NUREG-1556, Volume 5, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
1	Mike Thompson, MikRon, Inc.	General	Numerous hyperlinks in the NUREG revision don't work.	**Comment accepted:** All hyperlinks in the document were checked and corrected, as needed.
2	Mike Thompson, MikRon, Inc.	Page 1-2, Figure 1-1	Blood irradiators don't "sterilize" blood, they protect from graph vs. host disease. Change "Sterilize Blood" in the caption in Figure 1-1.	**Comment accepted:** We changed it to read…Can be Used in Blood Banks.
3	Mike Thompson, MikRon, Inc.	Page 1-3, Line 27-28	The sentence in lines 27-28 states that, "This is done because 10 CFR Part 20 sets dose limits in terms of rem (Sv), rather than rad or roentgen." The International System of Units equivalent for rad should be listed next to rad.	**Comment accepted:** In accordance with 10 CFR 20.1004, "Units of Radiation Dose," we left rem (Sv) in the sentence, added (Gy) after rad, but removed "or roentgen" from the end of the sentence because roentgen is not a unit of dose. The sentence now reads: This is used because 10 CFR Part 20 sets dose limits in terms of rem (Sv), rather than rad (Gy).
4	U.S. Department of Health and Human Services, National Institutes of Health	Page 8-10, Lines 26-36	Section 8.7.1 (Radiation Safety Officer) has a new paragraph beginning halfway down Page 8-10 describing the ability of the RSO to appoint an "Alternate RSO." Lines 33-36 note that, "These individuals should have the same management support and decision-making authority as the RSO that is necessary to accomplish the tasks to which they have been assigned. Please note that only the primary RSO is named on an NRC license." Does this mean that any "Alternate RSOs" must also have a	**Comment partially accepted:** "Alternate RSOs" are not required to have a delegation of authority. The delegation of authority is for the RSO listed on the license. We do agree that the "Alternate RSOs" should have the same management support and decision-making authority as the

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			Delegation of Authority ensuring that decision-making authority has been conveyed?	RSO. Alternate RSOs were not discussed in the first version of NUREG-1556, Volume 5. But we understand that there are Alternate RSOs and we wanted to address this matter. The following language is being used in this revision of the volume, on section 8.7.1, page 8-10, 3rd paragraph: "The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals, sometimes referred to as "alternate RSOs," "site RSOs," or "irradiator custodians." And the last sentence in this paragraph was changed to read,: "Please note that only the primary RSO is named on an NRC license, but the "alternate RSOs," "site RSOs," or "irradiator custodians" can be names as Authorized Users on the license."
5	U.S. Department of Health and Human Services,	Page 8-12, Line 17	Section 8.7.2 (Authorized Users) has the expectation that all AUs should be named on the license. The definition of an AU includes several functions, some of which are carried out by the irradiator owners (custodians) and some by Radiation Safety. The	**Comment partially accepted:** The Authorized User is the point person for the irradiator. It is helpful to the NRC to have another name on the license

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	National Institutes of Health		question is whether an applicant or licensee would need to name all the custodians plus pertinent Radiation Safety personnel on the license application and then amend the license every time an individual left or a new individual joins a licensee's organization. For larger licensees it would be fairly cumbersome to have to amend the license documentation every few months.	besides the RSO. That way, when an inspector arrives at the facility and the RSO is not available, the inspector may ask for the Authorized User. The "Response from Applicant" section was modified to provide two choices to the applicant: that any AU should receive training as described in Appendix F or that the applicant will provide alternative information demonstrating that the AUs are qualified by training and experience. A note was added stating that the applicant may be asked to submit the proposed AU names in the application for inclusion in the license.
5	U.S. Department of Health and Human Services, National Institutes of Health	Page 8-38, Lines 35-43	Section 8.10.8 (Maintenance) has new language within the "**Response from Applicant**" section that states a licensee must obtain NRC approval prior to any use of a non-OEM (Original Equipment of the Manufacturer) part during most kinds of repair/maintenance of an irradiator. Since most licensees do not do their own repairs, how would a licensee know if a third party performing irradiator repair work is using OEM parts or not? Is it the expectation that the third-party company would obtain NRC approval for non-OEM parts? What is the	**NO CHANGE NEEDED** It has come to the NRC's attention that some service providers have used non-OEM parts when repairing irradiators that have left the irradiator not in compliance with their Sealed Source and Device Registration (SSD) certificate. The use of OEM parts is also discussed in Section 8.10.9 and Appendix K

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			expected turnaround time for NRC approval, given that this scenario is likely to happen (many irradiators are old and originally manufactured parts may no longer be available)? Note that the requirement for advanced NRC approval may result in substantial delay for an irradiator repair in these cases, which would be a severe hardship to users who depend upon the availability of an irradiator for time-sensitive research experiments and direct clinical care.	from NUREG-1556, Volume 18, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses." A self-shielded irradiator licensee is responsible for complying with the SSD. Service providers should inform self-shielded irradiator licensees when using non-OEM parts and should follow guidance in NUREG-1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses." While the NRC is unable to provide a timeframe for an approval of non-OEM part, it is best to plan ahead. However, the NRC identifies that there will be cases when the irradiator is not operational or the irradiator malfunctions and the end user needs the device repaired as soon as possible. When these instances would result in a severe hardship to the licensee, please inform the appropriate NRC regional office immediately for timely assistance.

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6	Mike Thompson, MikRon, Inc.	Page J-9, Lines 21-24	Change A. and B. in the "**NRC Correspondence**" portion of Appendix J, "Suggested Self-Shielded Irradiator Audit Checklist" from correspondence issued since the previous audit has been **received** and actions taken to correspondence **reviewed** and actions taken, **if applicable**?	**Comment accepted:** Changed to read as follows: Have all NRC correspondence (e.g., NRC Regulatory Issue Summaries, NRC Bulletins, NRC Information Notices, and NMSS Newsletters) issued since the previous audit and applicable to self-shielded irradiator licensees been reviewed? For the correspondence that is applicable to self-shielded irradiator licensees, has appropriate action been taken, (e.g., training, updating procedures, etc.), as necessary?