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FSME-14-012—OPPORTUNITY TO COMMENT ON DRAFT NUREG 1556, VOLUME 11, REVISION ONE "CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES: PROGRAM-SPECIFIC GUIDANCE ABOUT LICENSEES OF BROAD SCOPE".

Thank you for the opportunity to comment on the newly updated NUREG 1556 Volume 11.

Page	Paragraph/Location	Comment
General comments		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.
	"	The NRC should make greater use of bullets, spacing and white space, and examples.
	"	No more sample licenses – while this may not affect applicants, this definitely agreement states, who use this NUREG for licensing guidance.
	"	There appears to be only minor reference to part 37 security requirements in this NUREG. It is not listed as a regulation under 8.10.6 Safe Use of Radionuclides and Emergency Procedures or executive management responsibilities
	"	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 ?
		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
3	3rd and 4th Bullet	What about security procedures? 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 **direct** supervision of an authorized user. I recommend dropping the requirement of direct supervision, for supervision of trained personnel.

25	8.2.1	**Notification Of Bankruptcy Proceedings:** It is very interesting that one of the first items mentioned, **for which no action is required by the applicant,** is the discussion of **notification of bankruptcy proceedings**. This is an issue which really belongs under management responsibility/control and/or under change of control, It seems like a very negative way (**expectation of failure!**) 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 application. The issues that go under management control also could be more consolidated and organized.
27	Discussion	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.
30	8.5.2, criteria	The acronym 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. 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.

31	Paragraph 4 and Discussion:	In the paragraph beginning with new rag 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. In the first discussion paragraph, to 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. 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.
31-32	Last paragraph	The paragraph states that licensees must transfer records important to decommissioning to the new licensee before license back to these 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. 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.
35	Paragraph 1 and bullets	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.
36	Discussion	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.
37	Last two Paragraph	Frequency of RSC meetings: perhaps it should be noted here that the medical rags specify a quarterly frequency for RSC meetings, and a specific makeup of that committee, for medical broads.
40	Criteria and Discussion	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 under criteria, that the rags 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.
41	Duties of the RSO	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?
42	RSO qualifications and training	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.
45	Discussion, paragraph 2	Videotapes are old technology. Suggest just video, or DVD.
50	1st Bullet under Response…	5th word – ***used***, replace with ***uses***. Why past tense? Should be present tense. This is an ongoing action.
50	3rd Bullet under Response.	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.
53	Second paragraph, last sentence.	References appendix P,(previous appendix). New reference is App K (immediately above Table 8.1).
53	Table 8.1	"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?
58	additional references	The NRC does not seem to recommend NCRP or ICRP publications as additional references. Is there a reason for this?
64	Response from applicant	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. Just because this procedure was a model procedure for the last edition, doesn't mean it is up to today's standards of technology.
67 - 68	decay in storage	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." A good **guidance** 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.]
70	Disposal of specific waste as if it were not radioactive	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.
73 – 74	Timely notification of change of control	This is where bankruptcy should be discussed, rather than in the application process. There should be a statement about timely notification as well.
F – 1	group 1 to 4	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.
F	N/A	The IAEA Saftey 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.
N-5	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,
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

Editorial comments:

** No more "Sample License" (former Appendices D, E, F, & G)? NOT GOOD.
** Appendix F—are we really still using IAEA nomenclature and limits from literally 40 years ago? Is there nothing better yet?
** Abbreviation for "ALARA": Is there really any need for "is" in that acronym?
** Abbreviation: May want to add RIS and ARSO.
** new tables on pgs 8 & 9 are good
** p.11—new stuff for "Mgmt Responsibilities", includes safety culture ref
** p.13 "…NRC's safety culture policy statement and traits are not incorporated into the regulations"
** Why no path for electronic app submission? Even the prior/current version provides for that.
** p.19/Part 6—good, new info about SRSI.
** p.28: Where did the 200mCi RAM/20 Ci H-3 limits come from?
** p.33/Item 8.5.3==NEW
** p.36/8.7.1, have deleted "NRC expects executive management to be knowledgeable of the program".
** should use "their" in all those cases where "his/her" is used, likewise "they" for "he/she".
** 8.7.3—added new paragraph with stricter info submission requirements for RSO. Also, new warning not to submit personal info.
** 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.
** 8.8—does anyone still use "videotapes" anymore?
** 8.9—when they say "…(iodination or titration"…", do they mean "tritiation" rather than "titration"?
** 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.
** One too many "onlys" in the paragraph beginning "Appendix F provides…".
** 8.10.1—paragraph beginning "Appendix H contains…" needs a hyphen for non-medical.
** Added "ALARA principles" to annual audit list. Good idea.
** 8.10.2—"Criteria"…delete the word "General".
** 8.10.3—Reference to "old" appendix P, when new reference should be App K (immediately above Table 8.1).
** 8.10.4—should make it clear that the limits referenced ARE the 10% of allowable maximum limits which require monitoring.
** "Table 8.3 Documents that Contain Guidance Relating to Personnel Monitoring and Bioassay **Which** (not "that") May Be Applicable". No more guidance for H-3 bioassay?
** 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".
** 8.10.9—"Security Program for Category 1 and Category 2 Materials"---NEW SECTION.
** 8.10.11—"Extended Interim Storage The NRC does not consider storage **as an acceptable** substitute for…."

** 8.10.11—Release Into Air and Water"—2nd paragraph, 2nd sentence: "The regulations in10 CFR 20.2003 authorizes….". This should be "**authorize**", not "authorizes".
** 8.10.11—Disposal of Specific Waste as if it Were Not Radioactive—last paragraph: "…in a manner that will not permit their use as food for **either** humans or animals", not "…permit their use either as food…".
** 9.1—NEW SECTION
** 11—TERMINATION OF ACTIVITIES: Criteria: 4th 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 **not "final leak tests",** since "leak tests" refer only to sealed sources while "final survey" correctly refers to the proper form of survey/test desired when decommissioning.
** 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.