

Nuclear Medicine Department

USP <825> NM department assessment checklist



Identify which activities your department performs:

Yes	No	Section	Activity**
_____	_____	3	Immediate use of sterile RPs
_____	_____	*	Preparation of sterile RPs beyond immediate use
_____	_____	12.3	Direct infusion systems
_____	_____	10.4	RBC labeling
_____	_____	10.3	WBC labeling
_____	_____	11.1	Radiolabeling food for GI emptying
_____	_____	11.2	Sterile compounding
_____	_____	11.3	Sterile compounding using a nonsterile drug substance or components
_____	_____	12.4	Transporting generators between facilities

* All other sections of <825> apply **See definitions in USP <825>

Now that you've reviewed what activities your department performs, turn the page to see some SOP's you may need to implement.

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Standard operating procedures (SOPs)	Patient ready unit doses	+ Immediate use of sterile RPs	+ RBC labeling
Drug security (42 CFR 482.25)	.	.	.
General cleanliness, cleaning log (42 CFR 482.25)	.	.	.
Temperature log if drugs are stored in hot lab (42 CFR 482.25)	.	.	.
Aseptic technique — disinfecting septa (Section 1.2)	.	.	.
Time limit of one hour from first container puncture or exposure of any critical site involved (Section 3)	.	.	.
How to maintain DC free of blood borne pathogens (Section 7.6)	.	.	.
Complaint handling (Section 14.2)	.	.	.
Adverse event reporting (Section 14.3)	.	.	.
Hand hygiene (Section 4.4)	.	.	.
Garbing (Section 4.4)	.	.	.
Labeling (Section 12.2)	.	.	.
Drug preparation (Section 10)	.	.	.
Performance of drug QC (Section 10)	.	.	.
Documentation (Section 9)	.	.	.
Drug preparation of UltraTag® if in-vitro method used (Section 10.4)	.	.	.
Drug preparation of PYP™ in saline if in-vivo method used (Section 10.4)	.	.	.
How to maintain DC free of blood borne pathogens (Section 7.6)	.	.	.

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Work with your hospital pharmacy department to:

- Ensure that radiopharmaceuticals are on your hospital's formulary **Current list of FDA-approved radiopharmaceuticals**
- **Current list of FDA-approved RPs and contraindications**
- Have hospital pharmacy department countersign all drug utilization portions of Nuclear Medicine protocols

* Other activities such as radiolabeling food for GI emptying, direct infusion systems, etc. will require unique directive SOPs not listed.

Please visit [cardinalhealth.com/usp825](https://www.cardinalhealth.com/usp825) for additional resources and to download the documents listed above.

