			1		
	State section	NRC Section	RATS ID	Category	Subject and Comment
1	20.3.3.317 TERMS AND	§ 30.34 Terms and conditions	2018-1	В	Sent to NRC for review and comment prior to
	CONDITIONS OF LICENSES:	of licenses			implementation of the revisions
	I. Generators. Each licensee				
	preparing technetium-99m	(g) Each licensee preparing			
	radiopharmaceuticals from	technetium-99m			
	molybdenum-	radiopharmaceuticals from			
	99/technetium-99m	molybdenum-			
	generators or rubidium-82	99/technetium-99m			
	from strontium-82/rubidium-	generators or rubidium-82			
	82 generators shall test the	from strontium-82/rubidium-			
	generator eluates for	82 generators shall test the			
	molybdenum-99	generator eluates for			
	breakthrough or strontium-	molybdenum-99			
	82 and strontium-85	breakthrough or strontium-			
	contamination, respectively,	82 and strontium-85			
	in accordance with	contamination, respectively,			
	20.3.7.706 NMAC of this	in accordance with § 35.204			
	chapter. The licensee shall	of this chapter. The licensee			
	record the results of each	shall record the results of			
	test and retain each record	each test and retain each			
	for 3 years after the record is	record for 3 years after the			
	made. The licensee shall	record is made. The licensee			
	report the results of any test	shall report the results of any			
	that exceeds the permissible	test that exceeds the			
	concentration listed in 10	permissible concentration			
	CFR 35.204(a) at the time of	listed in § 35.204(a) of this			
	generator elution, in	chapter at the time of			
	accordance with 10 CFR	generator elution, in			
	<u>35.3204.</u>	accordance with § 35.3204 of			
		this chapter.			
2	20.3.3.315 radioactive	§ 32.72 Manufacture,	2018-1	В	Sent to NRC for review and comment prior to
	material for medical use	preparation, or transfer for			implementation of the revisions
	under 20.3.7 NMAC.	commercial distribution of			

Τ		radioactive drugs containing	
		hyproduct material for	
	L(1)(d) The applicant	medical use under part 35	
	[satisfies] [commits] the	(a)(4) The applicant commits	
	following labeling	(a)(4) The applicant commus	
		to the following labeling	
	requirements.	requirements:	
	J.(2)(f)(l) each individual's	(b)(5)(I) A copy of each	
	certification by a specialty	individual's certification by a	
	board whose certification	specialty board whose	
	process has been recognized	certification process has	
	by the [department,	been recognized by the	
	NRC][Commission] or	Commission or an	
	agreement state as specified	Agreement State as specified	
	in Subsection C of 20.3.7.714	in § 35.55(a) of this chapter;	
	NMAC, incorporating 10 CFR	or	
	35.55(a), with the written		
	attestation signed by a		
	preceptor as required by		
	Subsection C of 20.3.7.714		
	NMAC, incorporating 10 CFR		
	35.55(b)(2); or		
	(ii) the [department,		
	NRC [[Commission] or		
	agreement state license, or		
	(iii) the permit issued by a		
	NRC master material		
	licensee. or		
	(iv) the permit issued by a		
	[department		
	NRC [[Commission] or		
	agreement state licensee, or		
	NRC master materials		
	permittee of broad scope or		

	the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or J.(4) [Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.] [A licensee shall satisfy the labeling requirements in paragraph (d) of this section.] [(5) Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.]	(d) A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section.			
3	20.3.7.7 DEFINITIONS: C. [<u>"Associate Radiation</u> <u>Safety Officer (ARSO)</u> " means <u>an individual who—</u> (<u>1) Meets the requirements</u> in §§ 35.50 and 35.59; and (<u>2) Is currently identified as</u> an Associate Radiation Safety	 § 35.2 Definitions. Associate Radiation Safety Officer means an individual who— (1) Meets the requirements in §§ 35.50 and 35.59; and (2) Is currently identified as an Associate Radiation Safety 	2018-1	В	Sent to NRC for review and comment prior to implementation of the revisions

Officer for the types of use of	Officer for the types of use of		
byproduct material for which	byproduct material for which		
<u>the individual has been</u>	the individual has been		
assigned duties and tasks by	assigned duties and tasks by		
the Radiation Safety Officer	the Radiation Safety Officer		
<u>on—</u>	on—		
(i) A specific medical use	(i) A specific medical use		
license issued by the	license issued by the		
Commission or an Agreement	Commission or an		
State; or	Agreement State; or		
<u>(ii) A medical use permit</u>	(ii) A medical use permit		
issued by a Commission	issued by a Commission		
master material licensee.]	master material licensee.		
[D][<mark>E.]</mark> "Authorized			
medical physicist" means			
(Continue new			
designation to T)			
V. Ophthalmic physicist	Ophthalmic physicist means		
<u>means an individual who—</u>	an individual who—		
(1) Meets the requirements	(1) Meets the requirements		
<u>in § 35.433(a)(2) and § 35.59;</u>	in § 35.433(a)(2) and § 35.59;		
<u>and</u>	and		
(2) Is identified as an	(2) Is identified as an		
ophthalmic physicist on a—	ophthalmic physicist on a-		
(i) Specific medical use	(i) Specific medical use		
license issued by the	license issued by the		
Commission or an Agreement	Commission or an		
<u>State;</u>	Agreement State;		
(ii) Permit issued by a	(ii) Permit issued by a		
Commission or Agreement	Commission or Agreement		
State broad scope medical	State broad scope medical		
<u>use licensee;</u>	use licensee;		

	(iii) Medical use permit issued by a Commission master material licensee; or (iv) Permit issued by a Commission master material licensee broad scope medical use permittee.] [UI][W]. "Output" means	(iii) Medical use permit issued by a Commission master material licensee; or (iv) Permit issued by a Commission master material licensee broad scope medical use permittee.			
	(Continue new designation to end of definitions)				
	[AA][CC][Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer [or an Associate Radiation Safety Officer].	Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.	2018 1	119.5	
4	A. Radiation Safety Officer.	§ 35.24 Authority and responsibilities for the radiation protection program.	2018-1	Η&S	Sent to NRC for review and comment prior to implementation of the revisions
	(1) A licensee or licensee's management shall appoint a radiation safety officer, who	(b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in			

agrees, in writing, to be	writing, to be responsible for		
responsible for implementing	implementing the radiation		
a radiation protection	protection program. The		
program. The licensee,	licensee, through the		
through the radiation safety	Radiation Safety Officer, shall		
officer, shall ensure that	ensure that radiation safety		
radiation safety activities are	activities are being		
being performed in	performed in accordance		
accordance with licensee-	with licensee-approved		
approved procedures and	procedures and regulatory		
regulatory requirements. [A	requirements. A licensee's		
licensee's management may	management may appoint, in		
<u>appoint, in writing, one or</u>	writing, one or more		
more Associate Radiation	Associate Radiation Safety		
Safety Officers to support the	Officers to support the		
Radiation Safety Officer. The	Radiation Safety Officer. The		
Radiation Safety Officer, with	Radiation Safety Officer, with		
written agreement of the	written agreement of the		
licensee's management, must	licensee's management,		
assign the specific duties and	must assign the specific		
tasks to each Associate	duties and tasks to each		
Radiation Safety Officer.	Associate Radiation Safety		
These duties and tasks are	Officer. These duties and		
restricted to the types of use	tasks are restricted to the		
for which the Associate	types of use for which the		
Radiation Safety Officer is	Associate Radiation Safety		
listed on a license. The	Officer is listed on a license.		
Radiation Safety Officer may	The Radiation Safety Officer		
delegate duties and tasks to	may delegate duties and		
the Associate Radiation	tasks to the Associate		
Safety Officer but shall not	Radiation Safety Officer but		
delegate the authority or	shall not delegate the		
responsibilities for	authority or responsibilities		
	for implementing the		

	implementing the radiation protection program.	radiation protection program.			
5	20.3.7.702 G. Written Directive (3)(e) for high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions and total dose; or (f) [for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders, before implantation: treatment site, the radionuclide and dose; and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total	§ 35.40 Written Directive (b) (5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;	2018-1	H&S	Sent to NRC for review and comment prior to implementation of the revisions
	dose)-][For permanent implant brachytherapy: (i) Before implantation: The treatment site, the radionuclide, and the total	 (b)(6) For permanent implant brachytherapy: (i) Before implantation: The treatment site, the radionuclide, and the total 			

	(ii) After implantation but	(ii) After implantation but		
	before the patient leaves the	before the patient leaves the		
	post-treatment recovery	post-treatment recovery		
	<u>area: The treatment site, the</u>	area: The treatment site, the		
	number of sources	number of sources		
	implanted, the total source	implanted, the total source		
	strength implanted, and the	strength implanted, and the		
	<u>date; or</u>	date; or		
	(g) for all other	(7) For all other		
	brachytherapy, including low,	brachytherapy, including low,		
	medium and pulsed dose	medium, and pulsed dose		
	<u>rate remote afterloaders,</u>	rate remote afterloaders:		
	before implantation:	(i) Before implantation: The		
	treatment site, the	treatment site, radionuclide,		
	radionuclide and dose; and	and dose; and		
	after implantation but before	(ii) After implantation but		
	completion of the procedure:	before completion of the		
	the radionuclide, treatment	procedure: The radionuclide;		
	site, number of sources, total	treatment site; number of		
	source strength and	sources; total source		
	exposure time (or the total	strength and		
	dose); and date.]	exposure time (or the total		
		dose); and date.		
5	20.3.7.702	§ 35.40 Written Directive	2018-1	Sent to NRC for review and comment prior to
	G. Written Directive	(c)		implementation of the revisions
	(2) A written revision to an	(1) A written revision to an		
	existing written directive may	existing written directive may		
	be made if the revision is	be made if the revision is		
	dated and signed by an	dated and signed by an		
	authorized user before the	authorized user before the		
	administration of the dosage	administration of the dosage		
	of unsealed	of unsealed byproduct		
	[<u>byproduct</u>][radioactive]	material, the brachytherapy		
	material, the brachytherapy	dose, the gamma		

	dose, the gamma	stereotactic radiosurgery		
	stereotactic radiosurgery	dose, the teletherapy dose,		
	dose, the teletherapy dose or	or the next fractional dose.		
	the next fractional dose. If,			
	because of the patient's			
	condition, a delay in order to			
	provide a written revision to			
	an existing written directive			
	would jeopardize the			
	patient's health, an oral			
	revision to an existing			
	written directive is			
	acceptable, provided that the			
	oral revision is documented			
	as soon as possible in writing			
	in the patient's record. A			
	revised written directive			
	documenting the oral			
	revision must be prepared,			
	dated and signed by the			
	authorized user within 48			
	hours of the oral revision.			
6	20.3.7.702	§ 35.41 Procedures for	2018-1	Sent to NRC for review and comment prior to
	H. Procedures for	administrations requiring a		implementation of the revisions
	Administrations Requiring a	written directive.		
	Written Directive.	(b)		
	(2)			
	(e) Determining if a medical	(5) Determining if a medical		
	event, as defined in §	event, as defined in §		
	35.3045, has occurred; and	35.3045, has occurred; and		
	(f) Determining, for	(6) Determining, for		
	permanent implant	permanent implant		
	brachytherapy, within 60	brachytherapy, within 60		
	calendar days from the date	calendar days from the date		

	the implant was performed	the implant was performed			
	the total source strength	the total source strength			
	administered outside of the	administered outside of the			
	troatmont site compared to	treatment site compared to			
	the total source strength	the total source strength			
	decumented in the past	desumented in the past			
	documented in the post-	implemented in the post-			
	implantation portion of the	implantation portion of the			
	written directive, unless a	written directive, unless a			
	Written Justification of	written justification of			
	patient unavailability is	patient unavailability is			
	documented.	documented.		_	
7	20.3.7.714 TRAINING	§ 35.50 Training for Radiation	2018-1	В	Sent to NRC for review and comment prior to
	REQUIREMENTS:	Safety Officer and Associate			implementation of the revisions
		Radiation Safety Officer			
	A. Radiation Safety Officer				
	and Associate Radiation				
	<u>Safety Officer</u>]. The				
	regulations of the NRC set				
	forth in 10 CFR 35.50 are				
	hereby incorporated by				
	reference.				
8	20.3.7.714 TRAINING	§ 35.51 Training for an	2018-1	В	Sent to NRC for review and comment prior to
	REQUIREMENTS:	authorized medical physicist.			implementation of the revisions
	B. Training for an Authorized				
	Medical Physicist. The				
	regulations of the NRC set				
	forth in 10 CFR 35.51 are				
	hereby incorporated by				
	reference.				
9	20.3.7.714 TRAINING	§ 35.55 Training for an	2018-1	В	Sent to NRC for review and comment prior to
1	REQUIREMENTS:	authorized nuclear			implementation of the revisions
	C. Training for an Authorized	pharmacist.			
1	Nuclear Pharmacist. The	.			
	regulations of the NRC set				

	forth in 10 CFR 35.55 are hereby incorporated by				
10	20.3.7.714 TRAINING REQUIREMENTS: D. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist and Authorized Nuclear Pharmacist. The regulations of the NRC set forth in 10 CFR 35.57 are hereby	§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.	2018-1	В	Sent to NRC for review and comment prior to implementation of the revisions
11	20.3.7.714 TRAINING REQUIREMENTS: F. Training for Uptake, Dilution, and Excretion Studies. (For use of unsealed radioactive material under 20.3.7.704 NMAC) The regulations of the NRC set forth in 10 CFR 35.190 are hereby incorporated by reference.	§ 35.190 Training for uptake, dilution, and excretion studies.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
12	20.3.7.706 PERMISSIBLE MOLYBDENUM- 99, STRONTIUM-82 AND STRONTIUM-85 CONCENTRATIONS: B. Measurement.	§ 35.204 Permissible molybdenum-99, strontium- 82, and strontium-85 concentrations.	2018-1	H&S	Sent to NRC for review and comment prior to implementation of the revisions

	 (1) A licensee preparing technetium-99m radiopharmaceutical from molybdenum- 99/technetium-99m generators shall measure the molybdenum-99 concentration [of the first object of the second of the 	(b) A licensee that uses molybdenum- 99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum- 99 concentration in each			
	eluate after the receipt of the generator to demonstrate compliance with Subsection A of this section][in each eluate from a generator to demonstrate compliance with Subsection A of this section of this section].	eluate from a generator to demonstrate compliance with paragraph (a) of this section.			
	D. Reporting. [The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with 10 CFR 35.3204.]	(e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with § 35.3204.			
13	20.3.7.714 TRAINING REQUIREMENTS: G. Training for Imaging and Localization Studies. (For use of unsealed radioactive material under 20.3.7.705 NMAC) The regulations of	§ 35.290 Training for imaging and localization studies.	2018-1	В	Sent to NRC for review and comment prior to implementation of the revisions

	the NRC set forth in 10 CFR				
	35.290 are hereby				
	incorporated by reference.				
14	20.3.7.708 USE OF UNSEALED	§ 35.300 Use of unsealed	2018-1	В	Sent to NRC for review and comment prior to
	RADIOACTIVE MATERIAL FOR	byproduct material for which			implementation of the revisions
	WHICH A WRITTEN	a written directive is			
	DIRECTIVE IS REQUIRED:	required.			
	A licensee may use any	A licensee may use any			
	unsealed radioactive material	unsealed byproduct material			
	[identified in 10 CFR	identified in §			
	<u>35.390(b)(1)(ii)(G)</u>	35.390(b)(1)(ii)(G) prepared			
	prepared for medical use and	for medical use and for which			
	for which a written directive	a written directive is required			
	is required that is [either]:	that is—			
15	20.3.7.714 TRAINING	§ 35.390 Training for use of	2018-1		Sent to NRC for review and comment prior to
	REQUIREMENTS:	unsealed byproduct material			implementation of the revisions
	H. Training for Use of	for which a written directive			
	Unsealed Radioactive	is required.			
	Material for Which a Written				
	Directive is Required. (For				
	use of unsealed radioactive				
	material under 20.3.7.708				
	NMAC) The regulations of				
	the NRC set forth in 10 CFR				
	35.390 are hereby				
	incorporated by reference.				
16	20.3.7.714 TRAINING	§ 35.392 Training for the oral	2018-1	В	Sent to NRC for review and comment prior to
	REQUIREMENTS:	administration of sodium			implementation of the revisions
	I. Training for the Oral	iodide I–131 requiring a			
	Administration of Sodium	written directive in quantities			
	Iodide I-131 Requiring a	less than or equal to 1.22			
	Written Directive in	gigabecquerels (33			
	Quantities Less than or Equal	millicuries).			
	to 33 millicuries (1.22				

	gigabecquerels). The regulations of the NRC set forth in 10 CFR 35.392 are hereby incorporated by reference.				
17	20.3.7.714 TRAINING REQUIREMENTS: J. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 33 millicuries (1.22 gigabecquerels). The regulations of the NRC set forth in 10 CFR 35.394 are hereby incorporated by reference.	§ 35.394 Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).	2018-1	В	Sent to NRC for review and comment prior to implementation of the revisions
18	20.3.7.714 TRAINING REQUIREMENTS: K. Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive. The regulations of the NRC set forth in 10 CFR 35.396 are hereby incorporated by reference.	§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.	2018-1		Sent to NRC for review and comment prior to implementation of the revisions
19	20.3.7.710 MANUAL BRACHYTHERAPY: G. Decay of Strontium-90 Sources for Ophthalmic Treatments.	§ 35.433 Strontium-90 sources for ophthalmic treatments.	2018-1		Sent to NRC for review and comment prior to implementation of the revisions

	The regulations of the NRC set forth in 10 CFR 35.433 are hereby incorporated by reference. [(1) Only an authorized medical physicist shall calculate the activity of each strontium 90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Subsection F of 20.3.7.710 NMAC. (2) A licensee shall retain a record of the activity of each strontium 90 source in accordance with Subsection S				
20	of 20.3.7.715 NMAC.] 20.3.7.714 TRAINING REQUIREMENTS: L. Training for Use of Manual Brachytherapy Sources. (For use of radioactive material under 20.3.7.710 NMAC) The regulations of the NRC set forth in 10 CFR 35.490 are hereby incorporated by reference.	§ 35.490 Training for use of manual brachytherapy sources.	2018-1	В	Sent to NRC for review and comment prior to implementation of the revisions
21	20.3.7.714 TRAINING REQUIREMENTS:	§ 35.491 Training for ophthalmic use of strontium- 90.	2018-1	В	Sent to NRC for review and comment prior to implementation of the revisions

	M. Training for Ophthalmic Use of Strontium-90. (For use of radioactive material under 20.3.7.710 NMAC) The regulations of the NRC set forth in 10 CFR 35.491 are hereby incorporated by reference.			
22	20.3.7.712 SEALED SOURCES FOR DIAGNOSIS: A. Use of Sealed Sources for Diagnosis. A licensee shall use only sealed sources for	 § 35.500 Use of sealed sources and medical devices for diagnosis. (a) A licensee must use only 	2018-1	Sent to NRC for review and comment prior to implementation of the revisions
	diagnostic medical uses [as approved in the sealed source and device registry.] [if the sealed sources are	sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved		
	approved in the Sealed Source and Device Registry for diagnostic medicine. The	in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources		
	sealed sources may be used for diagnostic medical uses that are not explicitly listed in	may be used for diagnostic medical uses that are not explicitly listed in the Sealed		
	the Sealed Source and Device Registry but must be used in accordance with the	Source and Device Registry but must be used in accordance with the		
	and limitations described in the Sealed Source and Device	and limitations described in the Sealed Source and Device		
	<u>B. A licensee must only use</u> <u>medical devices containing</u> <u>sealed sources for diagnostic</u>	(b) A licensee must only use medical devices containing sealed sources for diagnostic		
	medical uses if both the	medical uses if both the		

-					
	sealed sources and medical	sealed sources and medical			
	devices are approved in the	devices are approved in the			
	Sealed Source and Device	Sealed Source and Device			
	Registry for diagnostic	Registry for diagnostic			
	medical uses. The diagnostic	medical uses. The diagnostic			
	medical devices may be used	medical devices may be used			
	for diagnostic medical uses	for diagnostic medical uses			
	that are not explicitly listed in	that are not explicitly listed			
	the Sealed Source and Device	in the Sealed Source and			
	Registry but must be used in	Device Registry but must be			
	accordance with the	used in accordance with the			
	radiation safety conditions	radiation safety conditions			
	and limitations described in	and limitations described in			
	the Sealed Source and Device	the Sealed Source and Device			
	Registry.	Registry.			
	C. Sealed sources and devices	(c) Sealed sources and			
	for diagnostic medical uses	devices for diagnostic			
	may be used in research in	medical uses may be used in			
	accordance with an active	research in accordance with			
	Investigational Device	an active Investigational			
	Exemption (IDE) application	Device Exemption (IDE)			
	accepted by the U.S. Food	application accepted by the			
	and Drug Administration	U.S. Food and Drug			
	provided the requirements of	Administration provided the			
	10 CFR 35.49(a) are met.	requirements of § 35.49(a)			
	[<u>D.</u>][B] Survey Instrument. A	are met.			
	licensee authorized to use				
	radioactive material as a				
	sealed source for diagnostic				
1	purposes shall have available				
	for use a portable radiation				
	survey meter capable of				
	detecting dose rates ranging				
1	from 0.1 millirem (1				

	millisievert) per hour to 1000			
	millirems (10 millisieverts)			
	per hour. The instrument			
	shall be operable and			
	calibrated in accordance with			
	section Subsection C of			
	20.3.7.703 NMAC.			
23	20.3.7.714 TRAINING	§ 35.590 Training for use of		
	REQUIREMENTS:	sealed sources and medical		
	N. Training for Use of Sealed	devices for diagnosis.		
	Sources for Diagnosis: (For			
	use of radioactive material			
	under 20.3.7.712 NMAC) The			
	regulations of the NRC set			
	forth in 10 CFR 35.590 are			
	hereby incorporated by			
	reference.			
24	20.3.7.711 PHOTON	§ 35.610 Safety procedures		
	EMITTING REMOTE	and instructions for remote		
	AFTERLOADER UNITS,	afterloader units, teletherapy		
	TELETHERAPY UNITS AND	units, and gamma		
	GAMMA STEREOTACTIC	stereotactic radiosurgery		
	RADIOSURGERY UNITS:	units.		
	D(4) [Prior to the first use for	(d)(1) Prior to the first use for		
	patient treatment of a new	patient treatment of a new		
	unit or an existing unit with a	unit or an existing unit with a		
	manufacturer upgrade that	manufacturer upgrade that		
	affects the operation and	affects the operation and		
	safety of the unit, a licensee	safety of the unit, a licensee		
	shall ensure that vendor	shall ensure that vendor		
	operational and safety	operational and safety		
	training is provided to all	training is provided to all		
	individuals who will operate	individuals who will operate		
1	the unit. The vendor	the unit. The vendor		

	operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.] [(4)][(5)] A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in: (Continue re-designation) [(8)][(7)]A licensee shall retain a copy of the procedures required by Subparagraph (d) of Paragraph (1) and Subparagraph (b) of Paragraph (5[4]) of this subsection in accordance with Subsection U of 20.3.7.715 NMAC.	operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training. (g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.			
25	20.3.7.711 PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS:	§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.	2018-1	H&S	Sent to NRC for review and comment prior to implementation of the revisions

	O. Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units. (1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement [or at intervals not to exceed 5 years, whichever comes first;] to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.	(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.			
26	20.3.7.714 TRAINING REQUIREMENTS: O. Training for Use of Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units (For use of radioactive material under	§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	2018-1	В	

	20.3.7.711 NMAC). The regulations of the NRC set forth in 10 CFR 35.690 are					
	reference.					
27	20.3.7.716 REPORTS: A. Report and Notification of a Medical Event. (1) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from <u>byproduct</u> [radioactive] material , except permanent implant brachytherapy, results in:	 § 35.3045 Report and notification of a medical event. (a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which— (1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in— 	2018-1			
	(b)(i) an administration of a wrong radioactive drug containing <u>byproduct</u> [radioactive] material;	(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;				
	[(d) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material	(2) For permanent implant brachytherapy, the administration of byproduct				

(excluding sources that were	material or radiation from		
implanted in the correct site	byproduct material		
but migrated outside the	(excluding sources that were		
treatment site) that results	implanted in the correct site		
<u>in—</u>	but migrated outside the		
(i) The total source strength	treatment site) that results		
administered differing by 20	in—		
percent or more from the	(i) The total source strength		
total source strength	administered differing by 20		
documented in the post-	percent or more from the		
implantation portion of the	total source strength		
written directive;	documented in the post-		
(ii) The total source strength	implantation portion of the		
administered outside of the	written directive;		
treatment site exceeding 20	(ii) The total source strength		
percent of the total source	administered outside of the		
strength documented in the	treatment site exceeding 20		
post-implantation portion of	percent of the total source		
the written directive; or	strength documented in the		
(iii) An administration that	post-implantation portion of		
includes any of the following:	the written directive; or		
the wrong radionuclide;	(iii) An administration that		
the wrong individual or	includes any of the following:		
human research subject;	(A) The wrong radionuclide;		
sealed source(s) implanted	(B) The wrong individual or		
directly into a location	human research subject;		
discontiguous from the	(C) Sealed source(s)		
<u>treatment site, as</u>	implanted directly into a		
documented in the post-	location discontiguous from		
implantation portion of the	the treatment site, as		
written directive; or	documented in the post-		
a leaking sealed source	implantation portion of the		
resulting in a dose that	written directive; or		

exceeds 0.5 Sv (50 rem) to an	(D) A leaking sealed source		
organ or tissue.	resulting in a dose that		
	exceeds 0.5 Sv (50 rem) to an		
	organ or tissue.		