RETURN CONCURRENCE COPY TO NMCELROY, 396-SS

AA73-1
PDR
M. 32

07 16 85

The Honorable Morris K. Udall, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

The Nuclear Regulatory Commission (NRC) is proposing to revise its regulations that apply to the medical uses of radioisotopes.

The NRC has licensed about 2200 medical facilities and 300 physicians in private practice to use radioactive materials to diagnose and to treat patients. The NRC receives about 100 new applications, 500 renewal requests, and 1800 license amendment requests each year.

Due to the evolution in the medical use of radioisotopes over the last thirty years, radiation safety requirements that apply to medical use are found throughout the regulations, regulatory guides, standard license conditions and other sources. Therefore, license applicants must submit a substantial amount of information to show that all radiation safety requirements will be met, including a description of the radiation safety procedures used in meeting the requirements, available facilities and equipment, and key users' training and experience. The Agency reviews the applicant's program before issuing a license. The Agency must approve any change in a licensee's radiation safety program.

The primary purpose of the proposed revision is to consolidate the requirements. Under the proposal, all requirements would be clarified and published in one place, 10 CFR Part 35 of NRC regulations. The revised regulation would give both licensees and NRC staff a clearer basis for licensing, operation, and inspection activities. This will make regulation simpler and more efficient for both licensees and the Agency.

OFFICE							
SURNAME							
DATE							

OFFICIAL RECORD COPY

The NRC staff will continue to review the applicant's radiation safety procedures to determine whether they are adequate to meet the requirements of the regulations. However, to permit licensees to make prompt use of new safety methods and to adjust their radioactive materials programs to meet new needs caused by changes in demand for patient care services or patient load, licensees would be able to make minor changes in their radiation safety programs without NRC review provided the regulations are met. Changes would require approval of the licensee's Radiation Safety Officer, and at a hospital, its Radiation Safety Committee.

Some types of program changes that would still require a formal NRC review and license amendment include adding new physician users, new medical uses, and new locations of use.

The proposed revision of 10 CFR Part 35 of NRC regulations will be published for public comment in the Federal Register. The proposed regulation and a draft regulatory guide will be mailed to current licensees and other interested individuals for comment.

Sincerely,

(Signed) John G. Davis

John G. Davis, Director
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Proposed revision of 10 CFR Part 35, "Medical Use of Byproduct Material"
2. Draft Public Announcement

cc: Rep. Manual Lujan

Identical letters sent to:
The Honorable Edward J. Markey, Chairman
Subcommittee on Energy Conservation and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, D. C. 20515

cc: Rep. Carlos Moorhead

The Honorable Alan K. Simpson, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, D. C. 20510

cc: Senator Gary Hart

DISTRIBUTION
FCML r/f
FC Central File
NMSS r/f
NLMcElroy
JHickey
VLMiller
DRChapell
RECunningham
DBMausshardt
JGDavis
JDelmedico-OCA

*See previous concurrence

OFFICE	FCML	*FCML	*FCML	DD/FC	D/FC	DD/NMSS	D/NMSS
SURNAME	NLMcElroy:ht	JHickey	VLMiller	DRChapell	RECunningham	DBMausshardt	JGDavis
DATE	06/ /85	06/ /85	06/ /85	06/ /85	06/25/85	06/13/85	06/ /85

Walker
Walker
dcb
nlm

AA 73-1
PDR
B.1

Source Documents for the Revision of Part 35

The following list identifies specific sections of source documents that were used in the revision of 10CFR Part 35 "Human Use of Byproduct Material." The list is not complete because it only identifies principle sources. Informal contacts with recognized experts, the regulated industry, and NRC staff are not identified. There is no inference to be drawn from the order of appearance.

Source Documents

10CFR Part 35

United States Pharmacopeia XX

FRN's, NRC letters

NMSS Mobile Service checklist

AAPM petition

Teletherapy Calibration Meeting

Code of Practice for x-ray therapy

ANSI Guidelines for maintaining Cobalt-60

ANSI Procedures for periodic inspection

ANSI Dose Calibrators

ANSI Instrumentation test and calibration

Regulatory Guide 8.18 ALARA at Medical Institutions

Material Licensing Branch Standard Conditions

Draft Regulatory Guide for Teletherapy

Regulatory Guide 10.8 Medical Programs

nlm 3-15-83

Source Documents for Revision of Part 35

Source	Disposition
35.1 Purpose and Scope	35.1
35.2 License Required	35.2
35.3 Definitions	35.15; human use and physician redefined; others words added
35.4 Application form	35.16
35.11 Specific licenses. . .institutions	
a meet 30.33	35.1 requires compliance with Part 30
b Medical Isotopes Committee	35.31
c Adequate facilities	deleted; not radiation safety
d AU has T&E	Subpart J
e Previous experience	Subpart J
35.12 Specific licenses. . .individuals	
a1 meet 30.33	35.1 requires compliance with Part 30
2 outside a medical institution	35.16
3 access to a hospital	deleted; not radiation safety
4 AU has T&E	Subpart J
b1 use at a medical institution is limited	35.35; 35.80
2 bring in and take out	35.80; 20.301
3 medical institution has no license	deleted; would interfere with medical care at an institution with no AU
35.13 Specific license. . .Sealed Source	
a meet 30.33	35.1 requires compliance with Part 30
b AU has T&E	Subpart J
35.14 Specific license for groups	
a1 meet 35.11, 35.12, or 35.13	see discussion above
2 AU has T&E	Subpart J
3 AU has T&E	Subpart J
4 adequate instruments	implicit by requiring certain measurements
5 adequate procedures	35.33; guidance given in new RG10.8
b1 to 3 limits authorized suppliers	35.49
4i follow generator and kit instructions	35.200
ii measure Mo-99 concentration	35.204
iii dont use if contaminated	35.204; limit changed
iv recordkeeping	35.204a
5i leak test sealed sources	35.59b
ii MDA .005uCi	35.59c3 and d
iii report leakers	35.59e
iv follow instructions	35.400; 35.500
v quarterly inventory	35.59g
vi don't open Co-60 cells	deleted; not allowed by instructions
vii count sources and survey implant patients	35.404a

35.14b6	if for diagnostic procedure other than in labeling, comply with chemical, physical form, route, dosage	35.100b and 35.200b; chemical deleted because it would be a new, unlisted pharmaceutical must request on new application form
c	allows in-vitro general license without filing NRC-483 application	35.58; sealed sources only; 6mCi
d	may receive sources for calibration and reference	
e1	leak test	35.59b
	exceptions	35.59f
2	MDA .005uCi	35.59c
3	report leakers	35.59e
f1	follow instructions	35.59a
2	quarterly inventory	35.59g
35.21	Teletherapy full calibration	
a	when	35.632a
b	what	35.632b
c	how	35.632d
d	decay each month	35.632e
e	qualified expert	35.632f
35.22	Teletherapy spot checks	
a	each month	35.633a
b	what	35.633b
c	qualified expert	35.633d and e
35.23	calibrate instruments	
a	full calibration	35.630a
b	spot check	35.630b
35.24	qualified expert	
a	certified	35.961a
b	T&E	35.961b; changed
c	footnote	35.29
35.25	Records	
a	full calibration and instruments	35.630c and 35.632g
b	spot check and instruments	35.630c and 35.633j
c	qualified expert T&E	35.33b5ii
35.31	General License	deleted; pharmaceuticals into 35.100a
35.41	Definitions of misadministration	35.15
35.42	Reports of therapy misadministration	35.37a and b
35.43	Reports of diagnostic misadministration	35.37c
35.44	Records of all misadministrations	35.37d
35.45	Rights and duties of licensees	35.45e
35.100	Groups of medical uses	
a	Group I	35.100a; I-125 as oleic acid and sodium iothalamate deleted
b	Group II	35.200a; Hg-203 as chlormerodrin deleted
c	Group III	35.200a; added generators for extraction, Tc-99m as disofenin or succimer
d	Group IV	35.300a
e	Group V	35.300a
f	Group VI	35.400 and 35.500; added iridium and tantalum as wire

United States Pharmacopeia XXp765 recommends .15uCi 99Mo/mCi Tc-99m	35.204
FRN February 9, 1979 Policy Statement 1. Continue to regulate for radiation safety of workers and public 2. Regulate safety of patients where justified by risk to patient and voluntary compliance is inadequate 3. Minimize intrusion into medical judgment	Followed
FCMS ltr May 3, 1979 Approved suppliers	35.49
FCMS ltr June 4, 1981 Decay in storage	35.92
OSD ltr August 4, 1980 Mo-99 breakthrough	35.204
IE bulletin September 15, 1980 Teletherapy timer accuracy	35.632b4 and 5
FRN December 2, 1982 AU T&E	Subpart J
FRN May 27, 1982 Regionalization	35.16
FRN September 13, 1982 Radiation Safety Committee at institutions	35.31
FRN January 18, 1983 Teletherapy room monitor and inspection and servicing	35.621, 35.645
NMSS May 10, 1979 checklist "Information to be submitted for a Mobile Nuclear Medicine License"	
3. Client management authorization	35.35b
5. Check of transported instruments	35.80d
6. Closeout survey	35.80e; deleted wipe test
7. Secure the material	35.80c
FRN September 1, 1981 Measurement of dosage	35.53
IE ltr April 16, 1979 Syringe and vial shields	35.60, 35.61
AAPM petition docketed November 13, 1981	
para 1	35.630a1
para 2	35.630a2
para 3	deleted; check sources may indicate need for calibration when not needed
para 4	35.630
Meeting January 21, 1982 re AAPM petition (Rodenbeck)	several experts said intercomparison is a good check

Code of practice for x-ray therapy linear accelerators (Medical Physics v2 n3 p110, May 1975)	
IIB reserve one dosimeter to use as primary local standard	35.632c
IIIA safety survey	35.642a
IIIB2 head survey	35.641a1
IIIC area survey	35.641a2
IVC coincidence of photon/light field	35.632b2
IVG verification of beam flatness	35.632b3
VII routine checks	35.633
ANSI N449-1974 Guidelines for Maintaining Cobalt-60. . . Teletherapy equipment	
3 General considerations (training of service personnel)	35.645b
4.1.1 Source condition indicator check	35.633g3
4.1.2 Door interlock	35.633g1
4.1.4 Source surface distance	35.633b4
4.1.5 Spot check and full calibration	35.632, 35.633
4.1.6 Timer	35.632b4 and 5, 35.633b1 and 2
4.1.7 Congruence of light and radiation field	35.632b2 and 35.633b3
4.1.11 Beam orientation interlocks	35.633g2
4.1.12 Central axis indicators	35.632b6 and 35.633b4
4.1.14 Source leakage	35.59e; reduced to .005uCi
4.1.19 Source housing leakage	35.641a1
ANSI N449.1-1978 Procedures for periodic inspection	consulted
ANSI N42.13-1978 Calibration and Usage of Dose Calibrator Ionization Chambers	
4.2.1 Geometry	35.50a4
4.2.2 Activity ranges	35.50a3
4.5.1 Reference source checks	35.50a1
4.5.2 Linearity check	35.50a3
4.5.5 Frequency of calibration	35.50a and b
4.6.1 Accuracy	35.50c
4.6.3 Corrective action	35.50c
ANSI N323-1978 Radiation protection instrumentation test and calibration	
4.2.2.1 Accuracy	35.51c
4.5 Records	35.51e
4.7.1 Primary calibration frequency	35.51a
4.7.3 Performance test frequency	35.51d
Regulatory Guide 8.18 ALARA at medical institutions	general guidance; not incorporated
Material Licensing Branch Standard Conditions Sept. 1979	
SLC-10 leak test	35.59
SLC-52 count and survey implant patients	35.404
SLC-53 30mCi release limit	35.75
SLC-62 visiting physician	35.34; added AgState AU's
SLC-63 Mo-99 contamination	35.204
SLC64 Teletherapy servicing restriction	35.605
SLC-65 Patient observation	35.622
SLC-66 Leak testing for teletherapy	35.59; reduced to .005uCi
SLC-68 Emergency instructions for users	35.610
SLC-69 Teletherapy room interlocks	35.620, 35.633g

SLC-70	Teletherapy surveys	35.641; 35.642
SLC-71	No changes in teletherapy facility	35.606
SLC-72	Inspection and servicing	35.645
SLC-94	Teletherapy room monitor	35.621
SLC-95	Decay in Storage	35.92

Draft Regulatory Guide for teletherapy March 1982

4.14	Facilities and equipment	35.604
5.	Amendments	35.17 and 35.606
A	Medical Isotope Committee	35.31 and 35.32
B	AU T&E	35.960
D	Calibration of Instruments	35.51
F	Teletherapy Survey Reports	35.641 and 35.642
G	Operating and Emergency Procedures	35.33, 35.610, 35.633, 35.59
H	Instruction of Personnel	35.33
I	ALARA Program	35.30
J	Amendments	35.17 and 35.606

Regulatory Guide 10.8 Medical Programs October 1980

4.4	footnote Supervision	35.38
	technicians	35.2
4.7	Medical Isotopes Committee	35.31; 35.33
4.8	Training and Experience	Subpart J
4.9	Instrumentation	35.50; 35.51
4.11	Xenon	35.90; 35.205
4.12	Personnel Training	35.33
4.13	Ordering and Receiving Material	35.33
4.14	Opening Packages	35.33
4.15	General Rules	35.33
4.16	Emergency Procedures	35.33; 35.610
4.17	Area Survey Procedures	35.70
4.19	Pharmaceutical Therapy	35.304
4.20	Sealed Source Therapy	35.405
4.21	Gases and Aerosols	35.90; 35.205
4.26	Signature	35.16
5.	Amendments	35.17; 35.606
A	(FRN December 2, 1982) T&E	Subpart J
B	Medical Isotopes Committee	35.31; 35.33
D	Survey Meters	35.51
D	Dose Calibrator	35.50
E	Procedures for Ordering	35.33
G	General Rules	35.33
H	Emergency Procedures	35.33
I	Area Survey Procedures	35.33; 35.70
J	Waste Disposal	35.33; 35.92
K	Pharmaceutical Therapy	35.33; 35.304
L	Sealed Source Therapy	35.33; 35.304
M	Gases	35.90; 35.205
N	Amendments	35.17
O	ALARA	35.30

Fee			1980 cases	1980 pro hrs	1980 hrs/ca	1981 cases	1981 pro hrs	1981 hrs/ca	cumulative cases	cumulative pro hrs	cumulative hrs/ca	
			1	2	3	4	5	6	7	8	9	
6.A.	1311-F Nuclear Laundries	N	0	0.0	—	1	0.0	—	1	0.0	—	12
		R	5	0.0	—	1	2.0	2.0	1	2.0	2.0	12
		A	0	0.5	—	3	1.5	0.5	3	1.5	0.5	3
7.A.	1311-3 Teletherapy	N	16	109.3	6.8	21	143.1	6.8	37	252.4	6.8	8
		R	76	260.5	3.4	75	453.1	6.0	151	713.6	4.7	7
		A	245	1307.9	5.3	272	1368.8	5.0	517	2676.7	5.2	7
7.B.	1311-1 Medical Institutions	N	74	522.0	7.1	30	360.6	12.0	104	882.6	8.5	5
		R	261	2085.5	8.0	162	2225.4	13.7	423	4310.9	10.2	4
		A	1006	3610.1	3.6	1043	4366.8	4.2	2049	7976.9	3.9	1
	1311-2 Plutonium Powered Cardiac Pacemakers	N	2	4.5	2.3	2	3.5	1.8	4	8.0	2.0	5
		R	10	18.1	1.8	22	37.7	1.7	32	55.8	1.7	4
		A	9	92.7	10.3	20	52.4	2.6	29	145.1	5.0	1
7.C.	1311-2 Medical Private Practice	N	24	0.0	—	24	19.8	0.8	24	19.8	0.8	5
		R	31	0.0	—	13	160.7	12.4	13	160.7	12.4	4
		A	100	52.3	0.52	62	206.2	3.3	162	258.5	1.6	1
	1311-4 Other Medical Licenses	N	1	0.0	—	1	0.0	—	2	0.0		5
		R	6	0.0	—	3	3.0	1.0	3	3.0	1.0	4
		A	14	0.0	—	18	0.0	—	32	0.0	—	1
8.A.	1311-Q Civil Defense	N	1	18.0	18.0	2	17.0	8.5	2	35.0	17.5	5
		R	4	16.0	4.0	7	34.5	4.9	11	50.5	4.6	4
		A	21	28.5	1.4	15	34.5	2.3	36	63.0	1.4	1
9.A	Sealed Source Device										19.5	15
	Sealed Source										19.5	3

RA73-1
PDR
B.2

McElroy

As of 3/15/84

Primary code		How many active licenses	
02110	Inst	119	1887
02120	Inst	1,746	1887
02121	Inst	22	1887
02200	Priv Prac	157	289
02201	Priv Prac	50	289
02210	Priv Prac	66	289
02220	Priv Prac	16	289
02300	Tele	373	

1887 + 373 = 2260

Assume 2200 Inst
350 PP

prim + sec 02110
02120
02121
02200
02201
02210
02220
02320

1983 Medical

Month	No. of Applications Recv'd	New Licenses	Other Amend.	Renewals	Terminations
January	193	13	136	39	5
February	220	6	166	44	4
March	251	13	177	56	5
April	220	12	136	66	6
May	225	6	140	74	5
June	213	7	141	61	4
July	210	17	135	53	5
August	223	7	147	59	10
September	240	18	147	66	9
October	207	10	147	45	5
November	210	15	148	35	12
December	223	19	152	49	3
	2635	143	1772	647	73

-73 terminations

2562

AA73-1
PDR
B.3

11-26-82

Analysis of Compliance Cost for Part 35 (9-23-82 draft)

General Notes:

Section: describes where the requirement is defined

DEFGHI: describes which class of licensee must comply; cf Subparts D through I in proposed Part 35; M refers to mobile service

Required/Option: R denotes a requirement; O denotes a privelege (with concomitant burdens if the privelege is exercised) contained in proposed Part 35

Frequency: 5-5 years; a-annually; cont-continuously; d-daily (250 days per year); w-weekly (52 weeks per year); m-monthly; q-quarterly; bi-e-biennially; bi-a-biannually; /adm-per administration

Recordkeeping: an estimate of hours spent generating records, reports, logs; cost of paper, forms, filing space are considered trivial and are not included

Equipment and supplies: an estimate of cost of capital equipment and consumable supplies needed; unless indicated otherwise, capital equipment is amortized over 5 years

Contract cost: an estimate of the fee charged for a service by an outside contractor; based on informal surveys

$/yr: total cost of compliance per year

New or RG, LC, Reg: N-a new requirement imposed by the proposed Part 35
RG-a recommended procedure, contained in a regulatory guide, that is frequently adopted by applicants
LC-a frequently imposed license condition, I&E order, or licensing branch policy
R-a current regulation

Note: RG, LC, and R imply <u>similar</u>, not verbatim, procedures or requirements

The final column is an abbreviation of the section title.

After the cost of complying with each individual section has been determined, six model licensees that are representative of the medical industry are described. For each of the six model licensees, the total regulatory compliance cost is estimated by adding up the cost of each section with which the model licensee would have to comply. Compliance costs for the six model licensees appear on the last page.

Footnotes

1 Assume $60/hour (cf $58.37/hour in Encl 3 p 9)
2 Assume $20/hour (cf $18.37/hour in Encl 3 p 9)
3 Filing fee required in Part 170
4 Assume one each two years based on current amendment load of 1303 requests in 1981 from an industry with 2631 licensees
5 Formal written ALARA program only required for institutions; cost of drafting the program is included in cost of preparing application
6 Radiation Safety Committee is only required at institutions; assume five members meeting for one hour
7 Assume about four investigations each year
8 Development of procedure is included in preparation of application
9 Required by Part 19; included in proposed Part 35 for clarity and completeness
10 Currently submitted for review by NRC
11 Cost of filing is considered trivial
12 Based on 15 studies/da (Encl 3 p 9) x 250 days/year x .01% = .375/year
13 Instruction and supervision are required by Part 19; included in proposed Part 35 for clarity and completeness
14 200 uCi Cs-137 calibrated source cost from APC Cat No 45 p 19*
15 Assume one instrument; most licensees contract this work to a consultant
16 Based on 15 studies/day x 250 days/year = 3750 adm/year; dose calibrator cost is $1750 from APC Cat No 45 p 61*
18 Calibrated check sources @ $75 each; NEN Cat Nov 1980 p 10
19 The cost of additional recordkeeping required in case of a leaking source has not been added because they are very rare
20 GM meter + detector + check source; APC Cat No 45 p 56*
21 NIH model from APC Cat No 45 p 9*
22 5 vial shields @ $90 from APC Cat No 45 p 90*
23 3750 labels/year @ $10/500 from APC Cat No 45 p 11*
24 Supplied by manufacturer gratis
25 Assume two clients per day, 250 days per year
26 Almost all hospitals have fume hoods installed in all laboratory areas
27 Xenon administration and trapping system from APC Cat No 45 p 22*
28 Assume one patient per month
29 Install one switch and run cable to console; guesstimate
30 Cost for monitor, battery pack, and check source from APC Cat No 45 p 109*
31 Suspended mirror; guesstimate
32 Victoreen condenser R-meter model 570 $1500, model 621 chamber $475, model 74-374 water phantom $500, $2475 ÷ 5 = $495; NBS calibration $400, 2-½ calibrations in five years, $1000 ÷ 5 = $200; Victoreen quotes by phone 11-23-82, calibration cost effective November 1981
33 Assume two days @ $100/hour
34 Cost of training professional staff has not been considered because these individuals would need this training for JCAH review and to avoid malpractice suits
35 Group H (diagnostic devices) receives about four new sources each year; Group I (teletherapy) receives one source each five years
36 Assume one patient per month; for each patient two additional days in a private room @ $500/day

* APC Cat No 45: Atomic Products Corporation, catalogue was received from supplier October 1982

Section	DEFGHI	Required/Option	Frequency	Pro' Recordkeeping	Tech[2]	Pro' Working	Tech[2]	Equipment and Supplies	Contract Cost	$/5yr	$/yr	New or RG	LC Reg
35.1	All										0	R	Purpose and scope
35.2	DE3GH	R	5y	20	10			190[3]		1590	318	R	Licens required
	I	R	5y	40	10			300[3]		2900	580	R	
35.8	All	R									0	R	OMB Approval
35.15	All	R									0	R	Definitions
35.16	All	R									0	R	Application Instructions
35.17	All	O	bi-e[4]	1	1			48[3]			60	R	Amendment
35.18	All	R	bi-e[4]	.5	.5						20	N	Notification
35.28	All	R									0	R	License issuance
35.29	All	O									0	R	Specific exemptions
35.30	All[5]	R									0	RG	ALARA Program
35.310.2	All[6]	R	g			5					1200	R	Rad Safety Committee
a4	All[6]	R	g		1						80	RG	meeting minutes on file
35.32	All	R	g[7]	1		1					480	RG	RSO general duties
35.3301	DE3G[35]	R	d		.1		.1				1000	R	Receipt of byproduct material
35.3303	All	R	event								8	R	Authority and Responsibility
35.3304	All	R									8	R	Safety education
35.3305	All	R									0	LC[10]	All, RSO training record
35.3306	All	R									0"	N	Recordkeeping system
35.34	All	O									0	LC	Visiting authorized user
35.356	M	R									0	LC	Mobile Service
35.37	All	bi-e[12]	1	1	1						70	R	Readministration
35.38	All	R									8[13]	RG	Supervision
35.49	All	R									0	R	Suppliers
35.5061[a1]	DEJ	R	d		.01		.01	185[14]			137	LC	Dose calibrator daily check
35.5062[a2]	DEJ	R	a		.1		.1	185			41	RG	Dose calibrator annual accuracy
35.5063[a3]	DEJ	R	q		.5		.5				80	RG	Dose calibrator linearity
35.5064[a4]	DEJ	R	5y		1		1				8	RG	Dose calibrator geometry

Section	DEFGHI	Required/Option	Frequency	Pro Recordkeeping Tech	Pro Working Tech	Equipment and Supplies	Contract Cost	$/5yr	$/yr	New or RG LC Reg	
35.51	DEFGHI	R	a				75		75[15]	LC	Survey meter calibration
35.53	DEF	R	1/sdm	.01	.01	1750			1850[16]	R	Dosage measurement
35.58	all	O							0	R	Cal and ref sources
35.59b	DEF	R	bi-a	.5	.5	75[18]			55	R	Sealed source leak test
	G	R	bi-a	1.0	1.0	75[18]			95	R	
	H	R	bi-a	.5	.5	75[18]			55	R	
	I	R	bi-a	.5	.5	75[18]			55	R	
35.59gh	all	R	y	.2	.2	385[20]			109	R	Sealed source inventory & survey
35.60	DE	R				130[21]			26	RG	Syringe shield
35.61	E	R				450[22]			90	RG	Vial shields
35.62	E	R				75[23]			75	RG	Syringe labels
35.63	E	R							0[24]	RG	Vial labels
35.70ab	DE	R	d	.1	.1				1000	RG	Exposure rate survey
35.70c	DE	R	w	.1	.1				208	RG	Contamination survey
35.75	FG	R	m			1000			12000[26]	LC	Release of patients
35.80c	M	R	2x d	.1	.1				2000	LC	Mobile exposure rate survey[25]
35.90	E	R							0[26]	LC	Storage of gases
35.92	DEF	O	m	.1	.5				144	LC	Decay in storage
35.100	D								0	R	NDE pharmaceuticals
35.200	E								0	R	Imaging pharmaceuticals
35.204	E	R	d	.02	.02				200	R	Mo-99 concentration
35.205	E	O				2000[27]			400	RG	Control of gases
35.300	F								0	R	Therapy pharmaceuticals
35.304	F	R							0	R	Safety instruction[9]
35.400	G								0	R	Brachytherapy sources
35.404	G	R	m	.1	.1				72	R	Brachytherapy patient release[28]
35.405	G	R							0	R	Safety instruction[9]
35.500	H								0	R	Diagnostic sources

Section	DEFGHI	Required/Option	Frequency	Pro Recordkeeping	Tech	Pro Working	Tech	Equipment and Supplies	Contract Cost	$/5yr	$/yr	New or RG LC Reg	
35.600	I	R									0	R	Teletherapy sources
35.604	I	R									0	R	Application - costed @ 35.2
35.605	I	R									0	R	Repair restriction
35.606	I	R									0	R	Amendments - costed @ 35.17
35.610	I	R	5y	.5	.5						8	R	Emergency instruction
35.620	I	R							200[29]		40	LC	Interlocks
35.621	I	R	d		.01		.01	595[30]			214	LC	Radiation Monitor
35.622	I	R							200[31]		40	LC	Viewing System
35.630	I	R						2475	400[32]		695[32]	R	Dosimetry System
35.632	I	R	a	4		12					960	R	Full Calibration
35.633a	I	R	m	.5		.5					720	R	Radiation Spot Check
35.633f	I	R	m		.1		.4				120	N	Safety Spot Check
35.641a1	I	R	5y	.5		.5					12	LC	Hood Survey
35.641a2	I	R	5y	4		4					96	LC	Area Survey
35.643	I	R	5y		.1		.4				2	N	Safety Survey
35.644	I	R	5y	1	1						16	LC	Survey Report
35.645	I	R	5y						160[33]		320	LC	Five Year Inspection
35.900	All	R									0[34]	RG	Training - RSO
35.910	D	R									0[34]	RG	Training - A, D, E
35.920	E	R									0[34]	RG	Training - imaging
35.930	F	R									0[34]	RG	Training - pharmaceutical Her
35.940	B	R									0[34]	RG	Training - brachytherapy
35.941	L	R									0[34]	RG	Training - Sr-90 only
35.960	I	R									0[34]	RG	Training - teletherapy
35.961	I	R									0[34]	RG	Training - OTCE

Model Licensees

1 Nuclear medicine diagnostic clinic not based in a hospital, 15 studies /day, 250 days/year

2 Nuclear medicine diagnostic clinic based in a hospital, 15 studies/day, 250 days/year

3 Case 2 plus twelve radiopharmaceutical therapies each year

4 Mobile service not based in a hospital, 7.5 studies per day are conducted at two client locations, 250 days/year, no xenon studies

5 Teletherapy based in a hospital that also has a nuclear medicine diagnostic clinic

6 Brachytherapy based in a hospital that also has a nuclear medicine diagnostic clinic, assume one brachytherapy patient each month

Model Licensees

Section	1	2	3	4	5	6
35.2	318	318		318	580	
35.17	60	60		60	60	
35.18	20	20		20	20	
35.31a2		1200				
35.31a4		80				
35.32	480	480		480		
35.33b1	1000	1000		1000		
35.37	70	70		70		
35.50b1 a1	137	137		137		
35.50b1 a2	41	41		41		
35.50b3 a3	80	80		80		
35.50b4 a4	8	8		8		
35.51	75	75		75		
35.53	1850	1850		925		
35.59b	55	55		55		95
35.59gh	109	109		109		109
35.60	26	26		26		
35.61	90	90		90		
35.62	75	75		38		
35.70ab	1000	1000		500		
35.70c	208	208		104		
35.75			12000			
35.80e				2000		
35.92	144	144		144		
35.204	200	200		200		
35.205	400	400				
35.404						48
35.610					8	
35.620					40	
35.621					219	
35.622					40	
35.630					695	
35.632					960	
35.633a					720	
35.633f					120	
35.641a1					12	
35.641a2					96	
35.642					2	
35.644					16	
35.645					320	
subtotal[1]			12000		3908	252
carryover[2]			7726		7726	7726
total cost	$6446	$7726	$19726	$6480	$11634	$7978

[1] total of entries in this column

[2] regulatory costs associated with having just a nuclear medicine imaging clinic

AA73-1
PDR
B.4

March 10, 1983

Debbie, I'll: Bozik, Bill Walker

re dose calibrator, ANSI N42.13-1978 ". . .Calibration and usage of dose calibrator. . ." is the latest edition available as of today (I called their sales department).

re Vacca item 4

1. S 4.3 says "Suitable standard sources . . .shall be used for routine calibration. . ."; it makes no mention of the suitable activity of those sources.

2. S 4.5.1 suggests use of 100 to 200 uCi 137Cs and 1 to 5 mCi 57Co for "regular testing" (read "daily check"). The S would require a check on each work shift.

3. S 4.6.1 says, for a source hotter than 100 uCi, the instrument should be accurate within 10%. "Accuracy of measurements. . .below 100 uCi may not fall within the ±10% limits and should be determined for each instrument. . ." This S recognizes that the instrument may not perform well below 100 uCi. The S does not require the use of a 100 uCi source for the accuracy test. [illegible] If the instrument is accurate below 100 uCi and is linear over the range of use (most do and are, at least every one I have seen), there is no measurement problem.

4. S 6.2 recognizes that non-linearity problems may be encountered above 100 uCi. A discussion of non-linearity below 100 uCi is conspicuous in its absence.

5. I think the coupling of the linearity test in S 35.50 with the accuracy test therein is sufficient to show accurate measurements.

6. I think the commenter has misinterpretted the standard.

nlm

AA73-1
PDR
B.5

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

Mail 10 21 82
mlm

September 16, 1982

NOTE FOR: Jim Lieberman, ELD

FROM: John Klucsik, ELD JK

SUBJECT: REGULATION AND LICENSING OF TECHNOLOGISTS IN NUCLEAR MEDICINE

In our recent phone conversation we discussed portions of the proposed Part 35 which deal with the activities of unlicensed medical technologists and the supervising physicians who would be identified on a hospital license. I understand your concern to be over the proposed rule's recognition of the technologist's activities and the imposition of regulatory requirements upon the technologist and the authorized (physician) user of byproduct material, rather than upon the (hospital) licensee.

Proposed section 35.2(a) includes the standard prohibition against handling material except in accordance with a — license. If nothing further were said, several choices would be available:

1. The unlicensed technologist could be precluded from handling material;

2. Each license could expressly authorize material-handling by identified technologists;

3. Each license could be interpreted to authorize or could expressly authorize material-handling by any agent of the licensee;

4. The regulations could expressly authorize material-handling by any agent of the licensee; or

5. The regulations could expressly authorize material-handling by any agent of the authorized (physician) user under his supervision.

Option 5 is the approach embodied in the proposed revision of Part 35. I understand option 3 to be the one you favor.

CONTACT:
43295

Doc 8509230261

Option 1 would disrupt the delivery of nuclear medicine services. Option 2 would be administratively cumbersome and as a practical matter would not work (although this is the system which is and would continue to be used for physicians).

Options 3 and 4 would follow the model used in reactor licensing. The licensee would be responsible for the acts of his agents. This approach will work in the medical setting if the agency relationships there are the same as those in the utility setting. Often they are not. Frequently, the hospital is the licensee. Physicians who are not on the hospital staff (are not agents of the licensee) may have practice privileges at the hospital and may be identified on the hospital's license as persons authorized to perform nuclear medicine procedures there. The technologist may be on the hospital staff but will take direction from the independent physician. (The technologist may be a borrowed servant when carrying out the independent physician's orders).

Options 3 and 4 would place civil liability upon the licensee hospital for actions of its borrowed servant, taken under the direction of a physician who was performing no service for the hospital and whom the hospital could control only by denial of his practice privileges. The principal drafters of the proposed revision of Part 35 believe that fixing liability upon a licensee who may have little practical control over how byproduct material is administered to patients will not result in the desired patient and worker safety regardless of the level of enforcement activity or the magnitude of the penalty imposed.

I believe that relying on an agency relationship between the violator and the licensee may present substantial evidentiary problems. One would have to establish the agency relationship between the licensee hospital and the authorized user physician (which may not exist); and between the licensee hospital and the technologist (which may not exist if the technologist is a borrowed servant or if the technologist is supplied by an independent nuclear medicine service). These problems are compounded if the licensee is such an independent service. Such a service would have absolutely no control over the authorized user (physician) regardless of whether he was on hospital staff or was an independent practitioner.

Option 5 avoids at least some of these problems by placing liability at the point of control. The authorized user

directs the technologist when the technologist is administering material. (See § 35.38). Where the licensee is more likely to have direct control, the duty of compliance is upon the licensee (see §§ 35.53, 35.70).

I understand you to have some reluctance to impose civil penalties upon impecunious technologists. You have noted that radiographers are in a similar position and that we there impose the penalty upon the licensee employer or principal. There are two differences. One is in the agency relationship discussed above. The other is in the effect of noncompliance. A radiographer's noncompliance may result in overexposure of himself and a piece of pipe. A medical technologist's or authorized user's noncompliance may result in overexposure of himself and the patient. The principal drafters believe it appropriate to place liability squarely upon those who have direct control over administration of material to patients. You should note that the duties placed directly upon authorized user physicians and supervised technologists relate only to the actual administration of material to patients. See §§ 35.200, 35.300, 35.400, 35.500. Other duties relating to surveys, calibrations, etc., are generally imposed upon the licensee.

After you have had a chance to review the attached portions of the proposed Part 35, please give Bill Walker, FCML, a call to schedule a conference among the three of us, Led Higgenbotham, IE, and members of Bill's task force as appropriate. Bill can be reached at X-74232.

Attachment:
Portions of Proposed
Part 35

cc: W. Walker, FCML
N. McElroy, ORPBR
L. Higgenbotham, IE
T. Dorian, ELD