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1.1	Department of Health			
1.2	Proposed Permanent Rules Re	lating to Radiation Con	trol	
1.3	4731.0100 DEFINITIONS.			
1.4	[For	text of subps 1 to 4, see M	<u>/I.R.]</u>	
1.5	Subp. 4a. Accelerator-prod	uced radioactive materia	al. "Accelerator-pro	oduced
1.6	radioactive material" means any	material made radioactive	e by a particle accel	erator.
1.7	[For t	ext of subps 5 to 31, see	M.R.]	
1.8	Subp. 32. By-product Bypr	oduct material. " <del>By-pro</del>	<del>duct</del> Byproduct ma	terial"
1.9	means:			
1.10	A. any radioactive mater	ial, except special nuclear	material, yielded i	n, or made
1.11	radioactive by, exposure to the radioactive by, exposure to the radioactive by a second s	adiation incident to the pr	ocess of producing	or <del>utilizing</del>
1.12	using special nuclear material; e	)f		
1.13	B. the tailings or wastes	produced by the extraction	n or concentration of	of uranium
1.14	or thorium from ore processed p	rimarily for its source mat	terial content, inclue	ding discrete
1.15	surface wastes resulting from ur	anium solution extraction	processes. Underg	round ore
1.16	bodies depleted by such these so	lution extraction operatio	ns <del>are not by-produ</del>	<del>et material.</del>
1.17	do not constitute byproduct mate	erial within this definition	2	
1.18	<u>C.</u> any discrete source of	f radium-226 that is produ	ced, extracted, or c	onverted
1.19	after extraction for commercial,	medical, or research activ	ity, or any material	that:
1.20	(1) has been made rad	dioactive by use of a parti	cle accelerator; and	
1.21	(2) is produced, extra	acted, or converted after e	xtraction for comm	ercial,
1.22	medical, or research activity; an	<u>d</u>		
1.23	D. any discrete source of	f naturally occurring radio	pactive material, oth	ner than
1.24	source material, that:			

Approved by Revisor\_\_\_\_\_

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2.1	(1) the United States Nuclear I	Regulatory Commis	sion, in consultation	<u>n</u>	
2.2	with the Administrator of Environmental	Protection Agency,	the Secretary of En	ergy,	
2.3	the Secretary of Homeland Security, and	the head of any oth	er appropriate feder	al	
2.4	agency determines would pose a threat sir	nilar to the threat po	osed by a discrete so	ource of	
2.5	radium-226 to the public health and safety	or the common de	fense and security; a	ind	
2.6	(2) is extracted or converted at	fter extraction for u	se in a commercial,	-	
2.7	medical, or research activity.				
2.8	[For text of subp	os 33 to 43a, see M.	<u>.R.]</u>		
2.9	Subp. 43b. Consortium. "Consortiun	n" means an associa	ation of medical use	<b>x</b>	
2.10	licensees and a PET radionuclide production	ion facility in the sa	me geographical are	ea that	
2.11	jointly own or share in the operation and	maintenance cost o	f the PET radionucl	ide	
2.12	production facility that produces PET radionuclides for use in producing radioactive drugs				
2.13	within the consortium for noncommercial distributions among its associated members for				
2.14	medical use. The PET radionuclide produ	ction facility within	the consortium mu	ist be	
2.15	located at an educational institution or a fe	ederal facility or a r	nedical facility.		
2.16	[For text of sub	ps 44 to 51, see M.	<u>R.]</u>		
2.17	Subp. 51a. Cyclotron. "Cyclotron" me	eans a particle acce	lerator in which the	charged	
2.18	particles travel in an outward spiral or cire	cular path. A cyclo	tron accelerates cha	rged	
2.19	particles at energies usually in excess of te	en MeV and is com	nonly used for prod	uction of	
2.20	short half-life radionuclides for medical u	se.			
2.21	[For text of sub	ps 52 to 60, see M.	<u>R.]</u>		
2.22	Subp. 60a. Discrete source. "Discrete	e source" means a ra	adionuclide that has	been	
2.23	processed so that its concentration within	a material has been	purposely increased	1 for use	
2.24	for commercial, medical, or research activ	vities.			
2.25	[For text of subp	os 61 to 139, see M	<u>.R.]</u>		

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3.1	Subp. 140. Medium dose-rate remote afterloader. "Medium dose-rate remote
3.2	afterloader" means a brachytherapy device that remotely delivers a dose rate of greater
3.3	than 200 rads (2 Gy), but less than or equal to 1,200 rads (12 Gy) per hour at the point
3.4	or surface where the dose is prescribed.
3.5	[For text of subps 141 to 147, see M.R.]
3.6	Subp. 147a. Nationally tracked source. "Nationally tracked source" means a sealed
3.7	source containing a quantity equal to or greater than Category 1 or Category 2 levels of
3.8	any radioactive material listed in part 4731.2820. In this context, a sealed source is defined
3.9	as radioactive material that is sealed in a capsule or closely bonded, in a solid form, and
3.10	which is not exempt from regulatory control. It does not mean material encapsulated
3.11	solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel
3.12	rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive
3.13	material at a quantity equal to or greater than the Category 1 threshold. Category 2
3.14	nationally tracked sources are those containing radioactive material at a quantity equal to
3.15	or greater than the Category 2 threshold but less than the Category 1 threshold.
3.16	[For text of subps 148 to 163, see M.R.]
3.17	Subp. 163a. Particle accelerator. "Particle accelerator" means any machine capable
3.18	of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of
3.19	discharging the resultant particulate or other radiation into a medium at energies usually in
3.20	excess of one megaelectron volt (MeV). For purposes of this definition, "accelerator" is
3.21	an equivalent term.
3.22	[For text of subps 164 to 171, see M.R.]
3.23	Subp. 171a. Positron emission tomography (PET) radionuclide production
3.24	facility. "Positron emission tomography (PET) radionuclide production facility" is
3.25	defined as a facility operating a cyclotron or accelerator for the purpose of producing
3.26	PET radionuclides.

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## 4.1

## [For text of subps 172 to 195, see M.R.]

4.2	Subp. 196. Radioactive waste or waste. "Radioactive waste" or "waste" means
4.3	those low-level radioactive wastes containing source, special nuclear, or radioactive
4.4	byproduct material that are acceptable for disposal in a land disposal facility. For the
4.5	purposes of this definition, low-level radioactive waste means radioactive waste not
4.6	classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or
4.7	byproduct material as defined in subpart 32, items B, C, and D.
4.8	[For text of subps 197 to 242, see M.R.]
4.9	Subp. 243. Total effective dose equivalent or TEDE. "Total effective dose
4.10	equivalent" or "TEDE" means the sum of the deep effective dose equivalent for external
4.11	exposures and the committed effective dose equivalent for internal exposures.
4.12	[For text of subps 244 to 269, see M.R.]
4.13	4731.0355 RECIPROCITY.
4.14	[For text of subps 1 and 2, see M.R.]
4.15	Subp. 3. Licenses of radioactive material, source and special nuclear material in
4.16	quantities not sufficient to form a critical mass.
4.17	[For text of items A and B, see M.R.]
4.18	C. The out-of-state licensee must not transfer or dispose of radioactive material
4.19	possessed or used under the general license under this part except by transfer to a person
4.20	who is specifically licensed by the NRC or an agreement state to receive the material or
4.21	who is exempt from the requirements for a license for the material under part 4731.3025.
4.22	[For text of items D to G, see M.R.]
4.23	[For text of subp 4, see M.R.]

4731.0355

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4.24	4731.1030 EXPOSURE NOT	TIFICATIONS AND REP	ORTS.	
5.1	]	For text of subp 1, see M.R	<u>.]</u>	
5.2	Subp. 2. Frequency of rep	ort. A licensee must annua	<del>lly advise each wo</del>	ərker of the
5.3	worker's dose as shown in reco	rds maintained by the licens	see according to pa	art 4731.2540.
5.4	Each licensee shall make dose	information available to we	orkers as shown ir	n records
5.5	maintained by the licensee und	ler the provisions of part 47	31.2540. The lice	ensee shall
5.6	provide an annual report to eac	ch individual monitored und	er part 4731.2210	of the dose
5.7	received in that monitoring year	ar if:		
5.8	A. The individual's occ	supational dose exceeds 100	) mrem (1 mSv) T	EDE or
5.9	100 mrem (1 mSv) to any indi-	vidual organ or tissue; or		
5.10	B. The individual reque	ests their report.		
5.11	Subp. 3. Report to former	employee; report to com	missioner.	
5.12	[For	text of items A and B, see	<u>M.R.]</u>	
5.13	C. When a licensee is r	equired under part 4731.26	10, 4731.2620, <u>or</u>	4731.2630 <del>,</del>
5.14	or 4731.2650 to report to the c	ommissioner any exposure	of an individual to	o radiation
5.15	or radioactive material, the lice	ensee must also provide the	individual a report	rt on <del>the</del>
5.16	individual's exposure data cont	the individual	l's exposure data in	ncluded in
5.17	the report to the commissioner	. The report must be transm	itted to the individ	dual no later
5.18	than the transmittal to the com	missioner.		
5.19	1	For text of subp 4, see M.R	<u>L]</u>	
5.20	4731.2020 OCCUPATIONAL	L DOSE LIMITS FOR AI	DULTS.	
5.21	[For	text of subps 1 and 2, see 1	<u>M.R.]</u>	
5.22	Subp. 3. Assessing dose. <u>V</u>	Vhen the external exposure	is determined by r	neasurement
5.23	with an external personal moni	itoring device, the deep-dos	e equivalent must	be used in
	4731.2020	5		

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5.24	place of the effective dose equivalent, u	inless the effective do	ose equivalent is det	ermined
5.25	by a dosimetry method approved by the	commissioner. The	assigned deep dose of	equivalent
6.1	must be for the part of the body receiving	ng the highest exposi	ure. The assigned sh	nallow
6.2	dose equivalent must be the dose average	ged over the contiguo	ous ten square centir	neters of
6.3	skin receiving the highest exposure. Th	e deep dose equivale	nt, lens dose equiva	lent, and
6.4	shallow dose equivalent may be assessed	ed from surveys or oth	her radiation measur	rements to
6.5	demonstrate compliance with the occup	pational dose limits if	the individual mon	itoring
6.6	device was not in the region of highest	potential exposure or	if the results of ind	ividual
6.7	monitoring are unavailable.			
6.8	[For text of	subps 4 to 6, see M.I	<u>R.]</u>	
6.9	4731.2200 SURVEYS AND MONITORING.			
6.10	[For text o	f subpart 1, see M.R.	1	
6.11	Subp. 2. Calibration required. Ex	ccept as otherwise rec	quired in this chapte	<u>r,</u> a
6.12	licensee must ensure that instruments a	nd equipment used for	or quantitative radia	tion
6.13	measurements, for example, dose rate a	nd effluent monitorin	ng, are calibrated per	riodically
6.14	at intervals not to exceed 12 months for	r the radiation measur	red.	
6.15	[For text	of subp 3, see M.R.]		
6.16	4731.2360 LEAK TEST REQUIREM	MENTS.		
6.17	Subpart 1. Sealed sources. Except	as otherwise required	l, sealed sources mu	st be
6.18	tested for leakage at intervals not to exe	ceed the intervals spe	cified in the certific	ate of
6.19	registration issued by the NRC or an ag	greement state.		
6.20	Subp. 2. Sealed source received fi	com another person.	In the absence of	a
6.21	certificate from a transferor indicating t	hat a leak test has be	en made within the	intervals
6.22	specified in the certificate of registratio	n issued by the NRC	or an agreement sta	te, prior

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6.23	to the transfer, a sealed source received	I from another pe	rson must not be put inte	o use
6.24	until tested and the test results received	<u>l.</u>		
7.1	Subp. 3. Storage of sealed sources	. Sealed sources,	except those containing	radium,
7.2	may be stored for a period of no more t	han three years w	vithout being tested for 1	eakage
7.3	and contamination. When sealed source	es are removed fr	om storage for use or for	r transfer
7.4	to another person and have not been tes	ted within the rec	uired leak test interval,	they must
7.5	be tested and test results received befor	e use or transfer.		
7.6	Subp. 4. Test samples. Test sample	es must be taken	from the source or from	the
7.7	surfaces of the device in which the sou	rce is mounted or	stored on which radioa	ctive
7.8	contamination might be expected to acc	cumulate.		
7.9	Subp. 5. Level of detection. The le	ak test must be ca	apable of detecting the p	oresence
7.10	of 0.005 microcurie (185 becquerel) of	radioactive mater	rial on the test sample.	
7.11	If the test reveals the presence of 0.0	005 microcurie (1	85 becquerel) or more	<u>of</u>
7.12	removable contamination, a report mus	t be filed with the	Department of Health a	according
7.13	to part 4731.3110 and the source must	be removed imm	ediately from service ar	nd
7.14	decontaminated, repaired, or disposed of	of according to De	epartment of Health regu	ulations.
7.15	Subp. 6. Tests administered by. T	ests for leakage r	nust be performed by th	<u>ie</u>
7.16	licensee or by other persons specifically	y licensed by the	NRC or an agreement st	tate to
7.17	perform these services.			
7.18	Subp. 7. Retention of leak test rec	ords. A licensee	shall retain leak test rec	ords for
7.19	three years. The records must contain the	he model number	and serial number, if as	signed, of
7.20	each source tested, the identity of each	source radionucli	de and its estimated acti	vity, the
7.21	measured activity of each test sample en	xpressed in micro	ocuries (becquerel), the d	late of the
7.22	test, and the name or initials of the indi	vidual who perfo	rmed the test.	
7.23	Subp. 8. Sources exempt from tes	ting. <u>A licensee</u>	need not perform a leak	test
7.24	on the following sources:			

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7.25	<u>A.</u>	sources containing only radio	pactive material with a	half-life of less th	ian
7.26	<u>30 days;</u>				
8.1	<u>B.</u>	sources containing only radio	active material as a ga	<u>tS;</u>	
8.2	<u>C.</u>	sources containing 100 micro	ocuries (3.7 MBq) or	less of beta or	
8.3	photon-er	nitting material or ten microcu	ries (0.37 MBq) or les	s of alpha-emitting	<u>, material;</u>
8.4	and				
8.5	<u>D.</u>	seeds of iridium-192 encased	in nylon ribbon.		
8.6	4731.240	0 WASTE DISPOSAL.			
8.7	Subpar	rt 1. General requirements. A	A licensee must dispos	e of licensed mater	rial only:
8.8	A.	by transfer to an authorized r	ecipient as provided u	nder parts 4731.05	25 to
8.9	4731.084	0, 4731.2450, and 4731.3000 t	o 4731.3175 or in Coc	le of Federal Regu	lations,
8.10	title 10, parts 60, 63, and 72;				
8.11	B.	by decay in storage;			
8.12	C.	by release in effluents within	the limits under part 4	731.2090; or	
8.13	D.	as authorized under parts 473	1.2410 to 4731.2440 c	or 4731.2460.	
8.14		[For text of	of subp 2, see M.R.]		
8.15	4731.240	5 DECAY-IN-STORAGE.			
8.16	Subpar	rt 1. Disposal in ordinary tra	sh. A licensee may he	old radioactive ma	terial
8.17	with half-	lives of less than or equal to 1	20 days for decay-in-s	storage before disp	osal
8.18	in ordina	ry trash if the licensee:			
8.19	<u>A.</u>	monitors radioactive material	at the surface before	disposal;	
8.20	<u>B.</u>	determines that its radioactivi	ity cannot be distinguis	shed from the back	ground
8.21	radiation	level with an appropriate radia	ation detection survey	meter set on its m	ost
8.22	sensitive	scale and with no interposed s	hielding; and		

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9.1	<u>C.</u>	removes or obliterates all r	adiation labels, exce	pt for radiation labels	on
9.2	materials	that are within containers ar	nd that will be mana	ged as biomedical was	ste after
9.3	they are r	eleased from the licensee.			
9.4	Subp	2. Record retention. The l	icensee shall retain	a record of each dispo	osal
9.5		years. The record must inclu			
		<u>,</u>			
9.6	<u>A.</u>	the date of the disposal;			
9.7	<u>B.</u>	the date on which the radio	active material was	placed in storage;	
9.8	<u>C.</u>	the radionuclide with the lo	ongest half-life;		
9.9	<u>D.</u>	the manufacturer's name, n	nodel number, and s	erial number of the su	irvey
9.10	instrumer	nt used, or a unique survey m	neter identification the	at can be cross-refere	nced to a
9.11	specific manufacturer, model, and serial number;				
9.12	<u>E.</u>	the background radiation le	evel;		
9.13	<u>F.</u>	the radiation level measured	l at the surface of ea	ch waste container; an	<u>ıd</u>
9.14	<u>G.</u>	the name of the individual	who performed the	lisposal.	
9.15	4731.245	0 TRANSFER FOR DISP	OSAL; MANIFES'	ГS.	
9.16		[For text o	f subps 1 to 3, see N	<u>/I.R.]</u>	
9.17	Subp.	4. Shipping byproduct ma	terial. Any licensee	shipping byproduct r	naterial,
9.18	as defined	l in part 4731.0100, subpart	32, items C and D, i	ntended for ultimate d	isposal at
9.19	a land dis	posal facility licensed under	Code of Federal Re	gulations, title 10, par	t 61, must
9.20	document	t the information on the NRC	C's Uniform Low-Le	vel Radioactive Waste	<u>Manifest</u>
9.21	and transf	fer this recorded manifest in	formation to the inte	nded consignee accor	ding to
9.22	part 4731	.2950.			

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## 9.23 4731.2460 DISPOSAL OF CERTAIN BYPRODUCT MATERIAL.

10.1	Subpart 1. Disposal of licensed material. Licensed material as defined in part
10.2	4731.0100, subpart 32, items C and D, may be disposed of according to Code of Federal
10.3	Regulations, title 10, part 61, even though it is not defined as low-level radioactive waste.
10.4	Therefore, any licensed byproduct material being disposed of at a facility, or transferred
10.5	for ultimate disposal under Code of Federal Regulations, title 10, part 61, must meet the
10.6	requirements of part 4731.2450.
10.7	Subp. 2. Disposal of byproduct material. A licensee may dispose of byproduct
10.8	material as defined in part 4731.0100, subpart 32, items C and D, at a disposal facility
10.9	authorized to dispose of such material according to federal or state solid or hazardous
10.10	waste law, including the Solid Waste Disposal Act, as authorized under the Energy
10.11	Policy Act of 2005.
10.12	4731.2510 RECORDS; SURVEYS.
10.13	Subpart 1. Record maintenance; three years. A licensee must maintain records
10.14	showing the results of surveys and calibrations required under parts 4731.2200 and
10.15	4731.2350, subpart 2, for three years after the record is made. The record must include:
10.16	$\underline{A}$ . the date of the measurements;
10.17	B. the manufacturer's name, model number, and serial number for the instrument
10.18	used to measure radiation levels;
10.19	$\underline{C}$ . the radiation level; and
10.20	D. the name or initials of the individual who performed the surveys or
10.21	calibrations.
10.22	[For text of subp 2, see M.R.]

4731.2510

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10.23	4731.2520 DETERMINATION OF PRIC	OR OCCUPATIO	NAL DOSE.	
11.1	Subpart 1. Determining occupational of	dose. For each ind	ividual who is likel	y to
11.2	receive in a year an occupational dose requ	iiring monitoring u	nder part 4731.221	0, a
11.3	licensee must <del>:</del>			
11.4	A. determine the occupational radia	ation dose received	during the current	year <del>;</del>
11.5	and.			
11.6	Battempt to obtain the records of e	cumulative occupat	ional radiation dosc	<del>).</del>
11.7	[For text of s	subp 2, see M.R.]		
11.8	Subp. 3. Compliance methods. In con	nplying with the re	quirements of subp	art
11.9	subparts 1 and 2, a licensee may:			
11.10	[For text of item	ns A to C, see M.R.	]	
11.11	Subp. 4. Record keeping.			
11.12	A. A licensee must record the expos	sure history of each	n individual, as requ	uired
11.13	by subpart 1 <u>or 2</u> , on a cumulative occupati	ional exposure reco	ord form prescribed	by the
11.14	commissioner, or other clear and legible rec	cord including all o	of the information re	equired
11.15	by the commissioner's form. The form or r	ecord must show e	ach period in whicl	n the
11.16	individual received occupational exposure	to radiation or radio	pactive material and	d must
11.17	be signed by the individual who received the	he exposure. For ea	ach period for whic	h the
11.18	licensee obtains reports, the licensee must u	use the dose shown	in the report in pre	paring
11.19	the exposure record. For any period in whi	ch the licensee doe	s not obtain a repor	rt, the
11.20	licensee must place a notation on the record	d indicating the per	riods and time for v	vhich
11.21	data are not available.			
11.22	[For text of item	ns B to E, see M.R.	1	
11.23	[For text of subp	os 5 and 6, see M.R	.]	

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11.24	4731.2640 REPORTS TO INDIVIDUALS; DOSE LIMITS EXCEEDED.
12.1	When a licensee is required, under part 4731.2620, or 4731.2630, or 4731.2650, to
12.2	report to the commissioner any exposure of an identified occupationally exposed individual
12.3	or an identified member of the public to radiation or radioactive material, the licensee must
12.4	also provide a copy of the report submitted to the commissioner to the individual a report
12.5	on the individual's exposure data included in the report to the commissioner. The report
12.6	must be transmitted at a time no later than the transmittal to the commissioner.
12.7	4731.2705 NATIONAL SOURCE TRACKING TRANSACTION REPORTING.
12.8	Subpart 1. Report required. Each licensee who manufactures, transfers, receives,
12.9	disassembles, or disposes of a nationally tracked source must complete and submit a
12.10	National Source Tracking Transaction Report as specified in subparts 2 to 6 for each
12.11	type of transaction.
12.12	Subp. 2. Manufacturing report requirements. Each licensee who manufactures
12.13	a nationally tracked source must complete and submit a National Source Tracking
12.14	Transaction Report. The report must include the following information:
12.15	A. the name, address, and license number of the reporting licensee;
12.16	B. the name of the individual preparing the report;
12.17	$\underline{C}$ . the manufacturer, model, and serial number of the source;
12.18	D. the radioactive material in the source;
12.19	E. the initial source strength in becquerels or curies at the time of manufacture;
12.20	and
12.21	F. the manufacture date of the source.
12.22	Subp. 3. Transfer report requirements. Each licensee that transfers a nationally
12.23	tracked source to another person must complete and submit a National Source Tracking
12.24	Transaction Report. The report must include the following information:

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13.1	<u>A.</u>	the name, address, and licen	se number of the re	porting licensee;			
13.2	<u>B.</u>	the name of the individual p	reparing the report;				
13.3	<u>C.</u>	the name and license number	er of the recipient f	acility and the shippin	<u>g</u>		
13.4	address;						
13.5	<u>D.</u>	the manufacturer, model, an	d serial number of	the source or, if not av	ailable,		
13.6	other info	ormation to uniquely identify	the source;				
13.7	<u>E.</u>	the radioactive material in the	ne source;				
13.8	<u>F.</u>	the initial or current source s	trength in becquere	ls or curies;			
13.9	$\underline{G}$ . the date for which the source strength is reported;						
13.10	<u>H.</u>	the shipping date;					
13.11	<u>I.</u>	the estimated arrival date; an	d				
13.12	<u>J.</u>	for nationally tracked source	es transferred as wa	ste under a Uniform			
13.13	Low-Lev	el Radioactive Waste Manifes	st, the waste manife	st number and the con	tainer		
13.14	identifica	tion of the container with the	nationally tracked	source.			
13.15	Subp.	4. Material received report	t requirements. Ea	ch licensee that receiv	ves		
13.16	<u>a nationa</u>	lly tracked source must comp	lete and submit a N	lational Source Tracki	ng		
13.17	Transacti	on Report. The report must in	clude the following	g information:			
13.18	<u>A.</u>	the name, address, and licen	se number of the re	porting licensee;			
13.19	<u>B.</u>	the name of the individual p	reparing the report;				
13.20	<u>C.</u>	the name, address, and licen	se number of the pe	rson that provided the	source;		
13.21	<u>D.</u>	the manufacturer, model, an	d serial number of	the source or, if not av	ailable,		
13.22	other info	ormation to uniquely identify	the source;				
13.23	<u>E.</u>	the radioactive material in the	ne source;				

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14.1	<u>F.</u>	the initial or current source s	strength in becquere	els or curies;	
14.2	<u>G.</u>	the date for which the source	ce strength is reported	<u>ed;</u>	
14.3	<u>H.</u>	the date of receipt; and			
14.4	<u>I.</u>	for material received under	a Uniform Low-Lev	vel Radioactive Waste	2
14.5	Manifest	t, the waste manifest number a	and the container ide	entification with the n	ationally
14.6	tracked s	source.			
14.7	Subp.	5. Disassemble report requ	uirements. Each lic	censee that disassemb	les
14.8	<u>a nationa</u>	ally tracked source must comp	plete and submit a N	National Source Track	ting
14.9	Transact	ion Report. The report must in	nclude the following	g information:	
14.10	<u>A.</u>	the name, address, and licer	nse number of the re	porting licensee;	
14.11	<u>B.</u>	the name of the individual p	preparing the report	2	
14.12	<u>C.</u>	the manufacturer, model, an	nd serial number of	the source or, if not av	vailable,
14.13	other info	ormation to uniquely identify	the source;		
14.14	<u>D.</u>	the radioactive material in t	the source;		
14.15	<u>E.</u>	the initial or current source	strength in becquere	els or curies;	
14.16	<u>F.</u>	the date for which the source	e strength is reporte	d; and	
14.17	<u>G.</u>	the disassemble date of the	source.		
14.18	Subp.	6. Disposal report require	ments. Each license	e who disposes of a n	ationally
14.19	tracked s	source must complete and sub-	mit a National Sour	ce Tracking Transacti	on Report.
14.20	The repo	ort must include the following	information:		
14.21	<u>A.</u>	the name, address, and licer	nse number of the re	porting licensee;	
14.22	<u>B.</u>	the name of the individual p	preparing the report	2	
14.23	<u>C.</u>	the waste manifest number;			

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15.1	<u>D.</u>	the container identification	with the nationally	tracked source;	
15.2	<u>E.</u>	the date of disposal; and			
15.3	<u>F.</u>	the method of disposal.			
15.4	Subp.	7. Report submission. The	reports discussed i	n subparts 2 to 6 mus	st be
15.5	submittee	d by the close of the next busi	ness day after the tr	ransaction. A single r	eport may
15.6	<u>be submi</u>	tted for multiple sources and	transactions. The r	eports must be submi	tted to
15.7	the Natio	nal Source Tracking System	by:		
15.8	<u>A.</u>	using the online National Second	ource Tracking Syst	tem;	
15.9	<u>B.</u>	electronically using a comp	uter-readable forma	<u>t;</u>	
15.10	<u>C.</u>	facsimile;			
15.11	<u>D.</u>	mail to the address on the N	National Source Tra	cking Transaction Re	eport
15.12	Form (N	RC Form 748); or			
15.13	<u>E.</u>	telephone with follow-up by	facsimile or mail.		
15.14	Subp.	8. Report corrections. Eac	h licensee must cor	rect any error in prev	iously
15.15	filed repo	orts or file a new report for an	y missed transaction	n within five business	s days of
15.16	the disco	very of the error or missed tra	ansaction. Errors m	ay be detected by a v	variety
15.17	of metho	ds including administrative re	eviews or by physic	al inventories require	ed by
15.18	regulation	n. In addition, each licensee	nust reconcile the in	nventory of nationally	y tracked
15.19	sources p	ossessed by the licensee agai	nst that licensee's d	lata in the National S	ource
15.20	Tracking	System. The reconciliation n	nust be conducted d	luring the month of Ja	anuary in
15.21	each year	. The reconciliation process	nust include resolv	ing any discrepancies	between
15.22	the Natio	nal Source Tracking System	and the actual inver	ntory by filing the rep	ports
15.23	identified	l by subparts 2 to 6. By Janua	ry 31 of each year,	each licensee must s	ubmit to
15.24	the Natio	nal Source Tracking System	confirmation that th	e data in the Nationa	l Source
15.25	Tracking	System is correct.			

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16.1	Subp. 9. Initial invento	ry. Each licensee	that possesse	es Category 1 or Ca	itegory 2
16.2	nationally tracked sources n	nust report its initia	al inventory	of Category 1 and (	Category 2
16.3	nationally tracked sources to	o the National Sou	rce Tracking	s System by January	y 31, 2009.
16.4	The information may be sub	omitted by using an	ny of the me	thods identified by	subpart 7,
16.5	items A to D. The initial inv	ventory report must	t include the	following informat	tion:
16.6	<u>A.</u> the name, address	s, and license num	ber of the re	porting licensee;	
16.7	B. the name of the in	ndividual preparing	g the report;		
16.8	<u>C.</u> the manufacturer,	, model, and serial	number of e	each nationally track	ked source
16.9	or, if not available, other inf	formation to uniqu	ely identify	the source;	
16.10	D. the radioactive m	aterial in the seale	d source;		
16.11	E. the initial or curre	ent source strength	in becquere	ls or curies; and	
16.12	$\underline{F}$ . the date for which	the source strengt	th is reported	<u>1.</u>	
16.13 16.14	4731.2750 ANNUAL LIN CONCENTRATIONS.	MITS ON INTAK	E AND DE	CRIVED AIR	
16.15	I	For text of subps	l to 5, see N	<u>1.R.]</u>	
16.16	Subp. 6. List of element	nts.			
16.17	Name	Symbol	Atomic 1	Number (AN)	
16.18	Actinium	Ac	89		
16.19	Aluminum	Al	13		
16.20	Americium	Am	95		
16.21	Antimony	Sb	51		
16.22	Argon	Ar	18		
16.23	Arsenic	As	33		
16.24	Astatine	At	85		
16.25	Barium	Ba	56		

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17.1	Berkelium	Bk	97	
17.2	Beryllium	Be	4	
17.3	Bismuth	Bi	83	
17.4	Bromine	Br	35	
17.5	Cadmium	Cd	48	
17.6	Calcium	Ca	20	
17.7	Californium	Cf	98	
17.8	Carbon	С	6	
17.9	Cerium	Ce	58	
17.10	Cesium	Cs	55	
17.11	Chlorine	Cl	17	
17.12	Chromium	Cr	24	
17.13	Cobalt	Co	27	
17.14	Copper	Cu	29	
17.15	Curium	Cm	96	
17.16	Dysprosium	Dy	66	
17.17	Einsteinium	Es	99	
17.18	Erbium	Er	68	
17.19	Europium	Eu	63	
17.20	Fermium	Fm	100	
17.21	Fluorine	F	9	
17.22	Francium	Fr	87	
17.23	Gadolinium	Gd	64	
17.24	Gallium	Ga	31	
17.25	Germanium	Ge	32	
17.26	Gold	Au	79	
17.27	Hafnium	Hf	72	
17.28	Holmium	Но	67	

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18.1	Hydrogen	Н	1	
18.2	Indium	In	49	
18.3	Iodine	Ι	53	
18.4	Iridium	Ir	77	
18.5	Iron	Fe	26	
18.6	Krypton	Kr	36	
18.7	Lanthanum	La	57	
18.8	Lead	Pb	82	
18.9	Lutetium	Lu	71	
18.10	Magnesium	Mg	12	
18.11	Manganese	Mn	25	
18.12	Mendelevium	Md	101	
18.13	Mercury	Hg	80	
18.14	Molybdenum	Mo	42	
18.15	Neodymium	Nd	60	
18.16	Neptunium	Np	93	
18.17	Nickel	Ni	28	
18.18	Niobium	Nb	41	
18.19	Nitrogen	N	<u>7</u>	
18.20	Osmium	Os	76	
18.21	Oxygen	<u>O</u>	<u>8</u>	
18.22	Palladium	Pd	46	
18.23	Phosphorus	Р	15	
18.24	Platinum	Pt	78	
18.25	Plutonium	Pu	94	
18.26	Polonium	Ро	84	
18.27	Potassium	Κ	19	

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19.1	Praseodymium	Pr	59	
19.2	Promethium	Pm	61	
19.3	Protactinium	Pa	91	
19.4	Radium	Ra	88	
19.4	Radon	Rn	86	
19.5	Rhenium	Re	75	
19.0	Rhodium	Rh	45	
	Rubidium	Rb	43 37	
19.8			44	
19.9	Ruthenium	Ru	44	
19.10	Samarium	Sm	62	
19.11	Scandium	Sc	21	
19.12	Selenium	Se	34	
19.13	Silicon	Si	14	
19.14	Silver	Ag	47	
19.15	Sodium	Na	11	
19.16	Strontium	Sr	38	
19.17	Sulfur	S	16	
19.18	Tantalum	Та	73	
19.19	Technetium	Tc	43	
19.20	Tellurium	Te	52	
19.21	Terbium	Tb	65	
19.22	Thallium	T1	81	
19.23	Thorium	Th	90	
19.24	Thulium	Tm	69	
19.25	Tin	Sn	50	
19.25	Titanium	Ti	22	
19.20	Tungsten	W	22 74	
17.21		••	, <b>.</b>	
19.28	Uranium	U	92	

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20.1	Vanadium	V	<b>,</b>	23			
20.2	Xenon	X	e	54			
20.3	Ytterbium	Y	b	70			
20.4	Yttrium	Y	-	39			
20.5	Zinc	Zı	1	30			
20.6	Zirconium	Z	r	40			
20.7	Subp. 7. Table of ALIs a	and DACs	•				
20.8			Table 1		Та	ble 2	Table 3
20.9 20.10	Atomic Number (AN), Radionuclide, and Class	1	2	3	1	2	
20.11	AN 1						
20.12	Hydrogen-3						
20.13	Water, DAC includes skin						
20.14	absorption	8E+4	8E+4	2E-5	1E-7	1E <b>-</b> 3	1E-2
20.15	Gas (HT or $T_2$ ) submersion <sup>1</sup> :						
20.16 20.17	Use above values as HT and $T_2$ oxidize in air and in the						
20.17	body to HTO.						
20.19	AN 4						
20.20	Beryllium-7						
20.21 20.22	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
20.23 20.24	Y, oxides, halides, and nitrates	_	2E+4	8E-6	3E-8	_	_
20.25	Beryllium-10						
20.26	W, see <sup>7</sup> Be	1E+3	2E+2	6E-8	2E-10	_	

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21.1 21.2 21.3	Y, see <sup>7</sup> Be	LLI (1E+3)	 1E+1	— 6E-9	2E-5 2E-11	2E-4	
21.4 21.5	<b>AN 6</b> Carbon-11 <sup>2</sup>						
21.6	Monoxide	_	1E+6	5E-4	2E-6		_
21.7	Dioxide		6E+5	3E-4	9E-7		
21.8	Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
21.9	Carbon-14						
21.10	Monoxide		2E+6	7E-4	2E-6		
21.11	Dioxide		2E+5	9E-5	3E-7		
21.12	Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
21.13 21.14 21.15	$\frac{\text{AN 7}}{\text{Nitrogen-13}^2}$ $\frac{\text{Submersion}^1}{\text{Submersion}^1}$	=	_	<u>4E-6</u>	<u>2E-8</u>	=	_
21.16	AN 8						
21.17	$\overline{\text{Oxygen-15}}^2$						
21.18	Submersion <sup>1</sup>	=	=	<u>4E-6</u>	<u>2E-8</u>	_	=
21.19	[The	remainder	r of the tab	le is uncha	nged.]		
21.20	FOOTNOTES:						
21.21 21.22	<sup>1</sup> "Submersion" means semi-infinite cloud of a			for subme	rsion in a	hemisph	erical
21.23 21.24 21.25	<sup>2</sup> These radionuclides h effective dose equivaled include a significant co	nt received	during ope	erations wi	th these ra	adionucli	des might

21.25 include a significant contribution from external exposure. The DAC values for all 21.26 radionuclides, other than those designated Class "Submersion," are based upon the 21.27 committed effective dose equivalent due to the intake of the radionuclide into the 21.28 body and do not include potentially significant contributions to dose equivalent from 21.29 external exposures. The licensee may substitute 1E-7  $\mu$ Ci/ml for the listed DAC to

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22.1 22.2 22.3	account for the submersion dose prospectively, but must use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits according to part 4731.2040.						
<ul> <li>22.4</li> <li>22.5</li> <li>22.6</li> <li>22.7</li> <li>22.8</li> <li>22.9</li> <li>22.10</li> <li>22.11</li> <li>22.12</li> <li>22.13</li> </ul>	<sup>3</sup> For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor according to part 4731.2020, subpart 5. If the percent by weight (enrichment) of U-235 is not greater than five, the concentration value for a 40-hour work week is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour work week must not exceed 8E-3 (SA) $\mu$ Ci-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, is: SA = 3.6E-7 curies/gram U U-depleted						
<ul><li>22.14</li><li>22.15</li><li>22.16</li></ul>	SA = $[0.4 + 0.38 \text{ (enrichment)} + 0.0034 \text{ (enrichment)}^2]$ E-6, enrichment > 0.72 where enrichment is the percentage by weight of U-235, expressed as percent. [For text of subp 8, see M.R.]						
22.17 22.18	<b>4731.2820</b> NATIONALLY TRACK The terabecquerel (TBq) values are	ED SOURCE	THRESHO		values		
22.10	specified are obtained by converting fi						
22.20	for practical usefulness only and are re-				•		
22.21		Category	1	Categor	ry 2		
22.22	Radioactive material	<u>(TBq)</u>	<u>(Ci)</u>	<u>(TBq)</u>	<u>(Ci)</u>		
22.23	Actinium-227	<u>20</u>	<u>540</u>	0.2	<u>5.4</u>		
22.24	Americium-241	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>		
22.25	Americium-241/Be	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>		
22.26	Californium-252	<u>20</u>	<u>540</u>	0.2	<u>5.4</u>		
22.27	Cobalt-60	<u>30</u>	<u>810</u>	<u>0.3</u>	<u>8.1</u>		
22.28	Curium-244	<u>50</u>	<u>1,400</u>	<u>0.5</u>	<u>14</u>		
22.29	Cesium-137	100	<u>2,700</u>	<u>1</u>	<u>27</u>		

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23.1	Gadolinium-153	1,000	27,000	<u>10</u>	270			
23.2	Iridium-192	<u>80</u>	2,200	<u>0.8</u>	<u>22</u>			
23.3	Plutonium-238	<u>60</u>	<u>1,600</u>	<u>0.6</u>	<u>16</u>			
23.4	Plutonium-239/Be	<u>60</u>	1,600	<u>0.6</u>	<u>16</u>			
23.5	Polonium-210	<u>60</u>	1,600	<u>0.6</u>	<u>16</u>			
23.6	Promethium-147	40,000	1,100,000	<u>400</u>	11,000			
23.7	Radium-226	<u>40</u>	<u>1,100</u>	<u>0.4</u>	<u>11</u>			
23.8	Selenium-75	<u>200</u>	<u>5,400</u>	<u>2</u>	<u>54</u>			
23.9	Strontium-90	1,000	27,000	<u>10</u>	<u>270</u>			
23.10	Thorium-228	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>			
23.11	Thorium-229	<u>20</u>	<u>540</u>	<u>0.2</u>	<u>5.4</u>			
23.12	Thulium-170	20,000	540,000	<u>200</u>	<u>5,400</u>			
23.13	Ytterbium-169	<u>300</u>	8,100	<u>3</u>	<u>81</u>			
23.14	23.14 4731.3025 EXEMPTION; CERTAIN CONCENTRATIONS.							
23.15	[For	text of subps 1 and	12, see M.R.	]				
23.16	Subp. 3. Introduction by s	pecific licensee. A	manufacture	er, processor, c	or producer			
23.17	of a product or material in an a	agreement state is e	exempt from	parts 4731.30	00 to			
23.18	4731.7280 to the extent that:							
23.19	A. the manufacturer, pr	ocessor, or produce	er transfers r	adioactive mat	terial			
23.20	contained in a product or mater	rial in concentration	ns not in exc	ess of those sp	ecified in			
23.21	part 4731.3140; and							
23.22	B. the radioactive mate	rial is introduced in	nto the produ	ict or material	by a			
23.23	licensee holding a specific licen	nse issued by <del>the ec</del>	mmissioner,	the NRC <del>, or a</del>	n agreement			
23.24	state expressly authorizing such	h introduction.						
23.25	The exemption in this subpart of	loes not apply to th	e transfer of	radioactive ma	aterial in any			
23.26	food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or							

23.27 inhalation by, or application to, a human being.

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a product or material knowing or having reason to believe that it will be transferred to

Subp. 4. Transfer limitations. No person may introduce radioactive material into

24.1

24.2

persons exempt under this part or equivalent regulations of the NRC or an agreement state, 24.3 except according to a specific license issued under part 4731.3305 or the general license 24.4issued under part 4731.0355 Code of Federal Regulations, title 10, section 32.11. 24.5 4731.3030 EXEMPTION; CERTAIN ITEMS CONTAINING RADIOACTIVE 24.6 24.7 MATERIAL. 24.8 Subpart 1. Exempt products. Except for persons who apply radioactive material to or incorporate radioactive material into the following products or persons who initially 24.9 transfer for sale or distribution the following products containing radioactive material, a 24.10 person is exempt from parts 4731.3000 to 4731.7280 to the extent that the person receives, 24.11 possesses, uses, transfers, owns, or acquires the following products: 24.12 A. timepieces or hands or dials of timepieces that: 24.13 (1) contain not more than the following specified quantities of radioactive 24.14 material: 24.15 (a) 25 millicuries of tritium per timepiece; 24.16 (b) five millicuries of tritium per hand; 24.17 (c) 15 millicuries of tritium per dial (bezels, when used, are considered 24.18 part of the dial); 24.19 100 microcuries of promethium-147 per watch or 200 microcuries (d)24.20 of promethium-147 per any other timepiece; 24.21 24.22 (e) 20 microcuries of promethium-147 per watch hand or 40 24.23 microcuries of promethium-147 per other timepiece hand; and 4731.3030 24

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25.1	(f) 60 microcuries of promethium-147 per watch dial or 120
25.2	microcuries of promethium-147 per any other timepiece dial (bezels, when used, are
25.3	considered as part of the dial); and
25.4	(g) one microcurie (0.037 MBq) of radium-226 per timepiece in intact
25.5	timepieces manufactured prior to November 30, 2007; and
25.6	[For text of subitem (2), see M.R.]
25.7	B. lock illuminators containing not more than 15 millicuries of tritium or not
25.8	more than two millicuries of promethium-147 installed on automobile locks. The levels
25.9	of radiation from each lock illuminator containing promethium-147 must not exceed
25.10	one millirad per hour at one centimeter from any surface when measured through 50
25.11	milligrams per square centimeter absorber;
25.12	C.B. balances of precision containing not more than one millicurie of tritium
25.13	per balance or not more than 0.5 millicurie of tritium per balance part manufactured
25.14	before December 17, 2007;
25.15	D. automobile shift quadrants containing not more than 25 millicuries of tritium;
25.16	E. C. marine compasses containing not more than 750 millicuries of tritium
25.17	gas and other marine navigational instruments containing not more than 250 millicuries
25.18	of tritium gas manufactured before December 17, 2007;
25.19	Fthermostat dials and pointers containing not more than 25 millicuries of
25.20	tritium per thermostat;
25.21	D. ionization chamber smoke detectors containing not more than one microcurie
25.22	( $\mu$ Ci) of americium-241 per detector in the form of a foil and designed to protect life
25.23	and property from fires;
25.24	G.E. electron tubes. For purposes of this item, "electron tubes" include spark
25.25	gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes,

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indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed
tube that is designed to conduct or control electrical currents. The exemption under this
item applies only if the levels of radiation from each electron tube containing radioactive
material do not exceed one millirad per hour at one centimeter from any surface when
measured through seven milligrams per square centimeter of absorber and if each tube does
not contain more than one of the following specified quantities of radioactive materials:

- 26.7 (1) 150 millicuries of tritium per microwave receiver protector tube or ten
  26.8 millicuries of tritium per any other electron tube;
- 26.9 (2) one microcurie of cobalt-60;
- 26.10 (3) five microcuries of nickel-63;
- 26.11 (4) 30 microcuries of krypton-85;
- 26.12 (5) five microcuries of cesium-137; or
- 26.13 (6) 30 microcuries of promethium-147; or

H. F. ionizing radiation measuring instruments containing, for purposes of 26.14 internal calibration or standardization, one or more sources of radioactive material. For 26.15 purposes of this item, an instrument's source may contain either one type or different 26.16 types of radionuclides and an individual exempt quantity may be composed of fractional 26.17 parts of one or more of the exempt quantities in part 4731.3145, provided that the sum 26.18 of the fractions does not exceed unity. For purposes of this item, 0.05 microcurie of 26.19 americium-241 is an exempt quantity under part 4731.3145. The exemption under this 26.20 item applies only if: 26.21

26.22 (1) each source contains no more than one exempt quantity under part26.23 4731.3145; and

26.24 (2) each instrument contains no more than ten exempt quantities<del>; or</del>.

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27.1	Ispark gap irradiators containin	<del>g not more than on</del>	e microcurie of cob	<del>alt-60</del>
27.2	per spark gap irradiator for use in electri	eally ignited fuel o	il burners having a f	iring rate
27.3	of at least three gallons (11.4 liters) per	<del>hour.</del>		
27.4	[For text of	of subp 2, see M.R.	1	
27.5	4731.3040 EXEMPT QUANTITIES.			
27.6	Subpart 1. Exempt quantities. Exce	pt as provided in su	ubparts 3 and 4 to 5,	a person
27.7	is exempt from parts 4731.3000 to 4731	.7280 to the extent	that the person rece	ives,
27.8	possesses, uses, transfers, owns, or acqu	ires radioactive ma	terial in individual q	uantities,
27.9	each of which does not exceed the applie	cable quantity in pa	rt 4731.3145.	
27.10	Subp. 2. Receipt under prior licens	e. A person who p	ossesses radioactive	material
27.11	received or acquired before September 2	5, 1971, under the	general license then	provided
27.12	under Code of Federal Regulations, title	10, section 31.4, <u>o</u>	r similar general lice	ense of a
27.13	state, is exempt from parts 4731.3000 to	4731.4360, and 47	31.6000 to 4731.72	<u>80 to the</u>
27.14	extent that the person possesses, uses, tra	ansfers, or owns su	ch radioactive mater	ial.
27.15	[For text of su	ubps 3 and 4, see N	[. <u>R.]</u>	
27.16	Subp. 5. Aggregation. No person m	ay, for purposes of	producing an increa	ased
27.17	radiation level, combine quantities of ra	dioactive material of	overed by this exen	nption
27.18	so that the aggregate quantity exceeds the	e limits set forth in	part 4731.3145, exe	cept for
27.19	radioactive material combined within a	device placed in us	e before May 3, 199	9, or as
27.20	otherwise permitted by this part.			
27.21 27.22	4731.3050 EXEMPTION; GAS AND RADIOACTIVE MATERIAL.	AEROSOL DETI	ECTORS CONTAI	NING
27.23	Subpart 1. Specific license exemption	on. Except for pers	ons who manufactu	re,

Subpart 1. Specific license exemption. Except for persons who manufacture,
process, produce, or initially transfer for sale or distribution gas and aerosol detectors
containing radioactive material, a person is exempt from parts 4731.2000 4731.1000 to

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4731.2090 and 4731.3000 to 4731.7280 to the extent that the person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas or aerosol detectors designed to protect life or property from fires and airborne hazards and manufactured, processed, produced, or initially transferred according to a specific license issued under Code of Federal Regulations, title 10, section 32.26, that authorizes the initial transfer of the product for use under this part. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a state under comparable provisions to Code of Federal Regulations, title 10, section 32.26, authorizing distribution to persons exempt from regulatory requirements. [For text of subp 2, see M.R.]
4731.3065 SPECIFIC LICENSES; APPLICATION.
[For text of subpart 1, see M.R.]

Subp. 2. Sealed source requirements. An application for a specific license to use
radioactive material in the form of a sealed source or in a device that contains the sealed
source must:

<u>A.</u> identify the source or device by manufacturer and model number as
 registered with the NRC under Code of Federal Regulations, title 10, section 32.210,
 <del>or</del> with an agreement state:, or for a source or a device containing radium-226 or
 <u>accelerator-produced radioactive material with a state under provisions comparable to</u>
 Code of Federal Regulations, title 10, section 32.210; or

- 28.21 <u>B.</u> contain the information identified in Code of Federal Regulations, title
  28.22 10, section 32.210(c); or
- 28.23C. for sources or devices containing naturally occurring or accelerator-produced28.24radioactive material manufactured prior to November 30, 2007, that are not registered
- 28.25 with the NRC under Code of Federal Regulations, title 10, section 32.210, or with

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29.1	an agreement state, and for which the a	pplicant is unable to p	provide all categorie	s of
29.2	information specified in Code of Federa	l Regulations, title 10	), section 32.210(c),	the
29.3	applicant must provide:			
29.4	(1) all available information	identified in Code of	Federal Regulation	<u>s,</u>
29.5	title 10, section 32.210(c) and this chap	ter concerning the sou	urce, and, if applical	ble,
29.6	the device; and			
29.7	(2) sufficient additional infor	mation to demonstrat	e that there is reason	nable
29.8	assurance that the radiation safety prope	erties of the source or	device are adequate	<u>e to</u>
29.9	protect health and minimize danger to li	fe and property. This	information must in	iclude a
29.10	description of the source or device, a de	scription of radiation	safety features, the	intended
29.11	use and associated operating experience	, and the results of a 1	ecent leak test.	
29.12	[For text of s	subps 3 to 6, see M.R	.]	
29.13	Subp. 7. Application to produce P	ET radioactive drug	s. An application fr	om a
29.14	medical facility, educational institution,	or federal facility to	produce positron em	ission
29.15	tomography (PET) radioactive drugs for	r noncommercial tran	sfer to licensees in i	its
29.16	consortium authorized for medical use	under NRC, or equiva	alent agreement state	e
29.17	requirements must include:			
29.18	<u>A.</u> <u>a request for authorization for a second seco</u>	or the production of P	ET radionuclides or	
29.19	evidence of an existing license issued by	the NRC, or an agree	ment state with requ	irements
29.20	for a PET radionuclide production facility	ty within its consortion	um from which it re-	ceives
29.21	PET radionuclides;			
29.22	B. evidence that the applicant is	qualified to produce	radioactive drugs for	<u>)r</u>
29.23	medical use by meeting one of the criter	ria in part 4731.3395,	subpart 1;	
29.24	C. identification of individuals a	uthorized to prepare	the PET radioactive	<u>}</u>
29.25	drugs if the applicant is a pharmacy, and	d documentation that	each individual mee	ets the

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30.1	requireme	ents of an authorized nuc	elear pharmacist as speci	fied in part 4731.33	95, subpart
30.2	<u>2; and</u>				
30.3	D.	information identified i	n part 4731.3395, subpa	rt 1, on the PET dru	igs to be
30.4	noncomm	nercially transferred to m	embers of its consortiun	<u>n.</u>	
30.5	4731.307	5 TERMS AND CONI	DITIONS OF LICENSI	ES.	
30.6		[For te	ext of subps 1 to 6, see N	<u>/I.R.]</u>	
30.7	Subp.	7. Molybdenum-99 ree	quirement. A licensee p	preparing technetiun	n-99m
30.8	radiophar	maceuticals from molyb	odenum-99 or technetiun	n-99m generators on	<u>r</u>
30.9	rubidium	-82 from strontium-82/ru	ibidium-82 generators m	nust test the generate	or eluates
30.10	for molyt	odenum-99 breakthrough	or strontium-82 and str	ontium-85 contamir	nation,
30.11	respective	ely, according to part 473	31.4435. The licensee mu	ust record the results	s of each test
30.12	and retair	n each record for three ye	ears after the record is m	nade.	
30.13		[For	r text of subp 8, see M.R	<u>.]</u>	
30.14	Subp.	9. Authorization to pr	oduce PET. Authorizati	on under part 4731.	.3065,
30.15	subpart 7	, to produce positron em	ission tomography (PET	Γ) radioactive drugs	for
30.16	noncomm	nercial transfer to medica	al use licensees in its cor	nsortium does not re	lieve the
30.17	licensee f	from complying with app	blicable FDA requirement	nts or other federal a	and state
30.18	requireme	ents governing radioactiv	ve drugs.		
30.19	<u>A.</u>	Each licensee authorize	ed under part 4731.3065	, subpart 7, to produ	ice PET
30.20	radioactiv	ve drugs for noncommer	cial transfer to medical u	use licensees in its co	onsortium
30.21	<u>must:</u>				
30.22		(1) satisfy the labeling	requirements in part 473	31.3395, subpart 1,	for each
30.23	PET radio	oactive drug transport ra	diation shield and each s	yringe, vial, or othe	r container
30.24	used to he	old a PET radioactive dr	ug intended for noncomr	mercial distribution	to members
30.25	of its con	sortium; and			

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31.1	(2) possess and use instru	mentation to measur	e the radioactivity of	the PET
31.2	radioactive drugs intended for nonco	ommercial distributio	n to members of its co	onsortium
31.3	and meet the procedural, radioactivi	ty measurement, inst	rument test, instrumer	nt check,
31.4	and instrument adjustment requirem	ents in part 4731.339	5, subpart 3.	
31.5	B. A licensee that is a pharm	acy authorized under	r part 4731.3065, subp	oart 7, to
31.6	produce PET radioactive drugs for n	oncommercial transf	er to medical use licer	nsees in its
31.7	consortium must require that any inc	lividual that prepares	PET radioactive drug	s must be:
31.8	(1) an authorized nuclear	pharmacist that mee	ts the requirements in	part
31.9	4731.3395, subpart 2; or			
31.10	(2) an individual under th	e supervision of an a	uthorized nuclear pha	irmacist
31.11	specified in part 4731.4407.			
31.12	<u>C.</u> <u>A pharmacy, authorized u</u>	nder part 4731.3065	, subpart 7, to produce	e PET
31.13	radioactive drugs for noncommercia	l transfer to medical	use licensees in its co	nsortium
31.14	that allows an individual to work as	an authorized nuclea	r pharmacist, must m	eet the
31.15	requirements of part 4731.3395, sub	part 2.		
31.16	4731.3145 EXEMPT QUANTITI	ES.		
31.17	Radioactive Material		Microcuries	
31.18	Antimony 122 (Sb 12	2)	100	
31.19	Antimony 124 (Sb 12	4)	10	
31.20	Antimony 125 (Sb 12	5)	10	
31.21	Arsenic 73 (As 73)		100	
31.22	Arsenic 74 (As 74)		10	
31.23	Arsenic 76 (As 76)		10	
31.24	Arsenic 77 (As 77)		100	
31.25	Barium 131 (Ba 131)		10	
31.26	Barium 133 (Ba 133)		10	

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32.1	Barium 140 (Ba 140)		10	
32.2	Bismuth 210 (Bi 210)		1	
32.3	Bromine 82 (Br 82)		10	
32.4	Cadmium 109 (Cd 109)		10	
32.5	Cadmium 115m (Cd 115m	n)	10	
32.6	Cadmium 115 (Cd 115)		100	
32.7	Calcium 45 (Ca 45)		10	
32.8	Calcium 47 (Ca 47)		10	
32.9	Carbon 11 (C 11)		1,000	
32.10	Carbon 14 (C 14)		100	
32.11	Cerium 141 (Ce 141)		100	
32.12	Cerium 143 (Ce 143)		100	
32.13	Cerium 144 (Ce 144)		1	
32.14	Cesium 129 (Cs 129)		<u>100</u>	
32.15	Cesium 131 (Cs 131)		1,000	
32.16	Cesium 134m (Cs 134m)		100	
32.17	Cesium 134 (Cs 134)		1	
32.18	Cesium 135 (Cs 135)		10	
32.19	Cesium 136 (Cs 136)		10	
32.20	Cesium 137 (Cs 137)		10	
32.21	Chlorine 36 (Cl 36)		10	
32.22	Chlorine 38 (Cl 38)		10	
32.23	Chromium 51 (Cr 51)		1,000	
32.24	Cobalt 57 (Co 57)		100	
32.25	Cobalt 58m (Co 58m)		10	
32.26	Cobalt 58 (Co 58)		10	
32.27	Cobalt 60 (Co 60)		1	
32.28	Copper 64 (Cu 64)		100	
32.29	Dysprosium 165 (Dy 165)	)	10	

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33.1	Dysprosium 166 (Dy 166)	100	
33.2	Erbium 169 (Er 169)	100	
33.3	Erbium 171 (Er 171)	100	
33.4	Europium 152 9.2 h (Eu 152 9.2 h)	100	
33.5	Europium 152 13 yr (Eu 152 13 yr)	1	
33.6	Europium 154 (Eu 154)	1	
33.7	Europium 155 (Eu 155)	10	
33.8	Fluorine 18 (F 18)	1,000	
33.9	Gadolinium 153 (Gd 153)	10	
33.10	Gadolinium 159 (Gd 159)	100	
33.11	Gallium 67 (Ga 67)	100	
33.12	Gallium 72 (Ga 72)	10	
33.13	Germanium 68 (Ge 68)	10	
33.14	Germanium 71 (Ge 71)	100	
33.15	Gold 195 (Au 195)	10	
33.16	Gold 198 (Au 198)	100	
33.17	Gold 199 (Au 199)	100	
33.18	Hafnium 181 (Hf 181)	10	
33.19	Holmium 166 (Ho 166)	100	
33.20	Hydrogen 3 (H 3)	1,000	
33.21	Indium 111 (In 111)	100	
33.22	Indium 113m (In 113m)	100	
33.23	Indium 114m (In 114m)	10	
33.24	Indium 115m (In 115m)	100	
33.25	Indium 115 (In 115)	10	
33.26	Iodine 123 (I 123)	100	
33.27	Iodine 125 (I 125)	1	
33.28	Iodine 126 (I 126)	1	

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34.1	Iodine 129 (I 129)		0.1	
34.2	Iodine 131 (I 131)		1	
34.3	Iodine 132 (I 132)		10	
34.4	Iodine 133 (I 133)		1	
34.5	Iodine 134 (I 134)		10	
34.6	Iodine 135 (I 135)		10	
34.7	Iridium 192 (Ir 192)		10	
34.8	Iridium 194 (Ir 194)		100	
34.9	Iron 52 (Fe 52)		10	
34.10	Iron 55 (Fe 55)		100	
34.11	Iron 59 (Fe 59)		10	
34.12	Krypton 85 (Kr 85)		100	
34.13	Krypton 87 (Kr 87)		10	
34.14	Lanthanum 140 (La 140)	)	10	
34.15	Lutetium 177 (Lu 177)		100	
34.16	Manganese 52 (Mn 52)		10	
34.17	Manganese 54 (Mn 54)		10	
34.18	Manganese 56 (Mn 56)		10	
34.19	Mercury 197m (Hg 197n	n)	100	
34.20	Mercury 197 (Hg 197)		100	
34.21	Mercury 203 (Hg 203)		10	
34.22	Molybdenum 99 (Mo 99	)	100	
34.23	Neodymium 147 (Nd 14	7)	100	
34.24	Neodymium 149 (Nd 14	9)	100	
34.25	Nickel 59 (Ni 59)		100	
34.26	Nickel 63 (Ni 63)		10	
34.27	Nickel 65 (Ni 65)		100	
34.28	Niobium 93m (Nb 93m)		10	

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35.1	Niobium 95 (Nb 95)		10	
35.2	Niobium 97 (Nb 97)		10	
35.3	Nitrogen 13 (N 13)		1,000	
35.4	Osmium 185 (Os 185)		10	
35.5	Osmium 191m (Os 191m)	)	100	
35.6	Osmium 191 (Os 191)		100	
35.7	Osmium 193 (Os 193)		100	
35.8	Oxygen 15 (O 15)		1,000	
35.9	Palladium 103 (Pd 103)		100	
35.10	Palladium 109 (Pd 109)		100	
35.11	Phosphorus 32 (P 32)		10	
35.12	Platinum 191 (Pt 191)		100	
35.13	Platinum 193m (Pt 193m)	)	100	
35.14	Platinum 193 (Pt 193)		100	
35.15	Platinum 197m (Pt 197m)	)	100	
35.16	Platinum 197 (Pt 197)		100	
35.17	Polonium 210 (Po 210)		0.1	
35.18	Potassium 42 (K 42)		10	
35.19	Potassium 43 (K 43)		<u>10</u>	
35.20	Praseodymium 142 (Pr 14	(2)	100	
35.21	Praseodymium 143 (Pr 14	(3)	100	
35.22	Promethium 147 (Pm 147	)	10	
35.23	Promethium 149 (Pm 149	)	10	
35.24	Radium 226 (Ra 226)		1	
35.25	Rhenium 186 (Re 186)		100	
35.26	Rhenium 188 (Re 188)		100	
35.27	Rhodium 103m (Rh 103m	1)	100	
35.28	Rhodium 105 (Rh 105)		100	
35.29	Rubidium 81 (Rb 81)		10	

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36.1	Rubidium 86 (Rb 86)		10	
36.2	Rubidium 87 (Rb 87)		10	
36.3	Ruthenium 97 (Ru 97)		100	
36.4	Ruthenium 103 (Ru 103)		10	
36.5	Ruthenium 105 (Ru 105)		10	
36.6	Ruthenium 106 (Ru 106)		1	
36.7	Samarium 151 (Sm 151)		10	
36.8	Samarium 153 (Sm 153)		100	
36.9	Scandium 46 (Sc 46)		10	
36.10	Scandium 47 (Sc 47)		100	
36.11	Scandium 48 (Sc 48)		10	
36.12	Selenium 75 (Se 75)		10	
36.13	Silicon 31 (Si 31)		100	
36.14	Silver 105 (Ag 105)		10	
36.15	Silver 110m (Ag 110m)		1	
36.16	Silver 111 (Ag 111)		100	
36.17	Sodium 22 (Na 22)		10	
36.18	Sodium 24 (Na 24)		10	
36.19	Strontium 85 (Sr 85)		10	
36.20	Strontium 89 (Sr 89)		1	
36.21	Strontium 90 (Sr 90)		0.1	
36.22	Strontium 91 (Sr 91)		10	
36.23	Strontium 92 (Sr 92)		10	
36.24	Sulfur 35 (S 35)		100	
36.25	Tantalum 182 (Ta 182)		10	
36.26	Technetium 96 (Tc 96)		10	
36.27	Technetium 97m (Tc 97m	)	100	
36.28	Technetium 97 (Tc 97)		100	
36.29	Technetium 99m (Tc 99m	)	100	

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37.1	Technetium 99 (Tc 99)	10
37.2	Tellurium 125m (Te 125m)	10
37.3	Tellurium 127m (Te 127m)	10
37.4	Tellurium 127 (Te 127)	100
37.5	Tellurium 129m (Te 129m)	10
37.6	Tellurium 129 (Te 129)	100
37.7	Tellurium 131m (Te 131m)	10
37.8	Tellurium 132 (Te 132)	10
37.9	Terbium 160 (Tb 160)	10
37.10	Thallium 200 (Tl 200)	100
37.11	Thallium 201 (TI 201)	100
37.12	Thallium 202 (TI 202)	100
37.13	Thallium 204 (Tl 204)	10
37.14	Thulium 170 (Tm 170)	10
37.15	Thulium 171 (Tm 171)	10
37.16	Tin 113 (Sn 113)	10
37.17	Tin 125 (Sn 125)	10
37.18	Tungsten 181 (W 181)	10
37.19	Tungsten 185 (W 185)	10
37.20	Tungsten 187 (W 187)	100
37.21	Vanadium 48 (V 48)	10
37.22	Xenon 131m (Xe 131m)	1,000
37.23	Xenon 133 (Xe 133)	100
37.24	Xenon 135 (Xe 135)	100
37.25	Ytterbium 175 (Yb 175)	100
37.26	Yttrium 87 (Y 87)	10
37.27	Yttrium 88 (Y 88)	10
37.28	Yttrium 90 (Y 90)	10
37.29	Yttrium 91 (Y 91)	10

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38.1	Yttrium 92 (Y 92)		100	
38.2	Yttrium 93 (Y 93)		100	
38.3	Zinc 65 (Zn 65)		10	
38.4	Zinc 69m (Zn 69m)		100	
38.5	Zinc 69 (Zn 69)		1,000	
38.6	Zirconium 93 (Zr 93)		10	
38.7	Zirconium 95 (Zr 95)		10	
38.8	Zirconium 97 (Zr 97)		10	
38.9 38.10 38.11	Any radioactive material listed above other than al emitting radioactive mate	pha-	0.1	
38.12 38.13	<b>4731.3150 RADIOACTIVE MATER</b> This part specifies quantities of radio	active materials r	_	
38.14	need for an emergency plan for respond	ing to a release.		
38.15 38.16	Radioactive material <sup>1</sup>		Release fraction	Quantity (curies)
38.17	Actinium-228		0.001	4,000
38.18	Americium-241		0.001	2
38.19	Americium-242		0.001	2
38.20	Americium-243		0.001	2
38.21	Antimony-124		0.01	4,000
38.22	Antimony-126		0.01	6,000
38.23	Barium-133		0.01	10,000
38.24	Barium-140		0.01	30,000
38.25	Bismuth-207		0.01	5,000
38.26	Bismuth-210		0.01	600
38.27	Cadmium-109		0.01	1,000
39.1	Cadmium-113		0.01	80

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39.2	Calcium-45		0.01	20,000
39.3	Californium-252		0.001	9 (20 mg)
39.4	Carbon-14 (noncarbon dioxide)		0.01	50,000
39.5	Cerium-141		0.01	10,000
39.6	Cerium-144		0.01	300
39.7	Cesium-134		0.01	2,000
39.8	Cesium-137		0.01	3,000
39.9	Chlorine-36		0.5	100
39.10	Chromium-51		0.01	300,000
39.11	Cobalt-60		0.001	5,000
39.12	Copper-64		0.01	200,000
39.13	Curium-242		0.001	60
39.14	Curium-243		0.001	3
39.15	Curium-244		0.001	4
39.16	Curium-245		0.001	2
39.17	Europium-152		0.01	500
39.18	Europium-154		0.01	400
39.19	Europium-155		0.01	3,000
39.20	Germanium-68		0.01	2,000
39.21	Gadolinium-153		0.01	5,000
39.22	Gold-198		0.01	30,000
39.23	Hafnium-172		0.01	400
39.24	Hafnium-181		0.01	7,000
39.25	Holmium-166m		0.01	100
39.26	Hydrogen-3		0.5	20,000
39.27	Iodine-125		0.5	1
39.28	Iodine-131		0.5	10
40.1	Indium-114m		0.01	1,000

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40.2	Iridium-192		0.001	40,000
40.3	Iron-55		0.01	40,000
40.4	Iron-59		0.01	7,000
40.5	Krypton-85		1.0	6,000,000
40.6	Lead-210		0.01	8
40.7	Manganese-56		0.01	60,000
40.8	Mercury-203		0.01	10,000
40.9	Molybdenum-99		0.01	30,000
40.10	Neptunium-237		0.001	2
40.11	Nickel-63		0.01	20,000
40.12	Niobium-94		0.01	300
40.13	Phosphorus-32		0.5	100
40.14	Phosphorus-33		0.5	1,000
40.15	Polonium-210		0.01	10
40.16	Potassium-42		0.01	9,000
40.17	Promethium-145		0.01	4,000
40.18	Promethium-147		0.01	4,000
40.19	Radium-226		0.001	<u>100</u>
40.20	Ruthenium-106		0.01	200
40.21	Samarium-151		0.01	4,000
40.22	Scandium-46		0.01	3,000
40.23	Selenium-75		0.01	10,000
40.24	Silver-110m		0.01	1,000
40.25	Sodium-22		0.01	9,000
40.26	Sodium-24		0.01	10,000
40.27	Strontium-89		0.01	3,000
41.1	Strontium-90		0.01	90

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41.2	Sulfur-35		0.5	900
41.3	Technetium-99		0.01	10,000
41.4	Technetium-99m		0.01	400,000
41.5	Tellurium-127m		0.01	5,000
41.6	Tellurium-129m		0.01	5,000
41.7	Terbium-160		0.01	4,000
41.8	Thulium-170		0.01	4,000
41.9	Tin-113		0.01	10,000
41.10	Tin-123		0.01	3,000
41.11	Tin-126		0.01	1,000
41.12	Titanium-44		0.01	100
41.13	Vanadium-48		0.01	7,000
41.14	Xenon-133		1.0	900,000
41.15	Yttrium-91		0.01	2,000
41.16	Zinc-65		0.01	5,000
41.17	Zirconium-93		0.01	400
41.18	Zirconium-95		0.01	5,000
41.19	Any other beta-gamma emitter		0.01	10,000
41.20	Mixed fission products		0.01	1,000
41.21	Mixed corrosion products		0.01	10,000
41.22 41.23	Contaminated equipment, beta-gamma		0.001	10,000
41.24 41.25	Irradiated material, any form other than solid noncombustible		0.01	1,000
42.1 42.2	Irradiated material, solid noncombustible		0.001	10,000

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42.3 42.4	Mixed radioactive waste, beta-gamma		0.01	1,000
42.5 42.6	Packaged mixed waste, beta-gamma <sup>2</sup>		0.001	10,000
42.7	Any other alpha emitter		0.001	2
42.8	Contaminated equipment, alpha		0.0001	20
42.9	Packaged waste, alpha <sup>2</sup>		0.0001	20
42.10	Combinations of radioactive materials	listed above <sup>1</sup>		
42.11	<sup>1</sup> For combinations of radioactive m	aterials, considera	tion of the need for	an
42.12	emergency plan is required if the sum of			
42.13	material authorized to the quantity liste	d for that material	in this part exceeds	s one.
42.14	<sup>2</sup> Waste packaged in Type B contained	ers does not requir	e an emergency plan	n.
42.15 42.16	4731.3215 GENERAL LICENSE; D CONTROLLING, AND OTHER DE	-	ASURING, GAU	GING,
42.17	[For text o	f subpart 1, see M	I.R.]	
42.18	Subp. 2. Applicability.			
42.19	A. The general license under su	bpart 1 applies or	nly to radioactive m	aterial
42.20	contained in devices that have been ma	nufactured or init	ially transferred and	l labeled
42.21	according to:			
42.22	(1) a specific license issued	under part 4731.33	330; <del>or</del>	
42.23	(2) an equivalent specific lic	cense issued by th	e NRC or an agreer	nent
42.24	state- <u>; or</u>			
43.1	(3) an equivalent specific lie	cense issued by a	state with provisior	<u>15</u>
43.2	comparable to part 4731.3330.			

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43.3	B. The devices must have been receive	d from one of	the specific license	es
43.4	described in item A or through a transfer made	under subpart	3, item M.	
43.5	Subp. 3. Requirements. A person who ac	quires, receive	es, possesses, uses, o	or
43.6	transfers radioactive material in a device accor	ding to the gei	neral license issued	under
43.7	subpart 1 must:			
43.8	[For text of items A	to K, see M.F	<u>.]</u>	
43.9	L. obtain written approval from the cor	nmissioner bef	fore transferring the	device
43.10	to another specific licensee not specifically ide	ntified in item	J; however, a holde	r of a
43.11	specific license may transfer a device for posse	ssion and use	under its own specif	ic license
43.12	without prior approval, if the holder:			
43.13	(1) verifies that the specific license	authorizes the	possession and use,	or
43.14	applies for and obtains an amendment to the lic	ense authorizi	ng the possession an	nd use;
43.15	(2) removes, alters, covers, or clear	ly and unambi	guously augments t	he
43.16	existing label, otherwise required by subpart 3,	, item A, so the	at the device is labe	led in
43.17	compliance with part 4731.2330; however, the	manufacturer,	model number, and	serial
43.18	number must be retained;			
43.19	(3) obtains the manufacturer's or initial	tial transferor'	s information conce	rning
43.20	maintenance that would be applicable under the	e specific licer	nse, such as leak tes	ting
43.21	procedures; and			
43.22	(4) reports the transfer under item k	<u>,</u>		
43.23	[For text of items M	to R, see M.I	<u>.]</u>	
43.24	Subp. 3a. Registration of generally licen	sed devices.		
44.1	A. A person to whom subpart 3 applies	shall register	generally licensed d	evices
44.2	according to items B and C. These devices cor	itain:		

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44.3	(1) at least ten millicu	ries (370 MBq) of cesiur	m-137;	
44.4	(2) at least 0.1 milliou	urie (3.7 MBq) of strontiu	m-90;	
44.5	(3) at least one milliou	urie (37 MBq) of cobalt-6	60; <del>or</del>	
44.6	(4) at least 0.1 milliou	rrie (3.7 MBq) of radium-	-226; or	
44.7	(5) at least one millic	urie (37 MBq) of americ	ium-241 or any oth	ıer
44.8	transuranic (any other element w	ith an atomic number gre	ater than uranium-	92) based on
44.9	the activity indicated on the labe	el.		
44.10	[For te	ext of items B and C, see	<u>M.R.]</u>	
44.11	<u>[Fc</u>	or text of subp 4, see M.F	<u>.]</u>	
44.12 44.13	4731.3230 GENERAL LICEN CALIBRATION OR REFERE		AND RADIUM-2	26
44.14	Subpart 1. License issued; a	mericium-241. Persons	listed in items A an	d B are
44.15	issued a general license A general	al license is issued to per	sons listed in this p	part to
44.16	own, receive, acquire, possess, u	se, and transfer, accordin	g to this part accord	ding to the
44.17	provisions of subparts 4 and 5, and	mericium-241 <u>or radium-</u>	226 in the form of a	calibration or
44.18	reference sources:			
44.19	A. a person who holds a	specific license issued by	the commissioner	• that
44.20	authorizes the person to receive,	possess, use, and transfer	radioactive materi	al; and
44.21	B. a government agency	that holds a specific licer	ise issued by the N	RC that
44.22	authorizes the person to receive,	possess, use, and transfer	radioactive materi	al.
44.23	Subp. 2. [See repealer.]			
44.24	Subp. 3. [See repealer.]			
45.1	Subp. 4. Calibration or refe	erence source requireme	ents. The general li	censes
45.2	under this part in subpart 1 apply	y only to calibration or re	ference sources that	at have

10/28/08 REVISOR SGS/PT RD3752 been manufactured or initially transferred according to a specific license issued to the 45.3 manufacturer under part 4731.3365 or by the NRC or an agreement state that authorizes 45.4 manufacture of the sources for distribution to persons generally licensed by an agreement 45.5 state. 45.6 Subp. 5. Additional requirements. 45.7 A. The general licenses issued under this part are subject to parts 4731.0260; 45.8 4731.1000 to 4731.2950; 4731.3025, subpart 4; 4731.3075, subparts 1, 2, 3, 5, and 6; and 45.9 4731.3110 to 4731.3135 and Code of Federal Regulations, title 10, part 21. 45.10 B. Persons who own, receive, acquire, possess, use, or transfer one or more 45.11 calibration or reference sources under the general licenses: 45.12 (1) must not possess at any one time, at any one location of storage or 45.13 45.14 use, more than five microcuries (185 kBq 0.185 kilobecquerels) of americium-241, five microcuries (185 kBg) of plutonium, or five microcuries (185 kBg) of or radium-226 45.15 45.16 in the sources; 45.17 (2) must not receive, possess, use, or transfer the source unless the source or storage container bears a label that includes one of the following statements statement 45.18 or a substantially similar statement that contains the information called for: 45.19 (a) "The receipt, possession, use, and transfer of this source, Model 45.20 ...., Serial No. ...., are subject to a general license and the regulations of the Nuclear 45.21 Regulatory Commission or of a state with which the Nuclear Regulatory Commission has 45.22 entered into an agreement for the exercise of regulatory authority. Do not remove this 45.23 label. 45.24 CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS 46.1 [AMERICIUM-241 or PLUTONIUM [or RADIUM-226, as appropriate]. DO NOT 46.2 TOUCH RADIOACTIVE PORTION OF THIS SOURCE. 46.3 (Name of manufacturer or initial transferor)"; or 46.4

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46.5	(b) -"The receipt,	possession, use, and trans	fer of this source, Me	odel
46.6	, Serial No, are subject	to a general license and th	e regulations of a lied	ensing
46.7	state. Do not remove this label	<del>.</del>		
46.8	CAUTION - RADIOACT	IVE MATERIAL - THIS S	SOURCE CONTAIN	S
46.9	RADIUM-226. DO NOT	FOUCH RADIOACTIVE	PORTION OF THIS (	SOURCE.
46.10	(Name of	f manufacturer or initial tra	msferor)";	
46.11	(3) must not transfer	r, abandon, or dispose of th	ie source except by tr	ansfer
46.12	to a person authorized by a lice	ense from the commissione	r, the NRC, or an agr	eement
46.13	state to receive the source;			
46.14	(4) must store the so	ource, except when the sour	rce is being used, in a	a closed
46.15	container adequately designed	and constructed to contain	americium-241 <del>, plute</del>	<del>mium,</del> or
46.16	radium-226 that might otherwis	se escape during storage; a	nd	
46.17	(5) must not use the	source for any purpose oth	her than the calibratic	on of
46.18	radiation detectors or the stand	ardization of other sources.		
46.19	<u>C.</u> Sources generally lic	ensed under this part befor	re January 19, 1975, r	nay bear
46.20	labels authorized by the regulat	tions in effect on January 1	, 1975. Sources cont	aining
46.21	radium-226 generally licensed	under this part and manufa	actured before Novem	nber
46.22	30, 2007, must be labeled acco	rding to the applicable stat	e regulations at the ti	me of
46.23	manufacture or import.			
46.24	Subp. 6. Limitation. The	general licenses under this	part do not authorize	e
46.25	the manufacture, export, or imp	port of calibration or refere	ence sources containi	ng
46.26	americium-241 <del>, plutonium,</del> or	radium-226.		
47.1 47.2	4731.3245 GENERAL LICE TESTING USE.	NSE; IN VITRO CLINIC	CAL OR LABORAT	ORY
47.3	Subpart 1. License issued.	A physician, veterinarian i	n the practice of vete	erinary
47.4	medicine, clinical laboratory, o	r hospital is issued a generation	al license to receive,	acquire,

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47.5	possess, transfer, or use, accord	ing to this part, the followi	ng radioactive mater	ials in
47.6	prepackaged units for use in in	vitro clinical or laboratory	tests not involving in	ternal or
47.7	external administration of radio	active material, or the radia	ation therefrom, to h	uman
47.8	beings or animals:			
47.9	A. iodine-125, in units n	ot exceeding ten microcuri	es (0.37 MBq) each;	
47.10	B. iodine-131, in units n	ot exceeding ten microcuri	es (0.37 MBq) each;	
47.11	C. carbon-14, in units no	ot exceeding ten microcurie	each; (0.37 MBq) each;	
47.12	D. hydrogen-3 (tritium),	in units not exceeding 50 r	nicrocuries (1.85 MI	<u>Bq)</u> each;
47.13	E. iron-59, in units not e	exceeding 20 microcuries ((	).74 MBq) each;	
47.14	F. selenium-75, in units	not exceeding ten microcur	ies <u>(0.37 MBq)</u> each	,
47.15	G. mock iodine-125 refe	erence or calibration source	s, in units not exceed	ling 0.05
47.16	microcurie (1.85 kBq) of iodine	-129 and 0.005 microcurie	<u>(0.185 kBq)</u> of amer	icium-241
47.17	each; and			
47.18	H. cobalt-57, in units no	t exceeding ten microcuries	s <u>(0.37 MBq)</u> each.	
47.19	[For	text of subps 2 to 6, see M	[. <u>R.]</u>	
47.20 47.21	4731.3250 GENERAL LICEN PRODUCTS CONTAINING	,	AND SELF-LUMIN	IOUS
47.22	Subpart 1. General license.	A general license is hereby	y issued to any perso	on to
47.23	acquire, receive, possess, use, o	r transfer, according to the	provisions of subpar	ts 2 to 4 <u>,</u>
47.24	radium-226 contained in the foll	owing products manufactur	ed prior to Novembe	r 30, 2007.
48.1	A. Antiquities originally	v intended for use by the go	eneral public. For th	<u>e</u>
48.2	purposes of this item, "antiquiti	es" means products origina	lly intended for use	by the
48.3	general public and distributed in	the late 19th and early 20	th centuries, such as	radium

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48.4	emanator	jars, revigators, radium v	vater jars, radon genera	tors, refrigerator cards	, radium
48.5	bath salts	s, and healing pads.			
48.6	<u>B.</u>	Intact timepieces contai	ning greater than one n	nicrocurie (0.037 MBc	<u>]),</u>
48.7	nonintact	timepieces, and timepiec	e hands and dials no lo	nger installed in timep	ieces.
48.8	<u>C.</u>	Luminous items installe	d in air, marine, or land	l vehicles.	
48.9	<u>D.</u>	All other luminous prod	ucts, provided that no	more than 100 items an	re used
48.10	or stored	at the same location at an	ny one time.		
48.11	<u>E.</u>	Small radium sources co	ontaining no more than	one microcurie (0.037	MBq)
48.12	of radium	n-226. For the purposes o	f this item, "small radi	um sources" means dis	screte
48.13	survey in	strument check sources, s	ources contained in rac	liation measuring instr	uments,
48.14	sources u	sed in educational demon	strations, such as cloud	l chambers and spintha	riscopes,
48.15	electron t	tubes, lightning rods, ioniz	zation sources, static el	iminators, or as design	ated by
48.16	the NRC.	<u>.</u>			
48.17	Subp.	2. Exempt provisions. I	Persons who acquire, re	eceive, possess, use, or	transfer
48.18		t material under the gener			
48.19		sions of parts 4731.1000 t		-	
48.20	Federal F	Regulations, title 10, part 2	21, to the extent that th	e receipt, possession, u	use, or
48.21	transfer o	of byproduct material is w	ithin the terms of the ge	eneral license; provided	d, that this
48.22	exemptio	n is not deemed to apply	to any person specifical	ly licensed under this	chapter.
48.23	Subp.	3. General requiremen	ts. Any person who ac	quires, receives, posse	sses,
48.24	uses, or t	ransfers byproduct materi	al according to the gene	eral license in subpart	<u>1:</u>
49.1	<u>A.</u>	must notify the commis	sioner if there is any in	dication that damage t	o the
49.2	product r	nay result in a loss of the	radioactive material. A	A report containing a b	orief
49.3	descriptio	on of the event, and the re	medial action taken, m	ust be furnished within	1 30 days
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49.4	to the Radio	active Materials Unit, M	linnesota Department	of Health, 625 Rober	rt Street N.,
49.5	<u>P.O. Box 64</u>	975, St. Paul, MN 5516	4-0975;		
49.6	<u>B.</u> <u>m</u>	ust not abandon produc	ts containing radium	-226. The product, an	nd
49.7	any radioact	ive material from the pro-	oduct, may only be d	lisposed of according	to part
49.8	<u>4731.2460 o</u>	r by transfer to a person	authorized by a spec	cific license to receive	e the
49.9	radium-226	in the product or as othe	erwise approved by th	ne NRC;	
49.10 49.11		ust not export products egulations, title 10, part		26 except according to	<u>o Code</u>
49.12	<u>D.</u> m	ust dispose of products	containing radium-22	26:	
49.13	<u>(1)</u>	at a disposal facility a	authorized to dispose	of radioactive mater	ial
49.14	according to	any federal or state soli	d or hazardous waste	a law, including the So	olid Waste
49.15	Disposal Ac	t, as authorized under th	e Energy Policy Act	of 2005;	
49.16	<u>(2)</u>	by transfer to a perso	n authorized to recei	ve radium-226 under	a
49.17	specific licer	nse issued by the NRC o	or an agreement state;	; or	
49.18	(3)	as otherwise approved	d by the commissione	er; and	
49.19	<u>E.</u> <u>m</u>	ust respond to written re	equests from the con	nmissioner to provide	• -
49.20	information	relating to the general li	cense within 30 cale	ndar days of the date	of the
49.21	request, or o	ther time specified in the	e request. If the gene	ral licensee cannot pr	ovide the
49.22	requested in	formation within the allo	otted time, the license	ee must, within that sa	ame time
49.23	period, reque	est a longer period to sup	pply the information	by providing the com	missioner a
49.24	written justi	fication for the request.			
50.1	Subp. 4.	Limitation. The gener	al license in subpart	1 does not authorize	the
50.2	manufacture	, assembly, disassembly	, repair, or import of	products containing ra	adium-226,
50.3	except that t	imepieces may be disass	sembled and repaired	<u>-</u>	

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### 50.4 4731.3315 PROHIBITION OF INTRODUCTION.

No person may introduce radioactive material in a product or material knowing or
having reason to believe that it will be transferred to a person that is exempt under part
4731.3025 or equivalent regulations of the NRC or an agreement state, except according
to a specific license issued under part 4731.3305 or the general license issued under part
4731.0355 Code of Federal Regulations, title 10, section 32.11.

### 50.10 4731.3365 SPECIFIC LICENSE; CALIBRATION OR REFERENCE SOURCES; 50.11 MANUFACTURE OR INITIAL TRANSFER.

50.12 Subpart 1. **Approval criteria.** An application for a specific license to manufacture or 50.13 initially transfer calibration and reference sources containing americium-241<del>, plutonium,</del> 50.14 or radium-226 for distribution to persons generally licensed under part 4731.3230 shall 50.15 be approved if:

50.16 A. the applicant satisfies the general requirements of part 4731.3070;

50.17 B. the applicant submits sufficient information regarding each type of calibration 50.18 or reference source pertinent to evaluation of the potential radiation exposure, including:

50.19 (1) chemical and physical form and maximum quantity of americium-241,
50.20 plutonium, or radium-226 in the source;

- 50.21 (2) details of construction and design;
- 50.22 (3) details of the method of incorporation and binding of the 50.23 americium-241<del>, plutonium,</del> or radium-226 in the source;
- 50.24 (4) procedures for and results of prototype testing of sources that are 50.25 designed to contain more than 0.005 microcurie (185 Bq) of americium-241<del>, 0.005</del>

- 51.1 microcurie (185 Bq) of plutonium, or 0.005 microcurie (185 Bq) of or radium-226, to
- demonstrate that the americium-241<del>, plutonium,</del> or radium-226, respectively, contained in

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51.3	each source will not be released o	or be removed from the s	source under normal	conditions
51.4	of use;			
51.5	(5) details of quality c	ontrol procedures to be	followed in manufa	cture
51.6	of the source;			
51.7	(6) a description of lab	beling to be affixed to the	ne source or the stor	age
51.8	container for the source; and			
51.9	(7) any additional info	rmation, including expe	rimental studies and	l tests,
51.10	required by the commissioner to f	acilitate a determination	n of the safety of the	source;
51.11	C. each source will contain	in no more than five mi	crocuries (185 kBq)	of
51.12	americium-241, five microcuries	(185 kBq) of plutonium	, or five microcuries	<del>(185 kBq)</del>
51.13	of or radium-226; and			
51.14	D. the commissioner deter	rmines, with respect to a	any type of source co	ontaining
51.15	more than 0.005 microcurie (185	Bq) of americium-241,	0.005 microcurie (1	<del>85 Bq) of</del>
51.16	plutonium, or 0.005 microcurie (1	<del>85 Bq) of <u>or</u> radium-22</del>	6, that:	
51.17	(1) the method of inco	prporation and binding of	of the americium-24	1 <del>,</del>
51.18	plutonium, or radium-226 in the s	source is such that the an	mericium-241 <del>, pluto</del>	<del>nium,</del> or
51.19	radium-226 will not be released o	r be removed from the s	source under normal	conditions
51.20	of use and handling of the source	; and		
51.21	(2) the source has been	n subjected to and has s	atisfactorily passed	the
51.22	prototype tests under part 4731.34	410.		
51.23	Subp. 2. Labeling requireme	ents. A person licensed	under this part must	affix to
51.24	each source or storage container f	for the source a label that	ıt:	
52.1	A. contains sufficient info	rmation relative to safe	use and storage of th	ne source;
52.2	and			

10/28/08 REVISOR SGS/PT RD3752 B. includes the following statement or a substantially similar statement that 52.3 contains the information called for: 52.4 "The receipt, possession, use, and transfer of this source, Model ..., Serial No. ..., 52.5 are subject to a general license and the regulations of the Minnesota commissioner 52.6 of health, the Nuclear Regulatory Commission, or a state with which the Nuclear 52.7 Regulatory Commission has entered into an agreement for the exercise of regulatory 52.8 authority. Do not remove this label. 52.9 CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS 52.10 AMERICIUM-241 OR PLUTONIUM OR RADIUM-226 [or RADIUM-226, as 52.11 appropriate]. DO NOT TOUCH 52.12 RADIOACTIVE PORTION OF THIS SOURCE. 52.13 (Name of manufacturer or initial transferor)" 52.14 Sources licensed under Code of Federal Regulations, title 10, before January 19, 52.15 1975, may bear labels authorized by the regulations in effect on January 1, 1975. 52.16 Subp. 3. Leak testing. 52.17 A. A person licensed under this part must perform a dry wipe test upon each 52.18 source containing more than 0.1 microcurie (3.7 kBq) of americium-241, 0.1 microcurie 52.19 (3.7 kBq) of plutonium, or 0.1 microeurie (3.7 kBq) of or radium-226 before transferring 52.20 the source to a general licensee under part 4731.3230. 52.21 B. The test must be performed by wiping the entire radioactive surface of the 52.22 source with a filter paper with the application of moderate finger pressure. 52.23 C. The radioactivity on the paper must be measured by using radiation 52.24 detection instrumentation capable of detecting 0.005 microcurie (185 Bq 0.185 kBq) of 52.25 americium-241, plutonium, or radium-226. 52.26 D. If the test discloses more than 0.005 microcurie (<del>185 Bq</del> 0.185kBq) of 53.1 radioactive material, the source must be deemed to be leaking or losing americium-241; 53.2

10/28/08 REVISOR SGS/PT RD3752 plutonium, or radium-226 and must not be transferred to a general licensee under part 53.3 4731.3230. 53.4 4731.3390 SPECIFIC LICENSE; MATERIAL FOR IN VITRO CLINICAL OR 53.5 LABORATORY TESTING; MANUFACTURE AND DISTRIBUTION. 53.6 An application for a specific license to manufacture or distribute radioactive material 53.7 for use under the general license under part 4731.3245 shall be approved if: 53.8 A. the applicant satisfies the general requirements of part 4731.3070; 53.9 B. the radioactive material is prepared for distribution in prepackaged units of: 53.10 (1) iodine-125 in units not exceeding ten microcuries (370 kBq) each; 53.11 (2) iodine-131 in units not exceeding ten microcuries (370 kBq) each; 53.12 (3) carbon-14 in units not exceeding ten microcuries (370 kBq) each; 53.13 (4) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) 53.14 each; 53.15 (5) iron-59 in units not exceeding 20 microcuries (740 kBq) each; 53.16 (6) selenium-75 in units not exceeding ten microcuries (370 kBq) each; and 53.17 mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of (7)53.18 iodine-129 and 0.005 microcurie (185 Bg) of americium-241 each; and 53.19 (8) cobalt-57 in units not exceeding ten microcuries (370 kBq) each; 53.20 C. each prepackaged unit bears a durable, clearly visible label that: 53.21 (1) identifies the radioactive contents as to chemical form and radionuclide; 53.22 53.23 and (2) indicates that the amount of radioactivity does not exceed: 53.24 (a) ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, or 54.1 54.2 selenium-75;

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54.3	(b) 50 microcuries (1.85 M	/IBq) of hydrogen-3	(tritium);	
54.4	(c) 20 microcuries (740 kB	8q) of iron-59; <del>or</del>		
54.5	(d) mock iodine-125 in un	nits not exceeding (	).05 microcuries (1.8.	5
54.6	kBq) of iodine-129 and 0.005 microce	urie (185 Bq) of am	ericium-241 each; and	d <u>or</u>
54.7	(e) cobalt-57 in units not e	exceeding ten micro	curies (370 kBq); and	1
54.8	(3) displays the radiation cau	tion symbol describ	oed in part 4731.2300	),
54.9	and the words "Caution, Radioactive	Material" and "Not	for Internal or Extern	nal Use
54.10	in Humans or Animals";			
54.11	D. the following statement, or a	substantially simila	r statement that conta	ins all
54.12	the information called for, appears on	a label affixed to early	ach prepackaged unit	or appears
54.13	in a leaflet or brochure that accompar	nies the package:		
54.14	"The radioactive material may be	e received, acquired	, possessed, and used	only by
54.15	physicians, veterinarians in the p	ractice of veterinary	medicine, clinical la	boratories,
54.16	or hospitals and only for in vitro	clinical or laborato	ry tests not involving	internal
54.17	or external administration of the	material, or the rad	iation therefrom, to h	uman
54.18	beings or animals. Its receipt, ac	quisition, possessio	n, use, and transfer ar	e subject
54.19	to the regulations and a general l	icense of the Minne	sota commissioner of	f health,
54.20	the Nuclear Regulatory Commiss	sion, or a state with	which the Nuclear Re	egulatory
54.21	Commission has entered into an	agreement for the ex	xercise of regulatory a	authority.
54.22	(Name	of manufacturer)";	and	
54.23	E. the label affixed to the unit, o	r the leaflet or broc	hure that accompanie	s the
54.24	package, contains adequate information	on as to the precaut	ions to be observed in	handling
54.25	and storing the radioactive material.	In the case of a mo	ck iodine-125 referen	ce or
55.1	colibration courses the information of			1:

55.1 calibration source, the information accompanying the source must also contain directions

to the licensee regarding the waste disposal requirements under part 4731.2400.

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# 4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE; MANUFACTURE, PREPARATION, OR TRANSFER.

55.5 Subpart 1. Approval criteria. An application for a specific license to manufacture,

55.6 prepare, or transfer for commercial distribution radioactive drugs containing radioactive

material for use by persons authorized according to parts 4731.4400 to 4731.4527 shall be

approved if the applicant:

- A. satisfies the general requirements specified in part 4731.3070;
- 55.10 B. submits evidence that the applicant is at least one of the following:
- 55.11 (1) registered or licensed with the United States Food and Drug

55.12 Administration as a drug manufacturer the owner or operator of a drug establishment that

55.13 engages in the manufacture, preparation, propagation, compounding, or processing of a

55.14 drug under Code of Federal Regulations, title 21, section 207.20(a);

55.15 (2) registered or licensed with a state agency as a drug manufacturer;

55.16 (3) licensed as a pharmacy by a state board of pharmacy; <del>or</del>

- 55.17 (4) operating as a nuclear pharmacy within a federal medical institution; or
- 55.18 (5) a positron emission tomography (PET) drug production facility
- 55.19 registered with a state agency;

55.20 C. submits the following information regarding the radionuclide:

55.21

(1) the chemical and physical form;

55.22 (2) the maximum activity per vial, syringe, generator, or other container of 55.23 the radioactive drug; and

- 56.1 (3) the shielding provided by the packaging to show it is appropriate for56.2 safe handling and storage of the radioactive drugs by medical use licensees; and
- 56.3 D. satisfies the following labeling requirements:

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(1) a label must be affixed to each transport radiation shield, whether it is 56.4 constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred 56.5 for commercial distribution and include the radiation symbol, the words "CAUTION, 56.6 RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name 56.7 of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specific 56.8 date and time. For a radioactive drug with a half-life greater than 100 days, the time 56.9 may be omitted; and 56.10

(2) a label must be affixed to each syringe, vial, or other container used 56.11 to hold a radioactive drug to be transferred for commercial distribution. The label must 56.12 include the radiation symbol, the words "CAUTION, RADIOACTIVE MATERIAL" 56.13 or "DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures that the 56.14 syringe, vial, or other container can be correlated with the information on the transport 56.15 radiation shield label. 56.16

- 56.17
- 56.18

### Subp. 2. Pharmacy licensees.

#### [For text of items A and B, see M.R.]

C. A licensee described in subpart 1, item B, subitem (3) or (4), may designate 56.19 a pharmacist as an authorized nuclear pharmacist if the individual is identified as of 56.20 December 2, 1994, as an authorized user on a nuclear pharmacy license issued by the 56.21 56.22 NRC or an agreement state. was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a 56.23 pharmacy at a government agency or federally recognized Indian tribe before November 56.24 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by 56.25 the NRC. 56.26

D. No later than 30 days after the date that a licensee described in subpart 57.1 1, item B, subitem (3) or (4), allows an individual to work as an authorized nuclear 57.2

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57.3	pharmacist under item A, subitem (2), uni	t (a) or (c), the lice	nsee must provide t	o the
57.4	commissioner a copy of:			
57.5	(1) the individual's certification	n by <del>the Board of Pl</del>	harmaceutical Speci	altics,
57.6	a specialty board whose certification proc	ess has been recogn	nized as specified in	part
57.7	4731.4413, subpart 1, with the written atte	estation signed by a	preceptor as require	d by part
57.8	4731.4413, subpart 1; or			
57.9	(2) the NRC or agreement state	e license, <u>or the per</u>	mit issued by an NI	RC
57.10	master materials licensee, or the permit is	sued by a licensee	of broad scope <u>, or t</u>	he
57.11	authorization from a commercial nuclear	pharmacy authorized	d to issue its own au	ıthorized
57.12	nuclear pharmacist; and or			
57.13	(2) (3) documentation that only	accelerator-produc	ced radioactive mate	erials
57.14	were used in the practice of nuclear pharm	nacy at a governme	ent agency or federa	lly
57.15	recognized Indian tribe before November	30, 2007, or at all o	other pharmacies be	fore
57.16	August 8, 2009, or an earlier date as notic	ed by the NRC; and	1	
57.17	(4) <u>a copy of</u> the individual's sta	ate pharmacy licens	ure or registration.	
57.18	[For text of sub	ps 3 and 4, see M.I	₹.]	
57.19 57.20	4731.3400 SPECIFIC LICENSE; SOU MANUFACTURE AND DISTRIBUTIO		ES FOR MEDICA	L USE;
57.21	Subpart 1. Approval criteria. An app	lication for a specif	ic license to manufa	acture
57.22	and distribute sources and devices contain	ning radioactive mat	terial to persons lice	nsed
57.23	according to parts 4731.4400 to 4731.452	7 for use as a calibr	ration, transmission	, or
57.24	reference source or for the uses listed und	er parts <u>4731.4404</u> ,	4731.4450, 4731.44	160, and
57.25	4731.4463 shall be approved if:			
58.1	[For text of iter	ms A to C, see M.R	<u>.]</u>	
58.2	[For text of sub	ps 2 and 3, see M.I	₹.]	
	4731.3400	57		

10/28/08 REVISOR SGS/PT RD3752 4731.3410 PROTOTYPE TESTS; CALIBRATION OR REFERENCE SOURCES 58.3 CONTAINING AMERICIUM-241, PLUTONIUM, OR RADIUM-226. 58.4 An applicant for a license under part 4731.3365 must, for any type of source that is 58.5 designed to contain more than 0.005 microcurie (185 Bq 0.185 kBq) of americium-241-58.6 0.005 microcurie (185 Bg) of plutonium, or 0.005 microcurie (185 Bg) of radium-226, 58.7 conduct prototype tests, in the order listed, on each of five prototypes of such source 58.8 58.9 that contains more than 0.005 microcurie (185 Bq 0.185 kBq) of americium-241, 0.005 microcurie (185 Bq) of plutonium, or 0.005 microcurie (185 Bq) of radium-226 as follows: 58.10 [For text of items A to F, see M.R.] 58.11 4731.3450 SERIALIZATION OF NATIONALLY TRACKED SOURCES. 58.12 Each licensee who manufactures a nationally tracked source after February 6, 2007, 58.13 shall assign a unique serial number to each nationally tracked source. Serial numbers must 58.14 be composed only of alphanumeric characters. 58.15 4731.3580 LIMITS FOR BROAD SCOPE LICENSES. 58.16 The following limits apply to specific licenses of broad scope issued under parts 58.17 4731.3500 to 4731.3580: 58.18 Column I Column II 58.19 **Radioactive Material** curies curies 58.20 Antimony-122 1 0.01 58.21 0.01 Antimony-124 1 58.22 0.01 Antimony-125 1 58.23 Arsenic-73 10 0.1 58.24 Arsenic-74 0.01 1 58.25 Arsenic-76 1 0.01 58.26 Arsenic-77 10 0.1 59.1 Barium-131 10 0.1 59.2 Barium-140 0.01 1 59.3

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59.4	Beryllium-7		<u>10</u>	<u>0.1</u>
59.5	Bismuth-210		0.1	0.001
59.6	Bromine-82		10	0.1
59.7	Cadmium-109		1	0.01
59.8	Cadmium-115m		1	0.01
59.9	Cadmium-115		10	0.1
59.10	Calcium-45		1	0.01
59.11	Calcium-47		10	0.1
59.12	Carbon-14		100	1
59.13	Cerium-141		10	0.1
59.14	Cerium-143		10	0.1
59.15	Cerium-144		0.1	0.001
59.16	Cesium-131		100	1
59.17	Cesium-134m		100	1
59.18	Cesium-134		0.1	0.001
59.19	Cesium-135		1	0.01
59.20	Cesium-136		10	0.1
59.21	Cesium-137		0.1	0.001
59.22	Chlorine-36		1	0.01
59.23	Chlorine-38		100	1
59.24	Chromium-51		100	1
59.25	Cobalt-57		<u>10</u>	<u>0.1</u>
59.26	Cobalt-58m		100	1
59.27	Cobalt-58		1	0.01
59.28	Cobalt-60		0.1	0.001
59.29	Copper-64		10	0.1
60.1	Dysprosium-165		100	1
60.2	Dysprosium-166		10	0.1
60.3	Erbium-169		10	0.1

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60.4	Erbium-171		10	0.1
60.5	Europium-152 9.2 h		10	0.1
60.6	Europium-152 13 y		0.1	0.001
60.7	Europium-154		0.1	0.001
60.8	Europium-155		1	0.01
60.9	Fluorine-18		100	1
60.10	Gadolinium-153		1	0.01
60.11	Gadolinium-159		10	0.1
60.12	Gallium-72		10	0.1
60.13	Germanium-71		100	1
60.14	Gold-198		10	0.1
60.15	Gold-199		10	0.1
60.16	Hafnium-181		1	0.01
60.17	Holmium-166		10	0.1
60.18	Hydrogen-3		100	1
60.19	Indium-113m		100	1
60.20	Indium-114m		1	0.01
60.21	Indium-115m		100	1
60.22	Indium-115		1	0.01
60.23	Iodine-125		0.1	0.001
60.24	Iodine-126		0.1	0.001
60.25	Iodine-129		0.1	0.01
60.26	Iodine-131		0.1	0.001
60.27	Iodine-132		10	0.1
60.28	Iodine-133		1	0.01
61.1	Iodine-134		10	0.1
61.2	Iodine-135		1	0.01
61.3	Iridium-192		1	0.01

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61.4	Iridium-194		10	0.1
61.5	Iron-55		10	0.1
61.6	Iron-59		1	0.01
61.7	Krypton-85		100	1
61.8	Krypton-87		10	0.1
61.9	Lanthanum-140		1	0.01
61.10	Lutetium-177		10	0.1
61.11	Manganese-52		1	0.01
61.12	Manganese-54		1	0.01
61.13	Manganese-56		10	0.1
61.14	Mercury-197m		10	0.1
61.15	Mercury-197		10	0.1
61.16	Mercury-203		1	0.01
61.17	Molybdenum-99		10	0.1
61.18	Neodymium-147		10	0.1
61.19	Neodymium-149		10	0.1
61.20	Nickel-59		10	0.1
61.21	Nickel-63		1	0.01
61.22	Nickel-65		10	0.1
61.23	Niobium-93m		1	0.01
61.24	Niobium-95		1	0.01
61.25	Niobium-97		100	1
61.26	Osmium-185		1	0.01
61.27	Osmium-191m		100	1
61.28	Osmium-191		10	0.1
62.1	Osmium-193		10	0.1
62.2	Palladium-103		10	0.1
62.3	Palladium-109		10	0.1

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62.4	Phosphorus-32		1	0.01
62.5	Platinum-191		10	0.1
62.6	Platinum-193m		100	1
62.7	Platinum-193		10	0.1
62.8	Platinum-197m		100	1
62.9	Platinum-197		10	0.1
62.10	Polonium-210		0.01	0.0001
62.11	Potassium-42		1	0.01
62.12	Praseodymium-142		10	0.1
62.13	Praseodymium-143		10	0.1
62.14	Promethium-147		1	0.01
62.15	Promethium-149		10	0.1
62.16	Radium-226		<u>0.01</u>	0.0001
62.17	Rhenium-186		10	0.1
62.18	Rhenium-188		10	0.1
62.19	Rhodium-103m		1,000	10
62.20	Rhodium-105		10	0.1
62.21	Rubidium-86		1	0.01
62.22	Rubidium-87		1	0.01
62.23	Ruthenium-97		100	1
62.24	Ruthenium-103		1	0.01
62.25	Ruthenium-105		10	0.1
62.26	Ruthenium-106		0.1	0.001
62.27	Samarium-151		1	0.01
62.28	Samarium-153		10	0.1
62.29	Scandium-46		1	0.01
63.1	Scandium-47		10	0.1
63.2	Scandium-48		1	0.01
63.3	Selenium-75		1	0.01

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63.4	Silicon-31		10	0.1
63.5	Silver-105		1	0.01
63.6	Silver-110m		0.1	0.001
63.7	Silver-111		10	0.1
63.8	Sodium-22		<u>0.1</u>	0.001
63.9	Sodium-24		1	0.01
63.10	Strontium-85m		1,000	10
63.11	Strontium-85		1	0.01
63.12	Strontium-89		1	0.01
63.13	Strontium-90		0.01	0.0001
63.14	Strontium-91		10	0.1
63.15	Strontium-92		10	0.1
63.16	Sulfur-35		10	0.1
63.17	Tantalum-182		1	0.01
63.18	Technetium-96		10	0.1
63.19	Technetium-97m		10	0.1
63.20	Technetium-97		10	0.1
63.21	Technetium-99m		100	1
63.22	Technetium-99		1	0.01
63.23	Tellurium-125m		1	0.01
63.24	Tellurium-127m		1	0.01
63.25	Tellurium-127		10	0.1
63.26	Tellurium-129m		1	0.01
63.27	Tellurium-129		100	1
63.28	Tellurium-131m		10	0.1
63.29	Tellurium-132		1	0.01
63.30	Terbium-160		1	0.01
64.1	Thallium-200		10	0.1
64.2	Thallium-201		10	0.1
64.3	Thallium-202		10	0.1

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64.4	Thallium-204		1	0.01
64.5	Thulium-170		1	0.01
64.6	Thulium-171		1	0.01
64.7	Tin-113		1	0.01
64.8	Tin-125		1	0.01
64.9	Tungsten-181		1	0.01
64.10	Tungsten-185		1	0.01
64.11	Tungsten-187		10	0.1
64.12	Vanadium-48		1	0.01
64.13	Xenon-131m		1,000	10
64.14	Xenon-133		100	1
64.15	Xenon-135		100	1
64.16	Ytterbium-175		10	0.1
64.17	Yttrium-90		1	0.01
64.18	Yttrium-91		1	0.01
64.19	Yttrium-92		10	0.1
64.20	Yttrium-93		1	0.01
64.21	Zinc-65		1	0.01
64.22	Zinc-69m		10	0.1
64.23	Zinc-69		100	1
64.24	Zirconium-93		1	0.01
64.25	Zirconium-95		1	0.01
64.26	Zirconium-97		1	0.01
64.27	Any radioactive material			
64.28	other than alpha-emitting			
65.1	by-product material not			
65.2	listed above		0.1	0.001

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## 4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE MATERIALS.

[For text of subps 1 and 2, see M.R.] 65.5 65.6 Subp. 3. License amendments. A licensee must apply for and receive a license amendment: 65.7 A. before the licensee receives, prepares, or uses radioactive material for a type 65.8 of use that is permitted under this chapter, but not authorized under the licensee's current 65.9 license issued under parts 4731.4400 to 4731.4527; 65.10 65.11 B. before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except: that the 65.12 licensee may permit an individual to work as an authorized user, an authorized nuclear 65.13 pharmacist, or authorized medical physicist for 60 days before being authorized on a 65.14 license if the individual is an authorized user, authorized nuclear pharmacist, or authorized 65.15 medical physicist for the same type of use: 65.16 (1) on a license issued by the NRC or an agreement state or on an 65.17 equivalent permit or license recognized by the commissioner, the NRC, or an agreement 65.18 state that authorizes the use of radioactive material in medical use or in the practice of 65.19 nuclear pharmacy; 65.20 (2) on a permit issued by an NRC or agreement state specific licensee of 65.21 broad scope that is authorized to permit the use of radioactive material in medical use 65.22 or in the practice of nuclear pharmacy; or 65.23 on a permit issued by an NRC master material licensee that is 66.1 (3)authorized to permit the use of radioactive material in medical use or in the practice of 66.2 nuclear pharmacy; 66.3 (1) for an authorized user, an individual who meets the requirements 66.4 under parts 4731.4415 and 4731.4433, subpart 1, item A; 4731.4436, subpart 1, item A; 66.5

66.6	4731.4443, subpart 1, item A; 4731.4444, item A; 4731.4445, item A; 4731.4458, subpart
66.7	1, item A; 4731.4461, item A; or 4731.4479, subpart 1, item A;
66.8	(2) for an authorized nuclear pharmacist, an individual who meets the
66.9	requirements under parts 4731.4413, subpart 1, item A, and 4731.4415;
66.10	(3) for an authorized medical physicist, an individual who meets the
66.11	requirements under parts 4731.4412, subpart 1, item A, and 4731.4415; or
66.12	(4) an individual who is identified as an authorized user, an authorized
66.13	nuclear pharmacist, or authorized medical physicist:
66.14	(a) -on a license issued by the NRC or an agreement state or on an
66.15	equivalent permit or license recognized by the commissioner, the NRC, or an agreement
66.16	state that authorizes the use of radioactive material in medical use or in the practice of
66.17	nuclear pharmacy; or
66.18	(b) -on a permit issued by an NRC or agreement state specific licensee
66.19	of broad scope that is authorized to permit the use of radioactive material in medical
66.20	use or in the practice of nuclear pharmacy;
66.21	[For text of items C to G, see M.R.]
66.22	Subp. 4. Notifications of changes.
66.23	A. A licensee must provide the commissioner a copy of the board certification
66.24	and written attestation signed by a preceptor, the license issued by the NRC or an
66.25	agreement state, the permit issued by an NRC or agreement state master material license
67.1	broad scope permittee, or the permit issued by an NRC or agreement state licensee
67.2	of broad scope for each individual no later than 30 days after the date that the licensee
67.3	allows, under subpart 3, item B, the individual to work as:
67.4	(1) -an authorized user;
67.5	(2) an authorized nuclear pharmacist; or

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10/28/08 REVISOR SGS/PT RD3752 (3) an authorized medical physicist. 67.6 B. A. A licensee must notify the commissioner by letter no later than 30 days 67.7 after: 67.8 (1) an authorized user, an authorized nuclear pharmacist, a radiation safety 67.9 67.10 officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change; 67.11 67.12 (2) the licensee's mailing address changes; (3) the licensee's name changes, but the name change does not constitute a 67.13 transfer of control of the license as described under part 4731.3075, subpart 2; 67.14 (4) the licensee has added to or changed the areas of use identified in the 67.15 application or license where radioactive material is used according to part 4731.4432 or 67.16 4731.4434; or 67.17 67.18 (5) the licensee permits an authorized user or an individual qualified to be a radiation safety officer under parts 4731.4411 and 4731.4415, to function as a 67.19 temporary radiation safety officer and to perform the functions of a radiation safety officer 67.20 as described under part 4731.4405, subpart 1, item C. 67.21 C. B. A licensee must mail required documents to the address under part 67.22 4731.0200, subpart 4. 67.23 Subp. 5. Exemptions; broad scope license. A licensee possessing a Type A specific 68.1 license of broad scope for medical use, issued under parts 4731.3500 to 4731.3580, is 68.2 exempt from: 68.3 A. subpart 2, item D, regarding the need to file an amendment to the license for 68.4 medical use of radioactive materials under part 4731.4404; 68.5 B. subpart 3, item B; 68.6

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68.7	C. subpart 3, item E, regarding	g additions to or cha	anges in the areas of	use at the
68.8	addresses identified in the application	or license;		
68.9	D. subpart 4, item A, subitem	(1), for an authoriz	ed user, an authorized	<u>l nuclear</u>
68.10	pharmacist, or an authorized medical	physicist;		
68.11	E. subpart 4, item B, subitem	(1), for an authorize	ed user, an authorized	l nuclear
68.12	pharmacist, or an authorized medical	<del>physicist;</del>		
68.13	F.E. subpart 4, item BA, sub	item (4), regarding	additions to or chang	es in the
68.14	areas of use identified in the applicati	on or license where	radioactive material	is used
68.15	under part 4731.4432 or 4731.4434; a	and		
68.16	G. F. part 4731.4410, item A.			
68.17	[For text of	subps 6 and 7, see	<u>M.R.]</u>	
68.18 68.19	4731.4409 PROCEDURES FOR A DIRECTIVE.	DMINISTRATION	NS REQUIRING W	RITTEN
68.20	[For tex	t of item A, see M.	<u>R.]</u>	
68.21	B. At a minimum, the procedure	s required by item A	A must address the fo	llowing
68.22	that are applicable to the licensee's us	e of radioactive ma	terial:	
68.23	(1) verifying the identity of the	ne patient or human	research subject;	
69.1	(2) verifying that the adminis	stration is in accord	ance with the treatme	ent
69.2	plan, if applicable, and the written di	rective;		
69.3	(3) checking both manual and	l computer-generate	d dose calculations; a	ind
69.4	(4) verifying that any comput	ter-generated dose of	calculations are corre	ctly
69.5	transferred into the consoles of therap	eutic medical units	authorized under part	t 4731.4404
69.6	<u>or</u> 4731.4463.			
69.7	[For tex	t of item C. see M.	R.]	

[For text of item C, see M.R.]

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# 69.8 4731.4420 MEASURING ACTIVITY OF UNSEALED RADIOACTIVE 69.9 MATERIAL; INSTRUMENTS REQUIRED.

69.10	A. For direct measurements performed according to part 4731.4422, a licensee			
69.11	must possess and use instrumentation to measure the activity of unsealed radioactive			
69.12	material before it is administered to a patient or human research subject.			
69.13	B. A licensee must ealibrate check and test the instrumentation required under			
69.14	item A according to nationally recognized standards or the manufacturer's instructions-			
69.15	and at the following intervals as applicable:			
69.16	(1) check each instrument for constancy at the beginning of each day of use;			
69.17	(2) test each instrument for linearity upon installation and at intervals not			
69.18	to exceed three months thereafter;			
69.19	(3) test each instrument for accuracy upon installation and at intervals			
69.20	not to exceed 12 months thereafter; and			
69.21	(4) test each instrument for geometry dependence upon installation.			
69.22	C. A licensee must-retain a record of each instrument calibration required under			
69.23	item B according to part 4731.4502, subpart 1 also perform the required checks and tests			
69.24	in this part following adjustment or repair of the instrument.			
70.1	D. The licensee must keep a record of geometry dependence for the duration of			
70.2	the use of the instrument and must retain a record of all other instrument checks and tests			
70.3	for three years. The records must include:			
70.4	(1) the model and serial number of the instrument;			
70.5	(2) the date of the check or test;			
70.6	(3) the results of the check or test; and			
70.7	(4) the name of the individual performing the check or test.			

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70.8 70.9	4731.4422 DETERMINATION OF DOSAGES; UNSEALED RADIOACTIVE MATERIAL.
70.10	A. A licensee must determine and record the activity of each dosage before
70.11	medical use.
70.12	B. For a unit dosage, the determination under item A must be made by:
70.13	(1) direct measurement of radioactivity; or
70.14	(2) a decay correction, based on the activity or activity concentration
70.15	determined by:
70.16	(a) a manufacturer or preparer licensed under part 4731.3395 or
70.17	equivalent requirements of the NRC or an agreement state; or
70.18	(b) an NRC or agreement state licensee for use in research according
70.19	to the radioactive drug research committee-approved protocol or an investigational new
70.20	drug protocol accepted by the Food and Drug Administration-; or
70.21	(c) <u>a PET radioactive drug producer licensed according to part</u>
70.22	4731.3065, subpart 7, or equivalent requirements of the NRC or an agreement state.
70.23	C. For other than unit dosages, the determination under item A must be made by:
70.24	(1) direct measurement of radioactivity;
71.1	(2) a combination of measurement of radioactivity and mathematical
71.2	calculations; <del>or</del>
71.3	(3) a combination of volumetric measurements and mathematical
71.4	calculations, based on the measurement made by a manufacturer or preparer licensed
71.5	under part 4731.3395 or equivalent requirements of the NRC or an agreement state-; or
71.6	(4) <u>a PET radioactive drug producer licensed according to part 4731.3065</u> ,
71.7	subpart 7, or equivalent requirements of the NRC or an agreement state.

D. Unless otherwise directed by the authorized user, a licensee may not use a
dosage if the dosage does not fall within the prescribed dosage range or if the dosage
differs from the prescribed dosage by more than 20 percent.

E. A licensee must retain a record of the dosage determination required underthis part according to part 4731.4503.

#### 71.13 **4731.4429 DECAY-IN-STORAGE.**

71.14 A. A licensee may hold radioactive material with a physical half-life of less

than <u>or equal to 120</u> days for decay-in-storage before disposal without regard to its

radioactivity, if the licensee: adheres to the requirements of part 4731.2405.

71.17 (1) -monitors radioactive material at the surface before disposal;

71.18 (2) -determines that its radioactivity cannot be distinguished from the

71.19 background radiation level with an appropriate radiation detection survey meter set on its

71.20 most sensitive seale and with no interposed shielding; and

71.21 (3) -removes or obliterates all radiation labels, except for radiation labels
 71.22 on materials that are within containers and that will be managed as biomedical waste

71.23 after they are released from the licensee.

71.24 B. A licensee must retain a record of each disposal under item A according
71.25 to part 4731.4508.

### 4731.4432 UNSEALED RADIOACTIVE MATERIAL; UPTAKE, DILUTION, AND EXCRETION STUDIES; WRITTEN DIRECTIVE NOT REQUIRED.

72.3 Except for quantities that require a written directive under part 4731.4408 or
72.4 4731.4409, a licensee may use any unsealed radioactive material prepared for medical use
72.5 for uptake, dilution, or excretion studies that is:

A. obtained from a manufacturer or preparer licensed under part 4731.3395 or
equivalent requirements of the NRC or an agreement state; or a PET radioactive drug

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72.8	producer licensed according to part 47	31.3065, subpart 7, or	equivalent requirem	nents of
72.9	the NRC or an agreement state;			
72.10	B. excluding production of PET radionuclides, prepared by:			
72.11	(1) an authorized nuclear pharmacist;			
72.12	(2) a physician who is an auth	orized user and who n	neets the requirement	nts
72.13	of part 4731.4436 or parts 4731.4436, subpart 1, item C, subitem (1), unit (b), subunit vii,			
72.14	and 4731.4443; or			
72.15	(3) an individual under the su	pervision, according to	) part 4731.4407, of	2
72.16	the authorized nuclear pharmacist in su	ubitem (1) or the physic	cian who is an auth	orized
72.17	user in subitem (2);			
72.18	C. obtained from and prepared fo	r a commissioner, NR	C, or agreement star	te
72.19	licensee for use in research according	to a radioactive drug re	esearch committee-a	pproved
72.20	protocol or an investigational new drug protocol accepted by the Food and Drug			
72.21	Administration; or			
72.22	D. prepared by the licensee for us	e in research accordin	g to a radioactive d	rug
72.23	research committee-approved applicati	on or an investigationa	ll new drug protocol	accepted
72.24	by the Food and Drug Administration.			
72.25 72.26	4731.4434 UNSEALED RADIOAC LOCALIZATION STUDIES; WRIT			
73.1	Except for quantities that require a	written directive under	part 4731.4408, a l	icensee
73.2	may use any unsealed radioactive mate	erial prepared for med	ical use for imaging	and
73.3	localization studies that is:			
73.4	A. obtained from a manufacturer	or preparer licensed u	nder part 4731.3395	or
73.5	equivalent requirements of the NRC of	r an agreement state of	a PET radioactive	drug

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73.6	producer licensed according to part 4731.3	3065, subpart 7, or e	quivalent requireme	nts of
73.7	the NRC or an agreement state;			
73.8	B. excluding production of PET radio	nuclides, prepared b	by:	
73.9	[For text of subite	ms (1) to (3), see M	. <u>R.]</u>	
73.10	[For text of item	ns C and D, see M.R	]	
73.11 73.12	4731.4435 PERMISSIBLE MOLYBDE <u>STRONTIUM-85</u> CONCENTRATION.		<u>FIUM-82, AND</u>	
73.13	A. A licensee may not administer to	humans a radiophar	maceutical that	
73.14	contains:			
73.15	(1) more than 0.15 microcurie of mo	lybdenum-99 per m	nillicurie of	
73.16	technetium-99m (0.15 kilobecquerel of m	olybdenum-99 per r	negabecquerel of	
73.17	technetium-99m)-; or			
73.18	(2) more than 0.02 microcuries o	f strontium-82 per r	nillicurie of	
73.19	rubidium-82 chloride injection (0.02 kBq	of strontium-82 per	MBq of rubidium-8	2
73.20	chloride); or			
73.21	(3) more than 0.2 microcuries of s	strontium-85 per mil	licurie of rubidium-	82
73.22	chloride injection (0.2 kBq of strontium-8	5 per MBq of rubidi	um-82).	
73.23	B. A licensee that uses molybdenum	-99/technetium-99m	generators for	
73.24	preparing a technetium-99m radiopharmad	ceutical must measu	re the molybdenum-	99
74.1	concentration of the first eluate after receipt	pt of a generator to	demonstrate complia	ince
74.2	with item A.			
74.3	<u>C.</u> <u>A licensee that uses a strontium-8</u>	2/rubidium-82 gener	rator for preparing a	
74.4	rubidium-82 radiopharmaceutical must, be	fore the first patient	use of the day, meas	sure the
74.5	concentration of strontium-82 and strontiu	m-85 radionuclides	to demonstrate com	oliance
74.6	with item A.			

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74.7	$\underline{C}$ . <u>D</u> . If a licensee is required to m	easure the molybden	um-99 concentration	or
74.8	strontium-82 and strontium-85 concent	rations, the licensee r	nust retain a record c	of each
74.9	measurement according to part 4731.45	09.		
74.10 74.11	4731.4440 UNSEALED RADIOACT REQUIRED.	IVE MATERIAL; `	WRITTEN DIREC	ΓΙVΕ
74.12	A licensee may use any unsealed rac	lioactive material pre	pared for medical us	e and
74.13	for which a written directive is required	I that is:		
74.14	A. obtained from a manufacturer of	r preparer licensed u	nder part 4731.3395	or
74.15	equivalent requirements of the NRC or	an agreement state;	or a PET radioactive	drug
74.16	producer licensed according to part 473	1.3065, subpart 7, or	equivalent requirem	ents of
74.17	the NRC or an agreement state;			
74.18	B. excluding production of PET ra	dionuclides, prepare	d by an authorized	
74.19	nuclear pharmacist, a physician who is	an authorized user an	nd meets the requirer	nents
74.20	under part 4731.4436 or 4731.4443, or	an individual under t	he supervision of eith	her, as
74.21	specified under part 4731.4407;			
74.22	C. obtained from and prepared by	a commissioner, NR	C, or agreement state	e
74.23	licensee for use in research according to	o an investigational n	ew drug protocol acc	cepted
74.24	by the Food and Drug Administration;	or		
74.25	D. prepared by the licensee for use	e in research accordin	ng to an investigation	nal
74.26	new drug protocol accepted by the Foo	d and Drug Administ	ration.	
75.1 75.2	4731.4509 MOLYBDENUM-99 <u>, STR</u> <u>CONCENTRATION</u> RECORDS.	CONTIUM-82, and	STRONTIUM-85	
75.3	A licensee must maintain a record of	f the molybdenum-9	9 concentration <u>or</u>	
75.4	strontium-82 and strontium-85 concentre	ration tests required u	under part 4731.4435	, item B,
75.5	for three years. The record for each me	asured elution of teel	metium-99m must in	clude:
75.6	A. for each measured elution of tee	chnetium-99m:		

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75.7	(1) the ratio of the measure	es <del>,</del> expressed as micro	curies of molybdenur	n
75.8	per millicurie of technetium techne	<u>tium-99m, (</u> or kilobec	querel of molybdenun	n-99 per
75.9	megabecquerel of technetium-99m	<u>);</u>		
75.10	$\mathbf{B}$ . (2) the time and date of the	e measurement; and		
75.11	$ \underbrace{\mathbf{C}}_{\cdot} (\underline{3}) $ the name of the individ	ual who made the mea	surement-; and	
75.12	B. for each measured elution of	of rubidium-82:		
75.13	(1) the ratio of the measure	es expressed as micro	curies of strontium-82	<u>-</u>
75.14	per millicurie of rubidium-82 (or k	Bq of strontium-82 pe	r MBq or rubidium-82	2), and
75.15	microcuries of strontium-85 per mi	llicurie of rubidium-82	2 (or kBq of strontium	n-85 per
75.16	MBq or rubidium-82);			
75.17	(2) the time and date of the	e measurement; and		
75.18	(3) the name of the individ	ual who made the mea	surement.	
75.19	<b>REPEALER.</b> Minnesota Rules, p.	arts 4731.3035; 4731.	3230, subparts 2 and	<u>3;</u>
75.20	4731.3305; 4731.3320; and 4731.4	508, are repealed.		