

VOLUME 6 EXTERNAL COMMENTS

| Comment No. | Commenter | Location in the Volume | Comment | Resolution |
|-------------|---------------------------------|------------------------|--|--|
| 1 | Virginia | Page vi, Foreword | Brian McDermott's name is listed as the Director. The RMP recommends updating this to the interim director, Pamela Henderson. | The signature block has been updated with the name of the current Division Director. |
| 2 | Wisconsin | Page viii | In line 8.10.7, capitalize "CFR" | Corrected |
| 3 | Wisconsin | Page viii | In the line for Appendix H, correct spelling of "CONSTRUCITON" | Corrected |
| 4 | Wisconsin | Page viii | In the line for Appendix J, correct spelling of "CALIBRAITON" | Corrected |
| 5 | Wisconsin | Page xv | Correct indent of "curie" | "Curie" deleted from abbreviations. |
| 6 | Russell N. Stein, VP, Gray Star | Chapter 8, Page 23 | At the end of the second to last paragraph, it states: "It is the applicant's responsibility to review the guidance in Appendix P to determine whether the categorical exclusion applies to the licensing action." It is unclear that Appendix P provides any guidance on categorical exclusion. Interpretation of Appendix P indicates that irradiators are categorically excluded and that the NRC will determine if any further environmental review is required, due to special circumstance, after the application has been submitted and fee paid. | Text modified. |
| 7 | Wisconsin | Page 24 | The second sentence under the table says that an initial security inspection <i>will</i> be conducted, and the third sentence says an initial security inspection <i>may</i> be conducted. Combine these sentences and use "will" or "may" (but not both) as appropriate. | Corrected. Sentence rewritten. |

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| 8 | Wisconsin | Page 31 | The first bullet under 'Response from Applicant' says "140° degrees F". Delete the degree symbol. | Corrected. |
| 9 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.8.1, Page 35 | <p>The first full paragraph after the bullets is specific to the additional individual required for responding to the "access control alarm" specific to a Panoramic irradiator. Further, it is not clear why this refers to "the independent backup access control alarm" vs. "the access control alarm". The "alarm" is part of the "backup control system", but it is not a backup alarm. Perhaps the wording should be:</p> <p>"For Panoramic Irradiators, instruction must be provided to at least one other individual who will be on site during operations on how to respond to the access control alarm and to promptly render or summon assistance."</p> | <p>The Working e (WG) does not agree with revising the text. The wording is taken directly from 36.23(b). The backup access control must have a visible and audible alarm.</p> |
| 10 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.9.1, Page 42 | <p>The initial paragraph on this page is an extension of requirements "For all irradiators" on the previous page. However, there are three distinct issues outlined in this paragraph:</p> <ol style="list-style-type: none"> 1. "An applicant should provide a schedule for construction activities associated with the irradiator." This would pertain to "all irradiators". 2. "This will allow the NRC to inspect and ensure construction activities meet design requirements as described in NRC Manual Chapter 2815, entitled "Construction and Preoperational Inspection of Panoramic, Wet-Source-Storage Gamma Irradiators...". This pertains only to "Panoramic wet-source-storage (ANSI 43.10 Category IV irradiators)" by definition. 3. "This will allow the NRC to inspect and ensure construction activities meet design requirements as described inAppendix P to this Volume, 'Interim Staff Guidance on Construction'". This would pertain to "all irradiators" <p>Issue 2 (above) does not fit in this section for "all irradiators".</p> | <p>The text was moved to the position after Figure 8.5.</p> |

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| 11 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.9.2, Page 43 | <p>The “Criteria” section is specific to irradiators that have a “radiation room”. Only Panoramic irradiators have a “radiation room”. Underwater irradiators do not have a “radiation room”. However section 8.9.2 includes both Panoramic and Underwater irradiators. Perhaps, better phrasing would be “Criteria: Panoramic irradiator facilities must have ‘access controls’ to prevent inadvertent entry into the radiation room and Underwater irradiator facilities must have a ‘personnel access barrier’ to prohibit access to the irradiator when it is unattended, as required by 10 CFR 36.23”</p> <p>Following the same reasoning, the first Response paragraph would be better worded as: “Submit specific information describing the access control system (Panoramic Irradiators) or personnel access barrier (Underwater irradiators) and how it works, which demonstrates compliance with the requirements of 10 CFR 36.23.”</p> <p>The last Response paragraph would be better worded as “Describe the site specific testing frequency of the access control system (Panoramic irradiators) or personnel access barrier (Underwater irradiators).</p> | <p>Text revised.</p> <p>Text revised.</p> <p>Text revised.</p> |
| 12 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.9.2, Page 44 | <p>The third full paragraph states that there is only one key and that only irradiator operators or facility management may have access to it. I have not found reference to this logic system within 10 CFR 36. However, it is not clear that a member of “facility management” who has not been adequately trained have access to the key. The “Key” should only be accessible to people who have received a minimum of operator training. This is only an opinion, but is consistent with the overall logic of 10 CFR 36.</p> | <p>The WG does not agree that management can be prohibited from possessing the key, unless the requirement currently in 36.31(a) is revised. This rule requires the use of one key at a time. However, it</p> |

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| | | | | <p>should be emphasized that only trained individuals can operate an irradiator. In addition, the new Part 37 restricts unescorted access to those who have been determined to be trustworthy and reliable.</p> |
| 13 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.9.2, Page 45 | <p>Similar to my comment on page 44 (above), I believe that access to the keys for the personnel access barrier for an Underwater irradiator be restricted to appropriately trained personnel. Also, this section should refer to keys or combinations depending on the type of locking device. This differs from a Panoramic irradiator's physical keys, which are part of the logic of the interlock system.</p> <p>For both of the comments above, page 66 states: "Only authorized users should have access to these keys." Unless a member of facility management has been designated as an "authorized user", including the associated training, then they should be considered a "member of the public" and not have unescorted access.</p> | <p>The WG does not agree that management can be prohibited from possessing the key, unless the requirement currently in 36.23(i) is revised. However, it should be emphasized that only trained individuals can operate an irradiator. In addition, the new Part 37 restricts</p> |

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| | | | | unescorted access to those who have been determined to be trustworthy and reliable. 36.23(i) does not currently address combination locks. |
| 14 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.9.2, Page 45 | The Underwater Irradiator section states: “The intrusion alarm must be able to detect unauthorized entry when the personnel access barrier is locked.” There are times when an onsite RSO or on-site Operator may want to lock the personnel access barrier without turning on the intrusion detection system. The wording should be modified. Perhaps: “The intrusion detection system must be able to detect an unauthorized breach of the personnel access barrier. Intrusion detection must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.” [Note: In this suggested wording I specifically did not use the word “activation”. In this instance, activation could be used, and confused, for either turning on the system, or the system alerting.] | The WG does not agree with revising the text. The wording is taken directly from 10 CFR 36.23(i), which states that there must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. The rule does not include any relief to that requirement. |
| 15 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.9.5, Page 50 | The third paragraph uses a poor example of why an individual needs to respond quickly. The example states that the responding person would “(e.g., prevent movement of irradiated product out of [the] pool in the event water is contaminated, or in the event that a | The WG does not agree with the comment to revise the |

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| | | | <p>loose source is embedded in the product carrier). There are two errors with this example. First, the paragraph is specific to a monitor located and designed to detect abnormal radiation levels <u>above the pool</u> per 10 CFR 36.29(b) and not the monitor referenced in 10 CFR 36.59(b). Thus, the reference to the water being contaminated is misleading. Second, as stated in the first paragraph, the monitor per 10 CFR 36.29(b) must automatically stop the conveyor. In the example, a person must respond promptly to prevent movement of irradiated product. Since the movement of the product has already been stopped by the action of the same monitor that alerted the responder, this example is illogical. i.e. The responder must prevent movement of the stopped product. I suggested that the parenthetical example be dropped to avoid potential confusion.</p> | <p>example. The WG does acknowledge that the primary intent of the radiation monitor in 36.59(b) is to detect radioactive contamination in pool water, as indicated in the Part 36 Statements of Consideration. However, the WG does not want to discount the possibility of the detection of abnormal radiation levels (due to contamination) by the 36.29(b) pool radiation monitor, due to the failure of the monitor required by 36.59(b). An area radiation monitor did detect pool water contamination</p> |

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| | | | | <p>during a panoramic irradiator event in 1982. In addition, for underwater irradiators, the pool monitor required by 36.29(b) is not required to stop the movement of product. The alarm must be capable of alerting an individual who is prepared to respond.</p> |
| 16 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.9.7, Page 53 | <p>The section is confusing because it does not sufficiently differentiate irradiators that have a moving source rack and those that do not. 10 CFR 36.35 “Source rack protection” refers to product that moves on a conveyor system. Section 8.9.7 primarily assumes that there is a pool and that the source rack moves (specifically raised and lowered). Perhaps better wording would be:</p> <p>Criteria: If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack (Panoramic irradiators) must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack of mechanism. [Note: This wording is primarily from 10 CFR 36.35.]</p> | <p>The WG does not agree that this section should be revised. The WG does acknowledge that 36.35, as written, appears to focus primarily on panoramic irradiators with product conveyor systems and</p> |

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| | | | <p>Discussion: For irradiators with a product conveyor system, the source rack must be physically protected from the movement of the conveyor system and the product handled by the conveyor system. For Panoramic irradiators, the system that moves the source rack must also be physically protected from the conveyor system.</p> <p>The fourth bulleted paragraph further confused the issue by also assuming that the source rack moves in “all irradiators with product conveyor systems”. This is not the case for Underwater irradiators. I suggest that Panoramic irradiators be referenced in conjunction with any movement of the source rack.</p> <p>[It is interesting to note that 10 CFR 36.35 addresses concerns about the movement of the product conveyance interfering with the source rack (and movement mechanism, if employed). But, it does not address the movement of the source rack (Panoramic irradiators) interfering with the product conveyor. In general, the source rack should be physically protected at all times from any physical interference, whether or not a product conveyor is used. However, this is an issue of 10 CFR 36 and not of this draft guidance]</p> <p>The comments (above) also apply to the Response from Applicant section.</p> | <p>does not clearly distinguish between source racks that move and those that do not. However, the WG does not want to discourage license reviewers from addressing source rack protection for underwater irradiators where there is product movement but no source rack movement.</p> |
| 17 | Wisconsin | Page 63 | Under ‘Response from Applicant’, add a bullet before the second statement. | Corrected. |
| 18 | Wisconsin | Page 65 and 66 | Remove the extra line break three lines up from the bottom of each page. | Corrected. |
| 19 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.10.6, Page 68 | The first block of Table 8.7 is specific to Panoramic irradiators. It should be stated as such. | Text revised. |
| 20 | Wisconsin | Page 70 | Add ‘and’ before “IN 04-18” in the Reference section | Corrected. |

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| 21 | Russell N. Stein, VP, Gray Star | Chapter 8, Section 8.10.10, Page 79 | The last sentence in the Discussion would be better stated as: "In the applicant's description of the procedures, specific the inspection and maintenance check frequency of the following items (as applicable):" [This list includes items that are applicable on some types of irradiators, but not other.] | Text revised.. |
| 22 | Wisconsin | Page 82 | In the discussion section, delete "The NSTS is a major security initiative of the NRC." This is understood and the statement does not add any additional information. | Text deleted. |
| 23 | Wisconsin | Page 82 | The sentence beginning "Table 1 of Appendix A" should be moved to be the first sentence in the preceding paragraph. Also, delete "The applicant should refer to this table to determine if its program exceeds the Category 1 or Category 2 authorization thresholds." | Comment not accepted. Revised language is consistent with other NUREG-1556 volumes as directed by NMSS/MSTR management. Language was approved by several other offices at the NRC ,including the regions. |
| 24 | Wisconsin | Page 82 | The last sentence on the page "Refer to 10 CFR Part 37 for these additional requirement" should give the exact citation for the requirements specific to transport of Category 1 quantities. | Comment accepted. Revised language, which is consistent with other NUREG-1556 volumes as directed by NMSS/MSTR management, |

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| | | | | addresses 10 CFR Part 37 requirements for the transport of Category 1 quantities. Language was approved by several other offices at the NRC ,including the regions. |
| 25 | Virginia | Section 8.10.13, "Security Program" | The RMP recommends that the guidance have documentation that states "A new license will not be issued until a pre-licensing inspection has occurred to ensure the security requirements of Part 37 have been implemented. An applicant is required to notify the NRC when they are prepared to have the security program inspected." This statement aids the licensing process and should cause the applicant to ask questions regarding this process. | Comment accepted. Language regarding "pre-licensing site visits" and "on-site security reviews" is included in Chapter 8 "CONTENT OF AN APPLICATION"; Section 8.1 "Item1: License Action Type." |
| 26 | Wisconsin | Page 87 | Correct spelling of "teletherapy" in the sentence under first box | Corrected. |
| 27 | Wisconsin | Page A-1 | Only one Information Notice includes the ADAMS Accession number. Either give the ML number for each document or delete from the entry for IN 04-13. | Reference to ML Number was removed. |

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| 28 | Russell N. Stein, VP, Gray Star | Appendix C | I believe that this is an excellent check list for preparing and reviewing an application. However, I do not believe that it serves any useful function by providing it with the application. Most of the boxes will be filled out as "Description Attached" where indicated with "[]". However, these are obvious and therefore redundant. In other cases the boxes are displayed on the assumption that it is one type of irradiator, and the application is for a different type. In this instance it would have to be filled out with "not applicable" or similar comment. Therefore, it will not provide useful information, will add to the length of the application and will lead to potential confusion. I suggest that it be used internally by both the applicant and the reviewer as a checklist, but not provided with the application. | Section 5.1: Paper Application, instructs an applicant to complete NRC Form 313 Items 5 through 11 on supplementary pages or use Appendix C. The applicant is not required to use Appendix C. |
| 29 | Wisconsin | Appendix C, Page C-2 | In Item No. 6, first bullet, correct Celsius abbreviation. | Corrected. |
| 30 | Russell N. Stein, VP, Gray Star | Appendix E | The number of hours of initial operator training is not in accordance with the text of the main document or 10 CFR 36. | The number of hours was removed to maintain consistency with the Part 36 Statements of Consideration. |
| 31 | Virginia | Appendix I | In Appendix I "Suggested Audit Checklist", the RMP recommends a section be added for the Part 37 security requirements to ensure the licensee is performing the new requirements. The items could include: T&R verifications completed and documentation is maintained; T&R list is updated and previous lists are being maintained; security plan is being maintained; LLEA has been contacted and provided training; and documentation of alarm system is maintained. | The text was modified to include examples of basic Part 37 security requirements. |
| 32 | Wisconsin | Page L-1 | In paragraph under second box, change "thermoluminescence" to "thermoluminescent" to match the definition as listed on page xvi. | Corrected. |

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| 33 | Wisconsin | Page M-2 | Input the equations into the Equation Editor feature of the word processor to prevent the spacing problem seen in the first equation. | Corrected with the addition of consistency template language. |
| 34 | Wisconsin | Page M-2 | Add a space in "200 becquerels". | Corrected. |
| 35 | Wisconsin | Page O-1 | Does the exemption from 10 CFR 36.23(a) allow the use of key cards instead of keys for access to rooms with converted teletherapy units? | The use of key cards would be evaluated during review of the 36.23(a) exemption request. The guidance for granting this exemption only requires the presence of an operator for the entire period of time that the key is in the control panel. |