Summary of Comments Received on Draft Revision 1 of NUREG-1556, Volume 13

Commented [KJ1]: In our final document, we will have a section of comments for the Revision 2. Note also that this section has numerous duplicated pages that the WG is unable to remove. The duplications need to be removed by NMSS.

For the tables in this Appendix, note that the page number reference associated with each comment under the location heading refers to the page number in the May 2007 NUREG-1556 Draft Report for Comment version of Volume 13, Rev.1, "Program-Specific Guidance About Commercial Radiopharmacy Licenses." Note that comments were requested on the specific changes in this NUREG related to the expanded definition of byproduct material and the ~~Naturally Occurring and Accelerator Produced Radioactive Material (~~NARM~~)~~ rule. Therefore, generally, only comments related to the NARM rule were considered. However, comments that were related to other issues were subsequently evaluated during the drafting of Revision 2 of this NUREG, and the U.S. Nuclear Regulatory Commission's (NRC's) responses to those comments are identified by "NRC Staff Subsequent Response."

Table S.1 Comment from Daniel J. Strom, Dated June 29, 2007

Location	Subject	Comment
Web site	Bookmarks and hyperlinks on Web site	Rev. 0 is extremely useful in teaching nuclear pharmacy students, but only after bookmarks were added. Please implement bookmarks in Adobe Acrobat and create hyperlinks for contents, list of tables, etc.
NRC Staff Response: The NUREG-1556 series of documents are posted on the NRC website in PDF format, which allows search and thumbnail images of pages. Volume 13, Rev. 1, has been posted with a Table of Contents that will provide hyperlinks to each section of the NUREG. This comment will be considered in future revisions and posting of documents in the NUREG-1556 series. **NRC Staff Subsequent Response:** Revision 2 of Volume 13 of the NUREG-1556 will be posted on the NRC website in PDF format, which allows searching the document for key words and phrases. In addition, the NUREG will be posted with a Table of Contents that will provide hyperlinks for accessing each section of the document. ~~These capabilities provide means for efficiently and effectively finding information within the document that may be considered useful for teaching nuclear pharmacy students.~~		

Table S.2 Comment from Michigan Department of Environmental Quality, Dated July 20, 2007

Location	Subject	Comment
General Comment	Public Dose	Radiochemical synthesis units using positron emission tomography (PET) radiopharmaceuticals release radioactive material to the air during their normal processes. The integrity of the transfer line or other hardware can catastrophically fail, releasing a bolus to the atmosphere. We strongly urge the Nuclear Regulatory Commission (NRC) to require PET radiopharmacies to submit an assessment of the potential doses to members of the public during routine use and during a catastrophic failure. We do not believe that the average NRC or state agreement inspector can adequately evaluate the ventilation system design and the computer modeling of public doses during a routine inspection. The complexity of the ventilation systems, the inherent limitations of the different computer codes, and the breadth of input data for the computer codes would be difficult for an inspector to evaluate during an on-site inspection. With the dose assessment submitted during licensing of the facility, NRC staff can adequately evaluate the premises and conclusions of the dose assessment. Then the inspector knows before the inspection that an annual release to the atmosphere of "x" curies of a radionuclide means a dose of "y" millirems to a member of the public. The inspector would need to verify during the inspection that the other input parameters in the dose assessment had not changed.
NRC Staff Response: The NRC staff must have sufficient information to make the necessary determination that the application meets the requirements in 10 CFR 30.33(a)(2) which in this case means the ventilation system will be adequate for the licensee to meet the requirements in 10 CFR 20.1101. The NRC evaluation will include both normal and equipment failure conditions. The NRC does not provide prescriptive guidance because of the flexibility the applicant has in designing facilities, choosing ventilation systems, and developing procedures to meet the requirements. It is the applicant's responsibility to provide sufficient information. During an NRC inspection, the licensee must be able to demonstrate, by measurement or calculation, that the annual dose limits for members of the public has not been exceeded. No change was made to the guidance document.		

Location	Subject	Comment
General Comment	Referenced ANSI Standards	The ANSI standards referenced in Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities" and Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," have been revised. These Regulatory Guides should be reviewed and revised. • ANSI N42.18 "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents" was revised in 2004. • ANSI N13.1 "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances From the Stacks and Ducts of Nuclear Facilities."
NRC Staff Response: The revised ANSI standards N42.18 and N13.1 have been reviewed and the reference in Appendix K of this guidance document has been updated to reflect the revised standards. Revision to Regulatory Guides 8.37 and 4.20 is beyond the scope of this guidance document revision.		

Location	Subject	Comment
Location	**Subject**	**Comment**
Abbreviations (Page xv)	Abbreviations	Abbreviations - Add the following: DU — Depleted Uranium LSC — Liquid Scintillation Counter NaI — Sodium Iodide NaI (Tl) — Sodium Iodide (thallium activated) rad — Unit of Absorbed Dose gy — Gray-SI unit of absorbed dose rem — roentgen equivalent man And delete: cm — centimeter mGy — milligray mR — milliroentgen mrem — millirem mrem/hr — millirem per hour mSv — millisievert mSv/hr — millisievert per hour And add SI prefixes: Prefix / Symbol / Factor / Examples micro / μ / 10-6 / μR milli / m / 10-3 / mCi, mR centi / c / 10-2 / cm kilo / k / 10+3 / kg, kBq mega / M / 10+6 / MBq giga / G / 10+9 / GBq tera / T / 10+12 / TBq
NRC Staff Response: The current Abbreviations section is consistent with NRC policy and the guidance documents in the NUREG-1556 series. Therefore, not all of the suggested changes have been made.		

Location	Subject	Comment
Location	**Subject**	**Comment**
Section 8.9 & Appendix C (Pages 8-31 and C-9)	Facilities and Equipment	"Response from Applicant" regarding "Facilities and Equipment." This section states, "Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101 (d)." What would be considered sufficient verification? Does a facility need to submit a computer model calculating the projected doses to members of the public at various nearby locations or will an unsupported statement that public doses are ALARA be considered sufficient?
NRC Staff Response: The applicant must provide sufficient information for NRC staff to determine that the application meets the requirements in 10 CFR 30.33, "General Requirements for Issuance of Specific Licenses." This information could include computer model calculations or measurements to verify that effluents from the facility will be ALARA. A single statement that public doses are ALARA would not be sufficient. Note that the table in Appendix C is a checklist that duplicates the response to text found in the main body (Chapter 8) of this document.		
Appendix H	Radiation Monitoring	"Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program" should include a discussion on the calibration of radiation detection equipment installed to monitor and quantify the activity released to the atmosphere. For PET radiopharmacies, stack exhaust monitors may be sodium iodide detectors mounted adjacent to the exhaust system. They are calibrated by releasing a known millicurie quantity of radioactive material. The number of counts above background can then be correlated with a known activity. This guidance document should state if the NRC will require subsequent periodic releases to annually (quarterly, monthly) "calibrate" these monitors or will the NRC accept a procedure using check sources to confirm that the response to the check sources has not changed since the initial calibration.
NRC Staff Response: In 10 CFR Parts 20, 30, and 32, there are no specific requirements for how and when radiation monitoring instruments are calibrated. Instruments should be calibrated in accordance with the instrument manufacturer's recommendations. Therefore, specific guidance on the calibration of air monitoring instruments is not provided in this document. **NRC Staff Subsequent Response:** Regulations in 10 CFR 20.1501(c) state that the licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured. It is beyond the scope of this document to describe calibration techniques for equipment such as air monitors. Users of such equipment should consult with the instrument's manufacturer or vendor, or refer to a nationally recognized standard for guidance on performing calibrations.		
Appendix I	Public Dose	"Public Dose" should mention that air intakes for the radiopharmacy building and for adjacent buildings need to be considered in the evaluation of doses to members of the public because of atmospheric releases.
NRC Staff Response: Appendix I currently provides general guidance on the methods that could be used for determining radiation doses to members of the general public. The NRC staff believes that the information in this Appendix is adequate. Therefore, no additional specific information needs to be added to this Appendix.		

Location	Subject	Comment
Location	**Subject**	**Comment**
Appendix P (Page P-4)	Airborne Effluent Release Monitoring	"Air Stack Release Monitoring." ANSI N13.1 "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances From the Stacks and Ducts of Nuclear Facilities."
NRC Staff Response: The revised ANSI Standard N13.1 has been reviewed and the reference in Appendix P of this guidance document has been updated to reflect the revised standards.		
Appendix P(Page P-6)	Airborne Effluent Release Monitoring	"References." • ANSI N13.1 "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities" was revised in 1999 and renamed "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities." • ANSI N42.18 "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents" was revised in 2004.
NRC Staff Response: The revised ANSI Standards, N13.1 and N42.18, have been reviewed and the references in Appendix P of this guidance document have been updated to reflect the revised standards.		
Entire Document	General Comment	Spelling errors were noted.
NRC Staff Response: The noted spelling errors have been corrected.		
Section 8.6.1 (Page 8-11)	Radioactive Drugs	In the definition of radioactive drugs, radiobiologics [radio Latin emitting rays; bio, bios Greek life, living; logics, logica Latin of reason, guiding principles] seems to be an incorrect choice of word and incorrect usage in this context. Monoclonal antibodies are non-living chemicals that may be considered as biological agents or radioactive drugs because they function in a certain way in living systems by seeking out cell-surface antigens, but the term radiobiologics is not a standard synonym for radiolabeled monoclonal antibody.
NRC Staff Response: The term “biologics” was used appropriately to indicate a biological product (e.g., monoclonal antibodies, or Tc-99m tagged red blood cells). The sentence clarifies that the term “radioactive drugs” has a broader meaning than radiopharmaceuticals because it also includes the radiobiologics regulated by the U.S. Food and Drug Administration (FDA) under its biologic license application process. Therefore, no change was made to the guidance.		

Location	Subject	Comment
Section 8.6.1 (Page 8-12)	Redistribution of Discrete Sources of Ra-226	If discrete Ra-226 sources are to be redistributed for beneficial reuse and reconfigured as targets for accelerator irradiation to produce new radioactive materials, the requirements in this section appear to be overly restrictive and inhibitive of this practice. For redistribution of discrete sources of radium-226, it may be impossible to confirm that the discrete sources of radium-226 will be obtained by a [or from a??] manufacturer authorized to distribute it. For most legacy sources, it will not be possible to identify the manufacturer. Manufacturer-supplied package inserts may not have been produced. Limitations on the ability of a licensee to alter Ra-226 packaging may prevent Ra-226 from being recombined into larger-activity sources for use in configurations that are necessary to use Ra-226 as a target for new isotope production. An example would be the use of Ra-226 to produce Ra-225, which decays to Bi-213 for medical applications.
NRC Staff Response: The redistribution of discrete sources of radium-226 (Ra-226) in this section is not referring to reconfiguring the Ra-226 as targets for accelerator irradiation. The redistribution of discrete sources of Ra-226 in this guidance document refers to discrete sources intended to be distributed under 10 CFR 32.74 to a medical use licensee that are distributed to a commercial radiopharmacy, which in turn, distributes them to a medical use licensee. The Ra-226 discrete source is then used by the medical use licensee for calibration of an instrument(s) or for medical use.		
Section 8.7 (Page 8-16)	Management	The commentary that "management responsibility and liability are sometimes underemphasized or not addressed in applications and are often poorly understood by licensee employees and managers" appears to be inappropriate and unnecessary in this guidance document. It should not be the purpose of this document to assume the competence of some applicant organizations. Delete text.
NRC Staff Response: This comment is not related to the naturally occurring and accelerator-produced radioactive material (NARM) rule and, therefore, is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG. **NRC Staff Subsequent Response**: This comment ~~isaddressed~~is addressed in Section 8.7 of draft~~this~~ revision 2 of this NUREG.		

Location	Subject	Comment
Location	**Subject**	**Comment**
Section 8.7.3 (Page 8-22)	Authorized Users	The statement that "applicants should pay particular attention to the type of radiation involved…For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters" seems unnecessary if the student has met the requirements in the text above and has studied the characteristics of ionizing radiation. Again, the NRC appears to be judging competency based on the assumption that a situation could exist where a trained authorized user understands gamma rays but not beta particles. Delete text.
NRC Staff Response: This comment is not related to the NARM rule and, therefore is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG. **NRC Staff Subsequent Response**: Pursuant to 10 CFR 30.33(a)(3), the application will be approved if the applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property; therefore, the ~~authorized user (~~AU~~)~~ must demonstrate training and experience with the type and quantity of material that is to be used at the pharmacy. Section 8.7.3 in draft Revision 2 of this NUREG was revised in response to this comment.		
Section 8.10.6 (Page 8-45)	Safe Use of Radionuclides	The Guidance assumes the radiopharmacy uses only Mo-99/Tc-99m generator systems, when many other types of generators are available or could be developed in the future. The elution breakthrough test is applicable to any radionuclide generator system in the radiopharmacy, not just Mo/Tc. Examples of other generator systems include: Sr-82/Ru-82, Sr-90/Y-90, Ac-225/Bi-215, Ac-227/Ra-223, and Ge-68/Ga-68.
NRC Staff Response: The NRC only has promulgated specific breakthrough test requirements for molybdenum-99/technetium-99m and strontium-82/rubidium-82 generator systems under 10 CFR 30.34(g). However, the strontium-82/rubidium-82 generator breakthrough test is not generally performed at the pharmacy, but at the medical facility before first patient use. Therefore, this guidance document only refers to the molybdenum-99 breakthrough measurements.		

Table S.3 Comments from CORAR, Dated August 1, 2007

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
NRC Staff Response: The NRC does have requirements for submitting a decommissioning plan in 10 CFR 30.36 (g)(1) that may apply to radiopharmacy applicants. Therefore, it would not be accurate to indicate that a decommissioning plan would not be required. Also, changes to NRC's decommissioning compatibility requirements for Agreement States are beyond the scope of this guidance document revision. Therefore, no change was made to the guidance document.		

Commented [s2]: ? The following page appears to be a duplicate of this one. WG Response: The next page needs to be removed. The technical editor must remove it because the WG cannot do so.

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Location	**Subject**	**Comment**

Sections 8.6.1 and 8.6.2 (Pages 8-11 and 8-14)		CORAR commented in 1999 on the original draft of Vol. 13 that the discussion in this section needed to include the characterization of the compounding of non-FDA approved radiochemicals as a nuclear pharmacy, and that NRC should state a position on acceptability of this practice. NRC responded in Appendix U of the proposed draft Vol. 13 that "fitness of a particular radiochemical for use in compounding radiopharmaceuticals for ultimate use in medicine is outside NRC's regulatory authority, and therefore, discussion of this issue is not appropriate in this guidance document." CORAR maintains that it is within the scope of NRC's regulatory authority to require a license to manufacture and distribute radiopharmaceuticals where an operation is using non-FDA approved radiochemicals to compound "radiopharmaceuticals" and FDA considers this subject to "manufacturing" requirements rather than within the scope of pharmacy practice.
NRC Staff Response: The NRC clearly states in 10 CFR 32.72(d) that nothing in 10 CFR 32.72, "Manufacture, preparation, or transfer for CommercialCommercialcommercial dCommercial istribution of RadioactiveRadioactiveradioactive drugs containing byproduct mRadioactive Drugs Containing Byproduct ~~aterial~~material for MedicalMedicalmedical uMedical se under part 35," relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs. The NRC considers that the fitness of a particular radiochemical (whether FDA-approved or not) is within the regulatory purview of the FDA and State boards of pharmacy to resolve and is beyond the scope of NRC's regulatory authority.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Section 8.6.1 (Page 8-11)	Distribution of Radioactive Material	CORAR recommends that discussion be added to this section to address the transfer of radioactive material from nuclear pharmacies to mobile nuclear medicine operations at temporary locations other than those specifically listed on a radioactive material license.
NRC Staff Response: This comment is not related to the NARM rule and, therefore, is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG. **NRC Staff Subsequent Response**: This comment ~~is now~~is addressed in Section 8.6.1 of the draft Revision 2 of this NUREG.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Location	**Subject**	**Comment**
Section 8.6.1 (Page 8-13)	Redistribution of Sealed Sources	CORAR commented in 1999 on the original draft of Vol. 13 that it opposed the requirement for an applicant to confirm that the manufacturer's labeling and packaging will not be altered for redistribution of sealed sources, as an unnecessary burden on nuclear pharmacies. NRC responded in Appendix U of the proposed draft Vol.13 with the statement that "if the packaging is not specified in the approval for initial distribution, then other persons may repackage the source or device for redistribution." CORAR suggests that NRC add this statement to section 8.6.1 of NUREG-1556, Vol. 13.

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
NRC Staff Response: This comment is not related to the NARM rule and, therefore, is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG. **NRC Staff Subsequent Response**: Matters of compatability for Agreement State regulations can be addressed during the rulemaking process and are beyond the scope of this guidance document and therefore not addressed in the draft revision 2 of this NUREG. ~~Inspector experience indicates radiopharmacies that redistribute sealed sources routinely do so without altering the manufacturer's labeling and packaging with minimal burden. In the event that a radiopharmacy desires to repackage a source or device for redistribution, it can submit a license amendment request to do so with the information necessary for approval. Therefore, no change was made to the guidance document~~.		

Commented [txh13]: Was this a response from Revision 1? WG Response: No. This verbiage and others associated with, "NRC Staff Subsequent Response" is the WG's review and response related to items that were not addressed in Rev 1.

Commented [s4]: •? I don't see how this is responsive to what I see as the gist of the comment. Aren't they simply asking for something that is in App. U to also be added to section 8.6.1? WG Response: maybe this ssc comment was related to another comment? This comment is not related to App U. It is possible with the duplication of pages in this section, that cannot be resolved by the WG, that comments were perhaps deleted?

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Section 8.9.2 (Page 8-30)	Facilities and Equipment for PET Radiopharmacies	In the discussion it states, "the majority of the radioactive effluents at a PET radiopharmacy are produced during the synthesis of the PET radiopharmaceutical." A reference is also made in this section to Appendix P as it provides more information on effluent monitoring. CORAR agrees that at least in some cases PET radionuclides do contribute to the profile of radioactive gaseous effluents. However, with the highlighted discussion here on PET, NRC should provide some detailed guidance on monitoring PET effluents and demonstrating compliance with relevant limits. There also is no such guidance in Appendix P.

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
NRC Staff Response: The NRC staff must have sufficient information to make the necessary determination that the application meets the requirements in 10 CFR 30.33(a) which in this case means that the equipment and procedures used to monitor effluent releases meet the requirements in 10 CFR Part 20, "Standards for protection against radiation." The NRC does not provide prescriptive guidance on monitoring for PET or other radionuclides because of the flexibility the applicant has in facility design, effluent monitoring equipment, and procedures. It is the applicant's responsibility to provide sufficient information. No change was made to the guidance.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Location	**Subject**	**Comment**

Section 8.10.1 (Page 8-31)	Audit Program	CORAR members have operations that are subject to the regulatory requirement to conduct annual audits of their Radiation Protection Programs. CORAR commented in 1999 on the original draft of Vol. 13 that it is imperative that NRC recognizes the efforts of a licensee to identify and take appropriate actions for self-identified deficiencies and not to penalize the licensee for its pro-active regulatory compliance program. NRC responded in Appendix U of NUREG-1556, Vol. 13, by stating that NRC enforcement policy (NUREG-1600) specifically affords inspectors the authority to withhold the issuance of a Notice of Violation for licensee identified violations in those cases where it is warranted and appropriated. CORAR appreciates this position but believes it does not go far enough because of the subjective nature of applicability and ongoing exposure of licensees to judgmental variability between inspectors. CORAR has addressed this issue separately with NRC in March 2007 in response to NRC Enforcement Policy; Proposed Plan for Major Revision, Federal Register volume 72, No. 16, page 3429, January 25, 2007. At that time CORAR commented that the Policy should address issues involving licensee disclosure of findings and other information as a result of audits conducted independent of NRC inspections. With regard to audits conducted by or on behalf of licensees, NRC should not require that the results of such audits be disclosed nor should NRC inspectors request copies of audit reports or findings. In addition, audit reports or findings should not be used by NRC to trigger NRC enforcement investigations.

NRC Staff Response: This comment is not related to the NARM rule and, therefore, is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG.

NRC Staff Subsequent Response: A stated purpose of the NRC's Enforcement Policy is to encourage prompt identification of violations of NRC requirements, and includes such recognition to potentially reduce the sanction where a licensee self-identifies a non-conformance. For example, where a licensee has self-identified the violation, the NRC Enforcement Policy Section 2.3.2.b.1 allows for the consideration to reduce a non-escalated cited NOV to a non-cited violation (NCV), and Section 2.3.4.b allows for potential reduction or elimination of the civil penalty in escalated violations. In addition, the NRC enforcement guidance exists to promote consistent and uniform disposition of violations, thus avoiding the potential of "judgmental variability between inspectors". Inspections routinely include review of licensees' self-identification and resolution of problems, including violations of NRC regulatory requirements because self-identification and resolution of problems, including violations of NRC regulatory requirements, is consistent with an effective radiation protection program. Assessment of licensees' self-identification and resolution of problems can include review of records of audits (reference 10 CFR 20.1101(c)) and other reviews of radiation protection program content and implementation that are required to be maintained pursuant to 10 CFR 20.2102(a)(2). NRC enforcement guidance allows that potential non-compliances may be identified through licensee internal audits. No change was made to the guidance in draft Revision 2 of this NUREG.

Location	Subject	Comment
Section 8.10.1 (Page 8-31)	Audit Program	In addition to the relief from civil penalty provided for Severity Level I–III violations in the current Policy, NRC should not cite a Notice of Violation for any non-reportable compliance problems self-identified and promptly and effectively corrected by the licensee. It would be reasonable for NRC to expect the finding, identification of root cause, and corrective action to be documented by the

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
		licensee for future reference. Alternatively, NRC could disposition these as Non-Cited Violations. NRC should ensure that discussion in section 8.10.1 of NUREG-1556, Vol.13 reflect these recommendations. Reference to the Enforcement Policy should be maintained so that any revisions to it will be incorporated by reference into this licensee guidance document.

NRC Staff Response: The recommendations regarding changes to this section are not related to the NARM rule and are beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG.

NRC Staff Subsequent ~~Response~~: ~~In accordance with Chapter 2.2.B of the NRC Enforcement Manual, potential noncompliances may be identified through licensee internal audits. Inspections routinely include review of licensees' self-identification and resolution of problems, including violations of NRC regulatory requirements because self-identification and resolution of problems, including violations of NRC regulatory requirements, is consistent with an effective radiation protection program. Assessment of licensees' self-identification and resolution of problems can include review of records of audits (reference 10 CFR 20.1101(c)) and other reviews of radiation protection program content and implementation that are required to be maintained pursuant to 10 CFR 20.2102(a)(2).~~ ~~Section~~**Response Section** 2.3.2 b of the NRC Enforcement Policy includes criteria for the disposition of a violation as a non-cited violation. That section does not state that non-reportable compliance problems that are licensee-identified and promptly and effectively corrected by the licensee are dispositioned as non-cited violations. No change was made to the guidance in draft Revision 2 of this NUREG.~~No change was made to the guidance.~~

Location	Subject	Comment
Section 8.10.2 (Page 8-35)	Radiation Monitoring Instruments	NRC in this section suggests that an applicant may respond with a statement that equipment used will meet the radiation monitoring specification published in A Table H.1 in Appendix H includes a list of instrument types and "specifications" intended to "help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities." However, a review of TableI.1 concludes that there really aren't any useful specifications provided. For example, energy ranges specified are "all energies." Efficiencies are specified as "moderate" or "high." These are very general and non-specific terms. We recommend that NRC include a table that includes real specifications that would be more useful to those who need this level of technical guidance.
NRC Staff Response: The information in this section and in Appendix H was never intended to provide specific information such as specific energy ranges. Therefore, the title of Appendix H and the text in Section 8.10.2 have been revised to better describe the general information available in the Appendix. **NRC Staff Subsequent Response**: ~~Table HI.1 in Appendix H of NUREG-1556, Vol. 13, Rev1, was not intended to provide specific information.~~ It is beyond the scope of this document to provide a comprehensive list of the different instrumentation types used in radiopharmacies and list each of those instrument's specifications. ~~Therefore,~~ Table H.~~J~~-1 has ~~been~~~~was deleted~~been deleted and ~~it was~~ replaced with general radiation monitoring instrument selection guidelines.		
Section 8.10.3 (Page 8-39)	Record Maintenance	Table 8.2 should be expanded to include the retention of written directives for three years in accordance with 35.2040-2041.
NRC Staff Response: Records for written directives are required to be maintained by the medical-use licensee in accordance with 10 CFR Part 35, "Medical Use of Byproduct Material," and not a commercial radiopharmacy licensee. Therefore, the retention of written directives was not added to Table 8.2.		
Section 8.10.4	Occupational Dose	NRC in recent years has paid significant attention to the issue of extremity dose and occupational monitoring at commercial nuclear pharmacies. CORAR and its members have approached NRC and have established a

Commented [txh15]: Was this a response from the last revision? WG Response: No. This verbiage and others associated with, "NRC Staff Subsequent Response" is the current WG's review and response to the comments that were not addressed during Revision 1.

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
(Page 8-40)		partnership in an effort to investigate the issue and develop needed guidance on methodologies for monitoring extremity dose to demonstrate compliance with 20.1201(a)(2)(ii). CORAR believes that guidance on extremity dose monitoring is warranted and strongly recommends that this section include discussion on this.
NRC Staff Response: The current guidance in this section provides general information regarding occupational dose requirements. Specific guidance on the methodologies for monitoring extremity dose is beyond the scope of this document revision as it does not relate to the NARM rule. This comment will be considered during any future revision of this NUREG. **NRC Staff Subsequent Response**: Section 8.10.4 of draft revision 2 of thie NUREG was revised in response to the comment.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Location	**Subject**	**Comment**
Section 8.10.4 (Page 8-41)	Occupational Dose	This section should provide some guidance on whether an evaluation conducted to determine that an individual's dose is not likely to exceed 10~~% of~~% of the applicable limit needs to be conducted initially or at a recurring (e.g., annual) frequency thereafter. CORAR believes that the evaluation only needs to be conducted initially unless there is a change in the procedure or operation that could result in a higher exposure.
NRC Staff Response: The current guidance in this section indicates that an evaluation of the dose an individual is likely to receive should be performed prior to allowing the individual to receive a dose and does not indicate that the evaluation should be performed at a recurring frequency thereafter. As indicated in Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," which is referenced in this section, if an individual's radiation exposure conditions change, the need to provide individual monitoring should be reevaluated.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Section 8.10.5 (Page 8-44)	Public Dose	There is discussion in this section on the need for licensees to control air emissions so that the constraint level of 0.1 mSv is not exceeded. However, there is no mention in this section of methods acceptable to NRC to demonstrate compliance with the constraint level. CORAR recommends that NRC provide in this section an acceptable method (e.g., EPA COMPLY code), or make reference to other NRC guidance that provides a method for demonstrating compliance with the constraint level.
NRC Staff Response: A reference to Regulatory Guide 4.20, "Constraints on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," was added to Appendix I. This regulatory guide provides guidance on acceptable methods that can be used to demonstrate compliance with the air emissions constraint level.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Section 8.10.6 (Page 8-44)	Safe Use of Radionuclides	Discussion in this section states, "licensees are responsible for the security and safe use of all licensed material from the time it arrives." CORAR recommends that NRC clarify the distinction between delivery of radioactive material by the carrier and receipt by the authorized consignee. This has implications with respect to the security of material in transport and obligations to report lost or missing shipments of radioactive material. It would be helpful for NRC to specify, or provide a reference that specifies, when a transfer from one licensee to another has been completed and at what point is security of the material transferred from the consignor to the consignee. It has been clarified by U.S. DOT in 49 CFR 171.8 regarding the definition of "unloading incidental to movement" that the cycle of transportation ends when delivery is made. This needs to be taken into consideration by NRC for additional discussion in this section.

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
NRC Staff Response: This comment is not related to the NARM rule and, therefore, is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG. **NRC Staff Subsequent Response**: Section 8.10.6 was revised in draft revision 2 of this NUREG to address this comment pertinent to the responsibility for reporting lost material during shipment by a common carrier. The responsibility for securing licensed material during shipment from one licensee to another depends on the circumstances and it is evaluated on a case-by-cases basis.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Location	**Subject**	**Comment**
Section 8.10.6 (Page 8-45, Figure 8.4)	Use of Appropriate Shielding	The picture intends to show the use of appropriate shielding in a nuclear pharmacy operation. Compared to actual nuclear pharmacy operations, it suggests a situation that does not employ best practices with regard to ALARA. For example, there are multiple unshielded containers in proximity to the extremities and no evidence of any remote or extended handling devices within reach. The handling is also done on a bench top that would be unacceptable for dispensing of radiopharmaceuticals. This picture should be left out of the guidance or replaced with a more acceptable example.

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
NRC Staff Response: This comment is not related to the NARM rule and, therefore, is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG. Note that this figure does represent the appropriate shielding for using/dispensing some radiopharmaceuticals (e.g., technetium-99m). **NRC Staff Subsequent Response**: Figure 8.8 of draft revision 2 of thie NUREG was revised to address the comment.		
Entire Document	General Comment	The term "radionuclides" instead of "radioisotopes" should be used here and throughout the document.
NRC Staff Response: The term "radioisotope(s)" has been changed to "radionuclide" when applicable.		
Section 8.10.7 (Page 8-49, Figure 8.6)	Radiation Surveys	The figure shows improper monitoring technique. The detector needs to be placed as close to the object being surveyed without making contact.

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
NRC Staff Response: This figure is meant only to illustrate that generally, users of unsealed licensed material should survey themselves before leaving restricted areas. Therefore, no change was made to this figure. **NRC Staff Subsequent Response**: Figure 8.6 of the draft revision 2 of this NUREG was revised to address the comment.		
Section 8.11 (Page 8-60)	Disposal by Decay-in-Storage	NRC suggests that waste held for decay should be held until a date when "ten half-lives of the longest-lived radioisotope have transpired." Other recent NRC guidance has dropped this requirement and only requires that residual radioactivity be determined to be indistinguishable from background prior to disposal. The guidance in this section should be made consistent with other NRC guidance.
NRC Staff Response: This text has been removed from this section, as the NRC staff agrees that waste should be held for decay until the radiation exposure rate cannot be distinguished from background radiation levels.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.
Appendix I (Page K-3)	Occupancy Factors	CORAR recommends that NRC incorporate into Table I.1 the occupancy factors from NCRP Report 147 (page 31) for planning and assessing public dose.
NRC Staff Response: This comment is not related to the NARM rule and, therefore, is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG. **NRC Staff Subsequent Response**: Table I.1 of the draft revision 2 of this NUREG was revised to address this comment.		

Location	Subject	Comment
General Comment	Authorized Nuclear Pharmacist	One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.
NRC Staff Response: Guidance regarding "grandfathering" of nuclear pharmacists has been added in Section 8.7.2.		
Section 8.2 (Page 8-2)	Timely Notification of Transfer of Control	It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.
NRC Staff Response: As discussed in this section, it is the licensee's responsibility, not the RSO's responsibility, to provide written notification prior to transferring control of the license. No change was made to this section.		
Section 8.5.2 (Page 8-9)	Financial Assurance	CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.

Location	Subject	Comment
Appendix P (Page P-6)	Air Stack Release Monitoring	The reference to ANSI N13.1 (1969) should be revised to refer to the updated 1999 version.
NRC Staff Response: The revised ANSI N13.1 has been reviewed and the reference in Appendix P of this guidance document has been updated to reflect the revised standards.		

Table S.4 Comments from Washington State Department of Health, Dated August 1, 2007

Location	Subject	Comment
Foreword (Page x)	General	The second paragraph, 3rd sentence should read: This expanded definition includes the material that is **produced**, extracted or converted after extraction for use for a commercial, medical, or research activity.
NRC Staff Response: The word "produced" has been added to this text.		
Section 8.5.1 (Page 8-5)	Sealed Sources or Devices	The fourth paragraph reads: It should also be noted that NRC's regulatory authority includes the new byproduct material produced prior to August 8, 2005. As a result, neither NRC, an Agreement State, nor a non-Agreement State may have performed a safety evaluation of the sealed source or device. Therefore, the sealed source or device may not have ~~an~~a Sealed Source and Device Registry (SSD) registration certificate. 10 CFR 30.32(g) ~~provideprovide~~provides~~provide~~ information that must be submitted for these types of sources. This paragraph is written poorly and the intent of the paragraph is unclear. The paragraph should be rewritten to clearly express the intent.
NRC Staff Response: This paragraph has been edited to clarify its intent.		
Section 8.9.2 (Page 8-30)	Shielding/ Remote Handling Equipment	The guidance should separate the shielding discussion from the remote handling equipment discussion. Descriptions of shielding should be provided for the transfer lines when transferring material from the cyclotron to the hot cell, and between the hot cell and the chemistry synthesis unit. Descriptions of shielding should also be provided for the physical hot cell, chemistry synthesis unit, both short lived and long lived (from target rebuilding) waste. The applicant should describe the remote handling equipment that will be used (i.e., manipulators in the hot cell, automatic transfer lines to move material between process stations).
NRC Staff Response: The discussion on shielding has been edited to differentiate between the description of the type of shielding and the remote handling equipment that will be used.		
Section 8.9.2 (Page 8-30)	Effluent Control and Monitoring	Examples of engineered controls to reduce the amount of material released should include the use of gas-trapping bags to capture the effluent from the chemistry synthesis unit. It is a common practice to hold up the high activity, short lived effluent in a bag for decay. This method is extremely effective in substantially reducing the amount of activity released as effluent to the air from a manufacturer of PET radiopharmaceuticals. If gas-trapping bags are used the applicant must address the location, shielding, and handling (emptying) of these gas-trapping bags.

Location	Subject	Comment
NRC Staff Response: In the discussion section of Section 8.9.2, the use of a containment system for the decay of effluents was mentioned. Holding and decaying short-lived effluents may be done in many different ways. Therefore, specific details on the type of containment system used (e.g., gas-trapping bags) were not added to this discussion.		

Location	Subject	Comment
Section 8.9.2 (Page 8-30)	Facilities and Equipment	The applicant should also discuss the procedures/ controls in place to assure the integrity of the transfer lines are not compromised prior to a transfer. A loss of material during a transfer from the cyclotron to the hot cell could result in a substantial amount of high activity material being spilled, potentially causing a high personnel exposure.
NRC Staff Response: The NRC does not require the applicant to provide specific procedures on operation/use of the equipment. However, the applicant should have, as part of its Radiation Safety Program, procedures that would prevent the loss of radioactive material.		
Section 8.9.2 (Page 8-32)	Facilities and Equipment	Figure 8.3 should appear in Section 8.9 not 8.10; Figure 8.3 should be moved to page 8-31 and the information on page 8-31 should be moved to page 8-32.
NRC Staff Response: Figure 8.3 has been moved into Section 8.9.2, "Facilities and Equipment for PET Radiopharmacies."		
Appendix ~~M~~K	Department of Transportation Requirements	Why was the information in Appendix K~~M~~ replaced completely? The Appendix M information contained in the original NUREG-1556, Volume 13, appeared to be informative and beneficial.
NRC Staff Response: The previous information in Appendix K~~M~~ was revised to help ensure that the applicant would have current transportation information as provided in the U.S. Department of Transportation (DOT) regulations. The previous information in Appendix K~~M~~ had very specific information regarding DOT regulations that may change, and NRC would not be able to ensure that any changes to this information could be immediately incorporated into this Appendix. **NRC Staff Subsequent Response**: Appendix K of the draft revision 2 of this NUREG includes current transportation information regarding DOT regulations. In addition, Appendix K states, "For additional transportation information, licensees may consult DOT's "A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials" or go to the DOT's W~~w~~eb site at http://hazmat.dot.gov.		

Table S.5 Comments from Washington University in St. Louis, Dated August 1, 2007

Location	Subject	Comment
Chapter 1 (Page 1-1)	Purpose of Report	In the first paragraph on page 1-1, the draft guidance states "…the phrases or terms, 'commercial radiopharmacy,' 'radiopharmacy,' 'nuclear pharmacy,' and 'pharmacy' are used interchangeably." We strongly recommend that NRC not include "pharmacy" as one of these interchangeable terms. We also recommend that a clarification statement be added noting that the interchangeable use of "commercial radiopharmacy," "radiopharmacy" and "nuclear pharmacy" does not necessarily mean the guidance applies for a noncommercial radiopharmacy or a noncommercial nuclear pharmacy.
NRC Staff Response: The term "pharmacy" was deleted from the list of interchangeable terms. As discussed in response to the next comment, the term "pharmacy" was replaced with the term "nuclear pharmacy" in the text where the change was appropriate. Also, the first sentence of this section indicates that this guidance document is for an applicant that is applying for a commercial radiopharmacy license. Therefore, additional text is not needed to indicate that this guidance is not for a noncommercial radiopharmacy.		

Location	Subject	Comment
Section 8.9	Facilities and Equipment	We recommend replacing all uses of the term "pharmacy" with "nuclear pharmacy," "radiopharmacy," or "pharmacy (radiopharmaceuticals)." The following examples show where the use of the term, "pharmacy", is giving either incorrect or unclear guidance. Without use of a clarifying term such as "nuclear pharmacy," "radiopharmacy," or "pharmacy (radiopharmaceuticals)," the following statements imply a state pharmacy license is appropriate to become a commercial radiopharmacy: **Page 8-26** – "Licensure as a pharmacy by a State Board of Pharmacy; or…" **Page 8-27** – "Applicants must provide: Copies of their registration or license from a State Board of Pharmacy as a pharmacy…" **Page 8-30** – "PET radiopharmacies must demonstrate that they are …licensed as a pharmacy by the State's Board of Pharmacy…" **Page C-9** – "Provide a copy of the registration or license from a State Board of Pharmacy as a pharmacy…" Without the use of "nuclear pharmacy" or "radiopharmacy," the following statement may be confusing by suggesting an individual only needs pharmacy experience: **Pages 8-20, C-7 & D-5** – "The individual practiced at a pharmacy at a Government agency or ~~f~~Federally recognized Indian tribe before April 8, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by NRC."
NRC Staff Response: The term "pharmacy" was replaced with the term "nuclear pharmacy" where applicable. It should be noted that most State Boards of Pharmacy only issue pharmacy licenses and not "nuclear" pharmacy licenses. Therefore, all uses of the term "pharmacy" were not replaced in the document.		

Location	Subject	Comment
Section 8.7.2 (Page 8-19)	Authorized Nuclear Pharmacist	In Section 8.7.2 Discussion, the draft guidance describes the sections of regulation defining the training and experience requirements to become an Authorized Nuclear Pharmacist (ANP) at a commercial radiopharmacy. We recommend that a statement be added to this section which discusses the "grandfathering" of a nuclear pharmacist who has used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both for medical or nuclear pharmacy uses. We suggest the following paragraph be added at the end of this discussion section: "Nuclear pharmacists who used accelerator-produced radionuclides or discrete sources of Ra-226 during the effective period of the waiver do not have to meet the requirements of 10 CFR 35.59, or the training and experience requirements in 10 CFR Part 35, Subpart B for those materials and uses. The criteria for such nuclear pharmacists are described in 10 CFR 32.72(b)(4) and acceptable documentation is discussed in Appendix E."
NRC Staff Response: Text has been added to this section to discuss the "grandfathering" of a nuclear pharmacist who has used only accelerator-produced radioactive materials for the preparation of radioactive drugs.		
Appendix E (Page G-5)	Training Documentation	The statement under "State or Territory where Licensed" on page G-5 indicates that pharmacists are licensed to prescribe drugs. This statement is incorrect, and we recommend the statement be corrected to say that pharmacists are licensed to dispense drugs.
NRC Staff Response: The statement has been corrected to say that pharmacists are licensed to practice pharmacy.		

Location	Subject	Comment
Appendix E (Page G-6)	Training & Experience Documentation	In Appendix E Part II Preceptor Attestation (page E-6), the current regulatory definition of preceptor is quoted, and we note that nowhere is it indicated that the preceptor must have the same "authorization" as is sought by the individual whose training and experience is being verified by the preceptor. As NRC is preparing to "grandfather" individuals who have used accelerator-produced radionuclides to be an ANP (or an AU, AMP or RSO), there is an opportunity to bring the training and experience criteria for ANPs (AUs, AMPs and RSOs) more in line with the preceptor definition. We agree that a preceptor statement from a current ANP is appropriate for those individuals seeking to become an ANP by the alternative pathway. WU strongly recommends that the NRC staff and, in particular, the NRC Commissioners reconsider the need for an ANP preceptor statement for those individuals who are board-certified by an NRC-recognized specialty board. Each of the specialty boards recognized by the NRC have proven to the NRC that their board eligible candidates meet the training and experience requirements for the type(s) of medical use for which they are recognized. In order to sit for a board exam, an individual requires the recommendation of a sponsor who verifies the individual has met all of the requirements to become board-certified. While this sponsor may not be an ANP, the sponsor is responsible to the board for recommending only individuals who meet the board's, and therefore the NRC's, requirements. Successful completion of the board exam by the individual gives further verification of the individual's training and experience. WU believes the current regulations imposing the additional requirement of an ANP preceptor statement is an unnecessary redundancy that has greatly complicated the process of approving an individual as an ANP, and has led to the trivialization of long-established radiopharmacy board-certification.
NRC Staff Response: Any revisions to the training and experience requirements would require a revision to NRC's current regulations. Therefore, this comment is beyond the scope of this guidance document revision.		

Location	Subject	Comment
Appendix E (Page E-6)	Training & Experience Documentation	We appreciate that NRC has taken care to ensure the continuing access of PET imaging techniques by allowing the "grandfathering" of individuals who have used accelerator-produced radionuclides to become ANPs (or AUs, AMPs or RSOs). We believe that NRC also "grandfathering" individuals who have received board-certification prior to NRC's recognition of a specialty board would be in line with the grandfathering for medical use of the new byproduct materials. In certain cases, such as those individuals who have been board certified by the American Board of Health Physics (ABHP) prior to January 1, 2005 and never named as RSO on a NRC or Agreement State license, an individual could not currently be named as an RSO based on their board-certification even though the ABHP made no changes in its certification process to receive NRC-recognition. WU also strongly recommends that NRC allow grandfathering of individuals who were board-certified prior to NRC-recognition for all specialty boards which receive NRC-recognition prior to the required implementation date, August 9, 2009, for the new byproduct definition.
NRC Staff Response: Any revisions to the training and experience requirements would require a revision to NRC's current regulations. Therefore, this comment is beyond the scope of this guidance document revision.		

Location	Subject	Comment
General Comment	Distribution of Radionuclides	WU plans to incorporate a commercial radiopharmacy license into our overall broad scope license for the distribution of copper-64 (Cu-64), and possibly other accelerator-produced radionuclides, to other research entities for their production of radiopharmaceuticals for human research use. WU's continued intent in supplying accelerator-produced radionuclides is to further the research and development of imaging techniques with eventual technology transfer to an entity that would commercially produce and distribute one or more of these radionuclides. Since these research entities, which are located throughout the U.S., do not meet NRC's proposed definition for being in a "consortium" with WU, we will be obligated to become a "commercial" radiopharmacy, even though our distribution of accelerator-produced radionuclides for eventual human use will continue to be for noncommercial research and development. We plan to list separately a license item for Cu-64, and possibly other accelerator-produced radionuclides, and plan to identify purpose of use as 10 CFR 32.72. Question – In Appendix D.5 (pages D-2 & D-3), the purpose of use is listed as 10 CFR 32.72 and 10 CFR 30.41. NRC has stated in the draft Federal Register Notice (SECY-07-0062, Enclosure 1, p.128): "In general, a PET radionuclide production facility may transfer excess PET radionuclides to other licensees that are authorized to receive such PET radionuclide transfer under 10 CFR 30.41." "An applicant's intent regarding noncommercial distribution, transfer, or commercial distribution will be evaluated as part of the licensing review process to ensure that the proper license or authorization is issued." Does NRC agree a licensee that is required to obtain a commercial radiopharmacy license to cover a subset of its transfer of radionuclides, such as described here for WU's situation, is allowed to make noncommercial transfers under 10 CFR 30.41 for radionuclides not included in commercial radiopharmacy license purpose of use?
NRC Staff Response: The commenter does not appear to be raising a comment on this guidance document, but rather to be asking a specific question as to licensing its activities. If there are any questions as to what authorizations are needed, licensees should contact their NRC regional office.		

Location	Subject	Comment
General Comment	Distribution of Radioactive Drugs	What guidance does NRC give license applicants for 10 CFR 32.72 distribution of radionuclides that may contain other radionuclide contaminants? Should not guidance on how to describe these potential contaminants be included in this document? Examples of these types of radiopharmaceuticals that are widely used include: Sm-153 Quadramet which can include Eu-154 and Eu-155 Tl-201 Thallous Chloride which can include Tl-200, Tl-202 and Pb-203 In-111 Indium Chloride which can include In-114m and Zn-65
NRC Staff Response: The NRC understands that some radionuclides may contain small amounts of radionuclide contaminants. Generally, NRC authorizes the possession and/or use of the main radionuclide and assumes that contaminants are part of the main radionuclide's characteristics. Therefore, the NRC staff does not believe that additional guidance is needed for describing radionuclide contaminants.		

Location	Subject	Comment
Section 8.5.1 (Page 8-7)	Sealed Sources	The draft guidance discusses what a radiopharmacy applicant should do if it possesses a sealed source containing the new byproduct material and there is no Sealed Source and Device (SSDR) certificate. NRC expects this applicant to provide information required under 10 CFR 30.32(g), which states: "An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either-- (1) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter or with an Agreement State; or (2) Contain the information identified in § 32.210(c)." 10 CFR 30.32(g)(1) appears to be asking for the SSDR, which seems redundant since NRC requests this information because there is no SSDR. To meet 10 CFR 30.32(g)(2), 10 CFR 32.210(c) states: "The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property." The information NRC requests may not be readily available to the applicant if the radiopharmacy purchased the source from someone else. If NRC asks for this information from every applicant possessing the sealed source, then it appears that NRC will be receiving multiple requests to do a safety evaluation for the same sealed source model. We recommend that NRC work directly with the sealed source manufacturers to begin conducting safety evaluations and issuing SSDR certificates. Guidance for applicants who only possess these sealed sources should be able to provide NRC with the manufacturer name, source model number and general physical description.

NRC Staff Response: The information required under 10 CFR 30.32(g)(1) and (2) applies to all sealed sources, devices, and sealed source-device combinations. As part of the NARM rule, a new paragraph (3) was added to 10 CFR 30.32(g) that allows a basis for the licensing of sealed sources and devices containing NARM that were manufactured before the effective date of the rule and for which all of the information required in 10 CFR 30.32(g)(1) and (2) is not available. Without this provision, an applicant who wanted to use the NARM source or device that was not registered in the SSDR would have been required to submit all of the safety information identified in 10 CFR 32.210(c), because this information had not been submitted already by the manufacturer or distributor as part of registering the source or device. When all the information required by 10 CFR 32.210(c) is not available, 10 CFR 30.32(g)(3) allows a basis for licensing these sources and delineates information that will be required to license a NARM source or device. The NRC recognizes that a number of "legacy" sources containing these materials were produced by manufacturers that are no longer in business or have stopped making the sources and/or devices some time ago. These are the sources for which NRC expects to receive information under the provisions of 10 CFR 30.32(g)(3). The text in this section of the guidance document has been revised to clarify this new provision.

Location	Subject	Comment
Section 8.6.1 (Page 8-12)	Verification of License Authorization	The draft document provides guidance on verifying whether a transferee is allowed to receive the type, form and quantity of byproduct material to be transferred. Supplying copies of licenses has become problematic in the security conscious world of NRC Increased Controls. In NRC's RIS 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," Appendix 3, material licensees are told to withhold authorized quantities, manufacturers, model numbers and locations of sealed sources and devices exceeding threshold values. For some licensees, like WU, supplying a copy of the NRC license with multiple areas blacked out can look unprofessional and suspicious. Comment & Recommendations – If NRC states the radiopharmacy should "verify that the address to which radioactive materials are delivered is an authorized location of use listed on the customer's license," and notes that the "most common form of verification" is possession of a "valid copy of the customer's NRC or Agreement State license", we are concerned that licensees will only accept copies of licenses as verification. We recommend either NRC delete mention of obtaining a copy of the license, or expand the explanation that another acceptable verification is a written certification by the licensee receiving the radioactive material that states the licensee is authorized by license or registration to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date. We also recommend that NRC include in this discussion that some licensees may choose to provide their own written verification and not to provide a copy of their license based on NRC guidance given in RIS 2005-31.
NRC Staff Response: This comment is not related to the NARM rule and, therefore, is beyond the scope of this guidance document revision. This comment will be evaluated during any future revision of this NUREG. **NRC Staff Subsequent Response**: Section 8.6.1 of the draft revision 2 of this NUREG was revised to remove language stating that having a copy of the recipient's license is the most common means of verifying that byproduct material will be transferred to an authorized recipient.		

Chapter 3 (Page 3-1)	Management Responsibility	Definition of "Management" should be similar to that found in Vol. 11 (Broad Scope). We suggest it be modified to read: " 'Management' refers to the processes for conduct and control of a Radiation Safety Program and to the individuals who are responsible for those processes and have authority to provide necessary resources to ensure safety and to achieve regulatory compliance."
NRC Staff Response: Changing the definition of "Management" for this guidance document is beyond the scope of this revision. The definition for "Management" found on page 3-1 of this guidance document is consistent with other NUREG-1556 guidance documents (e.g., NUREG-1556, Volume 12).		

Location	Subject	Comment
Section 8.5.1 (Page 8-8)	Unsealed Byproduct Material	To strengthen the idea that this draft document has been updated to include the new byproduct materials, we suggest that iodine-123 be included as an example for potentially volatile materials.
NRC Staff Response: Iodine-123 has been added as an example for potentially volatile materials in this section.		
Section 8.7.2 (Page 8-20)	Authorized Nuclear Pharmacist	Should the statement, "For an individual qualifying under 32.72(b)(5)" be corrected to reference 32.72(b)(4)?
NRC Staff Response: Changes have been made to the document to implement this correction.		
Section 8.9.1 (Page 8-29)	Facilities and Equipment	The ~~two~~2 bulleted items following Figure 8.2should be deleted since they are repeated text.
NRC Staff Response: The ~~two~~2 bulleted items following Figure 8.2 have been removed.		
Section 8.10.6 and Appendix C (Pages 8-45, 8-47, and C-11)	Safe Use of Radionuclides	To strengthen the idea that this draft document has been updated to include the new byproduct materials, we suggest that performing Sr-82 and Sr-85 breakthrough measurements also be included for elution from a Rb-82 generator.
NRC Staff Response: The NRC only has specific breakthrough test requirements for molybdenum-99/technetium-99m and strontium-82/rubidium-82 generator systems under 10 CFR 30.34(g). However, the strontium-82/rubidium-82 generator breakthrough test is not generally performed at the pharmacy, but at the medical facility prior to first patient use. Therefore, this guidance document only refers to the molybdenum-99 breakthrough measurements.		

Appendix E (Page E-4)	Typographical Error	The "[BOLD]" after IV. Recentness of Training should be deleted.
NRC Staff Response: The term “[BOLD]” has been deleted from this section.		
Appendix E (Page E-5)	Training and Experience Documentation	The Note on this page states, "An individual that is board eligible will not be considered for this pathway until the individual is actually board-certified." Does NRC consider an individual to be board-certified when they have received written confirmation that they successfully completed their board exam?
NRC Staff Response: Individuals are considered board-certified when they receive written confirmation from the specialty board that they are certified. Successful completion of the board exam may not mean that the individual is board-certified.		