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From: Lynne Fairobent <LynneF@acr.org>
To: "Roger Broseus (E-mail)" <rwb@nrc.gov>
Date: 6/4/02 4:33PM
Subject: ACR ASTRO AAPM comments NUREG-1556 Volume 9

Roger:

Per our discussion, attached are the comments on NUREG-1556 Volume 9 by ACR, ASTRO and AAPM. There are two file, one is the signed letter and second is the attachment containing the detailed comments. I will bring you hard copies on Thursday.

Lynne

<<ACR, ASTRO AAPM comments NUREG-1556, Volume 9 letter 6-4-02.doc>>
<<Attachment ACR, ASTRO AAPM comments 6-4-02.doc>>

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Hard file = ADM-013

E-RIDS = ADM-03
Add = R. Broseus (RWB)

June 4, 2002

Chief, Rules Directives Branch
Mail Stop T6-D59
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Draft NUREG-1556, Volume 9

The American College of Radiology (ACR), the American Society for Therapeutic Radiology and Oncology (ASTRO), and the American Association of Physicists in Medicine (AAPM) would like to commend the U.S. Nuclear Regulatory Commission (NRC) on their effort to revise 10 CFR Part 35 in its entirety. This has been a major regulatory undertaking that was conducted professionally and with numerous opportunities for public input.

Recognizing the importance of this regulatory change, ACR has formed a senior level Task Force to address the implementation of the new Part 35. This Task Force consists of members from ACR's Commissions on Nuclear Medicine, Radiation Oncology, Medical Physics, and General Radiology and Pediatrics. It also includes representatives from AAPM and ASTRO. Two-thirds of the Task Force representatives are physicians and one-third are physicists representing both diagnostic and therapy expertise. Milton Guiberteau, M.D., who chairs the ACR's Nuclear Medicine Commission, chairs the Task Force. ACR represents approximately 32,000 radiologists, radiation oncologists and medical physicists who may be impacted by the revised regulation. ASTRO has more than 6,350 members, including physicians (radiation oncologists), radiation scientists (radiobiologists, radiological physicists), radiation therapy technologists and radiation oncology nurses. These specialists make up the expert medical team that uses radiation to treat patients with cancer. The AAPM, which represents more than 4,500 medical physicists, is a Member of the American Institute of Physics. The AAPM promotes the application of physics to medicine and biology and encourages interest and training in medical physics and related fields.

Although ACR, ASTRO and AAPM are supportive of the revised regulation, we have several concerns about the implementation of this regulation and draft guidance in NUREG-1556, Volume 9. The following are key concerns of the three organizations:

1. Adopting the paradigm shift to a risk-informed performance-based regulatory system by the Agreement States.

2. Embracing the paradigm shift by the license reviewers and the inspection staff of the NRC and the Agreement States.

3. Assuring that no de facto regulations are added through guidance or license conditions.

4. Resolving the issues of board certification as a recognized and acceptable pathway for becoming an "authorized user," "authorized medical physicists" and radiation safety officer.

Attached are specific comments on NUREG, Volume 9. Representatives of all three organizations prepared these comments.

We commend NRC's commitment to an interactive process with the medical community in developing guidance related to the new Part 35.

If you have any questions regarding our concerns on implementation of this rule, please let us know. ACR, ASTRO and AAPM would be pleased to meet with you at your convenience to discuss this regulation. You may contact Lynne Fairobent, ACR at (703) 716-7550, Nancy Daly, ASTRO at (703) 227-0145, or Angela Furcron at (301) 209-3364.

Sincerely,

Harvey L. Neiman, MD

Harvey L. Neiman, M.D.
Chairman, ACR Board of Chancellors

Nora A. Janjan, M.D., F.A.C.P., F.A.C.R.
President, ASTRO

Robert G. Gould

Robert Gould, Ph.D.
President, AAPM

Attachment

cc: Roger Broseus, NRC
Milton Guiberteau, M.D.
Manuel Brown, M.D.
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J. Frank Wilson, M.D.
John Earle, M.D.
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Nancy Daly, ASTRO
Angela Furcron, AAPM
Lynne Fairobent, ACR

Attachment

The American College of Radiology (ACR), the American Society for Therapeutic Radiology and Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) are pleased to provide comments on the draft NUREG-1556, Volume 9 guidance document related to the revised 10 CFR Part 35.

General Comments:

1. NRC needs to clarify in the inspection procedures document and training of inspectors the paradigm shift to a risk-informed performance-based regulatory system. It should be stressed that use of the model procedures in NUREG-1556, Volume 9 are only one suggested method for demonstrating compliance with the revised Part 35. ACR, ASTRO and AAPM recommend that the guidance document state: "*These are model procedures that the NRC believes will, with high probability, achieve compliance with regulatory targets if properly implemented. They are not minimum standards and should not be used as a benchmark or standard for judging the adequacy of a licensee's procedure.*" This sentence should replace the second text box on page 5-1. It should also appear as the introductory text box of each model procedure.

2. In general section 8 is too prescriptive. Information is requested that is not required by 10 CFR §§ 35.12 and 35.15. For example, there is not a requirement that detailed facility-shielding calculations and materials must be submitted. Licensees must maintain survey results for inspection. The license application should require a statement of intent to comply with the regulations, but details referring to shielding reports or calculations are not required. In light of September 11, 2001 it would be better if this information were not available in the public domain.

3. NRC should establish a process whereby the guidance document can be maintained as a living document. This process should be flexible to allow for changes to reflect experience with the new regulations.

4. Appendices C and K should be redrafted to provide an example application, license and licensee audit program for each of the seven categories of medical use as specified on page 8-14. This would replace tables C.2. and C.3. Table C.1 must be revised to reflect the final language of section 8.

5. Although these comments do not contain any reference to the training and experience requirements, the ACR, AAPM and ASTRO intend to submit comments on the training and experience issue in a separate document following the ACMUI subcommittee meeting on June 21, 2002.

6. The NRC needs to redraft the guidance for 10 CFR § 35.1000. This guidance should discuss the process for triggering a licensing action under this provision of the rule. This section should emphasize the process of licensing a new modality under this provision and not dwell unnecessarily on any specific emerging technology (e.g., intravascular brachytherapy) or duplicate modality-specific license guidance published elsewhere. This guidance should also discuss the process for determining when a licensing action under 10 CFR § 35.1000 should be transferred to a new part of the regulation. The intent of 10 CFR § 35.1000 should be spelled out clearly, which we in the regulated community understand to be to facilitate the timely licensing of a new technology or a use of radioactive material that does not fall under existing parts of the regulation and to provide an arena for testing proposed regulatory and licensing requirements, but not to serve as a permanent substitute for regulation.

7. The reference for ordering AAPM documents/reports should be changed to Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from http://www.medicalphysics.org. See pages 8-44 and 8-86.

Section 8: Specific Comments on the Contents of an Application:

1. **8.6 Item 5: Radioactive Material.** (Page 8-7) There should be no requirement for the manufacturer's name and model number for sources and survey equipment. It is very restrictive and unnecessarily burdensome to require this information on sources. Based on this guidance it would appear that if the vendor on the license could not deliver the product, one would need a license amendment to purchase the isotope from another vendor. For some applications (e.g., permanent I-125 prostate seeds) there are approximately 12 different products that are equivalent from the clinical and radiation safety perspectives. The guidance should specify that the acceptable entry on the application be: "*any source listed in the Sealed Source and Device Registry (SSDR) that meets the source strength and use requested.*"

   Suggest inserting in the column titled: *Chemical/physical form*: "*sealed source as specified in the sealed source device registry.*" Licensees should not have to submit license amendments when vendors are changed.

2. **8.7 Item 5: Sealed Sources and Devices.** (Page 8-12) It appears that 10 CFR § 30.32(g) is inconsistent with a risk-informed performance-based philosophy of regulation. Requiring a licensee to submit the "manufacturer's name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 10 CFR § 35.65)" is extremely restrictive. This results in a license amendment every time a vendor is changed.

3. **8.7 Item 5: Sealed Sources and Devices.** Suggest deleting the paragraph on page 8-13 reference to National Institute of Standards and Technology (NIST) traceability.

4. **8.8 Item 6: Purpose(s) for which licensed material will be used.** Insert on page 8-15 following the first sentence "*However, if applying for all material authorized under 10 CFR § 35.300 the information shown in table 8.3 is not required. Table 8.3 provides examples of data entry if you are applying for a license under 10 CFR §§ 35.392 or 35.394 only and indicates iodine use for specific therapy treatment.*"

5. **8.9 Item 7: Individual(s) responsible for radiation safety program and their training and experience.** Suggest adding the following text to the second paragraph page 8-21 "*The committee description might include membership, meeting frequency, quorum and areas of oversight. Minutes should be maintained.*"

6. **8.16 Item 9: Facility Diagram.** (Page 8-31) Neither 10 CFR Parts 20 or 35 requires that detailed facility shielding calculations and materials be submitted. Licensees must maintain survey results for inspection, but need not submit them with a license application. The license application should require a statement of intent to comply with the regulations, but detailed shielding reports or calculations are not required. This section is too prescriptive. In light of September 11, 2001 it would be better if this information were not available in the public domain.

7. **8.17 Item 9: Radiation Monitoring Instruments.** (Page 8-40) 10 CFR § 35.61(b) states: *A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%.* There are 2 basic reasons that the indicated exposure rate would not be within 20% of the true exposure rate:

   a. The meter is non-linear and/or has not been adjusted to be accurate, and

   b. The meter is linear and adjusted to be accurate for a given energy, but the energy response of the meter results in over/under response due to differences in the energy spectrum of the radiation emitted from isotopes other than that in which it was calibrated.

   Energy response should not be a reason to disallow the use of a meter, provided of course that the energy response is known for the meter and an appropriate correction factor used. For instance, in Radiation Therapy, one typically uses the same meter to measure the exposure rate for Cs-137, Ir-192, I-125, and Pd-103. The energy range is from 21 keV for Pd-103 to 660 keV for Cs-137. Many meters commonly used today are not accurate across this wide range of energies. Licensees should not be forced to buy separate meters for each application. Instead, appropriate correction factors should be allowed for each

energy range.

8. **8.18 Item 9: Dose Calibrator and other equipment used to measure dosages of unsealed byproduct material.** (Page 8-41) Rewrite this description to explicitly state when dose calibrators are required.

9. **8.19 Item 9: Dosimetry Equipment – Calibration and Use.** (Page 8-43) Suggest inserting the following in lieu of the existing Paragraph 2 under Discussion: "*The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols accepted by nationally recognized bodies (e.g., AAPM, ACR, ACMP, ANSI). (Note: An AMP is not specified for brachytherapy sources.) The licensee's AMP must calculate the output of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by nationally recognized bodies (e.g., AAPM, ACR, ACMP, ANSI). The calibration procedures should address, in part: ...*"

10. **8.19 Item 9: Dosimetry Equipment – Calibration and Use.** (Page 8-44) Footnote 3 should read "*For brachytherapy sources, "first medical use" is defined as the first use following the effective date of the revised 10 CFR Part 35.*"

11. **8.19 Item 9: Dosimetry Equipment – Calibration and Use.** (Page 8-44) In the second bullet, delete the reference to 10 CFR § 35.432. This is not an appropriate reference here.

12. **8.19 Item 9: Dosimetry Equipment – Calibration and Use.** (Page 8-44) Delete the third bullet. See discussion above on the lack of a need to specify manufacturer's name and model number.

13. **8.20 Item 9: Other Equipment and Facilities.** (Page 8-45) The fourth paragraph of the Discussion section should read: "*For **teletherapy, GSR, and HDR facilities,** the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. A beam-on radiation monitor should be available for each therapy room that is equipped with an emergency power supply separate from the therapy unit meets the requirements of 10 CFR § 35.615(c).*"

14. **8.20 Item 9: Other Equipment and Facilities.** (Page 8-47) Delete the level of detail in the description of facilities. Delete the description of pulsed dose rate (PDR) requirements, as they are too prescriptive and not grounded in regulations. There is no regulatory basis for requiring fixed shielding for pulsed dose-rate brachytherapy. The description in 10 CFR § 35.615 is sufficient. These devices are designed for use in hospital rooms with minimal

structure modification and use restriction of hourly and weekly workload, rather than shielding, to maintain compliance with 10 CFR Part 20 limits.

16. **8.21 Item 10: Radiation Protection Program.** (Page 8-48) In the discussion paragraph, delete the second sentence, which states *the table in Appendix C may be helpful in determining what information must be provided when requesting a license.*

17. **8.22 Item 10: Audit Program**. (Page 8-50) Reference to Appendix K implies that unless not applicable, it must be followed. Revise the text to clearly state that Appendix K is only a suggested guide. Reference to 10 CFR Part 20 suggests that the appendix and discussion are too detailed. Appendix K should be redrafted and merged with Appendix C to provide a sample application, license and audit for each of the seven categories of use.

18. **8.25 item 10: Minimization of contamination**. (Page 8-57) Delete the entire paragraph titled *Response from Applicant.* This is not supported by regulation.

19. **8.33 Item 10: Area Surveys**. (Page 8-65) This section should only include information on area surveys. Delete the information that more appropriately belongs in section 8.35.

20. **8.40 Item 10: Safety Procedures for treatments where patients are hospitalized**. (Page 8-77). The third bullet should read: *Visibly post a "Radioactive Materials" sign on the patient's room and note on the door or in the patient's chart where and how long visitors may stay in the patient's room (10 CFR §§ 35.315 and 35.415).*

21. **8.41 Item 10: Procedures for device calibration, safety checks, operation, and inspection.** (Pages 8-78 to 8-86) All of the parathenticals that reference ANSI should be expanded to recognize other nationally recognized bodies such as AAPM, ACR, and ACMP.

    Suggest adding to the end of the first bullet on 8-81: "*...functioning properly, or a redundant or replacement source indicator light is shown to be functional.*"

22. **8.42 Item 10: Mobile Medical Service**. (Page 8-87) Replace the second sentence, last paragraph with: "*However, a single client site may be authorized only for a single class of service for each mode of service.*"

    A provider may choose to utilize a class 3 provider for mobile HDR, but desire class 1 services for mobile gamma cameras. For a given service, the client site will only have one level of service.

23. **8.43 Item 10: Transportation**. (Page 8-88) This section seems to be appropriate for

background information but not as guidance. If the appendix dealing with transportation remains as an appendix, this discussion should be moved to an appendix as an introduction.

25. **8.44 Item 11: Waste Management**. (Page 8-91) The discussion section is written too prescriptively. The words "should" and "must" should be deleted unless a specific regulation is cited (e.g., bullet 2, last bullet).

26. **8.44 Item 11: Waste Management**. (Page 8-92) It is not clear that the second bullet on this page is supported by regulation. Clarification is needed or this should be deleted.

27. **8.44 Item 11: Waste Management**. (Page 8-93) The discussion under the paragraph titled: *Returning sources* is inaccurate. Some brachytherapy sources are allowed to decay in storage as an acceptable disposal method. Change the first sentence to state: "*For material with a half-life (t1/2) > 120 days contained in brachytherapy, teletherapy, and GSR sources, the only option for disposal is transfer to an authorized recipient as specified in 10 CFR § 20.2001(a)(1).*"

Appendices

1. **Appendix A.** NRC should review and update this appendix. Many of the references contained in this appendix are out of date. In addition, suggest incorporating Appendix W *Transportation* in this appendix since Appendix W simply provided a list references related to transportation of radioactive materials.

2. **Appendix B.** The comments above related to Section 8 also apply to NRC Form 313.

3. **Appendix C.** As indicated in the general comments, Appendices C and K should be redrafted to provide an example application, license and licensee audit program for each of the seven categories of medical use as specified on page 8-14. This would replace tables C.2. and C.3. Table C.1 must be revised to reflect the final language of section 8.

    a. **Table C.2** ***Items 5 and 6 on NRC Form 313: Radioactive Material and Use***. This table should be revised to reflect the final language of section 8. The following items should be clarified at a minimum.

        i. It should not be necessary to submit the manufacturer's name and the model number of the sealed source requested or the survey instrument.

        ii. Also, there is no requirement to indicate whether patients will be released under 10CFR § 35.75 on form 313.

b. **Table C.3.** ***Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal.*** This table should be revised to reflect the final language of section 8. The following items should be clarified at a minimum.

i. Item 8: *Safety Instruction for Individuals Working in or Frequenting Restricted Areas.* Form 313 needs to be clarified in regard to what is required for submittal. It is not clear what the intent is of the "N/A" for this item on page C-10. Suggest inserting the language from page C-13 Item 10 Audit Program.

ii. Item 9. *Facility Diagram.* In light of September 11, 2001, NRC should reconsider the public availability of the type of information required in the suggested response. Additionally, there is no justification in the regulation for the prescriptiveness of this information.

iii. Item 9. *Radiation Monitoring Instruments.* 10 CFR Part 35 does not require that a licensee specify "The instrument type, sensitivity, and range for each type of radiation detected ..." as indicated in the first bullet of the Response from Applicant. This provision should be revised to reflect the current regulation.

iv. Item 9. *Dose Calibrator and Other Dosage Measuring Equipment.* There is no regulation that requires a backup dose calibrator. A facility could switch to unit doses. Secondly, there is no requirement that the person performing the calibration be authorized by the NRC or an Agreement State.

v. Item 9. *Other Equipment and Facilities.* There is no requirement that private rooms be used for unsealed source therapy treatments. In addition the level of detail requested seems unnecessary.

vi. Item 10. *Audit Program.* Suggest inserting the text under the suggested response on page C.10, Item 8 and deleting the existing text.

vii. Item 10. *Occupational Dose.* There is no requirement to submit the "facilities and equipment used for monitoring occupational doses."

viii. Item 10. *Minimization of Contamination.* The level of detail is unwarranted. There is no regulation requiring a description of how the facility's design

and the operation procedures facilitate decommissioning.

4. **Appendices D, E, O, Q, X, and Y:** No comments.

5. **Appendix F:** ***Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority.*** The last sentence of the *Model Delegation of Authority* on page F-2, which states: *It is estimated that you will spend ____ hours per week conducting radiation protection activities* should be deleted.

6. **Appendix G:** ***NRC Forms 313A and 313B.*** This section should be redrafted to reflect that the existing Subpart J is valid for a two-year transition period. Specific comments on NRC Form 313A will be provided in response to the Office of Management and Budget request for comments. At a minimum the form should indicate that medical physicists are licensed in some states.

7. **Appendix H:** ***Model Training Program.*** Refresher training should include topics with which the individual is not involved frequently and requires reaffirmation. Topics for refresher training need not contain review of procedures or basic knowledge that the trainee routinely uses and is familiar with. Many of the topics in the list provide no added benefit. Section 8.14 discussed above ties in with appendix H. Many of these items are unnecessary and should be deleted. Change "will contain" to "may contain" in all the training sections.

   - ***Model Training Program for Medical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources.*** (Page H-1) This paragraph should be rewritten to state: *Personnel will receive instruction, as appropriate, before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the date of instruction or training and the name(s) of the attendee(s) and instructor(s).*

   - ***Additional Training for Authorized Medical Physicists.*** (Page H-3) Delete this entire paragraph, as it is not required by the regulation.

8. **Appendix I:** ***Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program.*** Due to the significant errors in this appendix that would result in many constraints that are unnecessary for assurance of proper calibration and function, the AAPM and ACR are committed to forming a Task Group to develop a model procedure to demonstrate the compliance with Part 35 requirements to address

radiation monitoring instrument specifications for those described in the current Appendix I and model survey instrument calibration program requirements. AAPM and ACR request that NRC withdraw the current Appendix I from the draft and indicate that this appendix is being revised and will be published at a later date.

Examples of problems in Appendix I are:

a. Under "Equipment Selection" the emphasis is sensitivity/efficiency and totally disregards accuracy. This would lead one to believe that a meter equipped with a NaI(Tl) probe is always the best choice. In NCRP No.112, the NCRP lists three uses of portable instruments - Detection/search, relative response, and exposure control. For the detection/search perhaps a NaI(Tl) probe has the edge (although they are expensive, fragile, and at times too sensitive). However, for exposure control where the response priorities (in order of importance) are accuracy, precision, and sensitivity NaI(Tl) is a poor choice because of its' energy dependence (worse that an end-window GM.) The discussion of selection should also include portable ion chambers and energy-compensated GM survey meters.

b. Under "Model Procedures for Calibrating Survey Instruments" Appendix I states "one should use radioactive sealed source(s) that (among other things) – approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed". The range of energies being detected/measured in a Nuclear Medicine imaging lab range from primary gamma energies of 30 to 364 keV (511 if you count PET) plus all the associated scattered photons. A single source cannot test the response of the meter over the range of energies found in clinical practice. Ideally energy independent or energy compensated meters would be employed. The licensee should be allowed to use factors determined by measurements at different energies or be allowed to use manufacturers or published energy response curves for the meter.

10. **Appendix K:** ***Suggested Medical Licensee Audit.*** ACR, ASTRO and AAPM support the concept of an audit list but the level of detail provided in Appendix K is too extensive. See comments on Appendix C redraft. We suggest that a sample licensee audit be developed for each of the seven categories of use and combined with a sample application and license.

11. **Appendix L:** ***Model Procedures for an Occupational Dose Program.*** We believe that NRC needs to apply risk-informed performance-based paradigm to the implementation of 10 CFR Part 20. Examples of changes to this appendix are:

    a. ***External Exposure.*** (Page L-4). The third paragraph should be rewritten to

state: "*If an individual's dosimeter is lost, the licensee should evaluate the need to perform and document an evaluation of the dose the individual received and add it to the employee's record. This evaluation should be based on the employee's exposure history and that of co-workers performing similar functions. If the dose is not likely to approach the legal limit, then it might not be necessary to add the calculated exposure to the employee's dose record.*"

b. ***Investigational Levels – External Dose Monitoring.*** (Pages L-4 – L-6) Suggest inserting as an introduction to Table L.1: "*The following investigation level are not meant to be new dose limits. The intent of investigation levels is to serve as check points above which the results are considered sufficiently important to justify investigation.*"

Licensees may find that the number of investigational levels appropriate for their activities may be one, two or more. Licensees may wish to have investigational levels that are work activity specific to better identify areas for achieving a lower occupational exposure. Licensees may find the suggested investigational levels in the examples are either too high or too low for a particular work activity.

Suggest inserting the following on page L-6 between sentences two and three in the first paragraph: "*Examples of situations which may require higher investigational levels are (but not limited to) nuclear medicine technologists who also perform positron emission tomography (PET) studies, radiologists who perform fluoroscopy in addition to being an AU, and personnel involved in a large manual brachytherapy program.*"

c. ***Internal Exposure.*** (Page L-7) Suggest the following rewrite be substituted for the third paragraph on page L-7:

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

i. adequate equipment to perform bioassay measurements,
ii. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,
iii. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
iv. *the interval between bioassays,*
v.*action levels, and*

vi. *the actions to be taken at those levels.*

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" dated July 1993, Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, dated July 1992, and NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

12. **Appendix M:** ***Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits.*** Examples given are trivial and overly simplified. As presented, they minimize the professional expertise of the qualified individual making these determinations. New examples should be provided. The following are the items that should be considered in evaluating demonstration of public exposure dose:

    - Volatile radioisotopes (e.g., xenon or iodine-131)
    - Discharges to the sanitary sewage system
    - Demonstration of adequate facility design to maintain public exposure levels from nuclear pharmacies, therapy devices, patients having received therapeutic doses and are hospital bound, etc.

13. **Appendix N:** ***Emergency Procedures.*** As written, the emergency procedures for this guidance are not appropriate since they only include a model procedure for teletherapy. Model emergency procedures should be developed as appropriate for the modalities licensed in accordance with 10 CFR § 35.600. Sample procedures may be adopted from the manufacturers' emergency procedures or professional national organizations for guidance.

    - **Spill Kit (page N-2).** The first sentence should read: *Assemble a spill kit that contains the following items, as appropriate:*

14. **Appendix P:** ***Model Procedure for Safely Opening Packages Containing Radioactive Material.*** The first bullet on page P-1 should reflect the regulatory language in 10 CFR § 71.87(i) for consistency. Secondly, everywhere it states: *"notify the RSO immediately"* should be changed to state: *notify the RSO or appropriate supervisory personnel immediately.* The RSO may not always be on the premises.

15. **Appendix R:** ***Model Procedure for Area Surveys.*** This appendix needs to be redone to reflect consistency of current scientific knowledge. The following illustrate typical problems with the current text.

a. Ambient Radiation Levels – Bullet 3. There is no requirement for monthly surveys of laboratory areas, weekly surveys of use, storage, and waste areas, or quarterly surveys of source storage rooms. These items should be deleted.

b. Ambient Radiation Levels – Bullet 4. It is not necessary that the RSO be notified in all cases in which the trigger level is exceeded. Conceivably a nuclear medicine patient may happen to be sitting in a chair on the other side of a wall and a reading > 0.1 mrem/hr would result. In addition, an area may be restricted because an exposure rate greater than 5 mrem/hr may exist. Table R.1 does not have a regulatory basis, and would seem to create new rules.

c. Contamination Surveys. The regulatory basis for this section is unclear. This section needs to be re-written to demonstrate compliance with the new 10 CFR Part 35 rule.

16. **Appendix S:** ***Procedures for Developing, Maintaining, and Implementing Written Directives.*** The following changes need to be made:

a. Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources – F. There is no regulatory requirement for independent checks of full calibration. This item should be deleted.

b. Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources – G. The second sentence should be deleted. One does not necessarily measure the transmission through every block, bolus, and compensating filter material prior to use, nor after source replacement.

c. Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources. This section would be better served if teletherapy, GSR, and remote afterloading were not lumped together.

d. 10 CFR § 35.41 does not require audits of patient cases in conflict with p. S-5. While audits are frequently useful program review tools, there is no requirement for the proscriptive QMP-like audit specified in S-5.

17. **Appendix T:** ***Model Procedure for Safe Use of Licensed*** **Material.** The tenth bullet on page T-1 is inconsistent with Appendix R.

Appendix U: ***Release of Patients or Human Research Subjects Administered Radioactive*** **Materials.** General comment: this entire appendix is written too

prescriptively. Example: page U-20 states "*an occupancy factor of 0.25 is not considered appropriate when...*" Suggest, "*Because of XYZ, occupancy factors of at least XXX are generally used when...*" The option to follow different guidelines in unique situation should be preserved. The language of B.1.2 ("*The following occupancy factors maybe used...*") should be softened so the section does not read like a regulation.

a. Comment: In Appendix U under Supplement B.3 - Internal Dose (page U-26), it is stated "internal doses may be ignored in the calculations if they are likely to be less than 10% of the external dose." In example 4, internal dose is divided by the permissible TEDE of 0.5 rem (rather than the calculated external dose) to arrive at 3%.

However, in example 5, internal dose is divided by the calculated external dose (Thyroid Cancer) to arrive at "about 24%". The example then states, "thus, the internal dose and the external dose must be summed". When calculated this way, the percentage will always be 24% and it will always have to be added.

Recommendation: In example 4, reword the sentence to read "internal doses may be ignored in the calculations if they are likely to be less than 10% of the permissible dose of 5 millisievert (0.5 rem), because the internal dose would be significantly less than the uncertainty in the external dose." In example 5, the percentage should be calculated as in example 4 (i.e., divide by the permissible dose) and the example rewritten. If the licensee uses Equation B-6 to calculate internal dose and divides by the permissible TEDE of 0.5 rem, the 10% value will be reached at about 95 mCi.

b. Comment: Using Equation B-5 with the appropriate values from Table U.6 to calculate external dose and adding the internal dose calculated using Equation B-6, the permissible TEDE is reached at about 180 mCi. Thus, for those patients where an occupancy factor of 0.25 is appropriate (i.e., most patients), the common dosage of 200 mCi will require hospitalization.

Equation B-6 yields "a rough estimate of the maximum likely committed effective dose equivalent from internal exposure". It was developed for "worker intakes during normal workplace operations". It is noted that 10^{-6} is the common rule of thumb for fractional uptake, but that 10^{-5} is used to add a degree of conservatism. If 10^{-6} were used in equation B-6, internal dose would not be an issue. Reference B-4 demonstrates that, in general, for the 39 subjects 10^{-6} is an appropriate factor. However, in reference B-5, 10^{-5} is appropriate for half of the six hyperthyroid treatments. The two individuals with the highest uptakes in reference B-5 were 3

year and 4 months old. However, Equation B-6 uses a dose conversion factor of 53 rem/mCi. The EDE for a child (ICRP-53 - 15% thyroid uptake) can be over 4 times higher.

An article quoted by the NRC does identify the dose from internal contamination as a potentially significant fraction on the permissible TEDE. However, for the one thyroid cancer example in the article, the internal contamination was approximately 10^{-7} of the release activity. In the late 1970s, patients receiving outpatient hyperthyroid dosages were typically given minimal precautions, whereas thyroid cancer patients were hospitalized for several days, released when their residual activity was below 30 mCi, and given extensive precautions. The article does therefore support (with limited data) the fact that providing proper instruction will significantly limit the internal dose to other individuals.

Patients can be released from licensee control if the TEDE to any other individual "is not likely" to exceed 5 mSv (0.5 rem). The individual likely to receive the highest dose is the patient's spouse. For a spouse, following proper precautions, both internal and external dose can be significantly reduced and the permissible TEDE is not likely to be exceeded. Recently published data demonstrate that using Equation B-5 to calculate external dose is conservative and that measured doses are typically significantly less. New data on internal contamination of individuals from patients released containing high activity I-131 radiopharmaceuticals is needed.

Also, for children, following the proper precautions will significantly reduce their dose and extra precautions in the form of special instructions are warranted.

Recommendation: Either eliminate the estimation of internal dose in the Appendix Q calculation of the TEDE with the stated assumption that following proper precautions will limit both external and internal dose and that internal dose is expected to be a small fraction of the external dose. Alternately, since internal dose is a defined part of the TEDE, modify B.3 - Internal Dose to use a fractional uptake of 10^{-6} and rewrite the text to emphasize the importance of proper instruction to keep the uptake at or below 10^{-6}.

c. *Supplement B – Procedure for Calculating Doses Based on Patient-Specific Factors.* This section states that release may be based on "shielding by tissue" but does not have such a term in the equation. **Recommend** the inclusion of a multiplier B_p, where B_p is the patient specific shielding.

$$D(t) = 34.6\ \Gamma\ B_p Q_0 T_p E\ (1- e^{-0.693t/Tp})/\ r^2$$

Note also in Equation B-1, T_p is written as T.

d. Comment: In addition, *Section B.1.2 – Occupancy Factors to Consider for Patient-Specific Calculations* should be rewritten to include additional instructions for families with small children in order to help assure that the external and internal dose is kept ALARA. The inclusion of enhanced guidance for small children would be an important improvement of Appendix U.

18. ***Appendix V: Guidance for Mobile Services.*** *Mobil Services with Remote Afterloader Devices – Bullet 2* (Page V-8). Baseline surveys include source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position. This is reasonable as a baseline. However, the next sentence requires the baseline to be verified following relocation of the unit. This would require that a radiation survey would need to be performed about the treatment room (including roofs) at each site each day of use. This should be changed to require a survey of the source housing to demonstrate shielding integrity. Re-surveys of the treatment room should be performed following alterations of the treatment room, which would affect shielding. For class 2 and class 3 providers, most treatment rooms are shielded in concrete. It would be unreasonable to require a new survey of the room unless something has changed.