

Pharmacy Mobile Inspection Form

The Drug Control Division is utilizing all-inclusive mobile inspection forms that encompass multiple inspection types and business models. Inspection sections and/or inspection fields may intentionally remain blank when such sections and/or fields do not apply to the inspection type and/or business model for which the mobile inspection forms are being utilized. Please contact the Drug Control Agent who conducted your inspection if you feel an inspection section and/or inspection field was inadvertently left blank.

Nuclear Pharmacy Inspection

LVII. Nuclear Pharmacy

		Yes	No	Advised
Regulatory	Does the nuclear pharmacy hold appropriate federal and state licenses and permits to possess and distribute radioactive materials? [Section 20-576-61(b)(2)]			
	To whom is the license to operate the nuclear pharmacy issued?			
	Is the license to operate the nuclear pharmacy issued to a person who is, or who employs, nuclear pharmacists? [Section 20-576-61(a)]			
	Can the nuclear pharmacy make copies of all inspection reports prepared by any nuclear licensing agency available upon request for Department of Consumer Protection or Commission of Pharmacy inspection? [Section 20-576-61(b)(2)]			
Nuclear Pharmacists	Does each nuclear pharmacist hold a current pharmacist license issued by the Commission of Pharmacy? [Section 20-576-60(5)]			
	Is each nuclear pharmacist EITHER currently board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties OR identified as an authorized nuclear pharmacist on a United States Nuclear Regulatory Commission or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy? [Section 20-576-60(5)(A) and Section 20-576-60(5)(B)]			
Responsible Nuclear Pharmacist	Is a nuclear pharmacist responsible for all operations of the nuclear pharmacy? [Section 20-576-61(b)(1)(A)]			
	Which nuclear pharmacist is responsible for all operations of the nuclear pharmacy?			
	Is the nuclear pharmacist responsible for all operations of the nuclear pharmacy only supervising one nuclear pharmacy? [Section 20-576-61(b)(1)(B)]			

Nuclear Pharmacy Operation	Is a nuclear pharmacist present at all times that radiopharmaceutical services are being performed? [Section 20-576-61(b)(1)(C)]			
	Is a nuclear pharmacist present at all times that the nuclear pharmacy is open for business? [Section 20-576-61(b)(1)(C)]			
Nuclear Pharmacy Technicians	Does the nuclear pharmacy employ nuclear pharmacy technicians?			
	Is each nuclear pharmacy technician currently registered as a pharmacy technician with the Department of Consumer Protection? [Section 20-576-60(6)(B)]			
	Has each nuclear pharmacy technician EITHER completed a nuclear pharmacy technician training program provided by an accredited college program or an equivalent company sponsored program approved by the Commission of Pharmacy OR have one's name listed as an "Authorized User of Radioactive Materials" on the nuclear pharmacy's United States Nuclear Regulatory Commission or agreement state license? [Section 20-576-60(6)(C)(i) and Section 20-576-60(6)(C)(ii)]			
	Does each nuclear pharmacy technician work under the direct supervision of a nuclear pharmacist? [Section 20-576-60(6)(A)]			
Physical Premises	Does the nuclear pharmacy have ADEQUATE SPACE AND EQUIPMENT, commensurate with the scope of services required and provided? [Section 20-576-61(c)(1)]			
	Does the nuclear pharmacy have a RADIOPHARMACEUTICAL PREPARATION AND DISPENSING AREA? [Section 20-576-61(c)(2)]			
	Does the nuclear pharmacy have a RADIOACTIVE MATERIAL SHIPPING AND RECEIVING AREA? [Section 20-576-61(c)(2)]			
	Does the nuclear pharmacy have a RADIOACTIVE MATERIAL STORAGE AREA? [Section 20-576-61(c)(2)]			
	Does the nuclear pharmacy have a RADIOACTIVE WASTE DECAY AREA? [Section 20-576-61(c)(2)]			
	Is the nuclear pharmacy secure from entry by unauthorized personnel? [Section 20-576-61(c)(3)]			

Compounding and Dispensing Radiopharmaceuticals	Does the nuclear pharmacy compound and dispense radiopharmaceuticals that meet accepted standards of radiopharmaceutical quality, including, but not limited to, standards established by the United States Nuclear Regulatory Commission? [Section 20-576-61(c)(5)]			
	Does the nuclear pharmacy dispense radiopharmaceuticals only upon receipt of an order from a licensed practitioner or the practitioner's agent, or from a person authorized by the United States Nuclear Regulatory Commission or agreement state agency to possess such radiopharmaceuticals? [Section 20-576-61(c)(6)]			
	Does the nuclear pharmacy furnish radiopharmaceuticals and other drug products for office use to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners for individual patient use? [Section 20-576-61(d)(1)]			
	Does the nuclear pharmacy transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use in accordance with the regulations of the United States Nuclear Regulatory Commission and Regulations of Connecticut State Agencies? [Section 20-576-61(d)(1)]			
	Does the nuclear pharmacy redistribute United States Food and Drug Administration approved radioactive drugs?			
	Does the nuclear pharmacy process the radioactive drugs in any manner? [Section 20-576-61(d)(2)]			
	Does the nuclear pharmacy violate the product packaging? [Section 20-576-61(d)(2)]			
	Does the nuclear pharmacy maintain records for the ACQUISITION of all radiopharmaceuticals? [Section 20-576-61(c)(4)]			
	Does the nuclear pharmacy maintain records for the INVENTORY of all radiopharmaceuticals? [Section 20-576-61(c)(4)]			
Records	Does the nuclear pharmacy maintain records for the DISPOSITION of all radiopharmaceuticals? [Section 20-576-61(c)(4)]			
	Does the nuclear pharmacy immediately reduce a prescription to writing or record the order in an automated data processing system upon receiving an order for a radiopharmaceutical? [Section 20-576-62(a)]			

Records (continued)	Does the written or electronic record contain the NAME OF THE INSTITUTION? [Section 20-576-62(a)(1)]				
	Does the written or electronic record contain the NAME OF THE PRESCRIBING PRACTITIONER OR THE PRACTITIONER'S AGENT? [Section 20-576-62(a)(1)]				
	Does the written or electronic record contain the REQUESTED DATE OF DISPENSING? [Section 20-576-62(a)(2)]				
	Does the written or electronic record contain the CALIBRATION TIME OF THE RADIOPHARMACEUTICAL? [Section 20-576-62(a)(2)]				
	Does the written or electronic record contain the NAME OF THE PROCEDURE? [Section 20-576-62(a)(3)]				
	Does the written or electronic record contain the NAME OF THE RADIOPHARMACEUTICAL? [Section 20-576-62(a)(4)]				
	Does the written or electronic record contain the DOSE OR QUANTITY OF THE RADIOPHARMACEUTICAL? [Section 20-576-62(a)(5)]				
	Does the written or electronic record contain the PRESCRIPTION NUMBER assigned to the order? [Section 20-576-62(a)(6)]				
	Does the written or electronic record contain ANY SPECIFIC INSTRUCTIONS? [Section 20-576-62(a)(7)]				
	Does the written or electronic record contain the IDENTITY OF THE PERSON WHO DISPENSES the prescription or medication order? [Section 20-576-62(a)(8)]				
	Does the written or electronic record contain the PATIENT'S NAME IF the prescription or medication order is FOR A THERAPEUTIC OR BLOOD-PRODUCT RADIOPHARMACEUTICAL? [Section 20-576-62(a)(9)]				
	Outer Container Label	Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the NAME OF THE PHARMACY? [Section 20-576-62(b)(1)]			
		Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the ADDRESS OF THE PHARMACY? [Section 20-576-62(b)(1)]			

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NOT FOR

Outer Container Label (continued)

Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the NAME OF THE PRESCRIBING PRACTITIONER? [Section 20-576-62(b)(2)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the DATE OF DISPENSING? [Section 20-576-62(b)(3)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the PRESCRIPTION NUMBER? [Section 20-576-62(b)(4)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear, if radioactive, the STANDARD RADIATION SYMBOL? [Section 20-576-62(b)(5)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear, if radioactive, 'CAUTION: RADIOACTIVE MATERIAL'? [Section 20-576-62(b)(5)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the NAME OF THE PROCEDURE? [Section 20-576-62(b)(6)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the RADIONUCLIDE AND CHEMICAL FORM? [Section 20-576-62(b)(7)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the AMOUNT OF RADIOACTIVITY? [Section 20-576-62(b)(8)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the CALIBRATION DATE? [Section 20-576-62(b)(8)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the CALIBRATION TIME? [Section 20-576-62(b)(8)]			
Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the EXPIRATION TIME? [Section 20-576-62(b)(9)]			

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Outer Container Label (continued)	Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the APPROPRIATE DOSAGE UNITS? [Section 20-576-62(b)(10)]			
	Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear, IF A SOLID, the NUMBER OF ITEMS OR WEIGHT? [Section 20-576-62(b)(11)]			
	Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear, IF A GAS, the NUMBER OF AMPOULES OR VIALS? [Section 20-576-62(b)(12)]			
	Does the label on the outer container that consists of the radiation shielding and contains the dispensed radiopharmaceutical bear the PATIENT NAME WHEN INTENDED FOR INDIVIDUAL THERAPEUTIC USE OR THE WORDS "FOR PHYSICIAN USE" OR "FOR PHYSICIAN USE ONLY"? [Section 20-576-62(b)(13)]			
Immediate Inner Container Label	Does the label on the immediate inner container that contains the dose of radiopharmaceutical bear the NAME OF THE RADIOPHARMACEUTICAL? [Section 20-576-62(c)(1)]			
	Does the label on the immediate inner container that contains the dose of radiopharmaceutical bear the SERIAL NUMBER ASSIGNED TO THE PRESCRIPTION OR MEDICATION ORDER OF THE RADIOPHARMACEUTICAL? [Section 20-576-62(c)(2)]			
	Does the label on the immediate inner container that contains the dose of radiopharmaceutical bear the STANDARD RADIATION SYMBOL? [Section 20-576-62(c)(3)]			
	Does the label on the immediate inner container that contains the dose of radiopharmaceutical bear the WORDS "CAUTION: RADIOACTIVE MATERIAL"? [Section 20-576-62(c)(4)]			
Equipment and supplies	Does the nuclear pharmacy have RADIATION DETECTION AND MEASURING INSTRUMENTS CAPABLE OF ACCURATELY MEASURING QUANTITIES OF RADIOACTIVITY AND RADIATION? [Section 20-576-63(a)(1)]			
	Does the nuclear pharmacy have RADIATION SHIELDING? [Section 20-576-63(a)(2)]			
	Does the nuclear pharmacy have APPROPRIATE SUPPLIES AND EQUIPMENT FOR PERFORMING QUALITY ASSURANCE TESTING? [Section 20-576-63(a)(3)]			
	Does the nuclear pharmacy have a REFRIGERATOR? [Section 20-576-63(a)(4)]			

Equipment and Supplies (continued)	Does the nuclear pharmacy have MATERIALS FOR DECONTAMINATION OF ACCIDENTAL SPILLS OF RADIOACTIVE MATERIALS? [Section 20-576-63(a)(5)]			
	Does the nuclear pharmacy have APPROPRIATE SUPPLIES AND EQUIPMENT NECESSARY FOR COMPOUNDING AND DISPENSING STERILE PARENTERAL RADIOPHARMACEUTICALS? [Section 20-576-63(a)(6)]			
	Does the nuclear pharmacy have access to or maintain on the premises EITHER a copy of REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY OR a copy of the UNITED STATES PHARMACOPOEIA/NATIONAL FORMULARY (USP/NF)? [Section 20-576-63(b)(1)]			
	Does the nuclear pharmacy have access to or maintain on the premises a copy of the CURRENT RULES AND REGULATIONS OF THE NUCLEAR REGULATORY COMMISSION OR AGREEMENT STATE? [Section 20-576-63(b)(2)]			

LX. Additional Comments		Yes	No	Advised
1	Does the inspecting agent have any additional comments with respect to this nuclear pharmacy inspection?			

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