4/11/83

Note to Tom Rehm

RESPONSE TO COMMISSIONER AHEARNE ON SECY 83-62, PROPOSED REVISION OF PART 35 "HUMAN USE OF BYPRODUCT MATERIAL"

I am enclosing, as suggested, text for a memorandum to the Commissioners' Assistants for forwarding our breakdown chart on Part 35. I personally delivered a copy to Kate Bissell, Jim McDermott and Spiros Droggitis on April 8, 1983. If you have any questions or if the Commissioners' Assistants have any questions, I will be pleased to discuss them.

Bill Walker

Enclosure: As stated

OFFICE ►	FCML
NAME ►	WJWalker/ss
DATE ►	4/11/83

MEMORANDUM FOR: Roxanne Goldsmith, Program Analyst, OCM
Maria Lopez-Otin, Special Assistant, OCM

FROM: Thomas Rehm, Assistant for Operations, EDO

SUBJECT: SECY 83-62, PROPOSED REVISION OF PART 35 "HUMAN USE OF BYPRODUCT MATERIAL"

In response to SECY 83-62, proposed revision to Part 35 "Human Use of Byproduct Material", Commissioner Ahearn requested a breakdown of additions, deletions, etc. contrasting existing regulations with the revised Part 35. This was the information Kate Bissell requested at the March 7, 1983 briefing with William Walker, NMSS and John Klucsik, ELD. A copy of the breakdown is attached for your information. William Walker is available to answer any questions you may have about the chart. His extention is 74052.

Thomas Rehm
Assistant for Operations, EDO

Enclosure: As stated

Changes Made in the Proposed Revision of Part 35

This table first describes the content of major paragraphs in the current Part 35 and the reason for retaining or deleting each one. Then other major source documents are treated in a similar manner.

The following abbreviations are used:

A	added in the proposed revision
D	deleted in the proposed revision
C	clarified, frequently with modification, in the proposed revision
AU	Authorized User
RSO	Radiation Safety Officer
T&E	training and experience
BPM	byproduct material
SLC	standard license condition; a license condition included in many licenses
RG	Regulatory Guide
App	Appendix

	Topic	Current	Proposed	Why the Change was Made
A	definitions	35.3	35.15	expanded
	human use and physician Physician, podiatrist, dentist, mobile service, visiting AU			clarified added
D	adequate facilities	35.11c		medical care, not radiation safety
D	hospital access	35.12a3		medical care, not radiation safety
C	adequate T&E	35.12a4	35.900, .910, .920, .930, .940, .941, .950, .960	clarify "adequate"
C	private practitioner in an institution	35.12b2	35.35, .80	redefined as mobile service
D	institutional clients	35.12b3		more flexibility to hospitals for alternate service suppliers
C	adequate T&E	35.13b	35.940, .941, .950,.960	clarify "adequate"
D	adequate instrumentation	35.14a4		implicit in use and measurement requirements
C	adequate procedures	35.14a5	35.50., .51, .53, .59, .60, .61, .62, .63, .70, .75, .80, .90, .92, .204, .205, .304, .404, .405, .610, .620, .622, .641, .642, .645	clarify "adequate"
D	opening applicator cells	35.14b5ni		not allowed by package instructions

	Topic	Current	Proposed	Why the Change was Made
D	chemical form of radio radiopharmaceuticals	35.14b6i		"chemical" deleted; would be a new radiopharmaceutical
D	facit in vitro license (31.11)	35.14c		line item added to application form
C	teletherapy expert T&E	35.24b	35.961	clarified "minimum"
D	training expection	35.24[2]		may apply under 35.29
D	general in vitro license	35.31	35.100	safety measures similar to those for current 35.100(a) Group I
C	uptake dilution excretion radiopharmaceuticals	35.100 I	35.100	I-125 as oleic acid or sodium iothalamate deletion-not used
C	imaging radiopharma-ceuticals	35.100 II	35.200	Ag-203 as chlormerodium deleted-high patient dose
C	imaging radiopharma-ceuticals and generators	35.100 III	35.200	added generators for extraction (currently omitted)
A	brachytherapy	35.100 VI	35.400	added Ix and Ta wire used in Europe and under US broad license
A	diagnostic sealed scurces	35.100 VI	35.500	broken from 35.100 VI because hazard, worker dose, AU T&E are different
A	teletherapy	not listed	35.600	makes for complete listing of normal authorized BPM
C	Mo-99 in Tc-99m	35.14b4iii	35.204	consistency with United States pharmacopeia
A	Decay-in-storage	license condition	35.92	minimize unnecessary disposal by burial
C	teletherapy timer accuracy	35.21b	35.632b4 & 5	clarify "accuracy"
A	mobile service client management authorization	NMSS checklist item 3	35.35b	avoids unwanted use of BPM
	mobile instrument check	NMSS checklist item 5	35.80d	ensures instruments are working before handling BPM
	mobile closeout survey	NMSS checklist item 6	35.80e	ensures that BPM has not been left behind
	mobile secure the material	NMSS checklist item 7	35.80c	ensures curious client employee won't carry off BPM

	Topic	Current	Proposed	Why the Change was Made
A	dosage measurement	PRM and 35.41, .43	35.53	avoid unnnecessary patient dose
B	syringe and vial shields	I&E bulletin	35.60, 35.61	reduce worker exposure
A	AAPM teletherapy instrument calibration	petition ¶1 4yr. interval	35.630	calibration labs can't meet demand, instrument time is lost in transit, instruments shouldn't be shipped
A	¶2 intercomparisons must be supervised		35.630	ensures that a qualified individual oversees the calibration
D	¶3 constancy check			currently available constancy check sources are not sufficiently precise over long periods
A	¶4 records		35.630	specifies record retention requirement
A	leaking sealed sources	35.14e	35.59e	expands requirements to all sealed sources possess by licensee
A	release of radioactive patients	SLC-53	35.75	current SLC expressed in mCi inpatient can't be measured. mR/hr @ 1m can be measured, is more relevant
A	visiting authorized user	SLC-62	35.34	allows full time and emergency coverage
C	patient observation during treatment	SLC-65	35.622	establishes performance criterion
A	radiation and safety surveys for new teletherapy units	SLC-70	35.641, .42	minimize worker and public exposure, check safety devices
A	changes in teletherapy facility	SLC-71	35.606	minimize worker and public exposure
C	teletherapy applications	draft teletherapy RG 4.14	35.606	clarify "adequate" information
A	amendments	draft teletherapy RG 5.	35.17 & .606	specify when an amendment is needed