RES

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

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MAY 10 1984

MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety, NMSS

FROM: Karl R. Goller, Director
Division of Radiation Programs and
and Earth Sciences, RES

SUBJECT: COMMENTS ON DRAFT 10 CFR PART 35 REVISION AND REGULATORY GUIDE 10.8 REVISION

As requested by your memorandum of February 13, 1984, we have reviewed the draft rule on medical use of radioisotopes and the associated licensing guide 10.8. Our comments are enclosed.

Most of these comments are relatively minor and represent suggestions for improving clarity on points which we felt required amplification. As such, they should be treated as advisory rather than necessary. Comments that we feel are more important are designated by an asterisk (*).

If your have any questions on our detailed comments, please contact Harold Peterson (74578) or Dr. Judith Foulke (74563).

Karl R Goller

Karl R. Goller, Director
Division of Radiation Programs, and
Earth Sciences, RES

Enclosures:
1. Comments on Commission Paper
2. Comments on 10 CFR Part 35 Revision
3. Comments on Draft Regulatory Guide 10.8

ENCLOSURE 1

RES
HP Hal Peterson
& Judy Foulke

PART 35 COMMENTS

COMMISSION PAPER (2/13/84 Edition)

SECY paper, page 1, first paragraph last sentence for improved form, the last phrase "that were received" should go between "comments" and "from" or be deleted. It appears superfluous in its present position.

SECY paper, page 8 Proponents, line 7 we doubt that NRC can certify the applicant's knowledge of safe and unsafe or legal illegal procedures. What we could certify is that:

> "... the Commission has found that the applicant has sufficient knowledge of the NRC regulations and appropriate radiation protection practices to be able to use byproduct materials safely for human use."

SECY paper, page 12, 1st paragraph, last sentence: We doubt the statement that: "safe use can only be assured by unannounced inspections." Compliance with the NRC regulations, regulatory requirements and license conditions can be assured by unannounced inspections. These are necessary but not sufficient conditions for safe use:

> "; safe use can only be assured by the licensee's continuing commitment to safety as evidenced by compliance with regulations, continued re-evaluation of procedures and operations, and continued education and training for awareness of latest methods and procedures."

DRAFT REVISED PART 35

General Comments

*1. page 15 notes - These greatly improve the readability and specificity of the regulations. Because of this, consideration should be given to placing the notes as an explanatory portion directly in the regulation. Parts of the Statement of Considerations for Part 140 were incorporated in that rule, and provide a readily available explanation of what is intended.

*2. In some cases correct usage of technical terms has been compromised in an apparent attempt to improve readability by a semi-technical audience. (e.g., "dosage", "dose" in Note 3 on page 16). This might serve to confuse both the semi-technical reader (who encounters the correct usage and wonders which is which) and the radiation protection professional (who might think the NRC staff is incompetent). Suggest re-reviewing proposed rule to ensure that the usage of technical terms conforms to their precise technical meaning and, when this is done, that there is sufficient explanatory text to make the terms clear to the semi-technical (technician level) reader.

*3. The rule is slightly awkward because of the need to distinguish between the institutional licensee having an RSO and RSC and a private user where the user, RSC and RSO may be one person. If in fact the private user is designated in the rule as both the RSO and RSC, most of the instances where the separate distinctions are necessary could disappear giving a more concise rule.

*4. In some instances the zeal to consolidate requirements has resulted in procedural or data collection requirements which are far more detailed than NRC should require to ensure radiation safety. For example, the details of what should be in the minutes of the Radiation Safety Committee (§ 35.32(4)) is appropriate as a recommended practice in a Regulatory Guide not in a regulation to be strictly enforced. The rule should be gone through again to delete all but those requirements directly related to radiation protection or providing NRC proof of compliance.

*5. The typing process requires the operator to strike a code key followed by an "m" in order to get a Greek μ. In several places, particularly on the draft Regulatory Guide 10.8, the code was omitted, m was typed and "microcurie" was converted to "millicurie." As this is more than a simple typographic error, it might be advisable to spell out activity terms together with using the symbol. This way, if there is an error, the resultant disparity will call attention to it.

MAJOR SPECIFIC COMMENTS

COMMISSION PAPER - none

PROPOSED PART 35 FRN

Encl. 1, page 6 2nd line from bottom - R.G. 10.8 and NUREG-0267 cannot contain information which the NRC believes is "critical" for the safe use of byproduct material. That information had better be in a regulation which is enforcable rather than a Regulatory Guide which permits alternatives or a NUREG which has no legal regulatory status. Suggest:

"... contain suggested procedures approved by the NRC staff for meeting the specific requirements in these regulations."

Encl. 1, pages 12-13, delete use of RAM as acronym for Radioactive Materials

Encl. 1, page 34, Section 35.37 delete discussion of policy difference between Commission and staff - there is no need to bring it up. Once the Commission has reached a decision, whichever alternative was desired by the staff is of no consequence.

Encl. 1, page 48, Section 35.205. This section should at least acknowledge that the licensee will also have to meet EPA emission standards for the Clean Air Act. Add:

"Licensees will also have to comply with Clean Air Act emission limitations for radionuclides. Proposed standards were published by the Environmental Protection Agency as proposed 40 CFR Part 61 in the Federal Register of April 6, 1983 [48 FR 15076]."

Encl. 1, page 63, Section 31.11 It is not clear in the Statement of Considerations or in the Commission paper why staff is proposing to require a specific application for in-vitro use from institutions licensed for in-vivo use. This should be better justified.

Encl. 1, page 83, Section 35.16. If you literally follow the procedure outlined, applications that should go to Agreement States could come to NRC Headquarters. Needs a paragraph dealing with the Agreement States. Suggested text is given in our Specific Comments.

Encl. 1, pages 87-90. See general comment #4 and specific comments

Encl. 1, pages 110-112. There is considerable confusion among "pertechnetate", "pentatate" and "penetate"(?) both here and in the current Part 35. Needs to be closely checked.

Specific Comments

Encl. 1., page 4, first line - it might be helpful to preface the first sentence by:

"As authorized by the Atomic Energy Act of 1954, twenty-six states ..."

Otherwise it appears that the states just took the responsibility themselves.

Encl. 1, page 4, 3rd-paragraph line 2 suggest deletion of "can be safely" so it reads: "...more byproduct material than permitted by a general license."

This avoids the implication that activity levels above a general license may be "unsafe."

Encl. 1, page 5, 2nd full paragraph - last line appears to be puffery. It implies that licensees which do not follow NRC guidance pose a hazard to workers and the public which is not necessarily so since there may be several safe ways to do something only one of which is sanctioned by the NRC. Suggest deleting the sentence.

Encl. 1, page 5, General License - first paragraph - contains unquantified subjective value judgments, i.e., "present a very low health risk" and "acceptable level of safety." The discussion could well begin with the second paragraph (omitting "also" following "NRC") without a loss of meaning.

Encl. 1, page 6, line 2 - this refers to 1981 data, it is now 1984 - surely the data for 1982 have been processed. Otherwise you give the impression that more recent data have been omitted because they do not support the agreement. It isn't clear whether the following paragraph refers to the 1981 study or is more recent.

Encl. 1, page 6 2nd line from bottom - R.G. 10.8 and NUREG-0267 cannot contain information which the NRC believes is "critical" for the safe use of byproduct material. That information had better be in a regulation which is enforcable rather than a Regulatory Guide which permits alternatives or a NUREG which has no legal regulatory status. Suggest:

"... contain suggested procedures approved by the NRC staff for meeting the specific requirements in these regulations."

Encl. 1, page 11, line 5, suggest inserting "literally" before "meet" and after "not" as an individual who does not in any way meet the standards for training and experience should not be allowed to administer radioisotopes.

Encl. 1, page 11 Enforcement, line 8, what constitutes a "failure to follow technically valid procedures"? Since the procedures are either stated as license conditions or as agreement with R.G. 10.8 procedures the "technically valid" could be replaced by "agreed-to specified." This would clarify intent as indicated by the first sentence under "amendments."

*Encl. 1, pages 12-13, The use of the acronym "RAM" for radioactive materials while a convenience does tend to obscure the meaning - Suggest dropping RAM and spelling out "radioactive material" wherever it appears or using "radionuclides" as a substitute.

Encl. 1, page 13 (i) This section presumes that new applications would automatically include the new procedure, which might not be the case. It appears that the same endpoint could be achieved by:

"(i) The new radioactive material will be added by rulemaking to the appropriate use group in the regulations. However, use will be restricted to those licensees with an approved procedure on file with the NRC."

Encl. 1, page 15 Note 2, line 5 "examination"

Encl. 1, page 16, Note 3 The use of an unmodified dosage could confuse matters. Also the radiation biology usage of dose and the radiation safety usage should be the same - the amount of energy deposited per unit mass. Suggest:

"3. Dose and dosage. In pharmacy, the word "dose" is used to indicate the amount of a pharmaceutical administered. In radiation protection, dose is the amount of energy deposited per unit mass of tissue. In radiation protection terminology, the "amount" of a radiopharmaceutical to be administered is specified by the activity, expressed in subunits of the curie such as microcurie or millicurie. However, because of the long-standing practice, the quantity (activity) of a radioactive material given as a radiopharmaceutical will be termed the "administered dosage" and have units of activity, microcuries (μCi) or millicuries (mCi)."

Encl. 1, page 18 Note 8. The phrase beginning on line 5 of this note, "... and is more appropriately ..." is superfluous and should be deleted.

Encl. 1, page 19 3rd full paragraph (following #3) - Although this is informative, it really doesn't provide any guidance to the licensee. For example, should I hold records longer than the times given in 1-3 above, in the belief that longer times might be required in future regulations? Licensees understand that the NRC is liable to change its regulations, so the principal function of this paragraph is to introduce uncertainty and possibly result in confusion regarding the implementation of the record-keeping requirements in this revised rule. Suggest deletion.

Encl. 1, pages 21-22, "Transition Policy." The justification for permitting less stringent license conditions to act as an automatic exemption from more stringent regulations appears to be appropriate. However, the argument for requiring more stringent license conditions to prevail over less stringent requirements in the revised rule is extremely weak. Either the justification should be beefed up or, preferably, the policy should be reconsidered so that the less stringent requirements of the rule (which represent the Commission's and not solely the licensing staff's latest position) can be used to supersede the license condition. A simple way to do this is to suggest that the licensee make a copy of the license conditions and modify the requirements to conform to the new proposed Part 35 noting in the margin, the section and paragraph number

which he believes support these revisions. As none of the regulatory changes should introduce possibilities of serious or life-threatening overexposures, the licensee could be allowed to work under the "conditional marked-up" license until the next inspection when the changes should be discussed with the inspector. This would permit the substitution of less stringent conditions without an influx of applications for license renewals. There would be an inherent risk of a rise in non-compliance resulting from misunderstanding the new requirements, but this risk exists in any case.

Encl. 1, page 22 1st full paragraph, line 11, "particular" is transposed.

Encl. 1, page 25, the definition for Agreement State seems a bit informal even if this is explanatory. Suggest:

> "The term 'Agreement State' applies to those states that have entered into an agreement with NRC to assume responsibility for the licensing and inspection, and enforcement of regulations governing the safe use of source and byproduct materials and small quantities of special nuclear materials within their borders."

Encl. 1, page 28, Section 35.17 lines 4 and 5 - The condition "make it difficult for the Commission to determine whether a licensee is in compliance ..." does not appear to reflect the actual conditions in Section 35.17 of the proposed rule. These conditions do not affect whether NRC can determine compliance as much as they would clearly be violations of the current license. Suggest deletion of the phrase.

Encl. 1, page 30 top 4 lines. The reasons cited are not very strong support for the notification requirement. It appears that this could be dropped relying upon the application (from page 29) that there would be no assurance of safe operation beyond the few week period.

Encl. 1, page 30 last line - make discussion of fees begin a new paragraph as it is a separate subject.

Encl. 1 page 31 Section 35.29 first line insert "from the Commission" between "request" and "an"

Encl. 1 page 31 last 3 lines and top page 32, Suggest rewording for clarity:

"Non-institutional licensees (such as physicians in private practice), are not required to have a formal written ALARA program since the safe use of byproduct material is controlled by relatively few people compared to institutional licensees where cooperative efforts of many individuals may be required to maintain safe practices."

Encl. 1, page 32 § 35.32 lines 12-13. The underlying logic that a radiation safety committee is not required for situations which do not involve the cooperation of individuals from several different departments and the converse that a RSC is required when different departments are involved is not clear. It would seem that the only situation where a RSC is not required is when there are only a few (1-3) authorized users who can easily coordinate between themselves. An RSC should be required when there are a greater number of users regardless of their departmental affiliation. Changing this statement would not appear to affect the new RSC requirement in Part 35.

Encl. 1, page 33 second paragraph - delete second sentence which is very weak. Suggest:

"The committee should* review occupational exposures at least quarterly. Less frequent reviews might not be timely in identifying exposures above normal levels so corrective actions can be taken. More frequent reviews may require excessive staff time. The quarterly review ..."

*Writing "must" in a Statement of Considerations has no legal impact.

Encl. 1, page 34, Section 35.34 last line, Review by a regulatory agency does not necessarily ensure public health and safety. Suggest:

"... immediate review by the NRC is not required."

*Encl. 1, page 34 Section 35.37, delete last sentence as it provides no useful information to the public and points up an internal NRC policy difference. Since the Commission upheld the existing policy, there is no need for this sentence.

Encl. 1, page 36, Section 35.38 last sentence - delete as being superfluous as this should be self-evident.

Encl. 1, page 36 last paragraph break up into smaller sentences and re-write for clarity.

"... considerations because it increases doses to workers performing the tests but provides only a slightly greater probability of detecting a leaking source before spread of the contamination could occur."

Encl. 1, page 40, line 11. The meaning of "most conservative detection level" is not immediately apparent, i.e., what would liberal level be? Suggest: "lowest detection level."

Encl. 1, page 40, Section 35.60 line 1. Suggest:

"Syringes that contain byproduct material can be external radiation hazards..."

I doubt whether their being a hazard in all or even in most situations would be supportable.

Encl. 1, page 41, lines 2-6, How can a licensee evaluate the tradeoffs between the risk of spoiling the injection versus greater worker exposure? Suggest:

"... with the administration of the injection. This could prolong worker and patient exposure to radiation. In such cases where the location of the desired site of injection (or another substantive reason) would result in interference or an impediment to the injection using the shielded syringe, an unshielded may be used."

Encl. 1, page 42, Section 35.75 lines 1-2, drop the words "potentially hazardous" which serve no useful purpose except possibly to increase the anxiety of any nuclear medicine patients who might read them. Suggest:

"A patient whose body contains byproduct material is a source of external radiation and can be a source of radionuclide emissions which could result in internal radiation doses. In particular, patients who have had therapeutical dosages of radioisotopes may constitute substantial sources of radiation. The Commission ..."

Encl. 1, page 43, Section 35.90 1st line. Suggest:

"Some radiopharmaceuticals can present inhalation or immersion hazards (e.g., iodine-131 for inhalation and xenon-133 for immersion). Such hazards can be reduced by storing the sources in a fume hood or enclosing them in multiple barriers (such as sealable plastic bag within another plastic bag.)"

Encl. 1, page 44, 1st paragraph, line 8, suggest more emphasis on the reduction afforded:

"... ten half-lives was chosen because the time period represents about a thousand fold reduction. This will assure that ..."

Encl. 1, page 47, lines 5-7, suggest more informal:

"Because of the recent date of this prior rulemaking, the Commission is not specifically requesting comments on this portion of the rule."

Page 47, Section 35.204 first 2 sentences,. Suggest alternative:

"Technetium-99m is produced by the radioactive decay of longer-lived molybdenum-99. The molybdenum-99 usually remains in the isotope generator when the technetium-99m is eluted. Occasionally, however, unwanted traces of molybdenum-99 may accompany the technetium-99 as a contaminant."

Encl. 1, page 48, Section 35.205. This section should at least acknowledge that the licensee will also have to meet EPA emission standards for the Clean Air Act. Add:

"Licensees will also have to comply with Clean Air Act emission limitations for radionuclides. Proposed standards were published by the Environmental Protection Agency as proposed 40 CFR Part 61 in the Federal Register of April 6, 1983 [48 FR 15076]."

Encl. 1, page 50 Section 35.406 line 3 replace "nose count" with "source count" as brachytherapy sources don't have noses, tips maybe, but no noses.

Encl. 1, Page 51, 35.420 could be titled "Possession of High-Level Survey Instrument by Licensees performing Brachytherapy" to distinguish it from 35.220.

Encl. 1, page 55 Section 35.622 first sentence could imply that any movement could produce a 200 rad dose to healthy tissue. Suggest inversion of the sentences:

"A viewing system is needed to monitor the orientation of the patient and the telepherapy unit to assure that the radiation is correctly administered as prescribed. If there is appreciable movement of the patient, healthy tissue could receive unnecessary doses of up to 200 rads while the tissue scheduled to be treated would receive less than the optimum treatment dose."

Encl. 1, page 55, Section 35.630 first sentence. Suggest:

"Dosimetry equipment is needed to ensure that the dose actually given is the dose prescribed."

See p. 56 35.632 1st sentence for parallel construction.

Encl. 1, page 59, Section 35.644, Suggest addition to first line:

"Given the potential for high exposure to workers and the general public from improperly installed teletherapy units, ..."

*Encl. 1, page 63, Section 31.11. It is difficult to see why an institution licensed for <u>in vivo</u> medical use of radioisotopes has to specifically request permission to also do <u>in vitro</u> work, as the former appears to have a greater potential for causing overexposures. The stated reason (so that the Commission will know how many persons are doing <u>in vitro</u> testing) appears to be a very weak justification for the additional paperwork.

pp. 76-78. <u>Table of Contents</u> - The Staff paper indicated that the terminology regarding "Groups I-VI" was being dropped, but the listings for the Subpart has the "Group" in parentheses.

*Encl. 1, page 83 Section 35.16. This section omits reference to Agreement States. This could cause a reader in but not familiar with the Agreement

States program to submit an application directly to the NRC. As written an application from other than a non-agreement State submitted to a Regional Office, should be submitted to NMSS. Suggest redesignating old Section (e) as Section (f) and inserting a new Section (e) as follows:

"(e) If the applicant is not a Federal Agency and is located in Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Idaho, Kansas, Kentucky, Louisiana, Maryland, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Washington, application should be made to the State agency which administers the NRC Agreement State licensing program."

*Encl. 1, pages 87-88 Section 35.30. The subitems in Subsection (c) do not appear to be especially useful in preventing exposure although they may provide a basis for flogging a licensee for technical violations (such as not briefing management annually). Would suggest keeping the general requirement (c) and subitem (3) only. Subitems (3) and (4) appear to be redundant.

*Encl. 1, page 88 Section 35.31. Suggest:

"(1) Investigate and document spills, overexposures, and accidents, and implement corrective actionsas necessary."

The requirement to "investigate known instances of deviation from good practice ..." is too vague to be readily implemented.

Encl. 1, page 89-90 Section 35.32, item (3) requires the Radiation Safety Officer to be present at RCS meetings. Perhaps this requirement could be lightened by adding "... or an authorized representative from the radiation safety staff..."

Conditions (4) and (5) appear to be excessive intrusion into the operation of the licensee and as they do not directly affect radiation protection, should be confined to recommendations in a Regulatory Guide.

Encl. 1, page 91, Section 35.33. Section (a) appears to be desirable practice but it may be difficult or impossible to enforce. Suggest relegating to

a Regulatory Guide. In order to enforce it you would need to show that the RSO did not have sufficient authority or organization freedom, and only the RSO would be able to say he didn't, which would be a good way to become the ex-RSO.

Encl. 1, p. 100, Section 35.53 (a) and (b) - The necessity of having two requirements is not clear. It appears that one requirement would suffice:

"(a) Assay the activity of each radiopharmaceutical dosage before human use."

Encl. 1, page 107, Section 35.90 - The term "volatile radiopharmaceutical" is not defined. Would it be sufficiently clear that an inspector and licensee would not disagree whether a radiopharmaceutical were volatile or not? There is no universal standard for a volatile material.

*Encl. 1, page 110, item (3) (ii), page 111 item (12), page 112 (1), appear to be misspelled "pentatate" not "pentetate". The possible misspelling (or confusion with "pertechnetate") exists in the present rule at 35.14(b)(6)(i) ["penetate"], page 35-3 of Part 35. While 35.100 Schedule A (7) and (9) use "pertechnetate", Schedule A (10) mentions "ytterbium - 169 as pentatate sodium". For technetium, the designation "pertechnetate" is meaningful for TcO_4 = Pentatate might indicate an element in its five (V) valence state and could apply to technetium. It is unclear what "pentetate" might be. In either case it would be most unusual to find ytterbium in other than a trivalent (III) state. Suggest all references to "pertechnate", "pentatate" or "pentetate" be thoroughly checked particularly in view of the apparent discrepancies in the existing rule.

Encl. 1, Section 35.204 (a) - Also specifying this as a percentage of the technetium activity would be helpful and time-saving to the user.

Encl. 1, Section 35.205 - Needs to acknowledge that compliance is also required with EPA emission standards prepared under the Clear Air Act.

"... of this chapter and at levels below the Clear Air Act emission limits promulgated by the Environmental Protection Agency in 40 CFR Part 61."

Note that this is more of a notice of required compliance than our requirement as the compliance with the EPA standard would be required whether we explicitly require it or not.

Encl. 1 page 115 Section 35.315(f) - There is no limit on the dose rate from nonremovable contamination nor a requirement to survey external radiation levels. Although therapy radionuclides are generally short-lived, such requirements might be considered.

P. 119, § 35.520 - As written, there is a choice of two survey instruments, low-level OR high-level. Since this is a big difference, was and intended?

Encl. 1, page 122, (3). Suggest:

"... until the treatment room is resurveyed to ensure that only the patient is present, all treatment room entrance doors are closed..."

Something had to trip the interlock. An examination is required to ensure that another person did not enter the treatment room as the doors could be reclosed with a person inside.

Encl. 1, page 122(c): "... light which indicates in red or yellow when the beam is on."

Encl. 1, page 123, Section 35.621 - In addition to (f), would it make sense to require workers entering the teletherapy treatment room to wear an operating audible personal alarm radiation meter? These devices are relatively inexpensive, could be shared since only individuals entering the area need wear them, and would appear to be far more effective in preventing accidental overexposures than a visual indicator which may not be seen.

Encl. 1, page 124, Section 35.630 (2) lines 12-15 - The wording appears backwards - perhaps it was taken from AAPM documents. The requirements should be on the licensee to intercompare his source with others using the same source, not for him to use an appropriate teletherapy unit:

"A licensee with a cobalt-60 teletherapy unit shall intercompare dosimetry systems with other cobalt-60 teletherapy units. Similarly, a licensee with a cesium-137 teletherapy unit shall intercompare dosimetry systems against other cesium-137 teletherapy units."

Encl. 1, page 125, Section 35.632 - Subsections (a)(1) and page 127 Sections (e) and (f) - "radioactive decay" might be more easily understood by some readers than "physical decay."

Encl. 1, page 130 Section 35.633 - Would it be advisable to require that the licensee plot the output measurement value on semi-logarithmic paper versus time together with the calculated output decay line based upon the initial activity and radioactive decay constant? This would appear to provide a means for detecting gross fluctuations in output measurements.

Encl. 1, page 141 top (i) and page 144 (b)(1)(i) - can we really specify training requirements to 2 significant digits? Suggest making it "(i) 100 hours of radiation physics and instrumentation."

Encl. 1, page 141 (3) seems overly restrictive and biased towards the indicated institutions. What is needed is an alternative for persons educated outside the country or switching medical specialties. This could be accomplished by changing the "and" on line 4 to an "or". Another alternative is that the experience requirement be written similar to those of ophthalmic use or therapeutic use of radiopharmaceuticals.

Encl. 1, pages 142-143 - 35.950(b). In contrast to the other uses, the educational requirements appear very lax since they could be fulfilled in a 1-day course.

Encl. 1, pages 148, The definition of human use tends to confuse the medical licensing with the isotope use licensing. It was only apparent on the second reading that the meaning here omitted the Commission because we do not license people to practice medicine. But we (NRC) also do not prosecute people for illegally practicing medicine so why put in the requirement for a medical license? Suggest:

"(h) 'human use' means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings by or at the direction of a qualified physician."

Encl. 1, page 148, 30.34 as per earlier comment. Suggest also including the fraction or percentage of the technetium activity represented by the 0.15 µCi/mCi.

ENCLOSURE 3

COMMENTS ON PROPOSED REVISION 2 REGULATORY GUIDE 10.8

Page 1, lines 1-3: Suggest slightly different phrasing in order to improve clarity:

> "The NRC regulates the intentional use on or in humans of byproduct materials and the administration to humans of the radiations from by product materials. This type of use is regulated by the NRC under a specific license for human use of byproduct materials."

Page 4, Section 1.4.1, last line: It would be clearer if "alone" were inserted after "license", i.e.:

> "If the general license alone meets the applicant's needs, then only Form NRC-483 need be submitted to NRC."

Page 4, Section 1.4.2, first paragraph, last line, is confusing as it stands. Suggest

> "...experience requirements for applying for an institutional human use license."

Page 6, line 3: Suggest adding "non-research" prior to "institutions" to emphasize the routine nature of these procedures.

*Page 6, Section 1.4.4: A more complete description of the hybrid license should be presented here without inconveniencing the reader to look it up in Part 35.

Page 7, Section 3.2: Suggest adding an optional helpful hint at end:

> "It is usually possible to have portions of the blueprints photographically enlarged and made into reverse images (dark lines on light background) which will show the rooms or areas where radiation or radioisotopes will be used and adjacent rooms or areas with more detail than the original blueprint. These reverse image drawings also will permit hand- or typewritten notations to be added to denote special features of interest and can be small enough (e.g., 8 1/2" x 11") to be filed in conventional files."

Page 7, 3.3, lines 4-5, suggest a little more directness:

> "...the incomplete number(s) of the item(s) listed in the application directions which is (are) being addressed on that sheet and the date of the application. Good quality bond or other white (uncolored) stock and reproducible ink (black is preferred as some blue inks will not reproduce) which are suitable for repeated handling and for reproduction should be used."

Page 7, Section 4, 4th line: What is meant by:

> "...to provide an acceptable procedure in response to an item on the application form"? Does it mean "to provide an acceptable response to an item ...?" or "...to provide a procedure for preparing an acceptable response ...? Clarify.

Page 11, 3rd line suggest "...no additional submission ..." rather than "...no additional attachment ..."

Page 19, Appendix B, first sentence is very unclear:

1. To whom is it addressed, the Commission or the licensee?
2. Why is the licensee publishing anything?
3. Shouldn't it read "issued by the licensee" instead?

Page 20, Item a(1): I doubt that it would be possible for the RSC to determine whether an "applicant" will be able to be ALARA. Also the "applicant" here means someone who applies to the licensee to be allowed to use radioisotopes which is confusing compared to the NRC "applicant." Suggest:

> "(1) The RSC will thoroughly review the qualifications of each proposed radionuclide or radiation user. This review will determine whether the individual has sufficient training and experience to carry out the proposed use with respect to the types, form and activity of materials to be used and the proposed procedures for their use."

Page 21, Item a(3.): Despite the ICRP, I do not believe that procedures can be "justified." This requirement for justification has not been included in the proposed revision to Part 20, hence this "requirement" will not be traceable to our regulations. Furthermore, it is questionable whether a procedure

ordered by a qualified physician requires any other justification by the RSC. In order to avoid a potential conflict between the physician and the RSO or RSC, suggest revised text:

> "(3) The RSC will review proposed procedures for administration of radioisotopes or irradiation of humans to ensure that the proposed procedures will keep doses to personnel ALARA and that the quantity or dose administered is consistent with the information to be obtained from the procedure."

Under (b) the two items are (1) trivial and (2) not prudent. Suggest:

> "b. Delegation of Authority
>
> (1) The RSC delegates to the RSO the responsibility to ensure that the day-to-day operations are carried out consistent with applicable State, Federal, and local regulations and for reviewing ongoing procedures to ensure that the resultant radiation exposure is ALARA.
>
> (2) The RSO does not have the authority to revoke approval to use radiation or radioisotopes but any recommendations made along these lines by the RSO will be weighed heavily by the RSC."

Page 23, Section 3.a.(2), line 2: Why is this restricted to "external" exposures? Suggest some requirement that, if warranted, bioassay and other data on internal exposures would be reviewed at least semiannually.

Section 3(a)(3), line 2: How does the RSO know that constitutes an ALARA level in this respect? Suggest:

> "The RSO will review the results of radiation surveys in restricted and unrestricted areas to determine
>
> (1) whether they show that existing protection measures are adequate and provide an ample margin of safety;
>
> (2) whether they show any evidence of increases or decreases over time;
>
> (3) whether additional modifications to existing procedures or operations are warranted in order to further reduce these levels."

Page 23, Section 3b.: Too directed at ALARA; make more general:

"b. Educational Responsibilities"

The RSO will ensure that new workers receive instruction in radiation safety and proper radiation protection procedures prior to administering radiation or radioisotopes to humans.

Page 23, 3.c. belongs better under "5. Individuals Who Receive Occupational Radiation Exposure" that under "3. Radiation Safety Officer." The two sub-items could be placed under 3.b.

Page 24, 4 a.(?): Last sentence could be made slightly clearer if expanded by adding:

"...with non-radioactive materials to mock-up and improve procedures."

Page 24, 4.b.(1), line 2: Suggest minor modifications:

"(1) The authorized user will explain to all individuals supervised by the user the ALARA concept and the need to maintain all radiation exposures ALARA."

Page 25, 5: Use c from 3c. as "c." here.

Page 25, 6: This should be broadened to include bioassay results for internal emitters when internal radionuclide burdens might occur (e.g. radioiodine therapy).

Appendix D

Page 32, second para., line 2: "features"

Page 33: Suggest an item 4 in the model program be added:

"4. Whenever there is a serious breach of NRC regulations or licensee safety procedures."

Pages 32-33: The text notes that ancillary groups may need training (p.32), however, it is not indicated whether or not individuals not working with radiation and/or radioactive materials need the same degree of training as radiation workers. I suggest that some provision or indication be included to allow a much abbreviated training program for these ancillary workers (or a more thorough program for radiation workers). The outline on page 33 of topics appears suitable for the ancillary group but could be supplemented for the radiation workers.

Appendix E

Page 34, #3: This is not clear - if it fits my interpretation, it's also technically incorrect -

If "camera" means gamma camera, even if used in the "gross count mode," it would not have substantial advantages over other instrumentation. On the other hand, if the survey meter is a scintillator or GM probe run in the count mode (rather than dose rate), I believe not only would they have sufficiently sensitivity (except for low-energy betas), but they are the instruments most commonly used for surveying such contamination.

This item needs to be rechecked with someone familiar with the latest instruments and their capabilities.

Item #7, page 35: The wording of this item suggests that the worker might remove the monitor when not in areas where radioactive materials are stored. This could result in neglect to reapply the monitor when reentering the radiation area. Incidental exposures to radiation outside the storage areas (e.g. leakage through walls) may not be monitored in such circumstances. Suggest redoing 1st sentence:

> "Radiation workers should wear issued personnel monitoring devices at all times when at work. Persons who are incidentally exposed should wear monitoring devices when in radiation areas. These devices should be ..."

Appendix E

Page 35, 10: Suggest minor modification:

"10. Never pipette by mouth. Use automatic pipetting device or special pipette bulb as provided."

(This not only explains the alternative but also alerts management that such devices should be made available.)

11. Although obvious, suggest modifying to read:

"If necessary, decontaminate or, if short-lived radionuclides were involved, secure the area to permit radioactive decay to reduce levels."

Page 36, 13. last line suggest:

"...and patient's name and identification number."

As the correct dosage and isotope may be misadministered to the wrong person. Having both dose and name on the container should reduce this as should following the instructions in # 14.

Appendix F, page 37, item #1 is not clear in its intent. It appears to suggest that, if there are primary monitors (TLDs or film badges), then it is not necessary to review exposure data from secondary monitors like pocket ion chambers. This suggestion is valid for initial screening to spot the high exposures since the print-outs from the TLD reader or film badge company are easier to scan. However, there is value in using the backups to confirm that higher (or suspiciously low) exposures had occurred. For this reason suggest:

"1. The RSO will promptly review all primary reports (TLD or film badge) reports on occupational exposures to look for workers and groups of workers whose reported exposure is unusually high or low. Backup monitoring data, such as pocket ionization chamber data, may be useful in confirming these abnormal exposures, but need not be specially screened otherwise unless there was a failure of the primary dosimeter."

4. It is not clear what is meant by "a whole body monitor." Clearly it isn't a "whole body counter" but it should be stated as being a "TLD or other external dose monitor" to avoid confusion.

Appendix G, page 39

#3 suggest: "Using disposable gloves, clean up the spill with absorbent paper."

In the procedures for Minor Spills, item 6 states that the RSO will supervise the cleanup of the spill. This should be placed ahead of item 3, which instructs the person to clean up the spill. Under the stress of reacting to a spill, the person involved would probably carry out the steps as written, and the RSO would not be involved until the end.

page 40 #3 Suggest:

"3. Shield the spill if necessary. This ..."

Appendix H, page 42

Suggest new #1:

"1. The purchasing department will not process any order for radioactive materials unless accompanied by a written authorization from or signature of the Radiation Safety officer (RSO).

2. The RSO or designate..." (old #1) #2 becomes #3, etc.

This is necessary to provide the RSO the authority to carry out old item #1 which merely makes the RSO responsible without providing a mechanism for carrying out the responsibility, particularly if an order for radioactive material can bypass the RSO.

Appendix I

Page 45 item #1. Last line - the contamination limit in § 20.205(b)(2) is "0.01 microcuries per 100 square centimeters" which is written: "0.01 μCi/100 cm^2" and not "0.01 millicuries" (0.01mCi/100 cm^2).

It would appear to be worthwhile to include "10 millicuries of tritium, carbon-14, sulfur-35 or iodine-125" in addition to the examples of Class A materials. (Note that I-125 is not appropriate to be included in the Class A requirement as § 20.205 includes the above specific limit including I-125.)

Page 47, item g(2) to indicate mandatory nature add:

"... trash as required by section 20.203(f)(4) of 10 CFR Part 20."

Item g(3) should be a separate item h and should be expanded:

"h. Make a record of the receipt indicating receipt date, order number, material (radionuclide), activity, user, and the results of the package radiation survey (less than "<" symbols are permissible for recording the results providing that they are clearly distinguishable from numerical values.)"

Page 50, item 6.f. Omit comma.

Page 51. Refer to the molybdenum measurement requirements as Section 35.14(b)(4)(ii) of the current 10 CFR Part 35 or those in Section 35.204 of the 1984 proposed revisions," rather than the vague "The regulations require"

Page 53, item 2. When are the users supposed to initial the sheet? If it is when they remove a source, then say so. Needs more specificity.

Item 4. Combine this with item 2 (for list of individuals) and item 3 (for map of sources).

Item 6. Seems overly complicated and redundant - the patient data is required in item 5 so that it need not be repeated here. Just require initials to indicate return of source.

Item 7. Omit "ever."

Appendix J, page 54

Item 1. This does not follow paragraph 20.203(f)(4) (which should be referenced) and refers to empty uncontaminated containers whereas the item would permit defacing the radioactive material label on a container still containing radioactive materials. Such advice is not supported by the regulations.

The advice to deface labels after compaction does not appear reasonable or prudent. If vials or other glass or metal containers still containing small amounts of activity are crushed, then the defacing step may result in contamination. Better have the labels removed prior to compaction even though it requires more effort.

Page 55, item 2 add:

> "... and that radioactive material containers with more than exempt quantities of material are not mixed with the nonradioactive waste."

Page 55, item 2. The "boundary of the restricted area" is vague and nonspecific. Suggest adding:

> "... area which is the drain or holding tank which receives these wastes or, in the absence of a holding tank, the concentration limit must be met at the release point (sink or drain) unless there is documented evidence of the amount of dilution afforded by other hospital waste streams prior to passage offsite."

Page 55, item 3. "mCi" is not an abbreviation for microcurie which is the stated unit in § 20.306. Use both the name "microcurie" and the symbol, μCi, to avoid confusion.

Page 56, item 5. Suggest adding to first sentence: "..., those which can then be assumed to be uncontaminated for disposal purposes."

Note that items 5 and 6 apparently are in conflict with #1 on page 54; however, the recommended change to #1 would remove that conflict. Items 5 and 6 appear to be more consistent with § 20.203(f)(4).

Appendix K, page 55

The first statement in "Model Procedure for Disposal of Liquids and Gases," mentions evaporative release to the atmosphere. This would not be appropriate for radioactive ions in solution. Evaporating the solvent would leave the radioactive material adsorbed to the container. A section should be added to clarify the intent of this provision; i.e., liquids which are composed of atoms that are radioactive.

Appendix L

Page 58. 1a. Suggest adding "... surveyed daily."

* 1b. Second line, Do you really mean 200 millicuries? Or has the typist forgotten the shift key to get µCi? See 1b on page 59 which is 200 µCi.

Pages 58 and 59 1c and 1d. In item d the quarterly exposure survey interval seems overly long since the sealed source inventory can change. Suggest adding 1d to 1c with a monthly survey interval but retaining the ionization chamber instrument.

Suggest adding a #3 as follows:

> "3. Surveys should be immediately carried out in the sealed source and brachytherapy storage areas in the event of a missing or suspected damaged source."

And also in #1 under removable contamination add:

> "d. In the sealed source and brachytherapy storage areas quarterly or in the event of a suspected damaged source."

Appendix M page 61, item 1a add: "...[see item 3] on page 62."; to item 1b add: "... [see item 5] on page 63;" to item 1c add: "... [see item 6] on page 67;" to item 1d add: "... [see item 7] on page 69."

Page 63 item e and page 66 item h require some explanation of where the numbers arise from. Suggest adding to both items:

> "This procedure is based upon the fact that ^{99m}Tc decays by a factor of approximately 16 in a 24.1-hour period."

Pages 64 item i and page 66 item l.--Wouldn't it be advisable, if some of the points lie outside the 5% error bounds, to redo the linerity test to check that the malfunction really exists before taking corrective action?

*Page 69 #7, lines 9-11. What regulations require that at least a 10 microcurie Ra-226 source be used? Be specific - I could not find any regulation in Part 35 to support this. NBS guidance or Regulatory Guides should not be called "regulations."

Appendix N Page 71, 3rd paragraph - "should" in first line should be "must" or "shall" as second sentence rules out alternatives.

Appendix N

Page 71 item 3. In practice this may be difficult to achieve since the larger calibration sources are limited to a few longer-lived radionuclides (^{137}Cs, ^{60}Co, etc.) which have different energies from most medical isotopes (e.g. technetium-99m at 0.14 MeV versus cesium-137 at 0.667 MeV(^{137m}Ba) or cobalt-60 at 1.25 MeV average energy). Suggest you delete this requirement which, although desirable, appears to be impractical. One could use ^{144}Ce- ^{144}Pr for calibrating meters for work with technetium-99m. However, its 285-day half-life makes it an inconvenient and expensive calibration source.

Page 74, item 12. The survey meter would look like a Christmas tree if these were followed. In particular, 12d. (2) appears to be an excessive requirement since a graph would be needed for each of many scales. Perhaps there should

be a requirement to establish a folder or section of a notebook for each instrument giving the particulars on its life, and containing these calibration graphs. This would permit changes to be noted; whereas, if the graphs are on the instrument, they would be overlaid or destroyed when newer ones were added. The "note" does help avoid the congestion but a file or record section specifically for each instrument could prove useful.

Appendix O

Page 75 1st paragraph last sentence - it is doubtful that ensuring that radiation uses are in the public interest is legally part of NRC's mission. However:

> "... to assure that the use of byproduct material will not result in unnecessary radiation exposure from multiple administrations."

would appear to be within our responsibility to protect public health and safety.

Appendix P

Page 28. The model procedure does not include a warning about handling calibration sources directly with the fingers. Since fairly substantial (mCi) sources would be tested using the procedure, such a warning would be warranted to avoid excessive beta doses to the fingers.

*page 79, 4a. line 2 - 0.005 mCi" or 0.005 µCi? Item f on page 80 says 0.005 µCi, which appears to be correct.

Appendix Q

Page 84 section Q2; page 85, section 10.m.3.

Note that the proposed procedures are based upon determination of compliance with Section 20.105(b) and Appendix B of 10 CFR Part 20. The measurement of the effluent concentration is sufficient to show that the maximum concentration will not exceed Appendix B values. However, some caution would be helpful in extrapolating this compliance test to dose estimation - doses to the

public from gaseous effluents are proportional to the release rate (Ci/sec), not to the airborne concentration in the effluent. Diluting the release is only of slight value in reducing the offsite dose. Suggest adding in both places:

> "This method is adequate for evaluating compliance with § 20.105(b) and Appendix B of 10 CFR Part 20, however it should not be used to infer offsite doses."

Appendix R

Page 87 1st paragraph, line 5. refers to Appendix "P." This is Appendix "R." Appendix P is for leak testing.

Page 89, #8. Wouldn't it be better to:

> "8. Instruct visitor's to remain as far from the patient as possible consistent with their duties"

The idea of a "safe" line, whether it's referred to or not, would appear to have an unnecessary psycholcgical impact on the patient. If suggestion is adopted then forms such as p 123 will also require modification.

Page 89 #9 line 2 "esophagus"

Appendix S

Page 91 2nd paragraph, line 5, "ATT 10.0" should be "...ATT 10.o."

Page 92 item #6 see comment for page 89 #8.

Appendix V

Page 103 last line - unless it is standard practice for the ACMUI to review each application, it is not advisable to state that we "will" do so.

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

rec'd 4 09 84 RM

APR 06 1984

MEMORANDUM FOR: Norman L. McElroy
Material Licensing Branch, NMSS

FROM: John W. Clark, Sr. Cost/Program Advisor
Cost and Management Support Branch, RM

SUBJECT: REVIEW OF 10 CFR 35

The Cost Analysis Group (CAG) has reviewed the subject rule with regard to its cost analysis and has the following comments:

1. Although the cost analysis for the rule provides considerable detailed costs for six hypothesized classes of licensees, there is no accounting of the total number of licensees affected, nor total increase in cost to licensees of this rule revision.

2. We would have preferred to have seen at least a ball-park estimate of the costs of each of the other alternatives; if for no other reason than to provide the Commission with an indication of how cost-effective their decision was.

3. In the penultimate paragraph of page 3 of the Regulatory Analysis section you infer some additional implementation cost to NRC (i.e. training cost, onsite review costs), but you do not quantify them. A quantitative estimate would be desirable here.

4. In the penultimate paragraph, page 4 of the Regulatory Analysis section, line 6, addition of the underlined phrase to the following quote would add clarity: "need for significant increases in expenditures..."

Thank you for the opportunity to comment on your revision to 10 CFR 35.

John W. Clark

John W. Clark, Sr. Cost/Program Advisor
Cost and Management Support Branch, RM

cc: J. Sniezek, CRGR
E. Triner, RM/B
R. Hartfield, RM/BC
S. Feld, RM/BC
R. Wilde, NMSS

~~8504090106~~ 2pp.

Cost Analysis Group

John Clark + CRGR re reg analysis 3 27 84

JC: you must identify number of licensees (cf DM Bp 3)
total cost to all industry. You may estimate
or make intelligent guesses. done 3 28 nlm
done 3 28 nlm
what are expected dose increases or decreases (total)

cost out retraining of NRC licensing and
done 3 28 → inspection, cost to public, cost to other govt agency

prepare cost to read and figure out the reg,
but keep it in your pocket for now. Just stand
silent for most.

Encl 4 p 4 "need for sig incr in expenditures" done 3 28

Note to Dircks should indicate CRB has seen
pkg & whether or not comments were resolved.
done 3 28

Be sure to cost out no. & type of licensees affected
effect on public exposure → done 3 28 nlm
effect on wkr exposure →
← cost to NRC, licensee, & public
done (but in this case say none)