October 17, 2012

Responses to Comments on Draft Interim Staff Guidance Augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," for the Production of Radioisotopes

[ENTER DATE HERE]

PREFACE:

This document constitutes the U.S. Nuclear Regulatory Commission (NRC) staff response to public comments on the document *Draft Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," for the Production of Radioisotopes* and a companion document *Draft Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria," for the Production of Radioisotopes.*

These documents were prepared to augment the most recent guidance for the preparation of license applications for non-power reactors, *NUREG-1537, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, 1996,* in anticipation of new applications for facilities for manufacturing isotopes, including those for medical applications. Public comments were requested for each of three segments of the two documents in separate *Federal Register* Notices. Comments were received from organizations identified in this document as follows:

B&W	Babcock & Wilcox Technical Services Group
SHINE	SHINE Medical Technologies, Inc.
TRTR	National Organization of Test, Research, and Training Reactors

The following table identifies the solicitations and responses, the latter in terms of the location in the NRC's Agencywide Documents Access and Management System (ADAMS) Accession Numbers:

Draft ISG Published	*Federal Register* Notice Citation	ADAMS Accession No. of Public Comment			Total Comments
		B&W	SHINE	TRTR	
Section 12.12, Part 1, Environmental Report	76 FR35922, June 20, 2011	ML11217A018	ML11216A140	ML11220A263	41
Part 1&2, Chapters 1-6	76 FR 63668, October 13, 2011	ML11325A121	ML11325A120	ML11325A122	46
Part 1&2, Chapters 7-18*	77 FR 21592, April 10, 2012	ML12135A181	ML12136A120	n/a	29

*Except Section 12.12, Environmental Report

The draft ISG was published with the environmental report addressed in Section 12.12 of Chapter 12, "Conduct of Operations." Public comments and NRC staff responses related to the environmental report are referenced in terms of their Section 12.12 location

in the ISG. The environmental section grew to the point that it was decided to move that guidance to its own chapter when publishing the Final ISG. Therefore, the new Chapter 19 in the Final ISG contains the Environmental Review material originally located in section 12 of Chapter 12. The structure of Chapter 19 retains the structure previously designated as Section 12.12, which has been reduced to a pointer to Chapter 19.

The following pages contain a reference to the topic or text of the ISG to which a comment applies, the text of the comment which was submitted, and the NRC staff response to the comment.

SHINE Medical Technologies

July 28, 2011

Ms. Cindy K. Bladey
Chief, Rules, Announcements, and Directives Branch
Division of Administrative Services
Office of Administration
Mail Stop TWB-05-B01M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

6/20/2011
76FR35922
(1)

SHINE Medical Technologies, Inc.
Project No. 0792
SMT-2011-011

Subject: Comments on Interim Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities, Docket ID NRC-2011-0135

Dear Ms. Bladey:

The purpose of this letter is to provide comments on the proposed draft Interim Staff Guidance (ISG), NPR-ISG-2011-001, "Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities".

Comments on the proposed draft Interim Staff Guidance are contained in the enclosure to this letter. The enclosure includes both general and specific comments for identified sections. SHINE appreciates the opportunity to provide comments and hopes that the Staff will consider the merits of the requested feedback during the development of final Environmental Report guidance for medical isotope production facilities.

If you have any questions regarding this letter, please contact Mr. James Freels, Licensing Project Manager, at 865.719.5061.

Sincerely,

Gregory Piefer, PhD
CEO – SHINE Medical Technologies, Inc.

Enclosure: As stated

8123 Forsythia St, Suite 140 · Middleton, WI · 53562 · (877) 512-6554 · (608) 831-8110 fax
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Add = S. Sloan (SGS4)

No comments received on this page.

No comments received on this page.

Enclosure

Comments on Interim Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities

Docket ID NRC-2011-0135

SMT-2011-011
July 28, 2011

Comments on Interim Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities

Docket ID NRC-2011-0135

General Comments:

Not all medical isotope facilities will be based on the same technology. While some medical isotope facilities may employ reactor-based technologies, others may be based on less environmentally impactful technologies, such as particle accelerators or other non-reactor based technologies. The use of NUREG-1537, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, for all medical isotope facilities' licensing framework, including Environmental Reports is a sub-optimal licensing framework. This premise is supported by the recognition of the Staff that Interim Staff Guidance is needed to supplement NUREG-1537 for both the Environmental Report and the Safety Analysis Report. While there is no generic licensing framework for individual medical isotope production technologies, the Staff should be agile and responsive to the various medical isotope technologies' differing needs for regulatory interpretations while potential applicants are working to follow the licensing guidance for non-power reactors. The Staff should implement an expeditious internal process for assessing licensing issues and providing NRC policy and interpretation findings for the potential applicant's licensing process.

1-1 Medical isotope facilities based on these non-reactor technologies will be significantly smaller in physical size, have a much smaller plant footprint, represent a much lower hazard to the public and most importantly, have far less impact on the human environment than nuclear power reactors. In the proposed Interim Staff Guidance, there are numerous examples where the draft ISG requests information that is in excess of what is requested for nuclear power reactors in NUREG-1555: Standard Review Plans for Environmental Reviews for Nuclear Power Plants. The Staff should not request more information from medical isotope production facility Environmental Reports than it requests from the initial licensing of nuclear power reactors, as identified in many of the Specific Comments. It also appears that in numerous areas, the Staff has referenced NUREG-1555, Supplement 1, for the proposed language. NUREG-1555, Supplement 1, provides the Staff guidance in reviewing Environmental Reports for nuclear power plant license renewal, not their initial licensing, and is inappropriate for providing guidance related to medical isotope facility initial licensing.

1-2 Throughout the draft ISG, the radial distance to be considered in specific Environmental Report sections is identified as 50 miles (80 km). The 50 mile (80 km) radial distance for Environmental Report considerations is excessive for medical isotope production facilities. For nuclear power reactors, a radial distance of 50 miles (80 km) is appropriate as that distance is driven by the Ingestion Pathway distance identified in 10 CFR 50.47(c)(2). Therefore, for power reactors consideration of demographic considerations and socioeconomic impacts at a 50 mile radial distance is appropriate. However, for non-power reactors, as previously evaluated by the NRC and specified in NUREG-1537, Section 2.1.2, the radial distance needed for population distribution consideration in the Safety Analysis Report is identified as 8 kilometers. For non-power reactors accident considerations, the emergency planning zone guidance is provided in

NRC Responses to Comment 1-1

Potential applicants have described a broad range of technologies to produce radioisotopes. In addition, construction activities may vary from modifying equipment within existing facilities to building entirely new facilities on greenfield sites. The guidance document for licensing such facilities, NUREG-1537, was written in 1996, so in addition to expanding its scope technically the ISG was developed to address regulatory changes since that time. The NRC staff wrote the ISG using an approach that covers a range of potential technologies and construction methods. As such, NRC staff considered several guidance documents, including but not limited to NUREG-1555, "Environmental Standard Review Plan (ESRP) for New Site/Plant Applications," NUREG-1555, Supplement 1, "ESRP for Operating License Renewal," and NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs." For example, NRC staff considered NUREG-1555, Supplement 1, because this ESRP considers operations of nuclear reactors. Although Environmental Report(s) (ER) are intended for initial licensing, the ER(s) must cover the potential impacts during operations because applicants will need an operating license as well. As described throughout this document some aspects of the ISG have been refined to ensure it is appropriate for non-power reactors. Also see responses to comments 1-6, 1-7, 1-8, and 1-9.

NRC Response to Comment 1-2

The NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The NRC staff considered the environmental reviews performed for non-power reactors and those performed for power reactors and determined that that proposed 50-mi (mile) (80-kilometers (km)) radius was larger than necessary. The area was revised to a 5-mi (8 km) radius based on the smaller environmental impacts associated with radioisotope production facilities compared to power reactors. This area is consistent with NUREG 1537, Section 2.1, which requests geography and demography data within a 5-mi (8-km) radius. This 5-mi (8-km) radius is based on the hazards and potential radiological impacts associated with radioisotope production facilities. In addition, the NRC staff refined several data requests using resource appropriate definitions. If an applicant determines that a 5-mi (8-km) radius is too small or too large, the applicant can propose a different distance and provide a technical justification to support its position. The NRC staff will consider the information during its environmental review.

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1-2 cont. NUREG-0849, Standard Review Plan for the Review and Evaluation of Emergency plans for Research and Test Reactors, Appendix II, as referenced by NUREG-1537. Emergency planning zones are based on the hazard presented by research and test reactors and do not exceed 800 meters, unless thermal power is greater than 50 MW. For non-reactor based medical isotope facilities, there is no accident-driven need for consideration of a radius of 50 miles (80 km) and the socioeconomic impacts and demographic considerations from construction and operation are significantly smaller (approximately 10 to 100 times smaller) than for nuclear power reactors. The information requested in the draft ISG related to a 50 mile (80 km) radius is not warranted for non-reactor based medical isotope production facilities.

1-3 There are numerous examples where the distinction between the Safety Analysis Report and the Environmental Report become confused. The Environmental Report does not need to contain information regarding the impact of the environment on the facility; rather the Environmental Report should evaluate the impact of the facility on the environment. The former information will be found in the Safety Analysis Report and does not need to be included in the Environmental Report.

Specific Comments:

12.12.1.2 Applicable Regulatory Requirements, Permits and Required Consultations

1-4 Language used in this section is inconsistent with the language in 10 CFR 51.45(d). This ISG section identifies that the status of all Federal, State, local and other regulatory requirements, permits, and consultations be provided in accordance with 10 CFR 51.45(d). 10 CFR 51.45(d) requires that the Environmental Report list all *Federal* [emphasis added] permits, licenses, approvals and other entitlements along with their status of compliance (i.e., in compliance or not yet in compliance). Status of compliance is also required for applicable environmental quality standards and requirements such as zoning and land-use, thermal and other water pollution limitations or requirements which have been imposed by Federal, State, regional, and local agencies. The information requested in Section 12.12.1.2 exceeds what is required by 10 CFR 51.45(d) and should not create information needs beyond those required by regulations. (10 CFR 51.45(d); NUREG-1555, Section 1.2, Status of Reviews, Approvals and Consultations)

12.12.3.1 Land Use and Visual Resources

1-5 There is inconsistent use of the terms "region" and "vicinity" regarding the "site". These terms are not defined in the ISG, as they are in NUREG-1555 which specifies distinct differences between "site", "vicinity" and "region". For example, Section 12.12.3.1 asks for descriptions of land use conditions on and in the vicinity of the site, but the bulleted items ask for information related to the "region". Additionally, the same section introduces a new term, "area" which is also undefined. The inconsistent use of these terms should be modified based on a specific definition being created for the terms in a similar manner as in NUREG-1555. The site vicinity, as defined in NUREG-1555, should be utilized as the scope of off-site land use and visual resource impact studies. The 50 mile (80 km) radius around non-reactor based medical isotope production facilities is excessive and is not warranted. (NUREG-1555, Section 2.2.1, The Site and Vicinity)

NRC Response to Comment 1-3
The ISG has been updated to ensure that data needs focus on the potential impact of the proposed action on the environment, as appropriate. For example, Sections 12.12.3.3 and 12.12.4.2 (now Chapter 19, Sections 19.3.3 and 19.4.2) have been modified to focus on the potential impacts of the proposed action on the environment.

NRC Response to Comment 1-4
The environmental report should include, consistent with the language in 10 CFR 51.45(d) "a discussion of the status of compliance with applicable environmental quality standards and requirements including, but not limited to, applicable zoning and land-use regulations, and thermal and other water pollution limitations or requirements which have been imposed by Federal, State, regional, and local agencies having responsibility for environmental protection." The ISG provides guidance on the specific information that would be useful for NRC staff to understand and characterize the status of compliance. As noted in the ISG, the information should be provided only if it is applicable. The NRC requests and requires the assistance of applicants in providing the necessary information in order to facilitate a more efficient environmental review process as part of the construction permit and operating license application process. No change was made to the ISG based on the comment.

NRC Response to Comment 1-5
The terms "region," "vicinity," and "area" have either been defined or removed from the ISG. As discussed in the subsection of 12.12.2 (now Chapter 19, Section 19.2), "Site Location and Layout," the site is defined by the applicant in its ER.

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July 28, 2011

1-6 **12.12.3.2 Meteorology, Climatology**
This section states that the most recent 5 years of on-site or near-on-site meteorological data needs to be provided. This data need is excessive as only one year of onsite meteorological data is needed for nuclear reactor power plants. (NUREG-1555, Section 2.7, Meteorology and Air Quality)

1-7 **12.12.3.3 Geology, Soils and Seismology**
This section differs greatly from the same topical section in NUREG-1555 for nuclear power reactors. In NUREG-1555, there is little to no information requested relative to geology for power reactors, due to the extensive discussion in the Safety Analysis Report and the small potential for geological impacts by the construction, operation and decommissioning of a nuclear power reactor. This section appears to confuse the safety analysis impact from the geological setting on the plant, and the environmental impact from the plant on the geologic setting. This information request is excessive and should not request additional information over that needed for a nuclear power reactor for this section. In fact, medical isotope facilities will have a substantially lesser effect on the geological setting than power reactors due to their smaller size and weight, and the Staff should consider this when preparing the Interim Staff Guidance. (NUREG-1555, Section 2.6, Geology)

1-8 **12.12.3.5 Ecological Resources**
This section requests information related to the historical description of the ecological environment. The history of the ecological environment is not relevant to the impact of the proposed facility on the current and future environment, which is the intent of the Environmental Report. This information is not requested for nuclear power reactors and is considered extraneous for licensing a medical isotope production facility. (NUREG-1555, Section 2.4, Ecology)

12.12.3.8 Human Health
This section requests the following information:

- Historical exposures to radioactive materials to both workers and members of the public

1-9 It is not clear what is being requested for this line item, if there is no previous or currently operating nuclear facility at the proposed site location. The information request cannot be satisfied with a reasonable effort and is not relevant to the potential impact on the environment and the population from the proposed facility. This line item should be deleted from this section for new facilities, since, in many cases, it will be impossible to satisfy and no similar information request can be found in NUREG-1555 for new nuclear power plants. The information request should be limited to medical isotope facilities located near existing nuclear facilities or sites that once contained nuclear facilities. (NUREG-1555)

1-10 **12.12.4.2 Meteorology, Climatology, and Air Quality**
This section requests the following information:

- Description of design considerations for severe weather events

NRC Response to Comment 1-6
For radioisotope production facilities, the ISG states that offsite sources of meteorological data (e.g., airports) may be used in lieu of onsite data. Offsite data is generally less resource-intensive to gather as compared to onsite data because onsite data often requires construction of a meteorological data collection tower. Offsite data, rather than onsite data, is suggested because radioisotope production facilities pose less of a risk to the public and the environment. The length of available data from offsite data sources is most likely longer than the data available from a new onsite monitoring program. Further, the recommendation to use five years of meteorological data to perform an atmospheric dispersion analysis is consistent with Environmental Protection Agency (EPA)'s Guideline on Air Quality Models (70 FR 68218-68261). EPA's guidelines recommend that five years of representative meteorological data be used when estimating atmospheric dispersion for an air quality model.

For power reactors, onsite data is recommended. Since the publication of ESRP-1555, Regulatory Guide (RG) 1.23 was revised to suggest applicants provide 12 months of data for a power reactor construction permit application and 24 months data for a power reactor operating license application. For power reactors, RG 1.23 also suggests that onsite meteorological programs be used. No change was made to the ISG based on the comment.

NRC Response to Comment 1-7
The ISG has been updated to ensure that data needs focus on the potential impact of the proposed action on the environment, as appropriate. For example, Sections 12.12.3.3 and 12.12.4.2 (now Chapter 19, Sections 19.3.3 and 19.4.2) have been modified to focus on the potential impacts of the proposed action on the environment.

This page is repeated to show Comments 1-8, 1-9 and 1-10

12.12.3.2 Meteorology, Climatology

1-6 This section states that the most recent 5 years of on-site or near-on-site meteorological data needs to be provided. This data need is excessive as only one year of onsite meteorological data is needed for nuclear reactor power plants. (NUREG-1555, Section 2.7, Meteorology and Air Quality)

12.12.3.3 Geology, Soils and Seismology

1-7 This section differs greatly from the same topical section in NUREG-1555 for nuclear power reactors. In NUREG-1555, there is little to no information requested relative to geology for power reactors, due to the extensive discussion in the Safety Analysis Report and the small potential for geological impacts by the construction, operation and decommissioning of a nuclear power reactor. This section appears to confuse the safety analysis impact from the geological setting on the plant, and the environmental impact from the plant on the geologic setting. This information request is excessive and should not request additional information over that needed for a nuclear power reactor for this section. In fact, medical isotope facilities will have a substantially lesser effect on the geological setting than power reactors due to their smaller size and weight, and the Staff should consider this when preparing the Interim Staff Guidance. (NUREG-1555, Section 2.6, Geology)

12.12.3.5 Ecological Resources

1-8 This section requests information related to the historical description of the ecological environment. The history of the ecological environment is not relevant to the impact of the proposed facility on the current and future environment, which is the intent of the Environmental Report. This information is not requested for nuclear power reactors and is considered extraneous for licensing a medical isotope production facility. (NUREG-1555, Section 2.4, Ecology)

12.12.3.8 Human Health

This section requests the following information:

- Historical exposures to radioactive materials to both workers and members of the public

1-9 It is not clear what is being requested for this line item, if there is no previous or currently operating nuclear facility at the proposed site location. The information request cannot be satisfied with a reasonable effort and is not relevant to the potential impact on the environment and the population from the proposed facility. This line item should be deleted from this section for new facilities, since, in many cases, it will be impossible to satisfy and no similar information request can be found in NUREG-1555 for new nuclear power plants. The information request should be limited to medical isotope facilities located near existing nuclear facilities or sites that once contained nuclear facilities. (NUREG-1555)

12.12.4.2 Meteorology, Climatology, and Air Quality

1-10 This section requests the following information:

- Description of design considerations for severe weather events

NRC Response to Comment 1-8

Historical information is relevant to the environmental review because past disturbances to the ecological environment should be included as part of the affected environment, which describes the baseline conditions prior to the construction, operations, and decommissioning of the facility. In addition, NRC's regulations that implement NEPA require a cumulative impact analysis. The "cumulative impact" is the impact on the environment which results from the incremental impact of the proposed action (constructing and operating a radioisotope production facility) when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. The NRC requests and requires the assistance of applicants in providing the necessary information for the ER in order to facilitate a more efficient environmental review process as part of the construction permit and operating license application process.

NRC requests similar information for applications to construct and operate power reactors. For example, Supplemental Guidance to NUREG-1555 for Cumulative Effects discusses the need for environmental data regarding past actions, including historical disturbances to ecological resources. No change was made to the ISG based on the comment.

NRC Response to Comment 1-9

The section begins with the sentence "The applicant or licensee should provide the following information in the ER, as applicable." The NRC staff acknowledges that not all the requested information is available for certain types of radioisotope production facilities. The guidance is designed to cover a broad range of potential technologies and construction methods to construct and operate a radioisotope production facility. For example, an existing NRC licensee may decide to modify or expand its existing facility to produce radioisotopes. For that example, there would be historical radiation exposure information available to include in the ER. No change was made to the ISG based on the comment.

NRC Response to Comment 1-10

This data need has been removed from the ISG because the data need is not directly related to the affect of the proposed action on the environment.

1-10 cont.

The design considerations for severe weather events are not related to the impact of the facility on the environment; rather they are related to the facility design specifications in Chapter 3 of the Safety Analysis Report. This duplicative information should not be included in the Environmental Report. Design considerations related to the potential impact of severe weather events are not requested for nuclear power reactor Environmental Reports. (NUREG-1555, Section 2.7, Meteorology)

1-11

12.12.7 List of Preparers

This section states that the applicant or licensee should list the name, educational background, and summary or work experience for all personnel who have a role in preparing the Environmental Report. NUREG-1555 was reviewed for a similar statement; none was found during the review. This information is extraneous, is not requested for power reactors and need not be identified for medical isotope production facilities. (NUREG-1555)

NRC Response to Comment 1-11

This data need has been removed from the ISG because the information is not necessary for NRC to conduct its environmental review.

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6/20/2011
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(2)

August 2, 2011

Cindy K. Bladey
Chief, Rules, Announcements and Directives Branch
Division of Administrative Services
Office of Administration
Mail Stop: TWB-05-B01M
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

RECEIVED
RULES AND DIRECTIVES BRANCH

Subject: Comments on Interim Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities submitted by Babcock & Wilcox, Technical Services Group, Inc. Docket ID NRC-2011-0135

B&W appreciates NRC actions to prepare for the licensing of a medical isotope production facility and views this Interim Staff Guidance as an important step in that preparation. The attached comments are provided for NRC consideration in an effort to improve and clarify expectations for the content of the environmental report.

Thank you for considering these comments. If you have questions please me at 434-522-6313 or Steve Schilthelm at 434-522-6243.

Sincerely,

Dan Glenn
MIPS Program Manager
B&W Technical Services Group, Inc.

Attachment

cc: B&W MIPS Records

SUNSI Review Complete
Template = ADM-013

ERIDS = ADM-03
Add = S. Sloan (SECY)

No comments received on this page.

Babcock & Wilcox, Technical Services Group, Inc.
COMMENTS ON 'Draft Interim Staff Guidance for NUREG-1537, Part 1, Section 12.12," June 2011 (Request for comments, 76 FR 35922, Jun. 12, 2011, Interim Staff Guidance Regarding the Environmental Report for Application To Construct and/or Operate Medical Isotope Production Facilities)

	Section	Comment
2-1	General	It appears that the information requested represents an exhaustive list covering all possible applicant situations. While this is comprehensive, it also has the potential impact of creating expectations for information that will not be necessary in many cases (e.g., a "brown-field" site). Suggest that each section of the guidance be expanded to provide criteria for when information is and is not required in an effort to guide and inform both the applicant and the NRC Staff. This would eliminate the need for protracted discussion and justification of information that is not necessary to be submitted.
2-2	12.12	It should be stated that Section 12.12 of the Environmental Report should be submitted as a separate document in the application. Guidance should also be included regarding timing of the submittal in relation to the balance of the construction or operating application in accordance with 10 CFR 2.101 (e.g., maximum 6 month separation).
2-3	12.12.1	The expectation for "consultations" appears to go beyond the requirements of 51.45(d). Should "consultations" really be expected particularly if the chosen site is an existing "brown field" nuclear site? This expectation for consultations appears in several other parts of the document. Is there a difference in the applicants and the NRC responsibility for consultation?
2-4	12.12.2	Site Location and Layout. Given the limited scope of potential environmental impacts from MIPF construction and operation and its location on an existing industrial site, previous subject to NRC review, the requirement for descriptive information within 50 mile is excessive. A 10 mile area would be more reasonable.
2-5	12.12.3	The introductory two paragraphs appear to give the applicant discretion as to the content and detail of baseline information provided based on the "scope" of the proposed action. An explanation of "scope" would be helpful. Should "scope" be understood to include the significance and geographic extent of environmental impacts from activities and effluents associated with facility construction and operation?

NRC Response to Comment 2-1
Potential applicants have described a broad range of technologies to produce radioisotopes. In addition, applicants may conduct construction activities that vary from modifying equipment within an existing facility to building an entirely new facility on a greenfield site. The NRC staff wrote the ISG using an approach that covers a range of potential technologies and construction methods. Throughout the ISG, it states that applicants should only provide information if it is applicable to its design and construction method. As stated in the ISG, applicants may request pre-application meetings with NRC staff if they have questions regarding the information needed to support the environmental review. The NRC staff has added additional language in the ISG for clarification.

NRC Response to Comment 2-2
Applicants should interact with NRC staff to determine the most appropriate approach to application submittal, dependent on the individual circumstances of the license application.

NRC Response to Comment 2-3
The environmental report should, consistent with the language in 10 CFR 51.45(d), provide a discussion of the status of compliance for all applicable environmental quality standards and requirements. It is not possible to determine whether consultation with natural resource and cultural resource agencies are required *a priori*, without information on species, habitats, and cultural resources that may potentially occur within the affected area. A brownfield site may provide habitat for wildlife that can utilize urban areas and/or be within the viewshed of historic properties. Therefore, applicants are encouraged to consult and coordinate with other local, State, and Federal agencies to determine what permits, consultations, and surveys may be required. The NRC requests and requires the assistance of applicants in providing the necessary information in order to facilitate a more efficient environmental review process. No change was made to the ISG based on the comment.

This page is repeated to show Comments 2-4 and 2-5

Babcock & Wilcox, Technical Services Group, Inc.
COMMENTS ON 'Draft Interim Staff Guidance for NUREG-1537, Part 1, Section 12.12," June 2011 (Request for comments, 76 FR 35922, Jun. 12, 2011, Interim Staff Guidance Regarding the Environmental Report for Application To Construct and/or Operate Medical Isotope Production Facilities)

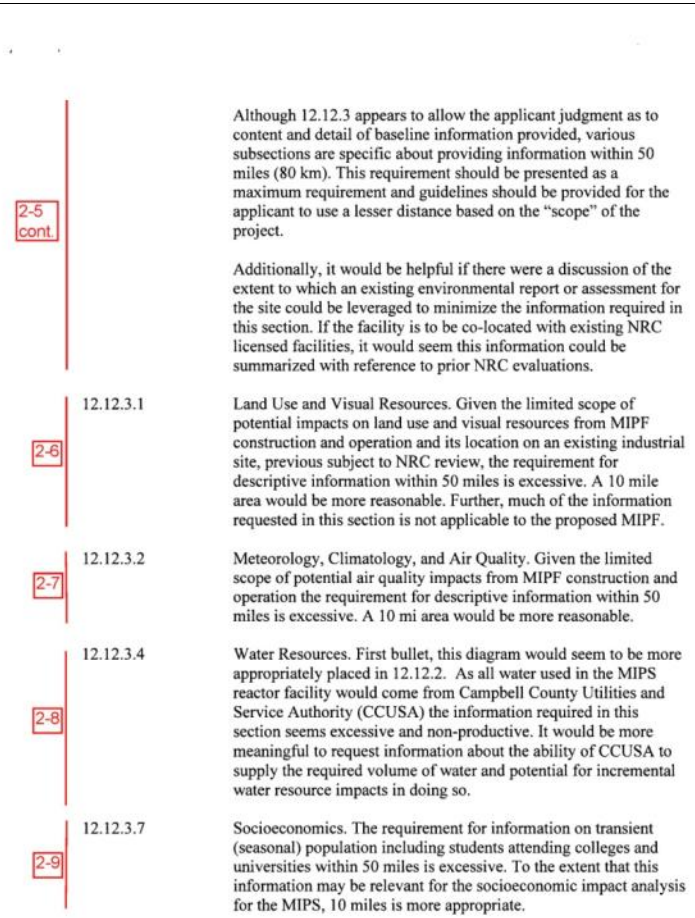
	Section	Comment
2-1	General	It appears that the information requested represents an exhaustive list covering all possible applicant situations. While this is comprehensive, it also has the potential impact of creating expectations for information that will not be necessary in many cases (e.g., a "brown-field" site). Suggest that each section of the guidance be expanded to provide criteria for when information is and is not required in an effort to guide and inform both the applicant and the NRC Staff. This would eliminate the need for protracted discussion and justification of information that is not necessary to be submitted.
2-2	12.12	It should be stated that Section 12.12 of the Environmental Report should be submitted as a separate document in the application. Guidance should also be included regarding timing of the submittal in relation to the balance of the construction or operating application in accordance with 10 CFR 2.101 (e.g., maximum 6 month separation).
2-3	12.12.1	The expectation for "consultations" appears to go beyond the requirements of 51.45(d). Should "consultations" really be expected particularly if the chosen site is an existing "brown field" nuclear site? This expectation for consultations appears in several other parts of the document. Is there a difference in the applicants and the NRC responsibility for consultation?
2-4	12.12.2	Site Location and Layout. Given the limited scope of potential environmental impacts from MIPF construction and operation and its location on an existing industrial site, previous subject to NRC review, the requirement for descriptive information within 50 mile is excessive. A 10 mile area would be more reasonable.
2-5	12.12.3	The introductory two paragraphs appear to give the applicant discretion as to the content and detail of baseline information provided based on the "scope" of the proposed action. An explanation of "scope" would be helpful. Should "scope" be understood to include the significance and geographic extent of environmental impacts from activities and effluents associated with facility construction and operation?

NRC Response to Comment 2-4
As discussed in the response to comment 1-2, the NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The area was revised to a 5-mile radius.

NRC Response to Comment 2-5
The guidance in Section 12.12.3 (now Chapter 19, Section 19.3) is intended to provide some flexibility to an applicant to provide a sufficient level of information to enable the NRC staff to perform an environmental review. The guidance is designed to cover a range of possible types of radioisotope production facilities. As such, sufficient information is needed from the applicant so that the NRC staff can evaluate the range of possible environmental impacts. The NRC staff believes the applicant is in the best position to make an informed decision on the appropriate level of information on the construction and operational activities associated with its proposed radioisotope production facility. As stated in the ISG, applicants may request pre-application meetings with NRC staff if they have questions regarding the information needed to support the environmental review. If the NRC staff cannot obtain adequate information from the applicant's ER to conduct its environmental review, the NRC staff will issue a request for additional information on the specific issue.

Regarding a new radioisotope production facility that may be located near an existing nuclear facility, the guidance requests historical information associated with the existing facility. Applicants may reference other studies if the other studies provide environmental data that is relevant to the environmental review of the proposed action.

No change was made to the ISG based on the comment.



2-5 cont.

Although 12.12.3 appears to allow the applicant judgment as to content and detail of baseline information provided, various subsections are specific about providing information within 50 miles (80 km). This requirement should be presented as a maximum requirement and guidelines should be provided for the applicant to use a lesser distance based on the "scope" of the project.

Additionally, it would be helpful if there were a discussion of the extent to which an existing environmental report or assessment for the site could be leveraged to minimize the information required in this section. If the facility is to be co-located with existing NRC licensed facilities, it would seem this information could be summarized with reference to prior NRC evaluations.

2-6

12.12.3.1 Land Use and Visual Resources. Given the limited scope of potential impacts on land use and visual resources from MIPF construction and operation and its location on an existing industrial site, previous subject to NRC review, the requirement for descriptive information within 50 miles is excessive. A 10 mile area would be more reasonable. Further, much of the information requested in this section is not applicable to the proposed MIPF.

2-7

12.12.3.2 Meteorology, Climatology, and Air Quality. Given the limited scope of potential air quality impacts from MIPF construction and operation the requirement for descriptive information within 50 miles is excessive. A 10 mi area would be more reasonable.

2-8

12.12.3.4 Water Resources. First bullet, this diagram would seem to be more appropriately placed in 12.12.2. As all water used in the MIPS reactor facility would come from Campbell County Utilities and Service Authority (CCUSA) the information required in this section seems excessive and non-productive. It would be more meaningful to request information about the ability of CCUSA to supply the required volume of water and potential for incremental water resource impacts in doing so.

2-9

12.12.3.7 Socioeconomics. The requirement for information on transient (seasonal) population including students attending colleges and universities within 50 miles is excessive. To the extent that this information may be relevant for the socioeconomic impact analysis for the MIPS, 10 miles is more appropriate.

NRC Response to Comment 2-6
As discussed in the response to comment 1-2, the NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The NRC staff determined that the information requested is likely relevant to radioisotope production facilities. The area was revised to a 5-mile radius.

NRC Response to Comment 2-7
As discussed in the response to comment 1-2, the NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The area was revised to a 5-mile radius.

NRC Response to Comment 2-8
The first bullet under "Water Resources" has been moved to 12.12.2 (now Chapter 19, Section 19.2), under "Water Consumption and Treatment." In 12.12.3.4 and 12.12.4.4 (now Chapter 19, Sections 19.3.4 and 19.4.4), additional data needs have been added to describe the situation where county water would be used.

As discussed in the ISG, applicants should provide data commensurate with the importance of the impact, with less important material summarized, consolidated, or simply referenced. If a proposed project will not use surface or groundwater during construction, operations, or decommissioning, then an applicant should explain this in the ER. In such cases, less detail would be needed to characterize surface and groundwater resources. However, a description of potentially affected surface and groundwater resources would still be needed in order to characterize the affected environment, or the baseline environmental conditions, and the potential impacts to surface and groundwater quality. The requested information will enable the NRC to meet its statutory obligations under Section 102(2) of NEPA and to fulfill its responsibilities under 10 CFR 51.70(b) to provide evidence that the necessary environmental analyses have been conducted.

NRC Response to Comment 2-9
As discussed in the response to comment 1-2, the NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The area was revised to a 5-mile radius.

2-10	12.12.4	In the first introductory paragraph, explain "direct and indirect impacts of the proposed action and alternatives as well as the cumulative impacts of other past, present, and reasonably foreseeable future actions." It would be helpful if each of the subsections included an introductory statement providing an overview of the analysis and supporting information to be covered in the subsection. Subsections 12.12.4.3 Geology, Soils, and Seismology, 12.12.4.4 Water Resources, and 12.12.4.8 Historic and Cultural Resources approach providing this information.
2-11	12.12.4.2	Meteorology, Climatology, and Air Quality. The guidance in this section is confusing. One would expect a focus on impact analysis of construction and operation; however, much of the information requested is descriptive and more appropriately placed either in section12.12.2 or section 12.12.3.2 as baseline information.
2-12	12.12.4.3	Geology, Soils, and Seismology. The lead sentence for the bullets should read: "In addition to the summary of the analysis of the potential impacts of seismic and other geological hazards the applicant or licensee should provide the following information in the ER:"
2-13	12.12.4.4	Water Resources. The analysis required is excessive relative to the proposed MIPS water consumption, source and effluent. For the most part, the analysis required is not relevant to the proposed MIPS.
2-14	12.12.4.5	Ecological Resources. Relative to Special Status Species, it should be made clear that the applicant need consult with FWS, NOAA and state and local agencies and tribes only when the applicant determines that there is a potential impact on special status species. Relative to Monitoring, it should be stated that the applicant's monitoring plan, if any, is based on findings of possible significant ecological impacts.
2-15	12.12.4.8	Historic and Cultural Resources. Given the limited scope of impacts of MIPS constructed and operated on an existing industrial site, the requirements of this section are excessive. The guidance should provide for no off-site impacts and limited potential for on-site disturbance.

NRC Response to Comment 2-10
The CEQ regulations at 40 CFR Part 1508, "Terminology and Index," define the three types of effects. In particular, 40 CFR 1508.7, "Cumulative Impact," provides the following definition: "Cumulative impact" is the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time. In addition 40 CFR 1508.8, "Effects," defines direct and indirect effects as follows: "Effects" include:

a. Direct effects, which are caused by the action and occur at the same time and place
b. Indirect effects, which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable.

These definitions have been added to the ISG.

Introductory sentences were not added to subsections in 12.12.4 (now Chapter 19, Section 19.4) because NRC staff determined that these subsections were sufficient and clear without additional introductory language.

NRC Response to Comment 2-11
Section 12.12.4.2 (now Chapter 19, Section 19.4.2) has been revised to request information regarding the impacts from the proposed action. Some portions of Section 12.12.4.2 (now Chapter 19, Section 19.4.2) were not revised because NRC staff determined that the data needs were relevant to the environmental review.

NRC Response to Comment 2-12
Section 12.12.4.3 (now Chapter 19, Section 19.4.3) has been revised using language suggested in comment 2-12.

NRC Response to Comment 2-13
The ISG considers a broad range of potential technologies and construction methods that may be used to construct and operate radioisotope production facilities. Some designs and construction methods may require more water resources than others. Applicants should provide data and analyses commensurate with the importance of the impact, with less important material summarized, consolidated, or referenced. If a proposed project will not use surface or groundwater during construction, operations, or

This page is repeated to show Comments 2-13, 2-14 and 2-15

2-10	12.12.4	In the first introductory paragraph, explain "direct and indirect impacts of the proposed action and alternatives as well as the cumulative impacts of other past, present, and reasonably foreseeable future actions." It would be helpful if each of the subsections included an introductory statement providing an overview of the analysis and supporting information to be covered in the subsection. Subsections 12.12.4.3 Geology, Soils, and Seismology, 12.12.4.4 Water Resources, and 12.12.4.8 Historic and Cultural Resources approach providing this information.
2-11	12.12.4.2	Meteorology, Climatology, and Air Quality. The guidance in this section is confusing. One would expect a focus on impact analysis of construction and operation; however, much of the information requested is descriptive and more appropriately placed either in section12.12.2 or section 12.12.3.2 as baseline information.
2-12	12.12.4.3	Geology, Soils, and Seismology. The lead sentence for the bullets should read: "In addition to the summary of the analysis of the potential impacts of seismic and other geological hazards the applicant or licensee should provide the following information in the ER:"
2-13	12.12.4.4	Water Resources. The analysis required is excessive relative to the proposed MIPS water consumption, source and effluent. For the most part, the analysis required is not relevant to the proposed MIPS.
2-14	12.12.4.5	Ecological Resources. Relative to Special Status Species, it should be made clear that the applicant need consult with FWS, NOAA and state and local agencies and tribes only when the applicant determines that there is a potential impact on special status species. Relative to Monitoring, it should be stated that the applicant's monitoring plan, if any, is based on findings of possible significant ecological impacts.
2-15	12.12.4.8	Historic and Cultural Resources. Given the limited scope of impacts of MIPS constructed and operated on an existing industrial site, the requirements of this section are excessive. The guidance should provide for no off-site impacts and limited potential for on-site disturbance.

NRC Response to Comment 2-13 (continued)
decommissioning, then an applicant should explain this in its ER. However, a description of potential impacts to surface and groundwater quality would still be needed. The requested information will enable the NRC to meet its statutory obligations under Section 102(2) of NEPA and, specifically, to fulfill its responsibilities under 10 CFR 51.70(b) to provide evidence that the necessary environmental analyses have been conducted. No change was made to the ISG based on the comment.

NRC Response to Comment 2-14
It is not possible to determine whether consultations with natural resource agencies are required *a priori*, without information on species and habitats that may potentially occur within the affected area. A brownfield site, such as a site with second growth forests, may provide habitat for wildlife and special status species. Therefore, applicants are encouraged to consult and coordinate with other local, State, and Federal agencies to determine what permits, consultations, and surveys may be required. The NRC requests and requires the assistance of applicants in providing the necessary information in order to facilitate a more efficient environmental review process. The ISG has been revised to state that applicants should provide water resource and ecological monitoring plans that are commensurate with the importance of the potential impacts and that include the results of consultation with local, State, and other Federal agencies.

NRC Response to Comment 2-15
It is not possible to determine whether impacts or consultations with the SHPO and tribes are required *a priori*, without information on the extent of ground-disturbing activities and cultural resources that may potentially occur within the affected area. A brownfield site may contain archeological resources, depending on the previous land use activities on the site. As described in Section 12.12.4.6 (now Chapter 19, Section 19.4.6), applicants should consult and coordinate with the SHPO, tribes, and other interested stakeholders to determine historic properties and provide documentation of this consultation to the NRC. No change was made to the ISG as a result of this comment.

2-16	12.12.4.11	This section discusses Design Basis Accidents (DBA). This concept is inconsistent with the treatment of accidents in the balance of NUREG 1537 which uses the term Maximum Hypothetical Accident (MHA) and does not specify the identification of DBAs. Given the size and nature of the facilities, it would appear that the treatment of accidents in NUREG 1537 is appropriate and it may be more appropriate to identify MHA(s) for the reactor and for the isotope processing parts of the facility.
2-17	12.12.4.12	Environmental Justice. Given the likely insignificant environmental impacts of the proposed MIPS, what is the appropriate region to assess a target population for environmental justice?
2-18	12.12.5	This section appears to expect a quantitative evaluation (12.12.5.3) and cost benefit analysis of alternatives. It would seem that a more qualitative assessment would be more appropriate for this type of facility.
2-19	12.12.5.3	Cost Benefit of the Alternatives. The information required is excessive for explaining the costs and benefits of the proposed MIPS and alternatives. Specific environmental impacts identified for discussion are not significant and do not reveal any meaningful alternative to the proposal.
2-20	12.12.5.4	Comparison of the Potential Environmental Impacts. Given the limited environmental impacts of the proposed MIPS and the limited alternatives, this table seems unnecessary.
2-21	12.12.7	We question the purpose and need for the applicant or licensee to list the name, educational background, and summary of work experience for all personnel who had a role in preparing the ER. Where in 10 CFR and regulatory guidance has this been previously required?

NRC Response to Comment 2-16
Section 12.12.4.11 (now Chapter 19, Section 19.4.11) of the ISG was changed to delete the use of Design Basis Accidents to be consistent with NUREG-1537.

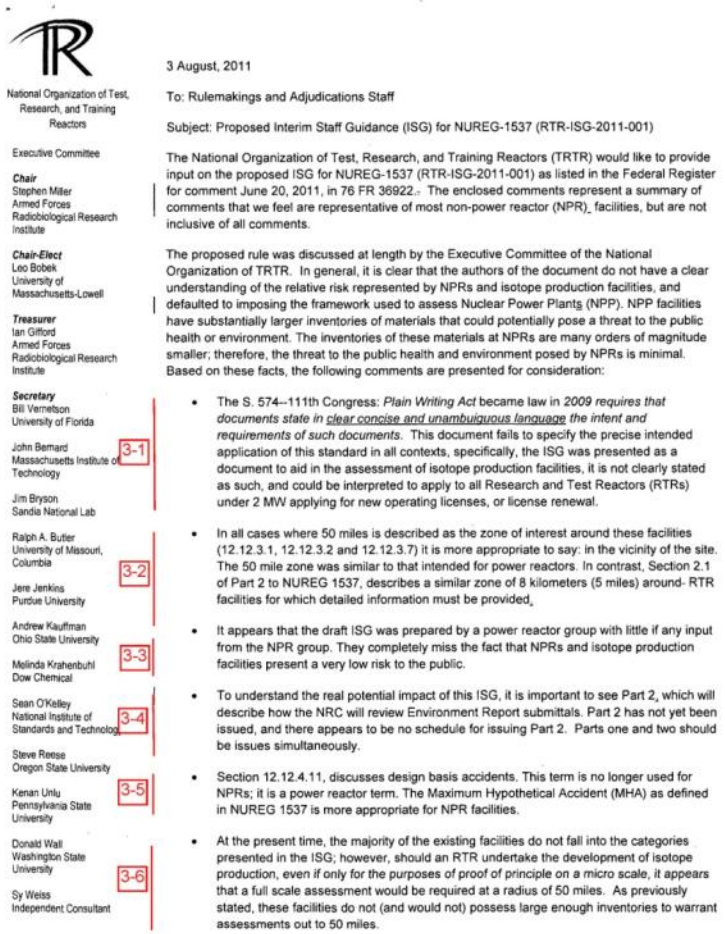
NRC Response to Comment 2-17
As discussed in the response to comment 1-2, the NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The area was revised to a 5-mile radius.

NRC Response to Comment 2-18
Section 12.12.5.3 (now Chapter 19, Section 19.5.3) requests both qualitative and quantitative information. Applicants should provide both qualitative and quantitative information, as appropriate. No change was made to the ISG based on the comment.

NRC Response to Comment 2-19
The environmental report should, consistent with the language in 10 CFR 51.45(c), consider the economic, technical, and other benefits and costs of the proposed action and its alternatives. The ISG provides guidance on the specific information that would be useful for NRC staff to understand and characterize the costs and benefits of the proposed action and alternatives. The NRC requests and requires the assistance of applicants in providing the necessary information in order to facilitate a more efficient environmental review process. No change was made to the ISG based on the comment.

NRC Response to Comment 2-20
It is not possible to determine the extent of environmental impacts *a priori*, without information on the affected environment and proposed construction and operational activities. Additionally, NRC's regulations in 10 CFR 51, Appendix A (5) "Alternatives including the proposed action," state that the EIS should present the environmental impacts of the proposed action and the alternatives in comparative form. No change was made to the ISG based on the comment.

NRC Response to Comment 2-21
This section has been removed from the ISG.



National Organization of Test, Research, and Training Reactors

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Independent Consultant

3 August, 2011

To: Rulemakings and Adjudications Staff

Subject: Proposed Interim Staff Guidance (ISG) for NUREG-1537 (RTR-ISG-2011-001)

The National Organization of Test, Research, and Training Reactors (TRTR) would like to provide input on the proposed ISG for NUREG-1537 (RTR-ISG-2011-001) as listed in the Federal Register for comment June 20, 2011, in 76 FR 36922. The enclosed comments represent a summary of comments that we feel are representative of most non-power reactor (NPR) facilities, but are not inclusive of all comments.

The proposed rule was discussed at length by the Executive Committee of the National Organization of TRTR. In general, it is clear that the authors of the document do not have a clear understanding of the relative risk represented by NPRs and isotope production facilities, and defaulted to imposing the framework used to assess Nuclear Power Plants (NPP). NPP facilities have substantially larger inventories of materials that could potentially pose a threat to the public health or environment. The inventories of these materials at NPRs are many orders of magnitude smaller; therefore, the threat to the public health and environment posed by NPRs is minimal. Based on these facts, the following comments are presented for consideration:

3-1

- The S. 574--111th Congress: *Plain Writing Act* became law in *2009 requires that documents state in clear concise and unambiguous language the intent and requirements of such documents.* This document fails to specify the precise intended application of this standard in all contexts, specifically, the ISG was presented as a document to aid in the assessment of isotope production facilities, it is not clearly stated as such, and could be interpreted to apply to all Research and Test Reactors (RTRs) under 2 MW applying for new operating licenses, or license renewal.

3-2

- In all cases where 50 miles is described as the zone of interest around these facilities (12.12.3.1, 12.12.3.2 and 12.12.3.7) it is more appropriate to say: in the vicinity of the site. The 50 mile zone was similar to that intended for power reactors. In contrast, Section 2.1 of Part 2 to NUREG 1537, describes a similar zone of 8 kilometers (5 miles) around- RTR facilities for which detailed information must be provided.

3-3

- It appears that the draft ISG was prepared by a power reactor group with little if any input from the NPR group. They completely miss the fact that NPRs and isotope production facilities present a very low risk to the public.

3-4

- To understand the real potential impact of this ISG, it is important to see Part 2, which will describe how the NRC will review Environment Report submittals. Part 2 has not yet been issued, and there appears to be no schedule for issuing Part 2. Parts one and two should be issues simultaneously.

3-5

- Section 12.12.4.11, discusses design basis accidents. This term is no longer used for NPRs; it is a power reactor term. The Maximum Hypothetical Accident (MHA) as defined in NUREG 1537 is more appropriate for NPR facilities.

3-6

- At the present time, the majority of the existing facilities do not fall into the categories presented in the ISG; however, should an RTR undertake the development of isotope production, even if only for the purposes of proof of principle on a micro scale, it appears that a full scale assessment would be required at a radius of 50 miles. As previously stated, these facilities do not (and would not) possess large enough inventories to warrant assessments out to 50 miles.

NRC Response to Comment 3-1
The ISG has been revised to specify that it is only applicable to radioisotope production facilities.

NRC Response to Comment 3-2
As discussed in the response to comment 1-2, the NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The area was revised to a 5-mile radius.

NRC Response to Comment 3-3
Potential applicants have described a broad range of technologies and construction methods to construct and operate radioisotope production facilities. The NRC staff wrote the ISG using an approach that covers a range of potential technologies and construction methods. As such, NRC staff considered several guidance documents, including but not limited to NUREG-1555, "Environmental Standard Review Plan (ESRP) for New Site/Plant Applications," NUREG-1555, Supplement 1, "ESRP for Operating License Renewal," and NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs." While writing the ISG, the NRC staff considered that radioisotope production facilities pose less risk than power reactors. No change was made to the ISG as a result of this comment.

NRC Response to Comment 3-4
Part 2 of the ISG describes NRC's internal standard review process. Part 2 is being issued with the ISG.

NRC Response to Comment 3-5
Section 12.12.4.11 (now Chapter 19, Section 19.4.11) was revised to delete the use of "Design Basis Accidents" to be consistent with NUREG-1537.

NRC Response to Comment 3-6
As discussed in the response to comment 1-2, the NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The area was revised to a 5-mile radius.

National Organization of Test, Research, and Training Reactors

3-7 • The- Atomic Energy Act, as amended, allows the Commission to impose the minimum regulation required to protect the public health and safety. These facilities pose little risk and the proposed addition to NUREG-1537 does not reflect the risk and therefore is in contradiction to the Act.

3-8 • Requirements that are out of proportion with the associated risk will only serve to stifle these critical activities and the development of a National isotope production capability.

3-9 • As it pertains to risk assessment, if the MHA for a typical NPR could be approximated by spilling a small glass of water; by comparison, a power reactor DBA would be the failure of the Hoover Dam. Power Reactor standards should never be applied here.

Respectfully

Stephen Miller

Chairman, National Organization of Test, Research and Training Reactors

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Kenan Unlu
Pennsylvania State University

Donald Wall
Washington State University

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Independent Consultant

NRC Response to Comment 3-7
The ISG does not contain or recommend any requirements on the construction and operation of a radioisotope production facility. The information requested by the ISG is related to information that will be used by the NRC staff to assess the potential environmental impacts associated with the construction and operation of a radioisotope production facility. The NRC requests and requires the assistance of applicants in providing the necessary information in order to facilitate a more efficient environmental review process as part of the construction permit and operating license application process. No change was made to the ISG based on the comment.

NRC Response to Comment 3-8
The NRC needs relevant information in order to perform an environmental review of an application for a radioisotope production facility to determine the potential impacts associated with the construction and operation of such a facility. Furthermore, the requested information will enable the NRC to meet its statutory obligations under Section 102(2) of NEPA, and specifically, to fulfill its responsibilities under 10 CFR 51.70(b) to provide evidence that the necessary environmental analyses have been conducted. The NRC requests and requires the assistance of applicants in providing the necessary information in order to facilitate a more efficient environmental review process as part of the construction permit and operating license application process. No change was made to the ISG based on the comment.

NRC Response to Comment 3-9
Potential applicants have described a broad range of technologies and construction methods to construct and operate radioisotope production facilities. The NRC staff wrote the ISG using an approach that covers a range of potential technologies and construction methods. As described in the ISG, applicants should provide data and analyses that are applicable to their proposed construction methods and operational processes. While writing the ISG, the NRC staff considered that radioisotope production facilities potentially pose less risk than power reactors. For example, as discussed in the response to comment 1-2, the NRC staff has reevaluated the potential impacts associated with a radioisotope production facility. The region was revised to a 5-mile radius. Additionally, as discussed in the response to comment 2-16, Section 12.12.4.11 (now Chapter 19, Section 19.4.11) of the ISG was changed to delete the use of Design Basis Accidents to be consistent with NUREG-1537. No change was made to the ISG as a result of this comment.

1. Two-step license application content	Licensing of these type facilities under 10CFR 50 requires both a construction permit and an operating license. While it is possible to submit these at the same time, it is more likely that licensees will use a two step licensing process. In this case, neither NUREG-1537 nor the augmenting guidance provides differentiation between the expected content of the construction application and the operating application. During the meeting between B&W and NRC in 2010 (ML100501028) B&W presented a high level description of the content of a construction application versus an operating application. While this description was brief and very high level it begins to describe the expectation. B&W believes it will be extremely important to provide some level of guidance for both the applicant and the reviewers regarding the content of the construction application and the operating application. Absent guidance there is high potential for misalignment between NRC and the licensee that could result in protracting the licensing process. **Suggestion/Recommendation**: Include a section in each chapter of the ISG (both Parts 1 and 2) that provides a general discussion of the content of a construction application versus an operating application.	**NRC Response** This is addressed in the ISG by augmenting the introduction to NUREG-1537 Part 1 with a section providing the current regulatory basis and general guidance. This new section describes the content required per 10 CFR Part 50 and the level of detail for both the construction permit application and the operating license application.

2. Applicability of 10 CFR Part 70	There are a number of places in the ISG where the requirements of 10CFR70 are either cited or implied to be directly applicable to the production facility. While the concepts of 10CFR70 regarding criticality safety, chemical safety and worker protection may be appropriate for consideration and inclusion, they should be done within the context of 10CFR50 for the production facility. Statements such as "per the requirements of 10 CFR 70" do not seem appropriate. A statement directing the applicant and reviewer to 10CFR70 for insight as to what has previously been found acceptable may be more appropriate and may avoid confusion regarding the true regulatory requirement for the production facility being rooted in 10CFR50. Similarly, the use of the term IROFS (defined in 10CFR70) applied to the production facility seems inappropriate for a facility licensed under 10CFR50. B&W believes introducing the term IROFS to the facility will not only complicate the licensing process but will ultimately be confusing to the facility operations staff who will be working in the context of both a utilization and production facility. Note that there are a number of specific comments listed below related to this topic. **Suggestion/Recommendation:** Review the ISG in its entirety for the use of 10CFR70 and terms such as IROFS to assure they are used as guidance or reference and do not state or imply that they are regulatory requirements for a facility licensed under 10CFR50.	**NRC Response** The ISG provides guidance to the staff reviewers who perform safety reviews of applications to construct or modify and operate radioisotope production facilities. The standard review plan (SRP) is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements. The ISG also makes information available to interested members of the public and the regulated industry and is intended to provide an understanding of the staff review process. The ISG is not a substitute for NRC regulations and compliance is not required. The approaches and methods in the ISG are provided as an acceptable means to meet the NRC regulations. Applicants using methods and solutions different from those described in the ISG should provide a basis for the staff to make the determination that an applicant is able to meet NRC regulations. As stated in the ISG, the NRC staff has determined that the use of Integrated Safety Analysis (ISA) methodologies as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are an acceptable way of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features.

		The introduction of the ISG has been revised to incorporate and emphasize the objectives of providing approaches, methods, and solutions that NRC will find acceptable. Other sections of the ISG, notably Chapter 12, Conduct of Operations; Chapter 13, Accident Analysis; and Chapter 14, Technical Specifications, have been revised to incorporate this position.
3. Small number of citations for Section 4a2	Section 4a2 is one of most important sections regarding AHR PSAR and FSAR development. This section is roughly 13 pages worth of guidance but cites only 3 external references. While the references cited are useful, there are many other documents available to the NRC that will allow them to edit the ISG, assess AHRs, and judge the adequacy of future designs. In particular, B&W encourages the NRC to consider the following documents: 1. *Status Report on the Water Boiler Reactor* by M.E. Bunker (1963) 2. *Experimental Studies on the Kinetic Behavior of Water Boiler Type Reactors* by M.E. Remley, J.W. Flora, D.L. Hetrick, et. al. (1958) 3. *Hazards Summary Report for the Walter Reed Army Medical Center Nuclear Research Reactor* by H.H. Cappel, R.S. Hart, and J.O. Henrie (1959) *4. Reactor Excursion Behavior* by W.E. Nyer, G.O. Bright, and R.J. McWhorter (1964) 5. *Aqueous Homogeneous Type Research Reactors* by W.E. Parkins, R.F. Wilson, W.N. McElroy, et. al. (1958) 6. *Inter-code Comparison Exercises for Criticality Excursion Analysis* by Y. Miyoshi, Y.Yamane, K. Okubo, et. al. (2009) While this list is by no means comprehensive, the	**NRC Response** The comment suggests additional references be included to those already present in Section 4a2.8, and also provides other references for consideration. The following references have been added to Section 4a2.8, *References*, Parts 1 and 2 of the ISG: 1. Barbry, F., "French solution reactor experience and contribution to the Feasibility of the use of LEU Fuelled Homogeneous Aqueous Solution Nuclear Reactors for the Production of Short Lived Fission Product Isotopes," IAEA-CRP/RCM, February, 2010. 2. Botts, J.L., Raridon, R.J., Costanzo, D.A., "Density, Acidity, and Conductivity Measurements of Uranyl Nitrate/Nitric Acid Solutions," ORNL/TM-6491, Oak Ridge National Laboratory, Oak Ridge, TN, October 1978. 3. Bunker, M.E. "Status Report on the Water Boiler Reactor," LA-2854, Los Alamos Scientific Laboratory, Los Alamos, NM, 1963. 4. Jerden, J.L. and Vandegrift, G.F., "Predictive Modeling of Solution Chemistry in an Aqueous Homogenous Reactor Used For Mo-99 Production," 30th International Meeting on Reduced Enrichment for Research and Test Reactors," Washington D.C., October 5-9, 2008. 5. Kimpland, R., Hayes, D., Grove, T., "Stability Analysis of the SUPO Reactor," LA-UR-04318, Los Alamos National Laboratory, Los Alamos, NM, June 2010.

	above documents will be useful references for the NRC in future work with AHRs. If requested, B&W can provide additional references.	6. McLaughlin, T.P., Monahan, S.P., Pruvost, N.L., Frolov, V.V., Ryazanov, B.G., Svirdov, V.I., "A Review of Criticality Accidents," LA-13638, Los Alamos, NM. 7. Mishosi Y. Yamane Y., Okubo K, Reverdy, L., Grivot, P., Konishi, H., Mitake, S., Liem, P.H. "Inter-code Comparison Exercise for Criticality Excursion Analysis [Benchmark Phase I: Pulse Mode Experiments with Uranyl Nitrate Solution in the TRACY and SILENE Facilities]," Nuclear Energy Agency, Organization for Economic Co-operation and Development, 2009. 8. Parkins, W.E., Wilson, R.F., McElroy, W.N., Henry, J.O., Williams, R.O., "Aqueous Homogenous Type Research Reactors," Second United Nations International Conference on the Peaceful Uses of Atomic Energy," 1958. 9. Remley, M.E., Flora, J.W., Hetrick, D.L., Muller, D.R., Gardner, E.L., Wimmer, R.E., Stitt, R.K., Gamble, D.P., "Experimental Studies on the Kinetic Behavior of Water Boiler Type Reactors," Proc. 2nd United Nations Int. Conf. Peaceful Uses of Atomic Energy, Geneva, Switzerland, Vol. 11, United Nations September 1958. 10. Souto, F.J., Kimpland, R.H., Hegar, A.S., "Analysis of the Effects of Radiolytic-Gas Bubbles on the Operation of Solution Reactors for the Production of Medical Isotopes," Nuclear Science Engineering, Vol. 150, 2005. 11. Spiegler, P., Bumpus, C.F., Norman, A., "Production of Void and Pressure By Fission Track Nucleation of Radiolytic Gas Bubbles During Power Bursts in a Solution Reactor," NAA-SR-7086, Atomics International, Canoga Park, CA, 1962. 12. Williams M.M.R., "Calculation of the Void Fraction and Void Coefficient in an Aqueous Homogeneous Reactor," Nuclear Science and Engineering, Vol. 168, 2011.

4. Void “collapse”	The term "collapse" is used throughout the ISG. However, "collapse" does not accurately reflect AHR phenomenology. There are indeed situations in which the voiding characteristics of the reactor change. These events can be initiated from various sources including changes in power and over pressurization. The term "collapse" implies a more catastrophic phenomenon than what has been observed in AHRs. While unusual gas evolution behavior has been observed in some AHRs (namely SHEBA), those observations were the exception and still resulted in bounded oscillatory behavior. Water boilers like SUPO, KEWB, SILENE, TRACY, and the Atomics International L-Series have all operated without observations of void "collapse." The differences in observation can most likely be attributed to the fuel base (Uranyl Floride for SHEBA, Uranyl Nitrate or Uranyl Sulphate for the others). A much more common mechanism for positive reactivity contribution relates to void compressibility. This mechanism is discussed at length in "Transient Criticality in Fissile Solutions--Compressibility Effects" (C.C. Pain, C.R.E. de Oliveira, A.J.H. Goddard, et. al. Nuclear Science and Engineering:138, 78-95 (2001)). **Suggestion/Recommendation**: Emphasize changes in void state instead of individual phenomena. Then, the NRC should have the applicant identify the most likely cause for changes in void state and, perhaps most importantly, quantify the reactivity effect for those changes in void state. Analyses should focus on the AHRs' power evolution as a function of time-dependent voiding changes.	**NRC Response** “Void collapse” has been changed to “changes in void fraction” throughout the ISG.

5. Power density as an instability issue	A major issue cited throughout the ISG is the contribution of power density to AHR instability. This linkage between power density and instability is problematic for several reasons. Firstly, the definition of "stability" must be clarified. Safety and stability are not mutually inclusive. A system may be characterized as stable but respond in an unsafe manner. Conversely, an unstable system can respond in a safe manner. The response is largely dependent on the design of the system. For example: a hypothetical AHR may be stable when $3 of reactivity is inserted. In this sense, stability means a finite insertion results in a finite, bounded response. However, if the vessel wall is too thin, the vessel may rupture resulting in failure. This would be an unsafe response to a theoretically stable system. Conversely, a hypothetical AHR may be unstable when an amount of reactivity is inserted causes unfavorably large variations in power and pressure. However, if the vessel wall is thick enough to withstand the subsequent pressure oscillations, no failure will occur. In this example, although the system was unstable, a safe response occurred due to engineered features. Thus, the NRC must carefully consider the applicants definitions of both stability and safety. Secondly, a linkage between power density and AHR instability has not been proven experimentally or analytically. If power density was the sole source of instabilities it is unlikely that AHRs would have such well behaved transient performance. Transients that caused	**NRC Response** The comment appears to refer to the Draft ISG in general, and does not cite specific sections or statements within the guide. The observed instabilities may have varied causes including recombiner capacity but power density seems to be one of the parameters that is related to stability. The NRC recognizes the need for this matter to be addressed in a manner that may be unique to the facility being licensed. Bullets are added to Section 4a2.5.3, *Operating Limits*, which read as follows: [Part 1, The applicant should present the following information on reactor operating limits:] • Stability should be defined with criteria for acceptable performance. The applicant should describe protection solutions to maintain power oscillations within operational or safety limits and may include operational limits on parameters such as power density. [Part 2, The acceptance criteria for the information on operating limits include the following:] • Analysis should show that power oscillations will not exceed the operational or safety limits and may include operational limits on parameters such as power density.

	high powers (order of MW) would have likely resulted in instabilities (as the power density would have been on the order of MW/l). In fact, unusual time-dependent behavior observed in AHRs at higher steady-state powers (order of kW/l) can mostly likely be attributed to the design of the system, not physics inherent in AHRs. For example, at SUPO's power level was chosen to be 25 kW. This limit was chosen based off of three observations (Bunker, 1963): 1. Large pressure fluctuations. The source of the pressure fluctuations was linked to recombiner performance. 2. "Transients [that are] either too large or too rapid to be completely cancelled by operation of the automatic control system." Linked to either or both recombiner performance and "sporadic local boiling ... in the spaces between cooling-coils loops". 3. Melting of the reflector's boron-loaded paraffin. From these observations, we can say while power density is a good indicator of system behavior, there is no clear indication that higher power densities resulted in unstable behavior in SUPO. However, we can say there is a direct link between certain design features of SUPO and undesirable system behavior. From these observations, it is not hard to project that a system with a larger recombiner, optimized cooling coil geometry and better reflector design could operate in a safe and stable manner at higher power densities.	

	Specific analytical calculations have also been performed to investigate AHR instabilities. While the studies are proprietary, results have indicated that it is not appropriate to generically associate power density with instabilities. It is one thing to observe instability onset at certain power levels, it is another thing entirely to be able to identify the parameter or phenomenological source of the instability. It should be noted that analytical results have indicated that other system parameters are worthy of more consideration than just power density. **Suggestion/Recommendation**: The NRC should have the applicant define "stability" for the system they are trying to license. As other design features and parameters will influence system behavior, the NRC should assess the system's "stability" and "safety" without specifically focusing on power density.	
6. No boiling	There may not be technical justification to disallow fuel solution phase change. In fact, boiling was identified as a stabilizing phenomenon that enhanced the safety characteristics of both SUPO and KEWB. For example, in SUPO "[d]uring the boiling mode of operation, the power is almost continuously varying, but the magnitude of the fluctuations is only 10-15% (Bunker, 1963)." From KEWB experimentation it was found "as the core temperature approaches the boiling point of the solution, the [temperature] coefficient increases rapidly and reaches a value of -0.032 %AK/°C" from -0.027 %AK/°C. KEWB experimenters also noted that boiling served as an "additional shutdown mechanism in the homogeneous solution reactor (Remley, 1958).	**NRC Response** If boiling is not precluded by design or operational limits, the consequences in terms of primary barrier integrity must be analyzed as part of the safety analysis. Also, there exists the possibility that boiling will result in enhanced transport of radioactive material from the core region to other locations in the plant (e.g. by means of entrainment). Section 4a2.6, *Thermal-Hydraulic Design*, of Part 1 of the ISG has been revised by adding the following bullet: • Boiling has been identified as a limiting phenomenon that could compromise primary barrier integrity. The applicant should identify operational limits and/or engineered safety features to preclude the onset of bulk boiling of the solution. One key concern is the influence of bulk boiling on the transport of radioactive

	Additional boiling experimentation was undertaken by the French with CRAC and SILENE. In the first documented cited in Section 4a2 of the ISG, an appendix by Barbry shows three possible scenarios for long term AHR transient response. The final scenario includes phase change. For times less than 100 minutes, the boiling behavior of the AHR is well characterized and categorically stable. Barbry shows that boiling must be sustained for long periods of time before concentration changes begin to alter reactivity. Proprietary analytical work has yielded results in line with the experimental results cited above. However, even without quantitative analyses, enough historical evidence exists to conclude that boiling is a phenomenon that can occur safely in an AHR. The bigger concern with boiling relates to the reliable operation of the reactor. Sustained phase change is likely to make operations more complex and less reliable. Thus, an AHR will most likely operate near but below the saturation temperature during steady state operations. There may be some operational transients that result in boiling but these are unlikely to jeopardize reactor stability or safety. **Suggestion/Recommendation**: The applicant must present analyses that demonstrate reactor stability and safety within the intended operational regime as well as likely operational transients. If this regime encompasses boiling, the influence of boiling must also be quantified.	material through the plant systems. In instances where the applicant does not preclude solution boiling during transient or accident conditions, the effect of bulk boiling should be analyzed.

Ch 3, p 4, IROFS	"features that enhance safety by reducing challenges to items relied on for safety (IROFS)" Refer to major comment regarding referencing to 10CFR70 and IROFS.	**NRC Response** NRC staff have determined that the designation of items relied on for safety and the provision of design features that reduce challenges to IROFS are parts of an acceptable way of demonstrating adequate safety for the radioisotope production facility. Applicants may propose alternate safety features and alternate methods of reducing challenges to the safety features. No change was made to the ISG as a result of this comment.
Ch 6b, p 35, IROFS	"Certain operations with fuel or un-irradiated SNM will be subject to the requirements of 10CFR70... defined as items relied on for safety (IROFS)" While fresh fuel at a reactor facility licensed under 10CFR50 is generally done by incorporating 10CFR70 into the license reference, B&W is not aware of any reactor facilities that have adopted the Subpart H requirements of 10CFR70 regarding IROFS. This would appear to set an undesirable precedent for this type facility. See also major comment regarding 10CFR70.	**NRC Response** NRC agrees that the regulatory requirements of 10 CFR Part 70, Subpart H, do not apply to the radioisotope production facility licensed under 10 CFR Part 50. Because certain processes and hazards in an isotope production facility are similar to those at fuel cycle facilities, staff believes that certain 10 CFR Part 70 acceptance criteria and methodologies, including the use of ISA, would be appropriate for a medical isotopes production facility licensing review. An ISA, performed adequately, would systematically identify potential accident sequences, designate IROFS to prevent or mitigate them, and describe management measures to be applied to assure IROFS' reliability and availability. The ISG provides guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements. Applicants suggesting methods and solutions different from those described in the ISG should provide a basis for the staff to make the determination needed to issue a license.

Ch 6b, p 36, 10CFR70	"the regulatory limits pertaining to chemical exposure prescribed in 10CFR70.61 will also apply to the radioisotope production facility" See major comment regarding 10CFR70.	**NRC Response** NRC agrees that the regulatory requirements of 10 CFR Part 70, Subpart H, do not apply to the radioisotope production facility licensed under 10 CFR Part 50, and this sentence has been revised accordingly. Because certain processes and hazards in an isotope production facility are similar to those at fuel cycle facilities, staff believes that certain 10 CFR Part 70 acceptance criteria and methodologies, including those pertaining to chemical safety, would be appropriate for a medical isotopes production facility licensing review. The ISG provides guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements.
Ch 4a2.2.1, p 8, All information should be current	What does the NRC mean by "current?" Very little "current" data exists on AHR behavior and operations. However, a significant amount of relevant historical data exists. If "current" refers to the design being submitted, this comment may be ignored.	**NRC Response** The statement “All information should be current” means that information used to justify the safe operation of a licensed facility should be considered valid and accurate at the time an application is submitted. Since much of the data on AHR performance is historic, the applicant should determine its validity for present application.
Ch 4a2.2.1, p 9, Critical vs sub-critical fuels	There will be a region of operation in which subcritical, critical and supercritical fuel will behave essentially identically. Consider radiolytic gas onset as another way to delineate fuel classification/description.	**NRC Response** The fifth bullet in Part 1 of Section 4a2.2.1, *Reactor Fuel*, has been modified in the ISG to reflect the comment. The second sentence has been changed to read as follows: “Separate descriptions should be given for conditions with and without significant power and gas generation (i.e., the gas evolved during irradiation should be included in the description of the fuel.)”

Ch 4a2.2.1, p 9, Power density and distribution	In AHRs, the liquid fuel form is able to deform and can be highly mobile depending on the reactor's design. In these situations the power distribution has less safety significance than heterogeneous reactors or even stagnant AHRs.	**NRC Response** No change was made to the ISG based on the comment. Power density is important in determining the level of mixing and the reactivity state of the reactor.
Ch 4a2.2.1, p 9, Void formation and collapse	See major comment above.	**NRC Response** See response to major comment 4.
Ch 4a2.2.[1], p 10, Prevent boiling … cause reactivity transient	Boiling of the coolant may not need to be "prevented." Analyses may indicate that boiling of the coolant is useful for steady state heat removal or coolant boiling may improve safety under certain transient conditions. The formation of radiolytic gas bubbles during a reactivity transient is a desirable safety feature. Radiolytic gas formation quickly "turns around" significant power transients (assuming the gas is saturated; if not saturated, gas onset will be delayed until the saturation limit is reached). This behavior is one of the main reasons AHRs were characterized as being safe (Parkins, 1958). The concern should be quantifying the magnitude of likely transients that are deemed operationally significant. The applicant must determine which individual phenomena are the most safety significant based upon the design of the reactor.	**NRC Response** The fourth sentence of the third bullet in Part 1 of Section 4a2.2.2, *Control Rods*, in the ISG has been changed from “How does the thermal-hydraulic design prevent boiling of the coolant and/or formation of radiolytic gas bubbles that may cause reactivity transients?” to read, “How does the thermal-hydraulic design keep the reactor within the specified operational and safety limits?”

Ch 4a2.3, p 12, Prevent loss of cooling	Analyses have indicated that loss of coolant may actually shutdown the reactor or cause a significant decrease in power. This was shown experimentally in SUPO (Bunker, 1963) and the CR&D water boiler (J.W. Flora, J.W. Shortfall, E.J. Strain, "Operating Characteristics of the Water Boiler," LRL-151, (1954)). If this is indeed the case, the loss of coolant could serve as a safety feature not a safety concern. Thus, the coolant loss must be assessed objectively, not with the initial goal of prevention. Maintaining cooling capacity is still an important part of the design process to ensure reactor reliability.	**NRC Response** While it may be true that loss of coolant may not be safety significant for some scenarios in specific designs, that may not be true in general. In the last sentence of the fourth bullet in Section 4a2.3, *Reactor Vessel and Pool,* the word “prevent” is replaced with “mitigate” in Part 1 of the ISG.
Ch 4a2.5.1, p 14, Limiting core configuration	While power density is a very useful indicator of reactor conditions, it may not be the most suitable way to define the limiting core configuration. For instance, the configuration with the most available excess reactivity is the one that would result in the largest reactor transient. Thus, the applicant should determine the limiting core configuration which may not necessarily be dictated by power density but other operating parameters.	**NRC Response** To address this comment, the second sentence of Part 1, Section 4a2.5.1, *Normal Operating Conditions*, in the ISG has been changed from: “The limiting core configuration for a reactor is the core that would yield the highest power density using the fuel specified for the reactor.” To read: ”The limiting core configurations for a reactor are the core conditions that would yield the highest power density, the highest excess reactivity, and other possible limiting parameters that are of safety interest using the fuel specified for the reactor.”
Ch 4a2.5.1, p 14, Effects of radiolysis	KEWB was developed to experimentally answer some of the questions outlined. One of the aforementioned reports offers an excellent and succinct summary of the KEWB program (Bunker, 1963).	**NRC Response** No change was made to the ISG based on the comment. The comments on Kinetics Experiment Water Boiler (KEWB) reactor are irrelevant since the applicant needs to provide a discussion of their own design.

Ch 4a2.5.1, p 14, Safety considerations	Power density and temperature are both important reactor responses on which to judge reactor performance. However, for atmospheric AHRs there is a clearly defined maximum temperature (governed by the solution's saturation temperature). This means temperature is self limiting and may not be a safety significant parameter during some transients. Other parameters must also be assessed; for example: pressure, hydrogen concentrations, etc. Thus, the safety considerations for different core configurations must be assessed objectively, not with the initial focus on power density and fuel temperatures.	**NRC Response** No change was made to the ISG based on the comment.
Ch 4a2.5.1, p 14, Power stability	Parameters that will influence reactor stability are not limited to surface frothing and voiding changes. Proprietary analyses have shown that surface effects like frothing and sloshing have less influence on stability than phenomena occurring in high worth regions like heat transfer and voiding.	**NRC Response** To address this comment, the last sentence of Part 1, Section 4a2.5.1, *Normal Operating Conditions*, in the ISG has been expanded to read: "This includes the power stability effects of uneven, stochastic surface frothing, changes in void fraction, and other phenomena such as heat transfer that may affect stability."
Ch 4a2.5.2, p 15, Reactivity coefficients	Quantifying the available amount of excess reactivity is equally important to showing reactivity coefficients are sufficiently negative.	**NRC Response** The staff agrees with the comment but finds that no change is needed.
Ch 4a2.5.2, p 15, Peak-to-average values	In a homogenous system that is deformable and mobile, peak-to-average fluxes are significantly less important that other thermal hydraulic properties. In a well mixed AHR, the temperature profile will not be proportional to the flux profile. Experiments from the TRACY showed that even under large reactivity insertions, the axial temperature profile was relatively flat (K. Nakajima, Y. Yamane, K. Ogawa, et. al. "TRACY Transient Experiment Databook 1) Pulse Withdrawal Experiment" JAERI-Data/Code 2002-005 (2002)). Recent computational analyses have shown a similar decoupling of fission and	**NRC Response** Peak to average values are important for void generation and power profiles that influence reactivity in the core. For additional clarification, the following sentence was inserted in the ISG after the third sentence of the third bullet in Part 1, Section 4a2.5.2, *Reactor Core Physics Parameters*: "Consideration should also be given to hot-spots as dictated by peak-to-average values for power density, temperature distribution, and void profile."

	temperature distributions was likely to have existed in the SUPO reactor (A.G. Buchan, C.C. Pain, M.D. Eaton, "Dynamics and heat transfer characteristics of the water boiler reactor - SUPO", International Conference in Nuclear Criticality (ICNC) (2011)).	
Ch 4a2.5.2, p 16, Limiting power density	See major comment above.	**NRC Response** No change was made to the ISG based on the comment.
Ch 4a2.6, p 17, Fuel solution boiling	See major comment above.	**NRC Response** The words “boiling does not occur” are changed to read “temperature and pressure limits are not exceeded” in the first sentence of fifth bullet of the ISG, Part 1, Section 4a2.6, *Thermal-Hydraulic Design.*
Ch 4a2.7, p 18, Malfunction or failure	This phenomenon was observed in SUPO during normal operations as cited above. KEWB went a long way in detailing this type of behavior. Researchers also quantified the reactivity effect of pressurization in the CR&D water boiler; in the CR&D water boiler the effect was small (J.W. Flora, J.W. Shortfall, E.J. Strain, "Operating Characteristics of the Water Boiler," LRL-151, (1954)). Suggest focusing on quantifying the positive reactivity feedback and its influence on time-dependent behavior which would capture instability issues and other operational issues as well.	**NRC Response** No change was made to the ISG based on the comment.

Ch 1.5, p 15, For AHR applicants	The applicant is likely to cite other facilities not included on the list. Some other facilities including: the KEWB reactors in Canoga Park, Ca; the L-54 at Walter Reed, SILENE in France; etc. Also, HRE is radically different from the other listed AHRs. HYPO, SUPO, and TRACY may all be characterized as "water boilers" whereas HRE cannot.	**NRC Response** The intent of the list of facilities in the ISG was to add AHR examples to the NUREG-1537 list of non-AHR prototype and developmental test facilities that might be used for comparison purposes. Other facilities more relevant to an application might certainly be identified and used for the purpose stated.
Ch 4a2.3, p 31, References 2 and 3	The above technical rationale appears to place too much emphasis on HRE observations. In "Two Years of HRE-2 Operation," P.N. Haubenreich details some of the conclusions from HRE operations (article published in Nuclear Science and Engineering, Volume 8, pages 467-479, 1960). Haubenreich notes "the HRE-2 core tank suffered damage by corrosion and local melting because of a combination of factors involving the chemical stability of the fuel solution and the hydrodynamics of the core tank. It is believed that these difficulties can be avoided, although, as emphasized by HRE-2 experience, careful design of the core is necessary." Reading through Haubenreich's article it is apparent that HRE-2 and water boilers (SUPO, KEWB, TRACY, SILENE, etc) are very different types of AHRs. Some of the most significant differences include: higher pressures, higher power, higher temperatures, less favorable core thermodynamics, and differing core cooling philosophies. Thus, drawing conclusions about water boilers from HRE-2 must be a careful and measured exercise. The lower pressure, lower power, and more favorable thermodynamics of water boilers is	**NRC Response** No change was made to the ISG based on the comment. No conclusions have been drawn. It is up to the applicant to ensure that their design does not have the problems identified in the cited references.

	again, a large reason they were characterized as being so safe. Specifically concerning corrosion in a water boiler (SUPO), according to Bunker *(Status Report of the Water Boiler Reactor,* 1963), corrosion contributed "a reduction in wall thickness of only -0.0001 in. On the other hand, if most of the corrosion has occurred in a localized area, the sphere could conceivably start leaking at any time." Bunker's observation is significant for two reasons. Firstly, bulk corrosion is unlikely to be a significant concern for vessel integrity. Secondly, localized corrosion is a more significant concern. However, a well mixed, chemically stable system is unlikely to experience localized corrosion as the mechanism for localized corrosion is fissioning of solid uranium against the vessel wall.	
Ch 4a2.5.1, p 35, Reactor kinetics	Can the NRC be more explicit about the meaning of "dynamic reactivity parameters of the instrumentation and control systems?"	**NRC Response** The first sentence of bullet five of ISG, Part 2, Section 4a2.5.1, *Normal Operating Conditions,* replaces the words, "parameters of" with "changes cause by" such that it reads: "The reactor kinetic parameters and behavior should be shown, along with the dynamic reactivity changes caused by the instrumentation and control systems."
Ch 4a2.5.1, p 35, Control system	What does the NRC mean by "an uncontrolled addition of reactivity?" Also, the magnitude of available the reactivity is probably the most important consideration when studying the loss of fuel barrier integrity from a nuclear transient.	**NRC Response** No change was made to the ISG based on the comment. Uncontrolled changes in reactivity are design specific. For clarification the following example has been added to bullet five of the ISG, Part 2, Section 4a2.5.1, *Normal Operating Conditions,* stating: (E.g., the reactivity control system shall be designed with appropriate limits on the rate and amount of reactivity increase that may occur during a reactivity insertion accident so as to prevent compromise of the primary barrier.)

Ch 4a2.5.1, p 35, Core configuration	The core of an AHR is more dynamic that the core of a heterogeneous reactor. This is especially true of the core's "configuration." In an AHR, the uranium concentration, pH, temperature, power density, geometry (e.g., solution level and surface shape) are all almost constantly changing. Depending on the number of variables considered necessary to define the core's configuration, this dynamic behavior could result in an almost infinite number of core configurations. However, the phenomena that cause the changes in the core's configuration are well understood, measureable, and quantifiable. Instead of defining a single core configuration, for an AHR, it might be more appropriate to define operating ranges for the reactor (e.g. temperature between 60-1000C, pH between 0.5-1.5, etc). Those ranges could then be used to define the reactor's core configuration. Other specific actions could also be used to define a new "core configuration." For example, the addition of new fuel could mark a new configuration.	**NRC Response** The staff agrees with the comment, but no changes are needed to the ISG.
Ch 4a2.5.1, p 36, Control rods	What does the NRC mean by "uncontrolled reactor transients?"	**NRC Response** The fourth bullet of the *Evaluation Findings* of ISG, Part 2, Section 4a2.5.1, *Normal Operating Conditions,* eliminates the word, “uncontrolled” and concludes the sentence with the qualifier “… that cause the reactor to exceed operating limits,” such that it reads: “The analyses address the steady power operation and kinetic behavior of the reactor and show that the dynamic response of the control rods and instrumentation is designed to prevent reactor transients that cause the reactor to exceed operating limits.”

Ch 4a2.5.3, p38, Xenon and samarium	Xenon will mostly come out of solution as it is a gas.	**NRC Response** No change was made to the ISG based on the comment. Gas solubility is part of the analysis required to show that it is not a problem. However, for clarity, the words "xenon and samarium override" in the first bullet of the ISG, Part 2, Section 4a2.5.3, Operating Limits, have been replaced and expanded to read "-fission product poison override (e.g. by samarium and/or dissolved xenon.)"
Ch 4a2.6, p 40, Power shape	The statement above is likely derived from HRE-2 operating experience. The NRC should consider that HRE-2 is a significantly different system than a well-mixed, low power, atmospheric pressure AHRs (e.g., water boilers). HRE-2 operated at temperatures between 200-300ºC. Water boilers operated at atmospheric pressure meaning the saturation temperature was around 100ºC. Thus, a hot spot in an atmospheric AHR would result in boiling and a maximum temperature equal to the saturation temperature. Also, boiling would result in the rapid formation of a large void which would substantially decrease the reactivity of the system (demonstrated experimentally in KEWB and SUPO reactors). HRE-2 operated between 1000-2000 psig. In this high pressure environment, radiolytic gas would remain in solution. In water boilers, radiolytic gas is produced once the solution's saturation limit is reached. Analytical work has indicated that the movement of radiolytic gas in the solution causes the fuel to be very well mixed. It can be hypothesized that the absence of radiolytic gas formation and movement in HRE-2 is partially responsible for unfavorable thermodynamic behavior. The likelihood of hot spots is large dependent on	**NRC Response** It is up to the applicant to show that their design does not have a problem. For additional clarity, the ISG replaces the last half of the first sentence of the second paragraph of Part 2, Section 4a2.6, *Thermal-Hydraulic Design*: "…however, the power shape may still cause some hot spots, which may lead to instability and ultimately fuel and fission product precipitation." The replacement wording is: "…however, the power shape may still cause some hot spots, which may have adverse safety impacts in terms of instability and/or fuel and fission product precipitation, a potential that the applicant's safety analysis should address."

	the design presented to the NRC. However, for the reasons cited above, water boiler type systems are extremely unlikely to exhibit "hot spots." Also, how "hot spots" "lead to instabilities" is unclear and would require additional clarification by the NRC.	
Ch 4a2.6, p 41, Departure-from-nucleate-boiling	The departure-from-nucleate-boiling ratio (DNBR) is not an applicable measurement for safety within an AHR. DNBR is appropriate for solid fueled reactors because the departure from nucleate boiling would result in a large increase in fuel temperature. However, in AHRs, the heat source is in the bulk solution (ie where the coolant is for solid fuels). The corresponding temperature increase in the solution would be limited to the saturation temperature of the solution (for atmospheric AHRs, this would be around 100°C) and additional heat transfer pathways would still exist (e.g., conduction through the vessel wall and mass transfer into the plenum through radiolytic gas formation and boiling).	**NRC Response** No change was made to the ISG based on the comment because the parent paragraph (the first bullet of Part 2, Section 4a2.6, *Thermal-Hydraulic Design)* prefaces the statement with: "These criteria could include the following:" However, for clarification, in the ISG the second sub-bullet is expanded to read: "The departure-from-nucleate-boiling ratio should be no less than 2.0 along any coolant coil. This could apply to the inner surfaces of cooling coils that might be internal to an AHR."
Ch 4a2.6, p 41, Fuel barrier	Per definitions on page 18, gas treatment system would be fission product barrier and submerged portion of cooling coils would be part of the fuel barrier. Both are part of the primary system boundary.	**NRC Response** As suggested by the comment, the ISG replaces the two references to "fuel barrier" with the term "primary system boundary" in the sixth bullet of Part 2, Section 4a2.6, *Thermal-Hydraulic Design*.
Ch 4a2.6, p 42, Pressure transient	Safety significant pressure transients can originate elsewhere in the gas management system.	**NRC Response** The staff agrees and has changed the ISG accordingly. The last two words of the first paragraph of Part 2, Section 4a2.7, *Gas Management System*, have been changed from "reactor core" to "reactor system."
Ch 4a2.6, p 43, Spike	In criticality accidents and a steady state AHRs, void formation will occur on different time scales. For criticality accidents, the solution's initial state is sub-critical and not saturated (no radiolytic gas is present). A certain amount of energy (a threshold value dictated by the solution's	**NRC Response** The staff agrees with the comment but sees no need for change to the ISG.

	properties) must be deposited in the system before radiolytic gas begins to come out of solution. Once this energy threshold has been reached, radiolytic gas no longer remains dissolve and voids being to form which has a rapid effect on "turning over" the power transient. In an AHR operating at steady state radiolytic gas will already be present. Thus, changes in reactivity will more-or-less instantly alter the voiding rate of the system. The result is that steady state AHRs will response quicker to reactivity insertions than an AHR in which the gas onset energy threshold has not been reached. **"The actual first spike yield and total fission yield during accidents and planned critical excursion can vary widely, so fairly conservative assumptions should be made concerning the assumed dynamics during a prompt critical excursion."** Experimental and analytical work has been effective in quantifying the magnitude of the first fission spikes and the total energy release during reactivity insertions for solution systems (Miyoshi, 2009). The magnitude of the first spike and total energy released are largely dependent on the magnitude and rate of the reactivity insertion. Even if large amounts of reactivity are present, a slow the rate of insertion yields relatively unremarkable transient evolution. Thus, limiting the speed of control elements should result in an AHR that can operate conservatively.	
Ch 4b.1, p 46 last 2 bullets	"implementation of... safety features of the production facility ...per the requirements of 10CFR70.... criticality safety program... chemical	**NRC Response** NRC agrees that the regulatory requirements of 10 CFR Part 70, Subpart H, do not apply to the radioisotope

	safety program" Refer to major comment regarding 10CFR70	production facility licensed under 10 CFR Part 50. This section has been revised to strike the requirements of 10 CFR Part 70, and these 2 bullets have been revised accordingly as follows: • The application contains a general description of provisions for criticality control including adherence to the double-contingency principle The application contains a description of adequate protections against chemical risks produced from licensed material, facility conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.
Ch 5a2.2, p 55, Liquid fuel solution	It is the applicant's responsibility to characterize the corrosive nature of the fuel solution. Characterizing the fuel as "highly corrosive" without defining "highly corrosive" or knowing the fuel base is presumptuous of the NRC.	**NRC Response** The first sentence of the fourth paragraph of Part 2, Section 5a2.2, *Primary Cooling System,* of the ISG has been changed from: “The liquid fuel solution in an AHR is expected to be highly corrosive and contain mobile radioactive fission product species.” to read as follows: “The liquid fuel solution in an AHR may be highly corrosive and will contain mobile radioactive fission product species.”
Ch 6b.3, p 75-76, References	References to 10CFR70and the term IROFS Refer to major comment regarding 10CFR70. First bullet: The applicant describes a facility criticality accident alarm system (CAAS) that meets the requirements of 10 CFR 70.24, “Criticality Accident Requirements.”	**NRC Response** NRC agrees that the regulatory requirements of 10 CFR Part 70, Subpart H, do not apply to the radioisotope production facility licensed under 10 CFR Part 50. The six bullets have been revised to read as follows: First bullet: The application describes a facility criticality accident alarm system (CAAS) that is capable of detecting a criticality that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an

		unshielded distance of 2 meters from the reacting material within one minute. Coverage of all areas is provided by two detectors. Additional bullet: The application describes a CAAS that uses gamma- or neutron-sensitive radiation detectors that will energize clearly audible alarm signals if accidental criticality occurs.
	EP bullet: The applicant shall institute emergency procedures per 10 CFR 70.24(a)(3) to include the following management provisions:	EP bullet: The application includes a commitment to maintain emergency procedures for each area in which this licensed special nuclear material is handled, used, or stored to ensure that all personnel withdraw to an area of safety upon the sounding of the alarm. These procedures must include the conduct of drills to familiarize personnel with the evacuation plan, and designation of responsible individuals for determining the cause of the alarm, and placement of radiation survey instruments in accessible locations for use in such an emergency. The application includes a commitment to retain a copy of current procedures for each area as a record for as long as licensed special nuclear material is handled, used, or stored in the area. The application includes a commitment to retain any superseded portion of the procedures for three years after the portion is superseded.
	IROFS bullet: The applicant meets the acceptance criteria in Section 13b of the standard review plan, as they relate to the identification, consequences, and likelihood of NCS accident sequences, as well as descriptions of IROFS for NCS accident sequences.	IROFS bullet: no change.
	Baseline Design Criteria bullet: The applicant describes how it performed the safety analyses for the new process and how the process satisfies the principles of the baseline design	Baseline Design Criteria bullet: The applicant describes how it performed the safety analyses for the new process and how the process provides for criticality control including adherence to the double contingency principle.

	criteria (BDC)) (refer to 10 CFR 70.64(a) & (b)). The applicant also explains how it applies defense in depth to higher risk accident sequences. Acceptable defense-in-depth principles for the criticality safety design are those that support a hierarchy of controls: prevention, mitigation, and operator intervention, in order of preference. 50 and 70 bullet: The applicant describes and commits to implementing and maintaining an NCS program to meet the regulatory requirements of 10 CFR Part 50 and 10 CFR Part 70. SER reasonable assurance bullet (p. 86): The applicant will develop, implement, and maintain a criticality accident alarm system in accordance with both the requirements in 10 CFR 70.24 and the facility emergency management program. The applicant will have in place an NCS program.	The applicant also explains how it applies defense in depth to higher risk accident sequences. Acceptable defense-in-depth principles for the criticality safety design are those that support a hierarchy of controls: prevention, mitigation, and operator intervention, in order of preference. This bullet has been deleted. SER reasonable assurance bullet (p. 86): The applicant will develop, implement, and maintain a criticality accident alarm system that meets the acceptance criteria in Section 6b.3 of this ISG. The applicant will have in place an NCS program that meets the acceptance criteria in Section 12.1.6 of this ISG.

1. ANSI standards	In the draft ISG, the Staff did not modify the ANSI/ANS standards referenced in NUREG-1537 Chapters 1 through 6. A number of referenced ANSI/ANS standards in NUREG-1537 have been withdrawn; however, they are still included within the NUREG and are not addressed through the ISG. The Staff should clarify the continued applicability of ANSI/ANS standards that have been withdrawn.	**NRC Response** Where American National Standards Institute/American Nuclear Society (ANSI/ANS) standards have been updated since publication of NUREG-1537, the ISG lists the newer revision in the standard in the bibliography or reference section of each chapter. While many standards listed in the NUREG have been withdrawn or are no longer maintained, they may still provide useful guidance.
2. Electronic submittals	NUREG-1537 states that it is the vehicle to utilize for all aspects of non-power reactor licensing. The implication is that the only documents that need to be submitted are included in NUREG-1537. Additionally, many of the identified plans and program descriptions can be included as Appendices in the application. Since NUREG-1537 was last issued, the NRC has provided guidance for electronic submittal of documents. The electronic submittal guidance used for new reactor license application submittals established a structure and framework for electronic submittals. The electronic submittal guidance suggests that if there are changes to certain parts of an application, the entire part of the application must be resubmitted. The draft ISG does not address electronic submittal guidance. Further, as the electronic submittal guidance is currently worded, it would require a complete resubmittal of all the documents should only one portion of the application requires revision.	**NRC Response** The section titled, "Introduction," of Part I of the ISG has been modified to include information on electronic submissions. "Guidance for Electronic Submissions to the NRC," Revision 6.1, dated May 27, 2011, provides guidance for submitting information electronically to the NRC (http://www.nrc.gov/site-help/e-submittals/guide-electronic-sub.pdf). Section 8, "New Reactor-Related Application Submittals," provides guidance for electronically submitting license applications for new reactors. A similar approach may be used for electronically submitting applications for new non-power reactors and new production facilities licensed under 10 CFR Part 50. Questions regarding electronic submissions should be addressed to the contact listed in 10 CFR 50.4. In response to the part of the comment regarding document revisions, an electronic application can be divided into separate parts so that a revision to one part doesn't require resubmission of the entire application. Section 8.3.6, "Document Updates," of the electronic submission guidance states a revision to any part of a document requires resubmission of the entire document. Section 8.2, "Folder Specifications," states that portions of a license application can be considered separate documents.

3. Proprietary Information	Additionally, the business nature of radioisotope production will require that a large number of items normally found in the license application will be requested to be withheld from public disclosure in accordance with 10 CFR 2.390. A modification to the license application structure to include a "Proprietary" part of the license application will be needed to locate the volume of information that will be considered proprietary. The Staff should review the structure of NUREG-1 537 within the context of the draft ISG to accommodate electronic submittals and revisions to portions of the application in order to take advantage of the electronic submittal process. This could be performed by creating a license application structure similar to that used by new reactor licensing efforts.	**NRC Response** While it is anticipated that the application will be made publically available, the staff acknowledges that there will also be significant information that will qualify to be withheld from public disclosure under 10 CFR 2.390 (commercial, technical, personal, security, etc.). All documents required as part of the application pursuant to 10 CFR 50.33 and 50.34 should be submitted in a publically available form. If sensitive information is required to fully meet the regulation or respond to the staff's needs, a non-public version of that document should be docketed or a non-public docketed special report should be referenced. A special section addressing the structure of the application has been added to the ISG that expands on this topic.
4. AHR terminology	The direction provided to applicants for the licensing of a production facility that employs the reaction vessel subcritical neutron multiplier method for producing radioisotopes is to follow the guidance in this ISG for AHRs, as appropriate. The AHR guidance is specific and thorough, but the terminology is not adequate to fully describe a subcritical neutron multiplier facility. For example, the AHR guidance requests information on control rods but not all non-reactor-based technologies will use control rods. They may employ methods to control the fission process that are unique to their technology, or may need no active control at all. Applicants should be able to use the most appropriate terminology to best describe the analogous process to the AHR terminology in a license application, even if the terminology and application structure are not identical to that in NUREG-1537 or the Interim Staff Guidance. Additionally, applicants may include information	**NRC Response** The NRC staff encourages early and frequent communications to address issues such as those cited. The NRC staff agrees with this comment and has addressed it in the following words which have been added to the ISG Introduction to Parts 1 and 2 in the section titled *Characterization of Potential Applications and Licensing Requirements*: "This ISG was prepared for evolving technologies that were not fully developed and demonstrated at the time of publication. This may especially be true for the accelerator-driven solution tank and to some degree new-generation AHRs. Where terminology in this ISG does not properly characterize new technology or its application, applicants should introduce appropriate substitute terminology and provide a definition."

	in an application so as to completely describe their facility even though this material may not be called for in the ISG, based on unique systems, structures and components related to a specific technology. The Staff should provide clarification to allow applicants to modify the structure and content of the Safety Analysis Report to provide details of the important systems, structures, components and processes and still follow the general guidance and framework of NUREG-1537 for a specific technology.	

Small source term and risk	Research reactors are utilization facilities designed specifically for scientific research and education. As such, research reactors do not produce electricity and are designated as non-power. The thermal power level of research reactors is generally hundreds to thousands of times lower than nuclear power production facilities. As a result, research reactors produce significantly lower levels of radiation and have very limited thermal hydraulic energy, resulting in minimal to no release and dispersal of radioactivity in the event of an accident. Their smaller size and simpler designs provide minimal risk to public health and environment. While often stated, it serves well to repeat and note the Atomic Energy Act Of 1954, as amended, directs the Commission to impose the minimum regulation required to protect the public health and safety and permit the conduct of widespread and diverse research and development.	**NRC Response** Like NUREG-1537, the ISG is sufficiently general to address facilities over the full range of power levels of currently licensed non-power reactors which is well below the power level of nuclear power reactors. The ISG is also sufficiently general such that it addresses commercial and industrial facilities (Class 103 license) which are not subject to the minimum regulation clause as well as research and development facilities (Class 104 license) to which the clause applies. The ISG is not a substitute for NRC regulations and conformance with the guidance is not required. The approaches and methods in the ISG are provided for information only. Methods and solutions different from those described in the ISG should provide a basis for the NRC staff to make the determination needed to issue or continue a license.

#1. Plain Writing Act	The Plain Writing Act, signed into law in 2010 and subsequent Executive Order 13563 require that documents and regulations be written as clear and concise and understandable. The proposed ISG document fails to specify the precise intended application of the guidance. Specifically, the ISG is presented as augmentation to NUREG 1537 where non-power reactors are used for the production of radioisotopes. However, it is not clearly stated as such. The purpose statement located in the introduction of the ISG could be interpreted such that the augmented ISG applies to all Research and Test Reactors (RTRs). TRTR requests clarification and a precise indication as to the intended application of the proposed ISG document.	**NRC Response** The ISG was developed in response to public interest in licensing new facilities for the production of radioisotopes, especially radioisotopes for medical use. As stated in the introduction to the ISG, "The ISG presented in this document augments existing guidance to define a means to expeditiously license medical isotope production facilities." The section of the introduction titled, "Licensing of 10 CFR Part 50 Utilization Facilities," explains that the ISG applies to an AHR as a utilization facility. For these reasons, the title of the ISG includes the phrase "for licensing radioisotope production facilities and aqueous homogeneous reactors." The ISG is to be used in conjunction with the existing NUREG-1537. As stated in the section of the introduction to the ISG titled, "Presentation of Interim Staff Guidance," the ISG applies to licensing of a heterogeneous reactor or an AHR as a utilization facility. The ISG provides updated references and contains revisions to reflect changes to the regulations for non-power reactors since 1996. The ISG also expands the guidance for submitting and reviewing an environmental report. The purpose of these changes is to better inform the applicant; the changes do not constitute any new NRC requirements. The NRC staff will use the ISG in conjunction with NUREG-1537 to review applications for new utilization facilities. The ISG applies to an application for a license for a new AHR as a utilization facility regardless of whether the facility will be involved in the production of radioisotopes. For example, an applicant for a license for an AHR for conducting neutron radiography should use the ISG along with NUREG-1537 to prepare the license application because the ISG contains detailed information related to licensing an AHR.

		As stated in the section of the introduction to the ISG titled, "Presentation of Interim Staff Guidance," the ISG applies to licensing of a radioisotope production facility pursuant to 10 CFR Part 50 for the separation of byproduct materials from the irradiated SNM. An applicant for a license for a production facility issued pursuant to 10 CFR Part 50 should use the ISG in conjunction with the NUREG-1537 when preparing the application as the NRC staff will do in reviewing such an application. The ISG may also be useful for preparing and reviewing an application for a license amendment for a utilization or production facility, depending on the circumstances. To improve the clarity of the ISG, the introductory wording of each chapter has been reviewed for consistency with other chapters. Standard wording has been adopted as applicable.
#2. Applicability to existing reactors	At present, it would appear the majority of the existing RTRs are not subject to the additional guidance presented in the proposed ISG. However, there is a concern the proposed ISG may negatively impact RTRs that produce or may produce limited amounts of radioisotopes for research and education purposes, either directly or through a separation process. TRTR requests clarification and a precise indication that limited radioisotope production for research and education purposes is excluded from the proposed ISG document.	**NRC Response** The ISG does not apply to the current experiment programs of presently licensed non-power reactors. NUREG-1537, Part 1, Chapter 10 of the ISG has been modified to clarify that the guidance in NUREG-1537 applies to experiment programs for utilization facilities. The definition of production facility in 10 CFR 50.2 states that laboratory scale facilities designed or used for experimental or analytical purposes related to processing of irradiated materials containing special nuclear material are not production facilities. This use of SNM would typically be part of the experiment program at a utilization facility licensed pursuant to 10 CFR Part 50 for which the guidance in NUREG-1537 applies.

1. Two-step license application content	Licensing of these type facilities under 10CFR 50 requires both a construction permit and an operating license. While it is possible to submit these at the same time, it is more likely that licensees will use a two step licensing process. In this case, neither NUREG-1537 nor the augmenting guidance provides differentiation between the expected content of the construction application and the operating application. During the meeting between B&W and NRC in 2010 (ML100501028), B&W presented a high level description of the content of a construction application versus an operating application. While this description was brief and very high level it begins to describe the expectation. B&W believes it will be extremely important to provide some level of guidance for both the applicant and the reviewers regarding the content of the construction application and the operating application. Absent guidance there is high potential for misalignment between NRC and the licensee that could result in protracting the licensing process. **Suggestion/Recommendation**: Include a section in each chapter of the ISG (both Parts 1 and 2) that provides a general discussion of the content of a construction application versus an operating application.	**NRC Response** This is addressed in the ISG by augmenting the introduction to NUREG-1537 Part 1 with a section providing the current regulatory basis and general guidance. This new section describes the content required per 10 CFR Part 50 and the level of detail for both the construction permit application and the operating license application.
2. Applicability of 10 CFR Part 70	There are a number of places in the ISG where the requirements of 10CFR70 are either cited or implied to be directly applicable to the production facility. While the concepts of 10CFR70 regarding criticality safety, chemical safety and worker protection may be appropriate for consideration and inclusion, they should be done within the context of 10CFR50 for the production facility. Statements such as "per the	**NRC Response** The ISG provides guidance to the staff reviewers who perform safety reviews of applications to construct or modify and operate radioisotope production facilities. The standard review plan (SRP) is intended to be a comprehensive and integrated document that provides methods or approaches that the staff has found acceptable for meeting NRC requirements. The ISG also makes information about licensing acceptance

	requirements of 10 CFR 70" do not seem appropriate for a production facility licensed under 10 CFR 50. A statement directing the applicant and reviewer to 10CFR70 for insight as to what has previously been found acceptable may be more appropriate and may avoid confusion regarding the true regulatory requirement for the production facility being rooted in 10 CFR 50. Similarly, the use of the term IROFS (defined in 10 CFR 70) applied to the production facility seems inappropriate for a facility licensed under 10 CFR 50. B&W believes introducing the term IROFS to the facility will not only complicate the licensing process but will ultimately be confusing to the facility operations staff who will be working in the context of both a utilization and production facility. This can be avoided by simply stating what accidents are to be prevented or mitigated by the use of known terminology within 10CFR50 such as Technical Specifications, Engineered Safety Features, etc. Note that there are a number of specific comments listed below [in the remainder of these B&W comments] related to this topic. Suggestion/Recommendation: Review the ISG in its entirety for the use of 10CFR70 and terms such as IROFS to assure they are used as guidance or reference and do not state or imply that they are regulatory requirements for a facility licensed under 10 CFR 50.	criteria widely available to interested members of the public and the regulated industry and is intended to improve industry and public stakeholder understanding of the staff review process. The ISG is not a substitute for NRC regulations and compliance is not required. The approaches and methods in the ISG are provided for information only. Methods and solutions different from those described in the ISG should provide a basis for the NRC staff to make the determination needed to issue or continue a license. Section 13b has been revised to remove explicit requirements to comply with 10 CFR Part 70, Subpart H; however, a radioisotope production facility license application must include a safety program which contains process safety information, an accident analysis (ISA or other equivalent methodology), and management measures.
3. Small number of citations for Section 13a	Section 13a is one of most important sections regarding AHR PSAR and FSAR development. This section is roughly 10 pages worth of guidance but cites only 4 external references.	**NRC Response** The comment suggests additional references be included to those already present in section 13a, and also provides other references for consideration. The

	While the references cited are useful, there are many other documents available to the NRC that will allow them to edit the ISG, assess AHRs, and judge the adequacy of future designs. In particular, B&W encourages the NRC to consider the following documents: 1. *Safeguards Summary For The AE-6 Reactor* by G.L. Blackshaw and C. H. Skeen, NAASR-5499, 1961 2. *Hazards Summary For The L-77 Laboratory Reactor For The University of Nevada Reno,* NP-12048, 1962 3. *Summary Review of the Kinetics Experiments on Water Boilers* by M.S. Dunenfeld and R.K. Stitt, NAA-SR-7087, 1963 4. *Changes of KEWB Reactor Cores - Evaluation of Significance with Regards to Associated Hazards,* NAA-SR-MEMO-4928, 1960 5. *Kinetics Experiments on Water Boilers "A" Core Report - Part 1: Program History, Facility Description, and Experimental Results* by J.W. Flora, et. al., NAA-SR-5415, 1962 While this list is by no means comprehensive, the above documents will be useful references for the NRC in future work with AHRs. An additional set of references were mentioned in B&W's previous set of comments (ML11325A121).	following references have been added to Section 13a.4, *References,* Parts 1 and 2 of the ISG: 1. Barbry, F., "French solution reactor experience and contribution to the Feasibility of the use of LEU Fuelled Homogeneous Aqueous Solution Nuclear Reactors for the Production of Short Lived Fission Product Isotopes," IAEA-CRP/RCM, February, 2010. 2. Dunenfeld, M.S., "Summary Review of the Kinetics Experiments on Water Boilers," NAASR-7087, Atomics International, Canoga Park, CA, 1963. 3. McLaughlin, T.P., Process criticality accident likelihood, consequences, and emergency planning, Nuclear Energy, Vol. 31, No. 2, April, 1992. 4. McLaughlin, T.P., Monahan, S.P., Pruvost, N.L., Frolov, V.V., Ryazanov, B.G., Svirdov, V.I., "A Review of Criticality Accidents," LA-13638, Los Alamos, NM, 2000.

4 Additional technical considerations	In B&W's previous set of comments (ML11325A121), several significant technical issues were identified. These issues include but are not limited to: dynamic void behavior, effects of boiling, and reactor stability. The major of these technical issues are also applicable to Chapters 7-18 of the ISG. For the sake of brevity, these issues will not be restated; instead, the Commission is encouraged to re-read the previous set of comments.	**NRC Response** The responses to the technical issues referenced can be found above in the responses to B&W comments on ISG Chapters 1-6.

Ch 10, p 48, Post-extraction not an experiment	This section states that all post extraction operations should be included in Chapter 10. While this may be an option, the integration of the facility may be better described by comprehensive discussion in an integrated manner throughout the balance of the SAR rather than try to isolate to this section.	**NRC Response** See the response to the SHINE comment below on Chapter 10 Experimental Facilities. The NRC staff revised Chapter 10 of the ISG.
Ch 11.1.5.1(1), p 49, ISA is not appropriate	Requiring an Integrated Safety Analysis and compliance with performance requirements of 10 CFR 70.61 is not appropriate for a production facility licensed under 10 CFR 50. Refer to General Comment #2	**NRC Response** A radioisotope production facility licensed under 10 CFR Part 50 is not required to comply with the performance requirements of 10 CFR 70.61. However, NRC staff has found the methods described in 10 CFR Part 70, Subpart H an acceptable way of demonstrating safety. Section 11.1.5.1 and bullets (1) and (2) have been revised, and an additional bullet provided for applicants to clearly distinguish between occupational workers and members of the public, and to describe how the consequences differ from each other and are controlled.
Ch 12.1.6, p 52, 10CFR70.61and 62 are not appropriate	Reference to requirements of 10 CFR70.61 and 62 are not appropriate for a production facility licensed under 10 CFR 50. Refer to General Comment #2	**NRC Response** This section has been revised to remove suggestions that compliance with Subpart H of 10 CFR Part 70 is required for a radioisotope production facility licensed under 10 CFR Part 50. A radioisotopes production facility license application, however, must include a safety program that contains process safety information, an accident analysis (ISA or other equivalent methodology), and management measures, per 10 CFR 50.36. As stated in the ISG, NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS, and establishment of management measures are an acceptable way of demonstrating adequate safety

		for the medical isotopes production facility. Applicants are free to propose alternate accident analysis methodologies, to propose alternate radiological and chemical consequence and likelihood criteria, to propose alternate safety features, and to propose alternate methods of assuring the availability and reliability of the safety features. Also, as used in the ISG, the term, "performance requirements" is not intended to suggest that the performance requirements found in 10 CFR 70.61 are being imposed against the licensees licensed under 10 CFR Part 50, only that their use as accident consequence and likelihood criteria by radioisotope production facilities may be found acceptable by the NRC staff.
Ch 12.11, p 56, Application of Part 70	This section states that all operations outside the reactor with SNM must be conducted under 10 CFR 70; however this is contrary to 10 CFR 50 and the Commission decision that without an exemption, the irradiated SNM (having sufficient fission product quantities) must be licensed as a production facility under 10 CFR 50. Refer to General Comment #2.	**NRC Response** This section has been revised to clarify that operations with SNM outside the reactor may be subject to the requirements of 10 CFR 70. Applicable portions of 10 CFR Part 70 requirements may be incorporated into the 10 CFR Part 50 license as license conditions. The following text has been added to Section 12.11 after the bulleted list of startup activities: The process safety information, ISA, and management measures should include startup operations, and IROFS should be identified if necessary to meet ISA performance requirements and to provide assurance of adequate safety during startup.
Ch 13a.2, p [92], Power oscillations	"... the nature of power oscillations at high-power density is not well characterized" And "… that normal power operation of an AHR will include irregular power oscillations" The conclusions are partially drawn from reference 2's discussion of HRE. HRE is not applicable to this ISG as it was a power reactor and had re-circulating. Suggest	**NRC Response** The comment is accepted; the second and third sentences of the first paragraph under "Fuel temperature/void-reactivity feedback" in Part 1, Section 13a.2, *Aqueous Homogeneous Reactor Accident Analysis,* of the ISG have been replaced by the following:

	including more pertinent, quantitative references on this subject as reference 2 is almost entirely a qualitative discussion. Experimental analyses from SUPO, KEWB, TRACY, or SILENE suggest that power oscillations are "well characterized." Additionally, the power oscillations are better described as stochastic and variable as opposed to "irregular." AHRs are likely to have different reactor noise characteristics than heterogeneous reactors due to the different reactivity feedback mechanisms but those stochastic and/or variable effects should not be described as "not well characterized" or "irregular."	"While in most cases the experience has shown that the stochastic power oscillations in AHRs are bounded, the nature of power oscillations at high power density depends on the specific design [see reference 3 of Section 13a4] and there have been no models that have been successful in calculating the power spectrum of the oscillations. It is expected that normal operation of an AHR will include stochastic and variable power oscillations owing to the dynamics of radiolytic gas formation and reactivity feedback."
Ch 13a.2.1.8, Pressure feedback	Pressure feedback effects are unlikely to cause the type of oscillations described in 13a.2.1.8. for a variety of reasons. These include but are not limited to 1) KEWB experiments quantified this effect and determined it had a small influence on system behavior and 2) FETCH studies have indicated the compressibility nature of the solution can actually improve the safety/stability characteristics of a system (C.C. Pain, et. al. "Transients Criticality in Fissile Solutions - Compressibility Effects" 2001).	**NRC Response** No change was made to the ISG based on the comment. Pressurization is mentioned here as a potential mechanism that could be considered. It has been included as an example of the type of interactions that should be considered.
Ch 13b, p 99-105, ISA methodology	This section begins with a discussion of 10 CFR 70 Subpart H which implies that it applies to a production facility. The irradiated uranium however must be handled in a production 105 facility licensed under 10 CFR 50. While B&W believes the ISA methodology provides a valuable tool and the performance requirements of 10 CFR 70.61 can provide a framework, specific reference to compliance with 10CFR70 is not appropriate. This section does recognize the need for Technical Specifications under 10 CFR 50.36 and the synergy between the results and safety features identified during the integrated safety analysis and Technical Specifications.	**NRC Response** The ISG provides guidance to the staff reviewers who perform safety reviews of applications to construct or modify and operate medical isotope production facilities. The SRP is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements (in the case of medical isotopes, 10 CFR Part 50). The ISG is not a substitute for NRC regulations and compliance with the ISG is not required. The approaches and methods in the ISG are provided for

	This concept should be expanded as specific references to 10CFR70 compliance are removed.	information only. Methods and solutions different from those described in the ISG should provide a basis for the staff to make the determination needed to issue or continue a license. Section 13b has been revised to remove the suggestion that compliance with Subpart H of 10 CFR Part 70 is required of a radioisotope production facility licensee pursuant to 10 CFR Part 50 and include the option to propose alternate accident analysis methodologies, performance criteria, and safety features. Other sections of the ISG, notably Chapter 14, Technical Specifications, have been revised to incorporate and revise this position.
Ch 14a.2-2.1, p 107, Safety of boiling	Boiling is not necessarily an unsafe or unstable phenomenon in AHRs. It should be up to the applicant to determine whether the reactor can boil safely. Let the applicant set the necessary LCOs, LSSSs, and SLs.	**NRC Response** The comment is accepted; the second paragraph of Section 14a.2-2.1, *Safety Limits and Limiting Safety System Settings,* of the ISG has been replaced by the following: "The following sentences should be added to the end of the section: 'For aqueous homogeneous reactors, there may be limits on the character and quality of the fuel that might warrant setting additional safety limits (i.e., the operating-power density, the uranium concentration, the volume, the pH, and the temperature and pressure of the fuel solution).'"
Ch 12.10b, p 114, Operator licensing regulations [belongs in Part 2]	The last sentence of this section refers to 10CFR70.61. This reference should be deleted as Page 114 the requirements for operator licensing in the Atomic Energy Act apply specifically to production facility operators. Thus the reference to 10CFR50 and 55 are sufficient and adequate and need to be clarified by referencing a regulation, 10CFR70, that does not apply to the production facility.	**NRC Response** While this comment is listed with the Part 1 comments, from its context it appears to belong in Part 2 where a very similar comment is made. The answer will therefore be consolidated in the response to the Part 2 comment on Section 12.10b, page 114.

All, Part 1 comments may apply to Part 2	Refer to specific comments on Part 1 as these comments generally apply to Part 2 corresponding sections.	**NRC Response** The Part 2 content was considered while addressing each of the above Part I comments.
Ch 12.10b, p 114, Operator licensing regulations	The last sentence of this section refers to 10 CFR 70.61. Operator licensing is only required for production facilities as properly referenced by 10CFR 50 and 55. Expanding this requirement to 10 CFR 70.61 is unnecessary and could lead to confusion regarding where operator licensing is required. What it says now: Members of the facility operations staff who manipulate the controls of the production facility or who perform other duties that are required to meet the performance requirements stipulated in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d) are fully qualified and licensed, in accordance with the requirements of 10 CFR 50.54(h) and 10 CFR Part 55, “Operator’s Licenses,” as augmented by this ISG	**NRC Response** The NRC has determined that the same technical and safety considerations apply to operators of production facilities and so will be applying 10 CFR Part 55 requirements accordingly. The last two paragraphs of section 12.10b, Part 2 of the ISG have been revised to address this issue.
Ch 13b.1.2, p 126, Application of Part 70	This section provides the most concise example of why B&W is concerned about references to 10CFR70as a requirement. The statement that, "the reviewer should determine ... the applicant is fully committed to implementing a safety program, including ISAs in accordance with the requirements of 10 CFR 70.62... and the management measures prescribed in Section 12.1.6 of this ISG" implies that the production facility will be dually licensed under 10CFR70and 10 CFR 50. B&W believes only the requirements of 10CFR50 should be applied and that specific commitments to 10CFR70requirements are inappropriate.	**NRC Response** The ISG provides guidance to the staff reviewers who perform safety reviews of applications to construct or modify and operate medical isotope production facilities. The SRP is intended to be a comprehensive and integrated document that provides methods or approaches that the NRC staff has found acceptable for meeting NRC requirements. The ISG is not a substitute for NRC regulations and compliance is not required. The approaches and methods in the ISG are provided for information only. Methods and solutions different from those described in this ISG should provide a basis for the staff to make the determination needed to issue or continue a license.

	That does not mean that B&W objects to use of the tools and concepts provided by 10 CFR 70. The ISA as a methodology would be an appropriate way to perform the accident analysis. However, the results must be captured within the context of 10 CFR 50. 10 CFR 50 requires appropriate safety programs, quality programs, configuration management, etc. This language should be modified to state that the applicant describes and commits to appropriate programs and processes to perform the safety analysis and implement the safety program and that 10 CFR 70 Subpart H and NUREG-1520 can be used as a reference to describe. (comment does stop here)	Section 13b has been revised to incorporate and emphasize this objective. Other sections of the ISG, notably Chapter 14, Technical Specifications, have been revised to incorporate and revise this position. Section 13b has also been revised to remove explicit requirements to comply with 10 CFR Part 70, Subpart H; however, a radioisotope production facility license application must include a safety program which contains process safety information, an accident analysis (ISA or other equivalent methodology), and management measures.
Ch 14b, p 138-141, Tech Specs vs IROFS	This section appropriately describes Technical Specifications (TS) as required by 10 CFR 50. The use of the term IROFS will ultimately be confusing to regulators and to operators. The term is not necessary within this licensing structure as long as TS are appropriately defined to prevent or mitigate the accidents of concern. Suggest eliminating all use of the term IROFS as it has no place in a 10CFR50 license and simply state the accidents that need to be prevented or mitigated through TS in a graded manner.	**NRC Response** Items relied on for safety are needed for processes outside the reactor since they are relied on to prevent potential accidents or mitigate the consequences of an accident. They are a form of technical specifications in that they establish terms for the safe operation of a facility, but are not bounding conditions for the safe operation of a facility. IROFS are structures, systems, equipment, components and activities that will make a high consequence event highly unlikely and an intermediate consequence unlikely. NRC staff have determined that the designation of IROFS and the provision of design features reduce challenges to IROFS are parts of an acceptable way of demonstrating adequate safety for the radioisotope production facility. Applicants may propose alternate term for designated safety features and alternate methods of reducing challenges to the safety features.

1. PSAR/FSAR Content	NUREG-1537 was written to allow applicants to submit one Safety Analysis Report to address the needed information for both a Preliminary Safety Analysis Report (PSAR) and a Final Safety Analysis Report (FSAR) supporting both an application for a construction permit and an operating license. If well planned, the final facility design and the final SAR descriptions, analyses, and conclusions will not differ significantly from those in an initial application and a one-step licensing process can be undertaken. As stated in NUREG 1537, the regulations in 10 CFR 2.105(c) do not preclude a joint application for a construction permit and the initial operating license. When utilized, this streamlined licensing process provides benefits for both the NRC staff and the applicant. As currently written, NUREG-1537's stated purpose is to describe an acceptable format and content of the safety analysis report (SAR) to be submitted to the NRC staff by an applicant or licensee of a non-power reactor for a new license. However, not all applicants would prefer this one-step joint application for various reasons, and would prefer to follow the conventional process of the two step licensing process under 10 CFR 50. NUREG 1537 and the draft Interim Staff Guidance (ISG) for the NUREG-1537 chapters do not provide sufficient guidance for the content necessary to submit a high quality PSAR for a construction permit, followed at a later date by an FSAR for the operating license. The NRC staff routinely provides regulatory guidance (i.e. NUREGs, Regulatory Guides, etc.) to minimize the possibility that regulations are interpreted differently by different applicants and licensees. However, NUREG-1537 and the draft	**NRC Response** This is addressed in the ISG by augmenting the introduction to NUREG-1537 Part 1 with a section providing the current regulatory basis and general guidance. This new section describes the content required per 10 CFR Part 50 and the level of detail for both the construction permit application and the operating license application.

	ISG do not provide the same level of differentiation needed for PSAR and FSAR scope, content and level of detail found in earlier regulatory guidance documents. For instance in Regulatory Guide 1.70, Revision 3, the NRC staff did provide information relative to the difference in scope, content and level of detail between a PSAR and FSAR. The NRC staff should consider guidance in NUREG-1537 that specifies the requisite information needed for scope, content and level of detail for applicants wishing to submit both a PSAR for the construction permit and an FSAR for an operating license to ensure consistency and completeness of content.	
¶ 2. Structure of Ch 7b, Part 2	Part 1 of the draft ISG should provide the framework and structure for the content of chapters within the SAR, irrespective of being a PSAR or FSAR. Information related to the structure and content should be located in Part 1 of the NUREG. In Chapter 7b of Part 2, guidance is provided for content and structure for the SAR, but the same information is not presented in Part 1. NRC staff should consider putting all necessary information related to content and structure for a SAR in Part 1 of the NUREG and not expect applicants and licensees to reference different Parts of the NUREG to determine structure and content.	**NRC Response** NRC staff agrees. A change has been made to the ISG so as to move the referenced material from Part 2 to Part 1.

Ch 9b.3, Fire protection	The draft ISG looks for information to be included in this section related to hydrogen or other combustible gases. These issues are addressed in Chapter 13 for the fission process as well as the radioisotope production facility specific hazard analysis and are not necessary to be repeated in this section. This section need only address the systems and programs necessary to detect, alarm and suppress a fire as needed for the Chapter 13 analysis.	**NRC Response** NRC staff agrees that fire protection programs are necessary only to the extent that they prevent or mitigate radiological or chemical consequences from the licensed materials. Section 9b.3 has been revised to reflect that fire protection systems and programs should be provided and described in the accident analysis and technical specifications sections of this ISG.
Ch 10, Post-extraction vs experiment	The draft ISG for NUREG-1537 suggests that the post-extraction radioisotope processing operations should be discussed in this section. This is only appropriate if the post-extraction radioisotope processing operations are being conducted as an experiment, one which might be used to optimize the post-extraction process. This type of operational decision would be evaluated under 10 CFR 50.59 as part of a normal change process. Clearly the intent of this section in NUREG-1537 is for experimental facilities used in conjunction with a non-power reactor. The many examples of the experiments described in NUREG-1537 do not have a nexus to post-extraction processes that are integral to the production of radioisotopes and described in other SAR chapters. Additionally, the language regarding the "AHR case where the reactor fuel is the target, the radioisotope extraction and post-extraction process is an integral part of the reactor operation." is inconsistent with the concept of having two different processes of interest in a SAR, the fission process and the radioisotope production facility processes. If the extraction and post-extraction processes are integral to the reactor operation (or fission process) then the line of demarcation between the reactor (or	**NRC Response** The staff revised Chapter 10 of Part 1 of the ISG to replace the second paragraph. The paragraph introduced confusion about experiments, reactor operations, and production facility operations. The NRC staff revised Chapter 10 to clarify that a production facility could include experimental facilities, and Chapter 10 of the safety analysis report (SAR) should include the appropriate information in Chapter 10 of NUREG-1537. Additionally, the definition of production facility in 10 CFR 50.2 states that laboratory scale facilities designed or used for experimental or analytical purposes related to processing of irradiated materials containing special nuclear material are not production facilities. This type of facility would typically be part of the experiment program at a utilization facility licensed pursuant to 10 CFR Part 50. The guidance in NUREG-1537 applies to this type of facility.

	fission process) and the radioisotope production facility does not exist. This suggests that all the processes are reactor- (or fission-) related and the concept of a separate radioisotope production facility is undermined by this statement. SHINE believes that there is a difference between the fission process and the radioisotope production facility process and that the regulations should recognize and accommodate this difference.	
Ch 11.3, Respiratory protection	The draft ISG states: *Under 10 CFR 20.1703(c)(4), the applicant must describe the installation of the ventilation and containment* systems *and how these will protect personnel from inhaling airborne concentrations of radionuclides that are above the SLs. The applicant should also describe the surveillance requirements that will be imposed on the ventilation and containment systems and the respiratory protection equipment. This information should be sufficient to support an understanding of how the worker will be protected and how a safe working environment will be maintained.* 10 CFR 20.1703(c)(4) addresses the scope and content of written procedures necessary to implement the regulations related to implementing and maintaining a respiratory protection program and does not address what the draft ISG states. The NRC staff should consider whether to cite a different regulation or instead remove the statements.	**NRC Response** The comment is valid and alternative wording in the ISG has replaced the two large, middle paragraphs of Part 1, Section 11.3, *Respiratory Protection Program*, with the following: "The applicant should describe how it plans to meet the requirements of 10 CFR Part 20 Subpart H, Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas' by one of three methods. • Pursuant to Part 20.1701 and in conjunction with ventilation equipment described in Chapter 9, Auxiliary Equipment. • Pursuant to Part 20.1702 and in conjunction with the use of other controls as discussed in this section or as referenced in this section and discussed elsewhere in the application. • Pursuant to Part 20.1703 and in conjunction with individual respiratory protection equipment used and maintained under a program described in this section of the application and in compliance with Part 20.1703".
Ch 12.1.6, Production facility safety program	The draft ISG states: The radioisotope production facility must have an established safety program, as required by 10 CFR 70.61, "Performance Requirements" and 10 CFR 70.62, "Safety Program and Integrated Safety Analysis." Based on the draft ISG	**NRC Response** NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 Subpart H and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10

	language, it is presumed that 10 CFR 70 Subpart H applies to all radioisotope production facilities using NUREG-1537 as its licensing model. However,10 CFR 70.60, in part, states the applicants or licensees to which 10 CFR 70 Subpart H applies: § 70.60 Applicability. The regulations in § 70.61 through § 70.76 apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be authorized to possess greater than a critical mass of special nuclear material, and engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity that the Commission determines could significantly affect public health and safety. While most radioisotope production facilities may possess greater than a critical mass of special nuclear material, they may not satisfy any of the other identified applicability criteria in 10 CFR 70.60. Unless the Commission determines that the radioisotope production facility could significantly affect public health and safety, then an additional criterion must be satisfied for Subpart H to be legally binding. Many of the additional criteria are not defined, such as enriched uranium processing and plutonium processing. The staff should note a distinction between "processing" special nuclear material (enriched uranium and plutonium) and "separation" of radioisotopes from special nuclear material (enriched uranium and plutonium). This	CFR 70.61, designation of items relied on for safety (IROFS), and establishment of management measures are an acceptable way of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features. Section 12.1.6 has been revised to reflect that 10 CFR 70, Subpart H is one acceptable way to demonstrate adequate safety.

	distinction is reflected in the Atomic Energy Act of 1954 (as amended) Section 161(m), and Section 161(t). The staff should consider clarifying which criteria apply to radioisotope production facilities with appropriate definitions or instead specify that a Commission determination that makes all radioisotope production facilities subject to this regulation.	
Ch 12.7, Emergency planning per NUREG-1520	The second sentence in the second paragraph of Part 1 states that Section 12.7 of Part 2 specifies the portions of NUREG-1520 that should be addressed. Section 12.7 of Part 2 has no direct references to NUREG-1520 but has included some of its suggested information in the text. Please clarify.	**NRC Response** Section 12.7 of Part 1 has been revised to delete references to NUREG-1520 and instead to refer to Section 12.7 of Part 2.
Ch 12.10b, Production facility operator training	The last sentence of the first paragraph states that the NRC will be imposing applicable Part 55 requirements to production facility operators. The corresponding paragraph in Part 2 seems to indicate that all the requirements of Part 55 will be imposed. Please clarify. The Atomic Energy Act of 1954, as amended, provides a definition of the term "production facility" in Chapter 2, Section 11, "Definitions". 10 CFR 50.2, "Definitions" also provides a definition of the term "production facility". These two definitions appear to be different. The draft Interim Staff Guidance (ISG) references the Atomic Energy Act in this section when discussing radioisotope production facilities. However, the Atomic Energy Act's use of the term "production facility" in Section 107 of the AEA is based on the AEA's definition of the term, not the definition provided in 10 CFR 50.2. Using the AEA definition for a production facility when the 10 CFR 50.2 definition differs can create	**NRC Response** The portion of Section 12.10b cited has been revised in the ISG so that Parts 1 and 2 are consistent. The revised wording is "…the NRC has determined that the same technical and safety considerations apply to operators of production facilities and so will also apply to relevant 10 CFR Part 55 requirements to production facility operators." Section 107 of the AEA is applicable to radioisotope production facilities because the intent of the AEA, as reflected in the definition of "utilization facility," is to ensure the safe and secure operation of facilities that use special nuclear material. While NRC authority derives from this section of the AEA, more of these facilities are captured in the definition of production facilities found in 10 CFR 50.2 .

	difficult issues of interpretation and compliance.	
Ch 12.14, ANSI/ANS standard reference	The referenced version of ANSI/ANS 15.11 is given as 2004. The latest version of this standard is 2009, and should be referenced instead.	**NRC Response** The reference to ANSI/ANS 15.11 has been revised from 2004 to 2009 in the ISG.
Ch 13a.2.1.1, Maximum Hypothetical Accident	The first listed MHA is the dispersal of the contents of the primary boundary with bypass of any scrubbing capacity. If the vessel forming the primary boundary is located in a relatively deep pool, then the requirement of bypassing scrubbing is going to eliminate the principal means for reducing the iodine inventory released from the pool. Scrubbing of iodine by the pool water is a physical process and should not be eliminated as part of an accident. This scenario of breaking the primary boundary and bypassing scrubbing is similar to a postulated double failure with the second "failure" being the elimination of a physical process. This first MHA should be re-defined without the "bypass of any scrubbing capacity" restriction.	**NRC Response** No change was made to the ISG based on the comment. The ISG is written such that the listed maximum hypothetical accidents (MHAs) provided in this section are possible MHAs that could be considered. The MHA is design-dependent and may not be based on the provided list.
Ch 13b, Subpart H accident analysis	In this section of the draft ISG, the Staff states: The regulations in Subpart H of 10 CFR Part 70 require licensees possessing and processing SNM in quantities that are greater than a critical mass to conduct integrated safety analyses (ISAs) of all such operations. In 10 CFR 70.62, the NRC requires that, through a well-defined safety program (refer to Section 12.1.6 of this ISG), all processes involving licensed material be examined through an ISA. As previously identified in comments for Section 12.1.6, these statements are incomplete as they are only reflective of a portion of the regulations. At least one of the additional criteria is required to be satisfied to make this regulation applicable.	**NRC Response** This section has been revised to remove explicit requirements to comply with 10 CFR Part 70, Subpart H; however, a radioisotope production facility license application must include a safety program which contains process safety information, an accident analysis (ISA or other equivalent methodology), and management measures. The ISG provides guidance to the staff reviewers who perform safety reviews of applications to construct or modify and operate radioisotope production facilities. The SRP is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements The ISG is not a substitute for NRC regulations and

		compliance is not required. The approaches and methods in the ISG are provided for information only. Methods and solutions different from those described in the ISG should provide a basis for the staff to make the determination needed to issue or continue a license. Section 13b has been revised to incorporate and emphasize this objective.
Ch 14b, Tech spec use of Subpart H	As identified in comments for Chapters 12.1.6 and 13b, the staff prescribes adherence to 10 CFR 70 Subpart H in this section, even though the criteria to follow this regulation is assumed without additional clarification. The staff should modify the wording to reflect the use of Subpart H, as applicable, unless other 10 CFR 70.60 criteria are specified or defined by the Commission.	**NRC Response** This section has been revised to remove suggestions that compliance with Subpart H of 10 CFR Part 70 is required of radioisotope production facilities licensed pursuant to 10 CFR Part 50; however, a medical isotopes production facility license application must include a safety program which contains process safety information, an accident analysis (ISA or other equivalent methodology that includes designation of IROFS), and management measures. The ISG provides guidance to the NRC staff reviewers who perform safety reviews of applications to construct or modify and operate medical isotope production facilities. The SRP is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements. The ISG is not a substitute for NRC regulations and compliance is not required. The approaches and methods in the ISG are provided for information only. Methods and solutions different from those described in the ISG should provide a basis for the NRC staff to make the determination needed to issue or continue a license. Section 14b has been revised to incorporate and emphasize this objective.