

**Resolution of Comments from the Public on the Proposed Revision to NUREG-1556, Volume 11, Consolidated Guidance about Materials Licenses — Program-Specific Guidance about Licenses of Broad Scope**

<b>Comment No.</b>	<b>Commenter</b>	<b>Location in the Volume</b>	<b>Comment</b>	<b>Resolution</b>
1	WA	General Comment	It is very difficult and time-consuming to review a document without knowing what has been changed. Since reviewing documents is not funded, perhaps the minimum impact should be imposed by the NRC on the regulatory programs and others providing review and comments.	NRC Staff appreciates the comment, but notes that the topic is outside its purview.
2	WA	General Comment	The NRC should make greater use of bullets, spacing and white space, and examples.	NRC Staff proposes no action because it believes that the layout and formatting of the document is adequate.
3	WA	General Comment	No more sample licenses – while this may not affect applicants, this definitely [affects] agreement states, who use this NUREG for licensing guidance.	NRC Staff proposes no action and notes that one of the reasons that NRC initiated the revision of the NUREG-1556 series was to remove information from the documents that could be used by an adversary to exploit the licensing process. As such, sample licenses were removed over concern that the information in these licenses could be used by an adversary.
4	WA	General Comment	There appears to be only minor reference to part 37 security requirements in this NUREG. It is not listed as a	NRC Staff agrees and has added extensive information

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			regulation under 8.10.6 Safe Use of Radionuclides and Emergency Procedures or executive management responsibilities	on, and references to, the requirements of 10 CFR 37, to sections 8.5.1, 8.7.3, 8.8, 8.9, 8.10.1, 8.10.3, 8.10.6, 8.10.8, 8.11, App. E, App. F, and App. G. Also, section 8.10.9 addresses the requirements in 10 CFR Part 37.
5	WA	General Comment	Security and control of radioactive materials is one of the ultimate responsibilities for executive management. Responsibilities of executive management appear to be in several different places. Why are they not consolidated?	NRC Staff disagrees with having executive management responsibilities consolidated. The NRC staff believes that the most appropriate place to address management responsibilities is in each topical section so that each of these sections provides guidance on all licensee responsibilities with respect to the topic.

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6	WA	General Comment	It is my understanding from working on a 1556 volume update that the guidance must follow regulatory statutes and cannot require what is not in the regulations. Yet, Safety Culture, is not regulated, and we have been told that it will NOT be made regulation, and safety culture is espoused in this NUREG	NRC Staff appreciates the comment. At this time, the NRC does not intend to incorporate safety culture into its regulations and NRC staff believes that the text is clear on this point. The safety culture provisions in this NUREG are guidance, not legally binding regulations or requirements. However, NRC Staff believes that it is important to introduce this topic and provide a link to additional resources as was done in section 3.2.
7	OAS	Section 8.7.3, App. C	Regarding Type C broad scopes, NRC refers throughout the document to “someone responsible for the day-to-day operations of the radiation safety program” while resisting calling this individual a RSO. The reason given is that NRC regulations do not specifically require a RSO for Type C broad scope licenses. However, although NRC regulations likewise do not specifically require a RSO for R&D, portable gauge or fixed gauges licenses, the corresponding NUREGs regularly refer to RSOs of these licenses. The distinction in the broad scope NUREG introduces unnecessary confusion. You should raise the distinction when the subject is introduced and state that, for the purposes of this document, this individual will be referred to as the RSO. Then, later in the document refer to the individual as the RSO.	NRC Staff agrees and revised the text in Section 8.7.3, “Radiation Safety Officer,” and Item 7, App. C as indicated: Criteria section: “Type C broad scope licensee management should appoint someone responsible for the day-to-day operation of the radiation safety program, <u>who will be named as the such as an RSO on the license.</u> ” Discussion section: “In a Type B <u>or Type C</u> broad scope license, the RSO is the individual responsible for implementing the radiation safety program. <del>In a Type C</del>

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				<p>broad scope license, the RSO is the technical contact person for matters related to the license.” Response from Applicant section: “For Type C applicants, submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program (e.g., the RSO, who will be contacted if there are additional questions about this application) and who is duly authorized to act for the applicant or licensee, as required by 10 CFR 30.32(c).”</p> <p>Item 7, App. C: “In addition, for Type C applicants:</p> <p>Submit the name of the person who will serve as the individual responsible for the day-to-day operation of the radiation safety program (e.g., RSO) who will be contacted if there are further questions about this application, and who is duly authorized to act for the applicant or licensee as required by 10 CFR 30.32(c).”</p>

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8	OAS		The NUREG-1556 Series is licensing guidance, and the Abstract specifically says the information is intended to assist licensees prepare applications. This draft document contains new information about NSTS and 10 CFR 37 that is tangential to the application process. 10 CFR 37 contains no licensing requirements. Consider consolidating the discussion of security programs and NSTS into an appendix, which could be referenced in Item 5 (Radioactive Material).	NRC Staff disagrees with the comment, and notes that one of the reasons that NRC initiated the revision of the NUREG-1556 series was to incorporate information into the documents about the 10 CFR Part 37 security requirements that have been implemented since the NUREG-1556 series documents were originally published.
9	WA	Editorial comment	** should use "their" in all those cases where "his/her" is used, likewise "they" for "he/she".	NRC Staff disagrees. While "they" and "their" are sometimes used as a common-gender third person singular pronoun, in this document, "he or she" and "his or her" are used for this purpose.

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10	OAS	Page vi	Page vi, 2nd paragraph: recommend deleting “This report takes a risk-informed, performance-based approach to licensing”. Essentially the same sentence is on the previous page.	NRC Staff agrees that it appears to be repetitive. Additional text has been added to the first sentence of the second paragraph on Page vi (i.e., “the use of radioactive material under a broad scope authorization”) to indicate that this paragraph refers only to Vol. 11, whereas the first paragraph on Page v applies to all documents of the NUREG-1556 series. This change is consistent with other volumes in the NUREG-1556 series.
11	OAS	Page vi	Page vi, 3rd paragraph, 3rd line: recommend replacing “they” with “applicants”.	NRC Staff agrees and revised the sentence as follows: “...may be acceptable if <u>applicants</u> <del>they</del> include a basis for the staff to make the determinations needed to issue or continue a license.”
12	OAS	Page ix	Page ix, Table 8.3: recommend deleting “that may be applicable” from the Table title. It is understood that the guidance may be applicable.	NRC Staff agrees and has changed the title of Table 8.4 (originally Table 8.3) to read: “Guidance on Personnel Monitoring and Bioassay.”
13	OAS	Page xiii	Page xiii: recommend adding AEA (Atomic Energy Act) to the Abbreviations. “AEA” is used in the footnote on page 9 without otherwise explaining the abbreviation.	NRC Staff agrees and added AEA to the list of abbreviations and spelled out Atomic Energy Act when it is first used in Chapter 2.

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14	OAS	Page 1	Page 1: In the first paragraph, recommend deleting the comma after "Whereas" and...	NRC Staff agrees and modified the text to substitute "Although" for "Whereas."
15	OAS	Page 1	...in the 3rd paragraph recommend replacing "should first have" with "first should have".	NRC Staff agrees and modified the sentence as follows: "Applicants should first have established limited scope licensed programs in accordance with the guidance described in the appropriate base NUREG(s) <del>and then use before they apply for this document to complete the application for</del> a broad scope license."
16	OAS	Page 2	Page 2, last paragraph: recommend replacing the second "broad" with "wide".	NRC Staff disagrees and made no change to the text.
17	WA	Page 3, 3 <sup>rd</sup> bullet	What about security procedures?	NRC Staff disagrees that security procedures should be included in the Overview of Broad Scope Programs section to which the commenter refers. This section deals with the regulatory framework provided in 10 CFR 33 for the licensing of broad scope programs; therefore, it would be inconsistent with its content to include security procedures. Please see the response to Comment 4 concerning additional information that has been added to the document

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				concerning the requirements of 10 CFR Part 37.
18	WA	Page 3, 4 <sup>th</sup> bullet	Most University labs are administered by a lab assistant, and the work is performed by research assistants and staff, rather than the authorized user. Work is performed at all hours of the day and night. It is unrealistic to expect that materials will always be used under the <b>direct</b> supervision of an authorized user. I recommend dropping the requirement of direct supervision, for supervision of trained personnel.	NRC staff took no action in response to the comment and notes that direct supervision is required in §33.17 (b), (c), and (d).
19	OAS	Page 8	Page 8, 1st paragraph: recommend deleting “The link will take you to another Web page where you can search for FSME Procedures.”	NRC Staff agrees and has deleted the sentence.
20	WA		Editorial Comments:  ** p.11—new stuff for “Mgmt Responsibilities”, includes safety culture ref	NRC Staff notes that no change to the document was suggested.
	WA		Editorial Comments:  ** p.13 “...NRC’s <u>safety culture policy statement and traits are not incorporated into the regulations</u> ”	NRC Staff notes that no change to the document was suggested.
21	OAS	Page 16	Page 16: recommend including 10 CFR 150 (i.e., Reciprocity) in the list of other regulations that may be applicable to broad scope licensees.	NRC Staff agreed and made the proposed change and added 10 CFR Part 150, “Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274,” to Chapter 4.
22	WA	Section 5, pages 17 - 18	** Why no path for electronic app submission? Even the prior/current version provides for that.	The NRC Staff agrees and has added section 5.4, “Electronic Applications,” to the document, which addresses the issue of

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				the submission of electronic applications.
23	WA	Section 8.2.1, page 25	<p><b>Notification Of Bankruptcy Proceedings:</b>  It is very interesting that one of the <u>first items mentioned</u>, <b>for which no action is required by the applicant</b>, is the discussion of <b>notification of bankruptcy proceedings</b>. This is an issue which really belongs under management responsibility/control and/or under change of control, It seems like a very negative way (<b>expectation of failure!</b> ) to start out an application on the subject of bankruptcy. This could be done so with more grace under the management responsibility segment and/or the financial surety section. While I understand this is important for program responsibility and control – it doesn't seem like the first issue to discuss for <u>application</u>. The issues that go under management control also could be more consolidated and organized.</p>	<p>NRC Staff made no changes to the text in response to the comment. While the NRC is sensitive to the fact that presenting information about bankruptcy with the introductory information to be provided on an application may be perceived as giving an impression of an expectation of failure, the desire to avoid such an impression is balanced by the fact that many licensees are not aware of the requirement to notify the NRC of bankruptcy proceedings and consequently fail to do so. Furthermore, this text is part of the 'boilerplate' verbiage that is common to many of the volumes of the NUREG-1556 series.</p>
24	OAS	Page 26	Page 26, paragraph directly above box: recommend replacing text with "...before receiving, using, or storing..."	NRC Staff agrees and has replaced "and" with "or" in the indicated sentence.
25	OAS	Section 8.3, Page 26	Page 26, note at end of Section 8.3: recommend deleting "later".	NRC Staff agrees and deleted "later" from the indicated sentence.

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26	OAS	Section 8.4, page 26	Page 26, first paragraph in Section 8.4: recommend changing last sentence to say "Notification of a contact change would not be considered...."	NRC staff agrees and changed the text as follows: "Notification of a contact change is only <u>provided in order to provide information and for informational purposes</u> and would not be considered an application ..."
27	WA	Discussion, page 27	An actual example or two of the typical ways to request byproduct material for a broad scope license (as written on the license) would be far more valuable than prose.	NRC staff agrees and added a new Table 8.1, which provides examples of ways in which licensed material could be requested and listed on a broad scope license.
28	WA	Page 28	** p.28: Where did the 200mCi RAM/20 Ci H-3 limits come from?	NRC Staff notes that no change to the document was requested. NRC Staff notes that the reference is found in NRC regulations in 10 CFR 32.210 (g)(2)(iii).
29	OAS	Page 28	Page 28, first paragraph: There is a stray period in the middle of the 2nd sentence. Also, recommend adding a space in "(200 mCi)of".	The NRC agrees and made the suggested change.
30	OAS	Page 28	Page 28, first paragraph: recommend deleting the comma after 10 CFR 33.13(c)(3)(ii)  and the stray comma after the end of the paragraph.	The NRC agrees and made the requested changes.

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31	OAS	Page 28	<p>Page 28, 2nd paragraph: recommend replacing first sentence with “Applicants should determine if any of the materials requested are Category 1 or Category 2 sources...”</p> <p>Also, in the last sentence recommend changing “Category I” to “Category 1”.</p>	<p>The paragraph to which the commenter refers was deleted as part of an overall review of the treatment in Vol. 11 of the requirements in 10 CFR 20.2207 and 10 CFR Part 37. Additional text has been added to the document as discussed in the response to Comment No. 4.</p> <p>NRC agrees and made the requested change to Category “1.”</p>
32	OAS	Page 29	<p>Page 29, last paragraph: Why doesn't this paragraph apply to Type A broad scope licenses also? Recommend changing.</p>	<p>NRC Staff did not make the suggested changes because Schedule A applies only to Type B and Type C licenses of broad scope; therefore, it is not relevant to Type A licenses of broad scope.</p>
33	WA	Section 8.5.2, Criteria, page 30	<p>The acronym (sic) FA is not introduced properly and should be done so in the second line after Financial Assurance, (FA), as it is used immediately thereafter but not prior to in this document. This acronym is not in the list of abbreviations list and on page xiii.</p> <p>Why do we have to use acronyms anyway when it is far easier with today's technology to use the proper terminology - which does not require interpretation. The acronym adds only confusion, not clarity.</p>	<p>NRC Staff agrees, in part, and has written out “financial assurance” upon first usage of the initialism, FA, with its first usage in Section 8.5.2 according to the NRC's writing style. In general, abbreviations are used in the document in accordance with the NRC's writing style.</p>

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34	WA	Paragraph 4 and Discussion, p 31	<p>In the paragraph beginning with new rag (sic) [NUREG] 1757... "The final statement the total amount of FA required to be provided is the sum of the FA required for each of these types of materials." This paragraph doesn't make clear that these types of material must also meet the requirements in paragraph 2.</p> <p>In the first discussion paragraph, to (sic) [two] parts of the rule are given: this handling breaks down the discussion into two parts these two parts should be applied to the following discussion paragraphs. This would help to break up the text and make it easier to read.</p> <p>Although the NUREG launches into bankruptcy issues very early in the application process, nowhere under the financial assurance does it mention the financial assurance is bankruptcy insurance for the NRC or the state to ensure decommissioning for public health and safety.</p>	<p>NRC Staff disagrees and did not make changes to the wording.</p> <p>NRC Staff agrees and has separated the text in the Discussion section into Financial Assurance and Recordkeeping for Decommissioning sections.</p> <p>NRC Staff notes that financial assurance is not bankruptcy assurance. The purpose of NRC's financial assurance requirements is to ensure that licensees are financially prepared to decommission their licensed sites in accordance with NRC regulations. The purpose of the bankruptcy notification requirements is to ensure that licensees inform the NRC when they file for bankruptcy so that the NRC can take steps to confirm that licensed materials and sites are secure and that safety is maintained and so that the NRC can notify the bankruptcy court and</p>

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				parties to the bankruptcy proceeding that the debtor has ongoing statutory and regulatory obligations as an NRC licensee.
35	WA	Last paragraph, page 31-32	The paragraph states that licensees must transfer records important to decommissioning to the new licensee before license back to these (sic) are transferred or assigned... It would seem common sense not to transfer a license without proper decommissioning of the facility before the new licensee takes over. In the event of mitigating circumstances, it seems obvious that a legal contract or memorandum of agreement , including the transfer of records, would be standard practice.	NRC Staff disagrees and made no changes to the text.
36	WA	page 32	On page 32, it seems that the response from the applicant would include a statement agreeing to maintain adequate records of radionuclides used, including form amount and areas in which they are used, spills, and other relevant releases, so that there are records “to transfer” in accordance with the regulations.	NRC Staff determined that the information referred to by the commenter is stated in the regulations under § 30.35(g) (i.e., “keep records of information important to the decommissioning of a facility in an identified location...”); therefore, it is not necessary to include the suggested text in the document.
37	OAS	Section 8.5.3, page 33	Page 33, Section 8.5.3: recommend matching formatting of other Section titles (change font to bold and don't use all caps).	NRC Staff agrees and has made the requested changes.

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38	WA	Paragraph 1 and bullets, page 35	It might be clearer to state that they must have additional licensing to authorize the four activities listed in the bullets, rather than saying they will not do them.	NRC Staff agrees and made the indicated changes to the text: "The exclusions stated in 10 CFR 33.17(a) provide that, unless specifically authorized by other parts of the regulations, persons licensed under broad scope licenses <u>are not permitted to do any of the following: will not do any of the following:</u> "
39	WA	Discussion, page 36	I don't understand why safety culture is not being discussed under executive management responsibility. Safety culture appears to be a stand – alone item in a separate section rather than an integral part of the program which must be established and maintained by upper management. Since safety culture is not regulated, the guidance must integrate this information under the expectations for executive management, if they expect the implementation of safety culture.	NRC Staff believes safety culture is adequately addressed in section 3.2, "Safety Culture," under "Management Responsibility." Therefore, no changes were made to the text.
40	WA	Section 8.7.1, page 36	** p.36/8.7.1, have <u>deleted</u> "NRC expects executive management to be knowledgeable of the program".	NRC Staff notes that no suggested changes to the text were made; therefore, no action was taken in response to this comment.
41	WA	Last two paragraphs, page 37	Frequency of RSC meetings: perhaps it should be noted here that the medical rags (sic) [regulations] specify a quarterly frequency for RSC meetings, and a specific makeup of that committee, for medical broads (sic).	NRC Staff believes that the current language is adequate and made no changes.

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42	OAS	Page 37	Page 37, top paragraph: recommend changing 2nd sentence to "The applicant should submit an organizational chart..."	NRC Staff agrees and has made the following changes to the text in the Response from Applicant section of Section 8.7.1: <del>"It is recommended that</del> <del>†</del> The applicant <u>should</u> submit an organizational chart that describes the management structure ..."

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43	WA	Criteria and Discussion, page 40	It seems odd that a type C broad scope license does not need an RSO, when every other license type requires an RSO as a liaison to the NRC or agreement state. And although you say in the first parent graph (sic) [paragraph] under criteria, that the rags (sic) [regulations] do not require an RSO, under the discussion you name the RSO of a type C broad scope license as the technical contact person. Your information is inconsistent.	Type C broad scope licensees differ from Type A and B broad scope licensees in that they are not required specifically by regulation to appoint a radiation safety officer (RSO). Although it is not an NRC regulatory requirement for Type C broad scope licensees to appoint an RSO, they are required to establish administrative controls and provisions related to procurement of byproduct material, procedures, recordkeeping, material control and accounting, and management review to ensure safe operations. The individual appointed by Type C broad scope licensees with responsibility for the day-to-day operation of the radiation safety program, including these functions, is usually the RSO, and it is the NRC's practice to identify the RSO on each specific license authorizing the possession and use of licensed material, including broad scope licenses.

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44	WA	Duties of the RSO, page 41	You have a bullet for investigating incidents and responding to emergencies but no bullet for required notifications to the NRC or agreement states. Should this be added?	NRC Staff agrees and has made the requested change.
45	WA	RSO qualifications and training, page 42	I was surprised to see that you do not make any reference to recommending that larger academic broad scope licenses should consider individuals with masters degrees or higher and or be a certified health physicist.	NRC Staff believes that this topic was addressed adequately on page 42: "The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested."
46	OAS	Page 43	Page 43, in the paragraph under the bullets: recommend revising the 2nd sentence to "...radiation safety aspects of proposed uses, prior to approval."	NRC Staff agrees and has made the requested change.
47	OAS	Page 44	Page 44, in box: The 3rd paragraph, 3rd line recommend removing extra spaces between "under" and "the".	NRC Staff agrees and has made the requested change.
48	OAS	Page 44	Page 44, last paragraph: recommend deleting comma between "also" and "contain".	NRC Staff agrees and has made the requested change.
49	WA	Section 8.8	** 8.8—possible typo in first line of "Discussion", an = sign which shouldn't be there? Also, bad first line which says "Requirements in 10 CFR 19.12(a)=establish the training that licensees must are required to provide..."--- the "must are" part is bad grammar, at the least	NRC Staff agrees and has made the requested change.
50	OAS	Page 45	Page 45, first Discussion paragraph, first line: recommend deleting "=" and either "must" or "are required to".	NRC Staff agrees and has made the requested change.
51	WA	Discussion, paragraph 2, page 45	Videotapes are old technology. Suggest just video, or DVD. ** 8.8—does anyone still use "videotapes" anymore?	NRC Staff agrees and has made the following change to the text in the Discussion section in Section 8.8: "Many licensees use <del>videotapes</del> <u>erinteractive media online</u> or

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				offline computer programs to provide training.”
52	WA	Section 8.9	** 8.9—when they say “...(iodination or titration”...”, do they mean “tritiation” rather than “titration”?	NRC Staff agrees and has changed “titration” to “tritiation” in the referenced section.
53	WA	Section 8.9	** 8.9—“Also note that if radioactive materials will be used in or on animals, licensees should discuss a description...”. Not sure about discussing a description.	NRC Staff agrees and has made the indicated changes to the text in Section 8.9: “Also note that if radioactive materials will be used in or on animals, licensees should <del>discuss</del> <u>provide a</u> description of the animal handling and housing facilities.”
54	WA	Section 8.9	** One too many “onlys” in the paragraph beginning “Appendix F provides...”.	NRC Staff agrees and made the requested change.
55	WA	Section 8.10.1	** 8.10.1—paragraph beginning “Appendix H contains...” needs a hyphen for non-medical.	NRC Staff agrees. The hyphenated “non-medical” will be used based on NUREG-1379, Rev. 2, NRC Editorial Style Guide.
56	WA	Section 8.10.2	** 8.10.2—“Criteria”...delete the word “General”.	The NRC Staff disagrees and no changes were made. The word “General” is the title of 10 CFR 20.1501.
57	WA	Section 8.10.3	** 8.10.3—Reference to “old” appendix P, when new reference should be App K (immediately above Table 8.1).	NRC Staff agrees and has made the requested change.
58	WA	Section 8.10.4	** 8.10.4—should make it clear that the limits referenced ARE the 10% of allowable maximum limits which require monitoring.	The NRC Staff believes that this is adequately referenced in the regulations and, therefore, no change to the text was made.

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59	WA	1 <sup>st</sup> Bullet under Response..., page 50	5 <sup>th</sup> word – <i>used</i> , replace with <i>uses</i> . Why past tense? Should be present tense. This is an ongoing action.	NRC Staff agrees and has made the requested change.
60	WA	3rd Bullet under Response..., page 50	Make the third bullet, the second item and move the second item to third. This puts what they need to do first, and then covers what they do not need to do. It also puts the horse in front of the cart, by describing the mechanism for audit, while informing them that they do not need to submit the entire program. If you want to be efficient combine these two paragraphs because one is an overview of the other.	NRC Staff agrees and has made the requested changes.
61	WA	Second para., last sentence, page 53	References appendix P, (previous appendix). New reference is App K (immediately above Table 8.1).	NRC Staff agrees and has made the requested changes.
62	WA	Table 8.1, page 53	“Not Labeled” - Excepted Packages and limited quantity packages received by many laboratories, are required to have the appropriate UN number on the outside of the box, identifying it as containing radioactive materials. It is good health physics practices to perform an incoming survey on these packages, even though transportation regulations do not require it. Many licensees require it in their procedures. - Can the guidance reflect what is generally considered good health physics practices?	NRC Staff agrees and added the following text to the table on package monitoring requirements: <u>“Excepted packages and limited quantity packages received by many laboratories are required to have the appropriate UN number on the outside of the box, identifying it as containing radioactive materials. It is good health physics practices to perform an incoming survey on these packages, even though transportation regulations do not require it.”</u>

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63	OAS	Page 54	Page 54, top paragraph: recommend deleting the quarterly sealed source inventory example because 10 CFR 35.67(g) specifies a semi-annual inventory.	NRC Staff agreed and deleted this text: “(e.g., sealed sources used for medical therapy are required to be inventoried every 3 months)”
64	OAS	Page 55	Page 55, bullet list: Why is NRC requiring applicants to confirm they will follow NSTS reporting requirements? This commitment duplicates what is already in the regulations. Recommend deleting this requirement.	NRC Staff disagrees and notes that one of the main reasons that the NUREG-1556 series is being revised is to include security information. In order to ensure that licensees are aware of the reporting requirement in 10 CFR 20.2207, the guidance recommends that applicants provide a positive affirmation of their commitment to follow NSTS reporting requirements. No changes were made to the text in response to this comment.
65	WA	Table 8.3, page 52	<p>** “Table 8.3 Documents that Contain Guidance Relating to Personnel Monitoring and Bioassay <b>Which</b> (not “that”) May Be Applicable”.</p> <p>No more guidance for H-3 bioassay?</p>	<p>NRC staff has changed the title of the subject table as follows and, therefore, the comment is no longer applicable: “<del>Documents that Contain Guidance on</del>Relating to Personnel Monitoring and Bioassay <del>that May be</del> Applicable.”</p> <p>A reference to Regulatory Guide 8.32, “Criteria for Establishing a Tritium</p>

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				Bioassay Program,” was added to the subject table in response to this comment.
66	OAS	Figure 8.2, page 57	Recommend deleting the box underneath Figure 8.2. TEDE was redefined and now includes “effective dose equivalent” instead of “deep dose”. Recommend replacing with a general sentence saying that TEDE means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.	NRC Staff agrees and moved the subject text box to Discussion, section 8.10.4, and revised the text as follows: “Total effective dose equivalent (TEDE) equals the effective dose equivalent (for external exposures) plus the committed effective dose equivalent (for internal exposures).”
67	OAS	Table 8.3, page 58	Page 58, Table 8.3: recommend deleting “that May be Applicable” from the title.	NRC Staff agrees and changed the subject title to the following: “Guidance on Personnel Monitoring and Bioassay.”
68	WA	Additional references, page 58	The NRC does not seem to recommend NCRP or ICRP publications as additional references. Is there a reason for this?	NRC Staff notes that there is no particular reason that references to NCRP and ICRP were not included in the document, but also notes that references in the document are not intended to be exhaustive.
69	OAS	Page 61	Page 61, paragraph beginning “Regulations in...”: In the last sentence, recommend adding “37” to the list of relevant Parts.	NRC Staff agrees with the comment and has added references and information concerning 10 CFR 37, Subpart B, 10 CFR 37.21(a), 10 CFR 37.45, and 10 CFR 37.49 to section 8.10.6.

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70	WA	Response from applicant, page 64	<p>The model leak test program published in the appendix O of this volume is inadequate for a broad scope program, or vendor program that is performing leak tests as a commercial service. The licensee must demonstrate that the instrument used for analysis is capable of detecting at least the 0.005 microcurie activity used to determine that a sources linking. If an instrument is calibrated with one source, then there should be correction factors applied when measuring nuclides of differing energies, or the licensee must determine efficiencies specific to the nuclide they are testing after each calibration. In their procedures the licensee must also show that the instrument, if not calibrated annually, such as liquid scintillation counters, has an adequate QA program to ensure their constancy, linearity, and accuracy of proper functioning.</p> <p>Just because this procedure was a model procedure for the last edition, doesn't mean it is up to today's standards of technology.</p>	NRC Staff agrees and notes that the Model Leak Test Procedures appendix has been revised for the entire NUREG-1556 series to address such issues as training of individuals who will perform leak testing and analysis, minimum detectable activity calculations, and a recommendation that the counting system be calibrated with a souce that has similar energy characteristics to those of the radiation in the sources that are being leak tested.
71	OAS	Page 65	Page 65, 3rd paragraph: In the second sentence, recommend adding "the" between "that" and "package".	NRC Staff agrees and made the requested change.
72	OAS	References, page 65	Page 65, References: recommend replacing the 1998 revision with the 2008 revision. <a href="http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/RAM_Regulations_Review_12-2008.pdf">http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/RAM_Regulations_Review_12-2008.pdf</a>	NRC Staff agrees and made the requested change.
73	OAs	Section 8.10.9, page 65	Page 65, Section 8.10.9, Note: recommend changing last phrase to "...an aggregate quantity of category 1 or category 2 radioactive material."	NRC Staff disagrees with the suggestion and notes that this wording has been changed so that it aligns with the text in 10 CFR 37.1: "aggregated Category 1 or Category 2 quantity of radioactive material...."

74	OAS	Page 66	<p>Page 66, top paragraph: recommend deleting “The NSTS is a major security initiative of the NRC”.</p> <p>Recommend changing next sentence to “The NSTS is a secure and accessible computer system...until they decay enough to no longer be considered high-risk.”</p>	<p>NRC Staff agrees and has deleted the sentence, “The NSTS is a major security initiative of the NRC.”</p> <p>NRC Staff disagrees, in part, and notes that the paragraph to which the commenter refers was moved to section 8.10.3 and revised as part of an overall review of the treatment in Vol. 11 of the requirements in 10 CFR 20.2207 and 10 CFR Part 37. The paragraph now reads as follows: “Category 1 and Category 2 sealed sources listed in Appendix E to 10 CFR Part 20 (i.e., nationally tracked sources) must be tracked in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207. The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NSTTR) to the NRC. The NSTTRs are maintained in the NSTS, a secure computer system that tracks Category 1 and Category 2 nationally</p>
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Comment No.	Commenter	Location in the Volume	Comment	Resolution
				tracked sources from the time they are manufactured or imported through the time of their disposal or export, or until the source activity decays to below Category 2.”
75	OAS	Page 66	Page 66, 2nd paragraph: recommend adding reference to the forthcoming NRC “Best Practices” guidance document for Part 37.	NRC Staff agrees and added a reference to NUREG-2166 to section 8.10.9.
76	OAS	Page 66	Page 66, 4th paragraph: recommend deleting entire paragraph. It is not necessary to highlight specific differences between Category 1 and 2 sources in this NUREG.	NRC Staff disagrees and notes that the subject paragraph has been revised as follows: “Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or Category 2 quantities of radioactive materials in transit. These requirements apply to licensees delivering such material to a carrier for transport, as well as cases in which licensees are transporting such material. Please note that the Subpart D requirements applicable to the transport of Category 1 quantities of radioactive material are more stringent than those applicable to Category 2 quantities.”

Comment No.	Commenter	Location in the Volume	Comment	Resolution
77	WA	Section 8.10.7	** 8.10.7—Leak Tests: refers to "...0.005 microcuries", this should not be plural since it is a quantity less than one, and should read "microcurie". Same comment for 8.10.11 "Disposal of Specific Waste as if it Were Not Radioactive".	NRC Staff agrees and has changed the text as suggested by the commenter.
78	WA	Decay-in-storage, page 67-68	<p>NRC might want to address the issue of exceptions, when the half-life of decay daughter products exceeds that hundred and 20 day half-life guidance. Only part 35 has a regulatory decay in storage limit of nuclides with less than a 120 day half-life. There are 2 or 3 experimental/Research and Development and medical nuclides: such as Lu-177m is a significant contaminant in the Lu-177 that is being used for research purposes. The 160 day half life of the Lu-177m would be additional cost if it can't be given an exception for a longer decay in storage, when adequate space is available, as is recommended in NCRP 143, Management techniques For Laboratories and Other Small Institutional Generators to Minimize Off-Site Disposal of Low Level Radioactive Waste, page 113.</p> <p>A good <b>guidance</b> document should provide legal, good common sense alternative options for new issues that are evolving. [NRC might consider removing that restrictive decay in storage regulation in part 35, next time the rules are open, as well as correcting inconsistent leak test limits in part 36, caused by rounding off.]</p>	NRC Staff disagrees and notes that this issue is addressed by the guidance in Response from Applicant, section 8.11, which recommends that applicants contact the appropriate regional office of the NRC for guidance to obtain approval of any method(s) of waste disposal other than those discussed in [Section 8.11].
79	WA	Disposal of specific waste as if it were not radioactive, page 70	FYI: although the licensee may dispose of the two bulleted waste items as if they were not radioactive; however the vendor does not have to receive that waste as nonradioactive. Double standard.	NRC Staff notes that no change to the text has been suggested by the commenter; therefore, no action was taken.

Comment No.	Commenter	Location in the Volume	Comment	Resolution
80	WA	Section 8.11, page 66	** 8.10.7—Leak Tests: refers to "...0.005 microcuries", this should not be plural since it is a quantity less than one, and should read "microcurie". Same comment for 8.10.11 "Disposal of Specific Waste as if it Were Not Radioactive".	NRC Staff agrees and has made the requested change.
81	WA	Section 8.11, page 71	** 8.11—Disposal of Specific Waste as if it Were Not Radioactive—last paragraph: "...in a manner that will not permit their use as food for <b>either</b> humans or animals", not "...permit their use either as food...".	NRC Staff disagrees and has added text consistent with 10 CFR 20.2005(b): "not permit their use either as food for humans or as animal feed."
82	WA	Section 8.11, page 68	** 8.11—"Extended Interim Storage The NRC does not consider storage <b>as an acceptable</b> substitute for...."	NRC Staff disagrees and did not make the suggested change because the suggested text would not provide additional clarification of the issue.
83	WA	Section 8.11, page 68	** 8.11—Release Into Air and Water"—2 <sup>nd</sup> paragraph, 2 <sup>nd</sup> sentence: "The regulations in 10 CFR 20.2003 authorizes....". This should be " <b>authorize</b> ", not "authorizes".	NRC Staff agrees and has made the suggested change.

Comment No.	Commenter	Location in the Volume	Comment	Resolution
84	External/unknown commenter	Section 8.11	<p>Sewer discharge</p> <p>Clarification is requested as to whether or not compliance with 10 CFR 20.2003 (or Agreement State equivalent) is sufficient or whether additional compliance with local resolution is also required.</p> <p>A local sewer district states that a discharge of any radioactive liquid waste into the sanitary sewer according to 10 CFR 20.2003 is a violation of local sewer resolution. The district claimed that such a discharge had to be approved by the district even though the district resolution didn't define "radioactive waste." State regulators (an Agreement State) stated that local governments could make more restrictive rules than the federal and state regulations for radiation protection and didn't see an issue with the district's claim.</p> <p>It is my understanding based on the below citation (42 USC § 2021) that local regulators cannot preempt federal radiation protection regulations.</p> <p>42 USC § 2021 (k) State regulation of activities for certain purposes Nothing in this section shall be construed to affect the authority of any State or local agency to regulate activities for purposes other than protection against radiation hazards</p>	<p>NRC Staff notes that Agreement States are not required to have a regulation that corresponds to 10 CFR 20.2003; therefore, the State (or a local government) can enact a stricter provision than what is set out in 10 CFR 20.2003. Providing information concerning Agreement State compatibility with individual regulations is outside the scope of this document; therefore, no changes to the text were made in response to this comment.</p>

Comment No.	Commenter	Location in the Volume	Comment	Resolution
85	WA	Section 11	** 11—TERMINATION OF ACTIVITIES: Criteria: 4 <sup>th</sup> bullet: “Submit to the appropriate...”. At the end of that bullet it refers to “final leak tests” which is changed from current volume which says “results of final survey”. It should be “results of final survey” and <b>not “final leak tests”</b> , since “leak tests” refer only to sealed sources while “final survey” correctly refers to the proper form of survey/test desired when decommissioning.	NRC Staff agrees and has made the indicated changes to the text: “...results of final <u>survey and</u> leak tests <u>results</u> with suggested change.
86	WA	Timely notification of change of control, pages 73-74	This is where bankruptcy should be discussed, rather than in the application process. There should be a statement about timely notification as well.	NRC Staff disagrees and notes that adequate information concerning timely notification of changes of control is presented in section 9.1. concerning bankruptcy notification. See response to Comment No. 23.
87	OAS	Page 77	Page 77, first bullet: recommend correcting justification of first two lines.	NRC Staff agrees and made the suggested change.
88	OAS	Page 78	Page 78, end of 2nd paragraph: recommend deleting stray period.	NRC Staff agrees and made the suggested change.
89	OAS	App.C, page C-4	Page C-4: recommend changing font in last bullet “prior to” to match the rest of the text.	NRC Staff agrees and made the suggested change.
90	OAS	App.C, page C-5	Page C-5, last paragraph: recommend deleting. See first comment (above).	NRC Staff agrees and made the suggested change.
91	OAS	App.C, page C-7	Page C-7: The second paragraph says that submission of the audit program is not required, but the third paragraph requests applicants to describe their audit mechanism. This appears to request opposite actions for the same topic. Recommend either clarifying how these paragraphs are different, or deleting either the second or the third paragraph	NRC agrees and changed the wording of the paragraphs to provide clarification that the audit program should not be submitted, but the audit mechanisms by management and RSO must be described.

Comment No.	Commenter	Location in the Volume	Comment	Resolution
92	OAS	App.C, page C-9	Page C-9: recommend deleting statement about complying with NSTS (see comment 25).	NRC Staff disagrees and notes that one of the main reasons that the NUREG-1556 series is being revised is to include guidance on security requirements. In order to ensure that licensees are aware of the reporting requirement in 10 CFR 20.2207, the guidance recommends that applicants provide a positive affirmation of their commitment to follow NSTS reporting requirements. No changes were made to the text in response to this comment.
93	OAS	App.C, page C-10	Page C-10, Public Dose: recommend retaining first sentence and deleting the rest of the paragraph.	NRC Staff does not agree that the rest of the paragraph should be deleted because this text has information that is necessary to assist the licensee.
94	OAS	App.C, page C-11	Page C-11, Security Program: in title, recommend changing Category I to Category 1.	NRC Staff agrees and has made the suggested change.
95	WA		** No more "Sample License" (former Appendices D, E, F, & G)? <u>NOT GOOD</u> .	See response to Comment No. 3
96	WA	App.F, page F-1	91 Sr? is this a typo should be strontium 90? Are these typos? , 125 Cs, 243Am? (241) Cf -249? (252) Please check all of the radionuclides in table F1 Many of these are rarely used isotopes or there are numerous typos.	App. F has been deleted. See response to Comment No. 97.

Comment No.	Commenter	Location in the Volume	Comment	Resolution
97	WA	App.F	The IAEA Safety Standard Series No. 1, Safe Handling of Radionuclides (1973) is out of date. The reference has been superseded by IAEA GSR Part 3 (Interim), 2011	NRC Staff agrees. Although IAEA GSR Part 3 (BSS) has superseded IAEA Safety Standards Series No. 1 (SS No. 1), the BSS does not provide laboratory classification criteria or safety recommendations for such facilities as did SS No. 1. Because no current alternative to the information from SS No. 1 is available, App. F was deleted.
98	WA	App.F	** Appendix F—are we really still using IAEA nomenclature and limits from literally 40 years ago? Is there nothing better yet?	App. F has been deleted. See response to Comment No. 97.
99	OAS	App.F, page F-2	Page F-2, Table F.2: Is there supposed to be a range of activities for Type B laboratories for Very High or High radiotoxic nuclides? If not, recommend explaining why a Type B laboratory is not appropriate for Very High or High radiotoxic nuclides.	App. F has been deleted. See response to Comment No. 97.
100	OAS	App.G, page G-2	Page G-2: recommending adding a period to end of first bullet.	NRC Staff agrees and made the requested change.
101	OAS	App.K, page K-2	Page K-2, first paragraph under “Materials Possessed”: recommend adding a period to end of first sentence.	NRC Staff agrees and made the requested change.
102	OAS	App.N, page N-1	Page N-1: recommend deleting “or for Type C broad scope licensees, the individual designated as responsible for the day-to-day operation of the radiation safety program). See General Comment 1.	NRC Staff agrees and made the requested change.
103	OAS	App.N, page N-6	Page N-6, top paragraph: recommend deleting “centimeters squared” and just use the abbreviation. The abbreviation is extensively used on the previous page.	NRC Staff agrees and spelled out “square centimeters” the first time it was used in the appendix and then used the

Comment No.	Commenter	Location in the Volume	Comment	Resolution
				abbreviation later in the appendix.
104	OAS	App.N,. page N-6	Page N-6, last paragraph: recommend deleting “the NRC” before “ADAMS”  and deleting “the” between “on” and “air sampling”.	NRC Staff disagrees because the text is correct as written. To ensure clarity, ADAMS was added to the list of abbreviations.  NRC Staff agrees and made the requested change
105	OAS	App.N, page N-7	Page N-7, Liquid Effluent: recommend deleting the bullet and just have as plain text.  Also recommend deleting “respectively”.	NRC Staff agrees and made the requested change.  NRC Staff agrees; however, a reference to 10 CFR 20.1302 was added making the use of “respectively” necessary.
106	WA	App.N, Table N.5 Acceptable Surface Contamination Levels	This table appears to be missing both transuranics and alpha emitters.  Since the NRC does not include release levels in regulation, these seem like very high levels of removable contamination for academic labs,	NRC Staff agrees and as a result, added transuranics to Table N.5. Transuranics include some alpha-emitting isotopes; however, alpha emitters per se were not added to the table because there was no such category in the source document for the table (i.e., Directive FC 83-23, “Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material”).

Comment No.	Commenter	Location in the Volume	Comment	Resolution
107	OAS	App.O, page O-2	Page O-2: recommend using Math Editor function of word processing program to display the equations.	NRC Staff agrees, in part. Before final publication the equations will be formatted using appropriate software.
108	WA	App.O	<p>The model leak test program published in the appendix O of this volume is inadequate for a broad scope program, or vendor program that is performing leak tests as a commercial service. The licensee must demonstrate that the instrument used for analysis is capable of detecting at least the 0.005 microcurie activity used to determine that a sources linking. If an instrument is calibrated with one source, then there should be correction factors applied when measuring nuclides of differing energies, or the licensee must determine efficiencies specific to the nuclide they are testing after each calibration. In their procedures the licensee must also show that the instrument, if not calibrated annually, such as liquid scintillation counters, has an adequate QA program to ensure their constancy, linearity, and accuracy of proper functioning.</p> <p>Just because this procedure was a model procedure for the last edition, doesn't mean it is up to today's standards of technology.</p>	NRC Staff replaced the current model leak test procedure with the one that will be used for consistency in the NUREG-1556 Series, which also addresses the issues raised in this comment.
109	WA	App.O, page O-1, Second to last bullet	You might consider adding a note that the box is on the next page. It's sort of gets lost in the huge white space	NRC Staff replaced the model leak test procedure with the one that will be used for consistency in the NUREG-1556 Series, which also addresses the issues raised in this comment.
110	OAS	App.P, page P-10	Page P-10: recommend referencing the 2012 version Emergency Response Guidebook instead of the 2008 version.	NRC Staff agrees and has inserted the appropriate reference.

Comment No.	Commenter	Location in the Volume	Comment	Resolution
111	OAS	App.P, page P-12	Page P-12: recommend moving this sentence to page P-3.	WG agrees and has moved the sentence as requested.
112	WA	Abbreviations	<p>** Abbreviation for "ALARA": Is there really any need for "is" in that acronym?</p> <p>** Abbreviation: May want to add RIS and ARSO.</p>	<p>NRC Staff notes that "is" is part of the definition of "ALARA" in Part 20 and therefore should remain in the acronym.</p> <p>NRC Staff agrees, in part. RIS was added to the list of abbreviations. No action was taken with regard to ARSO because it does not appear in the document.</p>
113	WA	App. R and S	** APPENDICES: Reviewed extant Appendices A-F. WOULD HAVE REVIEWED new Appendices R and S, except these new appendices do not seem to have been included with this draft revision.	<p>NRC Staff proposes no action as Appendices R and S were included in the draft document that was published for comment.</p> <p>(<a href="http://pbadupws.nrc.gov/docs/ML1401/ML14015A114.pdf">http://pbadupws.nrc.gov/docs/ML1401/ML14015A114.pdf</a>)</p>

The comments received have been posted in NRC's Agencywide Documents Access and Management System with the indicated Accession Numbers.

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