governmental regulatory body empowered to regulate pharmaceutical practices including granting and disciplining licenses of individuals and companies.

"Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.

"Prescription Drug Order" means a lawful order from a Practitioner for a Drug or Device for a specific patient, including orders derived from Collaborative Pharmacy Practice, that is communicated directly to a Pharmacist in a licensed Pharmacy.

Section 1. Purpose and Scope.

The Practice of Nuclear/Radiologic Pharmacy is hereby recognized as a specialty of Pharmacy practice, regulated by State Boards of Pharmacy. As such, the following model rules are included to address those areas specific or unique to this specialty practice. Nuclear/Radiologic Pharmacy Practice refers to a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other Drugs.

Section 2. Definitions.

(a) "Authentication of Product History" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

(b) "Internal Test Assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(c) "Nuclear Pharmacy" means a Pharmacy providing radiopharmaceutical services or, as provided in Section 3 of these Rules, appropriate area of any Institutional Facility.

(d) "Qualified Licensed Professional" means a non-Pharmacist individual (such as a physician, nurse, or technologist) who possesses a current state license, if applicable, and who has sufficient training and experience to safely handle and Dispense radiopharmaceuticals as defined by the respective requirements of [cite appropriate Nuclear Regulatory Commission (NRC) or Agreement State and State Board of Pharmacy law(s)].

(e) "Qualified Nuclear Pharmacist" means a currently licensed Pharmacist in the State of practice, who is certified as a Nuclear Pharmacist by the State Board of Pharmacy or by a certification Board recognized by the State Board of Pharmacy, or who meets the following standards:

(1) Minimum standards of training for “authorized user status” of radioactive material [cite State Radiation Control Agency or NRC licensure guide].

(2) Completed a minimum of 200 contact hours of instruction in nuclear Pharmacy and the safe handling and the use of radioactive materials from a program approved by the State Board of Pharmacy, with emphasis in the following areas:

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics of radioactivity;

(iv) radiation biology; and

(v) radiopharmaceutical chemistry.

(3) Attained a minimum of 500 hours of clinical nuclear Pharmacy training under the supervision of a qualified nuclear Pharmacist.

(f) “Radiopharmaceutical Quality Assurance” means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

(g) “Radiopharmaceutical Service” means, but shall not be limited to, the procurement, storage, handling, preparation, Labeling, quality assurance testing, Dispensing, Delivery, recordkeeping, and disposal of radiopharmaceuticals and other Drugs.

(h) “Radiopharmaceuticals” are radioactive Drugs as defined by the FDA and the _____ State Board of Pharmacy [cite appropriate law(s)].

Section 3. General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) Nuclear Pharmacy License. A license to operate a Pharmacy providing radiopharmaceutical services shall only be issued to a Qualified Nuclear Pharmacist. All personnel performing tasks in the preparation and Distribution of radioactive Drugs shall be under the direct supervision of a Qualified Nuclear Pharmacist. A Qualified Nuclear Pharmacist shall be responsible for all operations of the Pharmacy and shall be in personal attendance at all times that the Pharmacy is open for business. In emergency situations when a Qualified Nuclear Pharmacist is not present, designated Qualified Licensed Professionals may have access to the licensed area. These individuals may prepare single doses of radiopharmaceuticals for the immediate emergency, and must document such activities.

(b) Nuclear Pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space

requirements established for all pharmacies in the State or as otherwise defined by the _____ State Board of Pharmacy.

(c) The Nuclear Pharmacy area shall be secured from unauthorized personnel.

(d) Nuclear Pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive Drugs and other radioactive materials in accordance with [cite appropriate Pharmacy and radiological control agency or NRC Statute(s)].

(e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area. Detailed floor plans shall be submitted to the State Board of Pharmacy and the State Radiation Control Agency or NRC before approval of the license.

(f) Radiopharmaceuticals are to be Dispensed only upon a Prescription Drug Order from a Practitioner authorized to possess, use, and Administer radiopharmaceuticals.

(g) The permit to operate a Nuclear Pharmacy is conditioned upon an approved State Radiation Control Agency (RCA) or NRC license. Copies of the RCA or NRC inspection reports shall be made available upon request for Board inspection.

Section 4. Other Requirements.

All Nuclear/Radiologic Pharmacies shall also adhere to the principles outlined in the Rules for Pharmaceutical Care as these pertain to the practice of Nuclear Pharmacy. *(See Appendix A for Model Inspection Form for Nuclear Pharmacies.)*

Appendix A

Model Inspection Form for Nuclear Pharmacies

I. General Information

Type of Inspection:
Announced_____ Unannounced_____ Investigational_____
Date:_____ Time Inspection Started:_____

Time Inspection Completed:_____

A. Inspector's Name:_____

Position/Title:_____

Address:_____

_____

City:_____ State:_____ Zip Code:_____

Telephone:_____ Ext:_____

B. Nuclear Pharmacy

Name:_____

Address:_____

_____

City:_____ State:_____ Zip Code:_____

Telephone:_____ Ext_____

C. Facility Hours:

Time Open _____ Time Closed _____

Days Open _____ Total Hours _____

D. Prescription Department Hours:

Time Open _____ Time Closed _____

Days Open _____ Total Hours _____

E. Is a nuclear pharmacist present in the facility at all times that the pharmacy is open for business?

Yes_____No_____ If no, give explanation in the space below:

F. Name of Facility:_____

Manager:_____

Pharmacy License/Permit Number: _____

Expiration Date: _____

Renewal of Pharmacy License/Permit Number Current:Yes_____ No_____

Pharmacy License/Permit Number Posted: Yes _____ No _____

G. Facility Staff Information:

Pharmacists:

Name	Title or Position	Certificate Number	Certificate Posted (Yes or No)	Certificate Renewal Current (Yes or No)
1._____	_____	_____	_____	_____
2. _____	_____	_____	_____	_____
3. _____	_____	_____	_____	_____
4. _____	_____	_____	_____	_____
5. _____	_____	_____	_____	_____
6. _____	_____	_____	_____	_____
7. _____	_____	_____	_____	_____
8. _____	_____	_____	_____	_____
9. _____	_____	_____	_____	_____
10._____	_____	_____	_____	_____

(use additional sheets if necessary)

Have all pharmacists notified the Board of Pharmacy of any changes in mailing address and place of employment?

Yes _____ No _____ If no, give explanation in the space below:

Pharmacists' Education and Training

Name	Training BPS Board Certified (Yes or No)	Documentation Available (Yes or No)
1. _____	_____	_____
2. _____	_____	_____
3. _____	_____	_____
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____

(use additional sheets if necessary)

Qualifications of pharmacists are in accordance with State Board of Pharmacy standards for education and experience in the safe handling and use of radioactive pharmaceuticals and other related materials?
Yes _____ No _____ If no, give explanation in the space below:

Pharmacy Technicians/Supportive Personnel

Name	Title or Position	Certificate Current Number	Certificate Renewal Posted (Yes or No)	Certificate (Yes or No)
1. _____	_____	_____	_____	_____
2. _____	_____	_____	_____	_____
3. _____	_____	_____	_____	_____
4. _____	_____	_____	_____	_____
5. _____	_____	_____	_____	_____
6. _____	_____	_____	_____	_____
7. _____	_____	_____	_____	_____
8. _____	_____	_____	_____	_____
9. _____	_____	_____	_____	_____

(use additional sheets if necessary)

Pharmacy Interns

Name	Registration Number	Registration Renewal Current (Yes or No)	Registration Posted (Yes or No)
1. _____	_____	_____	_____
2. _____	_____	_____	_____
3. _____	_____	_____	_____
4. _____	_____	_____	_____
5. _____	_____	_____	_____

(use additional sheets if necessary)

Are all pharmacy interns, pharmacy technicians and/or supportive personnel performing tasks involving radioactive and associated non-radioactive drugs under the supervision of a licensed pharmacist in accordance with state pharmacy laws?
Yes _____ No _____ If no, give explanation in the space below:

H. Compliance Posture of the Facility and Staff Personnel

1. Are there any current citations or other disciplinary actions against the facility's pharmacy license/permit?
   Yes _____ No _____ If yes, give explanation in the space below:

2. Are there any current citations or other disciplinary actions against any existing staff personnel at the facility?
   Yes _____ No _____ If yes, give explanation in the space below:

3. If there are any current citations or other disciplinary actions against either the facility or the staff personnel, are the communications regarding these events properly posted (e.g., initial complaint letter along with written reply for corrective actions to be take, etc.)?
   Yes _____ No _____ If no, give explanation in the space below:

I. Radioactive materials (RAM) license for the facility:

_____

Date of Issuance: _____ Expiration Date: _____

If there is no current RAM license for the facility, give explanation in the space below:

1. Are there any current citations or other disciplinary actions against the facility's RAM license?

   Yes _____ No _____ If yes, give explanation in the space below:

J. Does the facility store or use any controlled substances?

Yes _____ No _____ If no, give explanation in the space below:

1. If yes, is all necessary documentation and registration available?

   Yes _____ No _____ If no, give explanation in the space below:

2. If yes, is the DEA permit properly posted?

   Yes _____ No _____ If no, give explanation in the space below:

3. DEA Permit Number_____ Permit Renewal Current: Yes ____ No ____

   Permit Expiration Date _____

   If the permit is not current, give explanation in the space below:

4. Are authorized signatures and/or power of attorney documentation maintained and appropriate for the current DEA permit, and is this documentation available?

   Yes _____ No _____ If no, give explanation in the space below:

K. Are facility operational policies and procedures written, maintained and followed for the purchase/receipt/storage/manipulation/compounding/distribution/quality assurance/disposal of radioactive and non-radioactive drugs?

Yes _____ No _____ If no, give explanation in the space below:

L. Have any documented events of the following nature taken place since the last inspection?

1. Misadministration of radioactive or non-radioactive drugs?

   Yes _____ No _____ If yes, give explanation in the space below:

   a) Is documentation available describing corrective actions to be taken to prevent reoccurrence of these events?

      Yes _____ No _____ If no, give explanation in the space below:

   b) Were any of these events reported to the State Board of Pharmacy and/or other appropriate state or federal agencies?

      Yes _____ No _____ If no, give explanation in the space below:

2. Product mislabeling of radioactive or non-radioactive drugs?

   Yes _____ No _____ If yes, give explanation in the space below:

3. Lost radioactive or non-radioactive drugs?

   Yes _____ No _____ If yes, give explanation in the space below:

a) Is documentation available describing corrective actions to be taken to prevent reoccurrence of these events?

Yes _____ No _____ If no, give explanation in the space below:

b) Were any of these events reported to the State Board of Pharmacy and/or other appropriate state or federal agencies?

Yes _____ No _____ If no, give explanation in the space below:

M. Inspection History

1. Date of last State Board of Pharmacy inspection:
   _____

2. List of non-compliance item(s) noted during last inspection:

Non-Compliant Item	Corrective Action Taken
a)	a)
b)	b)
c)	c)
d)	d)
e)	e)
f)	f)
g)	g)
h)	h)

(use additional sheets if necessary)

II. Facility, Equipment and Instrumentation

For the following sections, the key appearing below can be used as a guide for completing the "source of information" category as it appears for each statement. Items that **do not** apply to the operational perspectives of a given practice site can be indicated as such by writing "Not Applicable" or "N/A" in the space provided for that statement.

IO = Inspector's Observations
LS = Licensee Statement
RR = Records Review
WI = Worker Interview

A. Facility

		Yes	No	Source of Comment Information Number	N/A or
1.	Restricted areas are well defined and physically segregated by barriers from unrestricted areas.	_____	_____	_____	_____
2.	Access to restricted areas is secure from entry by unauthorized personnel.	_____	_____	_____	_____
3.	Access to the pharmacy is kept locked at all times when the pharmacist is not available.	_____	_____	_____	_____
4.	Pharmacy floor plans and layout design comply with all State Board of Pharmacy requirements.	_____	_____	_____	_____
5.	Shielding is present to prevent radiation exposure in unrestricted areas of the facility.	_____	_____	_____	_____
6.	Documentation that ventilation systems from fume hoods and biological cabinets are adequate to prevent the accidental release of airborne radioactive materials inside the facility.	_____	_____	_____	_____
7.	Pharmacy library contains current editions (as opposed to "copies") of all reference texts and other documents, as stipulated by State Board of Pharmacy requirements.	_____	_____	_____	

_____

a) United States Pharmacopeia/National Formulary (with supplements). _____ _____ _____ _____

		Yes	No	N/A or Source of Comment Information Number
b)	United States Pharmacopeia-Drug Information (USP-DI)	_____	_____	_____
c)	Radiological Health Handbook (or equivalent).	_____	_____	_____
d)	State laws and regulations pertaining to Pharmacy practice.	_____	_____	_____
e)	State and/or federal laws and regulations pertaining to the safe handling, use, storage, dispensing, transport, and disposal of radioactive and non-radioactive drugs.	_____	_____	_____
f)	Other reference texts as required by state Pharmacy laws.	_____	_____	_____

B. Equipment

1.	Equipment and supplies comply with applicable state and federal laws/ regulations governing the safe handling, use, storage, preparation, dispensing, distribution, and disposal of radioactive and non-radioactive drugs.	_____	_____	_____
	Including but not limited to:			
a)	Laminar air flow hood and/or biological safety cabinet	_____	_____	
b)	Fume hood	_____	_____	
c)	Dose calibrator	_____	_____	
d)	Analytical balance	_____	_____	
e)	Lead-shielded drawing station	_____	_____	
f)	Well scintillation counter	_____	_____	

g)	Assorted glassware	_____	_____
h)	Microscope	_____	_____
i)	Hemocytometer	_____	_____
j)	Chromatographic apparatus	_____	_____

		Yes	No	Source of Comment Information	N/A or Number
k)	Thermometers	_____	_____		
l)	Refrigerator	_____	_____		
m)	Radiation monitoring equipment	_____	_____		
n)	Syringe and vial shields	_____	_____		
o)	Decontamination supplies	_____	_____		
p)	Transport containers/boxes	_____	_____		
q)	DOT shipping labels	_____	_____		
r)	Other supplies as necessary	_____	_____		

C. Instruments

1.	Instruments (e.g. Geiger-Mueller survey meters, area ratemeters, Cutie Pie survey meter, etc.) comply with applicable state and federal regulations governing radioactive and non-radioactive drugs.	_____	_____	_____	_____
2.	Instrument maintenance and repair logs are maintained and documentation is available.	_____	_____	_____	_____
3.	Instruments are calibrated at intervals specified in the facility's radioactive materials license.	_____	_____	_____	_____
4.	Dose calibrator				
a)	Constancy checks are performed in accordance with state and/or federal regulations and documentation is available.	_____	_____	_____	_____
b)	Accuracy checks are performed in accordance with state and/or federal regulations and documentation is available.	_____	_____	_____	_____
c)	Linearity checks are performed in accordance with state and/or federal regulations and documentation is available.	_____	_____	_____	_____

		Yes	No	Source of Comment Information Number	N/A or
d)	Geometry checks are performed in accordance with state and/or federal regulations and documentation is available.	_____	_____	_____	_____

III. Nuclear Pharmacy Procedures

		Yes	No	Source of Comment Information Number	N/A or
A.	**Protective Clothing/Safety**				
1.	Safety principles and practices are adhered to as described in the facility's policy and procedure manual.	_____	_____	_____	_____
a)	Disposable gloves are readily accessible and worn when handling radioactive and/or biohazard material.	_____	_____	_____	_____
b)	Lab coats are readily accessible and worn by staff personnel when in restricted areas of the facility.	_____	_____	_____	_____
c)	Used needles and other biohazardous materials are disposed of properly.	_____	_____	_____	_____
d)	Facility employees have received training on infectious disease prevention. Documentation of such training is available.	_____	_____	_____	_____
e)	Dosimetry Badges readily accessible and worn appropriately?	_____	_____	_____	_____
B.	**Posting and Labeling**				
1.	Radiation caution signs are properly used and posted throughout the restricted areas of the facility.	_____	_____	_____	_____
2.	Biohazard caution signs are properly used and posted throughout the facility.	_____	_____	_____	_____
3.	Appropriate notices to employees are posted.	_____	_____	_____	_____
C.	**Visitors**				
1.	Cleaning and maintenance personnel are escorted when entering and leaving the facility.	_____	_____	_____	_____

		Yes	No	Source of Comment Information	N/A or Number
2.	Custodial and maintenance personnel have been given training as to the proper procedures for entering and leaving the facility, and such training is documented.	_____	_____	_____	_____

D. Receipt of Incoming Shipments of Radioactive and Non-Radioactive Drugs.

1.	Documentation is maintained for the receipt of drugs (radioactive, non-radioactive, and controlled substances) in accordance with state and federal regulations. _____	_____	_____	_____	
2.	Procedures are established for the receipt of drugs by the facility during times other than normal working hours. _____	_____	_____	_____	
3.	Procedures are established for the handling of incoming shipments of radioactive and non-radioactive drugs that are damaged, or for accidents (e.g. spills) that occur while attempting delivery within the facility. _____	_____	_____	_____	
4.	Both radioactive and non-radioactive drugs are stored under appropriate conditions. _____	_____	_____	_____	

E. Traceability and Inventory of Radioactive and Non-radioactive Drugs.

1.	Radioactive and non-radioactive drugs and/or chemicals can be traced to manufacturer's lot number. _____	_____	_____	_____	
2.	Incoming shipment records for radioactive and non-radioactive drugs and/or				

chemicals indicate date of receipt, source or manufacturer, lot number, amount or quantity, drug expiration date, calibration (if applicable), and documentation is available.

		Yes	No	N/A or Source of Comment Information Number
3.	Outgoing shipment records for radioactive and non-radioactive drugs contain all required information as specified by state pharmacy laws for legend drugs.	_____	_____	_____
4.	Inventory for radioactive and non-radioactive drugs (including controlled substances and chemicals) matches physical inventory, and documentation is available.	_____	_____	_____
5.	Receipt of expired radioactive drugs and radioactive waste is documented and the records indicate the type, nature, and quantity of item(s), the date of placement into waste storage, the date of removal (disposal) from storage, and the method of disposal, along with other information as specified by state and federal regulations.	_____	_____	_____
6.	Records of drug destruction and/or return (including shipments to manufacturers, DEA, etc.) are maintained and documentation is available.	_____	_____	_____
7.	Outdated and deteriorated drugs are removed from active inventory.	_____	_____	_____
8.	Outdated and deteriorated drugs are disposed of in accordance with state and federal regulations.	_____	_____	_____
9.	Drug product recalls.			
a)	Policies and procedures exist for responding to events involving drug			

	product recalls.	_____	_____	_____
b)	Events of drug product recalls and action taken in response thereto is documented and available.	_____	_____	_____

		Yes	No	N/A or Source of Comment Information Number
F.	**Dispensing**			
1.	Work area is neat and clean in appearance.	_____	_____	_____
2.	Proper aseptic technique is used in the preparation and dispensing of all parenteral drug products.	_____	_____	_____
a)	Adequate space and equipment is available for aseptic preparation and dispensing of parenteral drug products.	_____	_____	_____
b)	Personnel are adequately trained in aseptic technique and documentation of such training is available.	_____	_____	_____
3.	Syringe shields and other appropriate shielding are used during the preparation and dispensing of radioactive drugs.	_____	_____	_____
4.	Records are maintained for the compounding, preparation, dispensing and distribution of both radioactive and non-radioactive drugs in accordance with state and federal regulations.	_____	_____	_____
5.	Radioactive and non-radioactive drugs are dispensed upon a prescription order from a licensed (authorized user) medical practitioner.	_____	_____	_____
a)	Radioactive and non-radioactive drugs intended only for in vitro or animal research are dispensed to a non-medical practitioner authorized by the Nuclear Regulatory Commission or an agreement state agency, or			

other regulatory agency, to possess such drugs, and documentation recognizing such is available. _____ _____ _____

_____

		Yes	No	N/A or Source of Comment Information Number
6.	A registered nuclear pharmacy, upon receiving an oral prescription for a radioactive or non-radioactive drug, immediately reduces the prescription to writing in accordance with state pharmacy law.	_____	_____	_____
7.	Each radiopharmaceutical dosage is assayed in the dose calibrator and dispensed within ±10% of the prescribed patient dose.	_____	_____	_____
8.	Labeling for radioactive and non-radioactive drugs is done prior to dispensing in accordance with state and federal regulations.	_____	_____	_____
a)	Accuracy of the information content on all product labeling is verified by the licensed pharmacist on duty prior to drug dispensing.	_____	_____	_____
9.	The outer container of each radioactive drug dispensed has a label which contains the following information:			
a)	The standard radiation symbol.	_____	_____	_____
b)	The words “Caution-Radioactive.”	_____	_____	_____
c)	The radionuclide.	_____	_____	_____
d)	The chemical form.	_____	_____	_____
e)	The amount of radioactivity.	_____	_____	_____
f)	The calibration date and time.	_____	_____	_____

g)	The expiration date and time.	_____	_____	_____
h)	If a liquid, the volume.	_____	_____	_____
i)	If a solid, the number of dosage forms or weight.	_____	_____	_____
j)	If a gas, the number of vials or ampules.	_____	_____	_____
k)	The drug prescription or lot number.	_____	_____	_____

		Yes	No	N/A or Source of Comment Information Number
l)	The name, address, and phone number of the pharmacy.	_____	_____	_____
m)	If a drug is to be used for diagnostic imaging and does not require a patient name, then the words "For Physician Use Only" appears on the prescription label.	_____	_____	_____

(See Section III.G.7. for situations when a patient's name shall appear on the prescription label.)

10.	The immediate inner container of each radioactive drug dispensed has a label which contains the following information:			
a)	The standard radiation symbol.	_____	_____	_____
b)	The words "Caution-Radioactive Materials."	_____	_____	_____
c)	The radiopharmaceutical name.	_____	_____	_____
d)	The drug prescription or lot number.	_____	_____	_____
e)	The patient's name if the drug is intended for therapy, involves a radiolabeled blood cell component or monoclonal antibody, or is investigational in nature.	_____	_____	_____

G. Special Radiopharmaceutical Preparation and Labeling Procedures.

1.	Procedures for the radiolabeling of red blood cells are performed as stated in the facility's policy and procedures			

	manual and/or drug insert _____	_____	_____	_____
2.	Procedures for the radiolabeling of white blood cells are performed as stated in the facility's policy and procedures manual and/or drug insert. _____	_____	_____	_____

		Yes	No	N/A or Source of Comment Information Number
3.	Procedures for the radiolabeling of platelets (or other blood cell components) are performed as stated in the facility's policy and procedures manual and/or drug insert.	_____	_____	_____
4.	Procedures for the radiolabeling of monoclonal antibodies are performed as stated in the facility's policy and procedure manual, drug package insert or IND protocol.	_____	_____	_____
5.	Procedures for the radiolabeling and dispensing of radiopharmaceuticals for patient therapy are performed as stated in the facility's policy and procedure manual and/or drug package insert.	_____	_____	_____
6.	Procedures for the compounding of drugs labeled with positron-emitting radio-nuclides are performed as stated in the facility's policy and procedure manual.	_____	_____	_____
7.	The outer container labeling for and radioactive drug involving radiolabeled blood cell components, monoclonal antibodies, or whose use is intended for patient therapy, or is investigational in nature (under an IND protocol), shall list the patient's name.	_____	_____	_____

H. Quality Control of Radiopharmaceuticals

1.	Sterility testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP/NF, and documentation is available.	_____	_____	_____

2. Pyrogen testing is performed, when appropriate, as stated in the facility's policy and procedure manual or USP/NF, and documentation is available. _____ _____ _____ _____

		Yes	No	N/A or Source of Comment Information Number
3.	Breakthrough testing for the presence of the parent radionuclide in a generator eluate (e.g. Molybdenum Mo99 from a Mo99/Tc99m generator) is performed, when appropriate, as stated in the facility's policy and procedure manual and/or drug package insert, and documentation is available.	_____	_____	_____
4.	Breakthrough testing for the presence of column packing material in a generator eluate is performed, when appropriate, as stated in the facility's policy and procedure manual, or drug package insert and/or USP/NF, and documentation is available.	_____	_____	_____
5.	Radionuclidic purity testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP/NF, and documentation is available.	_____	_____	_____
6.	Radiochemical purity testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP/NF, and documentation is available.	_____	_____	_____
7.	Microscopic inspection is performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP/NF, and documentation is available.	_____	_____	_____
8.	pH testing is performed, when appropriate, as stated in the facility's policy and procedure manual and/or			

USP/NF, and documentation is available._____ _____ _____ _____

9. Other types of quality control testing procedures are performed, when appropriate, as stated in the facility's policy and procedure manual and/or USP/NF, and documentation is available._____ _____ _____ _____

		Yes	No	N/A or Source of Comment Information Number
a)	Chemical purity testing, and documentation is available.	_____	_____	_____
b)	Specific activity determinations, and documentation is available.	_____	_____	_____
10.	Facility employees have been properly trained to perform quality control testing procedures and documentation of such training is available.	_____	_____	_____
11.	Documentation available that leak testing of all sealed radioactive sources is performed, as stated in the facility's policy and procedure manual, and/or its radioactive materials license.	_____	_____	_____

I. Pharmacy Law

1.	Phone prescriptions are received only by authorized personnel in accordance with state pharmacy law.	_____	_____	_____
2.	Phone prescriptions are immediately reduced to writing and shall record information in accordance with state pharmacy law, including but not limited to:			
a)	The name of the practitioner and the institution he represents.	_____	_____	_____
b)	The date of the prescription.	_____	_____	_____
c)	The name and dose of the radio-pharmaceutical or non-radioactive drug.	_____	_____	_____

d) The serial number assigned to the prescription by the dispensing nuclear pharmacy. _____ _____ _____ _____

e) The patient's name. _____ _____ _____ _____

f) Any specific instructions, if required. _____ _____ _____ _____

		Yes	No	N/A or Source of Comment Information Number
3.	All prescriptions are reviewed by the pharmacist on duty and are initialed before dispensing.	_____	_____	_____
4.	Prescription orders and dispensing records for radioactive drugs contain all information stipulated by state and federal regulations:			
a)	Name and address of the pharmacy.	_____	_____	_____
b)	Drug prescription or lot number.	_____	_____	_____
c)	Date drug is dispensed.	_____	_____	_____
d)	Name and address of the clinic, hospital or office to which the drug(s) is dispensed.	_____	_____	_____
e)	Name of the licensed medical practitioner authorized to prescribe, receive, and use the drug(s).	_____	_____	_____
	[Note: See III.F.5a. pertaining to non-medical individuals who may also order, receive, and use the dispensed drug(s)].			
f)	The name of the dispensed drug.	_____	_____	_____
g)	Prescribed amount and/or activity of the dispensed drug.	_____	_____	_____
h)	Drug concentration at the requested time/date of calibration.	_____	_____	_____
i)	Drug calibration date and time.	_____	_____	_____

j)	Drug expiration date and time.	_____	_____	_____
k)	Initials of the dispensing pharmacist appear on all records pertaining to the compounding, preparation, and dispensing of the drug.	_____	_____	_____

		Yes	No	N/A or Source of Comment Information Number
5.	A copy of the clinic, hospital, or office's current radioactive material license, along with the names of individuals from these locals who can phone or transmit orders to the nuclear pharmacy, are kept on file and such documentation is available.	_____	_____	_____
6.	The facility's policy and procedure manual defines the roles and responsibilities of pharmacy interns and supportive personnel with respect to the acquisition, handling, use, preparation, dispensing, quality assurance testing, distribution, inventory control, and disposal, etc., of radioactive and non-radioactive drugs.	_____	_____	_____
7.	Transfer of drug products are limited to unopened containers with manufacturer's instructions attached (except in emergency situations).	_____	_____	_____
8.	Copies of any investigational new drug (IND) protocols, and patient consent forms, etc., for which the pharmacy may prepare and dispense the drug are maintained on file, and such documentation is available.	_____	_____	_____
a)	Copy of the Institutional Review Board approval form (or letter).	_____	_____	_____
b)	Copy of the Radiation Safety Committee approval form (or letter).	_____	_____	_____
c)	Letter from the manufacturer (sponsor) indicating that the			

physician requesting the IND drug is a qualified investigator. _____ _____ _____ _____

		Yes	No	N/A or Source of Comment Information Number
J.	**Regulatory (Miscellaneous)**			
1.	Documentation for any requests for facility remodeling (if appropriate) from either the city, county, or state is maintained.	_____	_____	_____
2.	Drugs and other materials are appropriately segregated and stored within the facility, such as:			
a)	Radioactive vs. non-radioactive drugs.	_____	_____	_____
b)	Reagents/germicides/disinfectants vs. drugs.	_____	_____	_____
c)	Irrigation and topical solutions vs. injectable drugs.	_____	_____	_____
d)	Flammable vs. nonflammable drugs.	_____	_____	_____
e)	Drugs vs. food.	_____	_____	_____
f)	Drugs vs. specimens.	_____	_____	_____
g)	Controlled substances.	_____	_____	_____
3.	DEA Schedule II drugs are stored in a locked area, and keys are possessed only by authorized staff personnel.	_____	_____	_____
4.	Access to current copies of all applicable Department of Transportation (DOT), Nuclear Regulatory Commission (NRC), Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), State Board of			

	Pharmacy, and other local, state, or federal regulations pertaining to radioactive and non-radioactive drugs are available.	_____	_____	_____
5.	All previous State Board of Pharmacy inspection reports and other related correspondence are available and readily retrievable.	_____	_____	_____

IV. Comments Section

A. List all comments in the space below, referencing section/item number. Use additional sheets if necessary.

V. Evaluation

A. Provide in the space below a brief evaluation of the facility's compliance posture and program effectiveness overall. Use additional sheets if necessary.

VI. Follow-up Recommendations

A. Provide in the space below a brief statement of actions required in order to bring the facility's operation into full compliance. Use additional sheets if necessary.

Signature of Inspector

_____

___

Printed Name of the Inspector

_____

___

Date_____ Time_____

Signature of Pharmacy Manager

_____

___

Printed Name of Pharmacy Manager

_____

___

Date_____ Time_____