[ed: first typed outline - nlm]

Part 35--Medical use of Byproduct Material

35.1		Purpose and Scope.	35.1. also refer to P19, 20, 21, 30.
35.2		Conformance requirement.	35.2
35.3		Definitions	
	a	medical use means the use of BPM for the diagnostic, prognostic, or therapeutic benefit of a human being or animal	
	b	human	
	b	human use means the internal or external administration of BPM, or the radiation therefrom, to human beings.	
	c	physician means. . .	35.3a
	d	supervision means. . .	RG10.8p3
	e	in vitro medical use means the use of BPM for the diagnostic or prognostic benefit of a human being or animal. It does not include human use or animal use.	
	f	therapy misadministration means. . .	35.41 except d
	g	animal use means the internal or external administration of BPM, or the radiation therefrom, to animals.	
		management means. . .	RG 8.18p2
	h	person means. . .	20.3a7 and 11
	i	individual means. . .	
35.4		Application forms	35.4
35.5		ALARA commitment	RG10.8P1.4, RG8.18, RG8.10, NUREG-0267, TP608-4
35.6		Training per 19.12 and 19.13	
35.7	a	Facility shall be adequate and maintained	30.33
	b	Equipment shall be adequate, maintianed, and calibrated per requirements herein	30.33
35.8		terms and conditions	30.34 except g
35.9		license expiration	30.36
35.10		renewal	30.37
35.11		amendments	30.38

35.12	Commission action on applications	30.39
35.13	transfer of BPM	30.41
35.14	records requirements and format	30.51
35.15	right to inspect	30.52
35.16	right to check facility and equipment	30.53
35.17	right to modify licenses	30.61
35.18	right to recall material	30.62
35.19	violations	30.63, add fine structure.
35.20	unless specifically exempted herein, see also P19, 20, 21, 30	
35.21	sealed source checks	
a	leak test	35.14e
b	inventory	35.14f
35.22	records of receipt	30.51
35.23	records of transfer and disposal	30.51
35.24	dose calibrator method of calibration	RG10.8AppD2
35.25	Survey meter calibration	RG10.8AppD1, TP608-4p8
35.26	LSC, SCA calibration	no known references
35.27	Package receipt procedures	10CFR20.205, RG10.8p8
35.28	Right of visiting physicians	SLC23, SLC62
35.29	Decay in Storage method	NMSS letter
35.30	decontrol of LSCW	20.306
35.31	sewer disposal	20.303
35.32	patient excreta	20.303d
30.33	see 170 for fees	
30.34	personnel monitoring per part 20	
30.35	records retention period two years unless otherwise noted.	
30.36	right to request exemption	34.51

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	Requirements for Group E users	exempt and registration kits, 35.31a1-6, 31.11a1-7
35.50	Eligibility. any person may apply for a group E license	
35.51	Authorized suppliers. manufacturer per 32.70 or 32.71, 35.22 herein.	
35.52	Authorized use. only per package insert. only for human use or in vitro medical use. Not for animal use.	35.11d1-7
35.53	Inventory. store in original container.	35.31c1,2, 31.11a1-7, 31.11c1
35.54	transfer and disposal	
a	another Group E licensee if in original container	
b	licensed rad waste company	
c	sewer	20.303
d	house waste	35.31c5. exempt the mock source.
e	decay in storage	
f	obliterate all radiation labels	
g	in such manner as to not be incorporated in food for humans or animals	
35.55	all use described above is exempted from training and record keeping requirements in this part.	consider release from receipt, transfer, disposal records.

	Requirements for Group I users	35.100 I (uptake, dilution, excretion)
35.100	Eligibility. any physician, management if in a hospital or clinic.	
35.101	Authorized suppliers. manufacturer per 32.72 or 32.73, 35.22 herein.	
35.102	Authorized use. per package insert. only for human use. not for animal use. if not for indications on package insert, nevertheless shall comply re form, dose, range.	35.14b6
35.103	Inventory. as needed. also, calibration and reference sources.	NRC313M, 35.14d.
35.104	Transfer and disposal.	
a	another Group I licensee if in original container	
b	licensed rad waste company	
c	sewer	
d	decay in storage	
e	obliterate all radiation labels	
f	in such manner as to not be incorporated in food for humans or animals.	

	Requirements for Group II users	35.100 II (imaging, unit doses only)
35.200	Eligibility. any physician, management if in a hospital or clinic.	
35.201	Authorized suppliers. manufacturer per 32.72 or 32.73. 35.22 herein.	
35.202	Authorized use. per package insert. only for human use. not for animal use. if not for indications on package insert, nevertheless shall comply with form, dose, range.	35.14b6
35.203	Inventory. as needed. also, calibration and reference sources.	NRC313M, 35.14d
35.204	Transfer and disposal.	
a	another Group II licensee if in original container	
b	licensed rad waste company	
c	sewer	
d	decay in storage	
e	obliterate all radiation labels	
f	in such manner as to not be incorporated in food for humans or animals.	
35.205	?xenon and particulates?	

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	Requirements for Group III users	35.100 III (imaging, generators)
35.300	Eligibility. any physician, management if in a hospital or clinic.	?training and experience?
35.301	Authorized suppliers. manufacturer per 32.73. 35.22 herein. cold kits only from authorized supplier.	35.14b2
35.302	Authorized use. per package insert. only for human use. not for animal use. if not for indications on package insert, nevertheless shall comply with form, dose, range.	35.14b6
35.303	Inventory. specify total activity of each parent type, including both active generator and generators in storage. also calibration and reference sources.	NRC313M 35.14d
35.304	Transfer and disposal.	
a	another Group III licensee if in original container	applies to both cold kits and generators
b	licensed rad waste company	
c	sewer	
d	decay in storage	
e	obliterate all radiation labels	
f	in such manner as to not be incorporated in food for humans or animals.	
30.305	?xenon and particulates?	

add 30.34g (Mo)

	Requirements for Group IV users	35.100 IV (therapy below 30mCi)
35.400	Eligibility. any physician, management if in a hospital or clinic.	?training and experience?
35.401	Authorized suppliers. manufacturer per 32.72, 35.22 herein	
35.402	Authorized use. per package insert. only for human use. not for animal use.	
35.403	Inventory. as needed. also, calibration and reference sources.	NRC313M 35.14d
35.404	Transfer and disposal	
a	another group IV licensee if in original container	
b	licensed rad waste company	
c	sewer	
d	decay in storage	
e	obliterate all radiation labels	
f	in such manner as to not be in corporated in food for humans or animals.	
35.405	?fume hood for iodine?	RG8.23P1.14
35.406	misadministration	35.42, 35.44, 35.45.

	Requirements for Group V users	35.100 V (therapy above Group IV)
35.500	Eligibility. any physician and hospital management.	?training and experience?
35.501	Authorized suppliers. manufacturer per 32.72, 35.22 herein.	
35.502	Authorized use. per package insert. only for human use. not for animal use.	
35.503	Inventory. as needed. also calibration and reference sources.	NRC 313M 35.14d
35.504	Transfer and disposal	
a	another group V licensee if in original container	
b	licensed rad waste company	
c	sewer	
d	decay in storage	
e	obliterate all radiation labels	
f	in such manner as to not be incorporated in food for humans or animals.	
35.505	fume hood for iodine storage. double containment.	RG8.23?1.14
35.506	misadministration	35.42, 35.44, 35.45
35.507	release patient only when less than 30mCi residual activity	SLC53

	Requirements for Group VI users	new group. diagnostic devices contained in 35.100 VI
35.600	Eligibility. any physician, management if in a hospital or clinic.	training required at 35.13b
35.601	Authorized suppliers. manufacturer per 32.74, 35.22 herein.	
35.602	Authorized use. per package insert.	
35.603	Inventory. Specify total activity for each type of use desired. Include both active and replacement source in storage. also calibration and reference sources.	35.14d
35.604	Transfer and disposal.	
a	another group VI licensee authorized for the specific device and source therein.	
b	licensed rad waste company	
c	supplier	
d	transfer to NRC or agreement state	
35.605	note sealed source requirements at 35.21 herein.	leak test and inventory
35.606	equipment shall be adequate and maintained and source shall be replaced per instructions of supplier.	

	Requirements for Group VII users	new group. therapy sealed sources in 35.100 VI
35.700	Eligibility. any hospital and physician.	training required at 35.13b
35.701	Authorized suppliers. manufacturer per 32.74, 35.22 herein.	
35.702	Authorized use. only as specified in group VII. Only for human use. not for animal use.	
35.703	Inventory. Specify total activity and supplier for each type of use listed in group VII. also calibration and reference sources.	35.14d
35.704	Transfer and Disposal.	
a	another group VII licensee authorized for the specific source,	
b	licensed rad waste company	
c	supplier	
d	transfer to NRC or agreement state	
35.705	note sealed source requirements at 35.21 herein.	leak test and inventory
35.706	survey patient, room, and count seeds and compare to number implanted before releasing patient.	35.14b5vii
35.707	Misadministration	35.42, 35.44, 35.45

	Requirements for Group VIIIusers	new group. teletherapy.
35.800	Eligibility. Any physician. also management if in a hospital or clinic	training required at 35.13b. List all users per TP608-4p22-24
35.801	Authorized suppliers. manufacturer per part 30, or 35.22 herein.	
35.802	Authorized use. Only as specified in group VIII. Does not authorized working on the unit, or relocation.	add research, training, materials. 0339p13PE, PIV. SLC19B. TP608-4
35.803	Inventory. Specify total activity for each source, and RHM. also calibration and reference sources. also U for shielding.	0339p6 35.14d SLC21
35.804	Site specific information.	
a	drawings, plans, elevations	TP608-4p10,11; 0339p6C,10D3
b	shielding	TP608-4p12, 35-37
c	interlocks	SLC17, 18
35.805	Machine specific information and survey	0339p17, TP608-4p11
35.806	Equipment	
a	Two calibrated survey meters, one on hand at all times.	
b	area monitor	SLC24
c	dosimetry system	
d	spot check system	
e	leak test system	
f	viewing system	
35.807	Post normal operating and emergency procedures	0339p12, 608-4p13
35.808	Full calibration	
a	when	35.21a
b	what is to be calibrated	35.21b
c	how the calibration is to be done	35.21c,d
d	instrumentation	35.23
e	who may do	35.21e, 35.24
35.809	Spot checks	
a	when	35.22a
b	what is to be checked	35.22b
c	instrumentation	35.23b
d	how the check is to be done	35.22c
e	who may do	35.22c

Requirements for Group VIII users continued

35.810	Head survey procedure	TP608-4,p38,p45
35.811	Environs survey, interlocks, et alia	TP608-4p40, SLC19
35.812	Misadministration	35.42, 35.44, 35.45
35.813	Five year service and maintenance	SLC20, 0339p19B
35.814	Isotope committee	TP608-4p38,p45