March 27, 2013

SUMMARY OF COMMENTS ON SA-300, REPORTING MATERIAL EVENTS

I. **Sent to Agreement States for Comment:** January 11, 2010 (FSME-10-002)

Comments/Dated: Wisconsin – 1/29/2010 (email)
Washington – 1/28/2010 (email)
Texas – 3/10/2010 (email)
Oregon – 3/12/2010 (email)

Response to/Resolution of Comments:

WISCONSIN

Comment 1: The definition of "Abnormal Occurrence" (given in Appendix J, p.52) should directly include the definition on the cited Federal Register page ("an unscheduled incident or event which the U.S. Nuclear Regulatory Commission (NRC) determines to be significant from the standpoint of public health or safety") and perhaps reference NUREG-0090 which has the more detailed Abnormal Occurrence criteria.

Response: We agree with the comment. The procedure was revised accordingly.

WASHINGTON

Comment 1: No substantive comments for the changes reference in proposed changes to FSME Procedure SA-300. The proposed procedures and changes should not require more of our staff time than the current version. In fact the addition to Section 7.4 which will add some guidance for medical event reporting may actually prove beneficial for us. Just out of curiosity, you could tell us why the procedure uses the designation “nuclear” and not “radioactive” when referencing to material?

Response: We appreciate the State’s insight and believe that this revised procedure will be more efficient and save time. The term “nuclear” is the general term used by the NRC when referencing “material”. Therefore, we use the term in this procedure. No changes were made to the handbook in response to this comment.

TEXAS

Comment 1: A general acknowledgement should be made regarding the rule citations within the "NRC Regulatory Reporting Requirements" table, presented in Appendix A of the revised SA-300 document. As this list will specifically delineate, several points of confusion could be eliminated if the brief summaries presented in the table clearly articulated all necessary criteria used to report an event. Many of the citations are incomplete, and consequently provide misleading information to Agreement State personnel reporting events.

Response: We appreciate the comment, however the purpose of the brief summaries in the table presented in Appendix A is to provide a general synopsis of the regulatory requirement. It is expected that the actual regulatory requirement (Title 10 of the Code of Federal Regulations) be used when determining if and when an event shall be reported. No changes were made to the handbook in response to this comment.

Comment 2: As revised, this document states in the Introduction, that it is to be used as "guidance for Agreement States on reporting [radioactive] material event information to the Nuclear Regulatory Commission (NRC) for events that occurred in their State." Therefore, because the document is specific in its scope, and Agreement States do not regulate nuclear power plants, all references to nuclear power plant incident reporting should be removed.

Response: We agree with the comment. All references to nuclear power plant incident reporting have been removed from the procedure.

Comment 3: Section I – Insert "radioactive" before "material events" for clarity. Suggest this addition be made throughout the document.

Response: We appreciate the comment, however consistent with the response to the State of Washington's Comment 1 above, Section I of the procedure has been revised to indicate "nuclear" material events and the term "nuclear" has been added throughout the document and handbook where the words "material events" have been used. No changes were made to the procedure or handbook in response to this comment.

Comment 4: Section III.A - Insert "into" between "enter" and "an" in the first sentence so that the sentence reads: "The Atomic Energy Act (AEA) allows the Commission to enter into an Agreement…"

Response: We agree with the comment. The procedure was revised accordingly.

Comment 5: Section V.C.3 - The State of Texas has encountered problems with patient confidentiality regulations and this item, which allows the NRC to publish the event reports onto their website. This item should be amended to explicitly state that the NRC does not wish State personnel to report information that is considered confidential and not intended for public release by the NRC in any manner.

Response: We appreciate the comment; however there are times when confidential information may be needed to complete the minimum event reporting requirements. States should follow NRC regulatory requirements for submitting information that may be confidential or sensitive information (e.g., 10 CFR 2.390). The procedure was revised to include following clarifying sentence:

> If such information is required to describe the event, the Agreement State should provide a bracketed copy of the information that identifies the information that should be protected and a redacted copy of the information that deletes such information.

Comment 6: Section V.C.4.a., last sentence - Clarify what circumstances necessitate the "on an as needed basis" criterion. Clarification would aid the Agreement States in providing the needed information without request from the RSAO, and subsequently reduce unnecessary inquiries to the Agreement States from NRC that interfere with the Agreement States' timely response to the incident/allegation.

Response: We appreciate this comment, however this procedure provides a general detail on the type of information the States are expected to provide regarding reporting of material events (i.e., Minimum Required Event information). The RSAO request for additional information would only be in the case where the information described in the procedure was not initially provided and/or the specific circumstances of the case require additional information. No changes were made to the procedure in response to this comment.

Comment 7: Abstract – The last sentence (third bullet) suggests adding language to clarify what the handbook is trying to ensure the consistency of (response?, reporting?, content?). Same bullet needs a comma and "and" after it.

Response: We appreciate the comment as to the need to clarify the meaning of consistency, but believe that it is clear that the term consistency refers to all aspects of event reporting. No changes were made to the handbook in response to this portion of the comment. We agree with the editorial comment. The handbook was revised accordingly.

Comment 8: Handbook, Section 1.1, first paragraph, second sentence - Suggest rewording to read:
"Analyzing the data reported regarding operating incidents…"

Response: We agree with the context of the comment, but revised the sentence to read "The reporting and analysis of ~~operating~~ incidents and events..."

Comment 9: Handbook, Section 1.1, first paragraph, third sentence - "Event" before "data", and changing the word "radiation" to "radioactive material".

Response: We appreciate your comment however; the national materials data referenced in this sentence did not only include event data. The use of the word "radiation" for this sentence is used because the General Accounting Office (GAO) report stated the recommendation this way. No changes were made to the handbook in response to this comment.

Comment 10: Handbook, Section 1.1, first paragraph - Suggest deleting the fourth sentence altogether, as it is redundant of the content in Section 1, above.

Response: We appreciate but disagree with the comment as it explains information that was provided in the 1993 GAO report. No changes were made to the handbook in response to this comment.

Comment 11: Handbook, Section 1.1, first paragraph - Suggest deleting the ninth and tenth sentences, as they are redundant.

Response: We appreciate the comment, but disagree with the comment. We have revised the sentences to read as follows to clarify the intent:

> Event analysis may also result in the issuance of ~~information notices~~ generic communications to provide information and guidance regarding safety concerns and issues. ~~warning of possible safety concerns and assessment of the need for regulatory changes or revisions. Feedback is provided to Agreement State regulators, the industry, and the public.~~

Comment 12: Handbook, Section 1.1, second paragraph -Suggest adding the following sentence to the beginning of the paragraph: "If conditions warrant, NRC communicates the results of these analyses to the Agreement States and Industry via generic communications."

Response: We appreciate this comment, but believe that the revisions made in response to Texas' Comment 11 address this issue. No changes were made to the handbook in response to this comment.

Comment 13: Handbook, Section 1.1, second paragraph - Reference to https://nmed.inl.gov - It is surprising that there is no 'nrc.gov' link which could be used to direct a user to a new contractor in the event that Idaho National Laboratory lost the contract to provide this service.

Response: We understand the comment, however at this time the NMED website address cannot be changed. No changes were made to the handbook in response to this comment.

Comment 14: Handbook, Section 1.3, first paragraph, third sentence - This handbook is an appendix to SA-300, it seems silly for it to have an appendix. Suggest rewording (attachment?).

Response: We appreciate but disagree with the comment. The style for handbook is to refer to the supplementary material at the end of a handbook as appendices consistent with the dictionary definition. This is consistent with the AD-100, *Format for FSME Procedures*. No changes were made to the handbook in response to this comment.

Comment 15: Handbook, Section 1.3, first paragraph, after the third sentence - Insert a statement(s) clarifying to the reader that the exact rule text should be consulted when determining if an event is reportable. Consider something similar to the statements:

> The criteria listed in ~~Appendix~~ Attachment A are only to be used as a reference, and they are not complete. Agreement State personnel should consult the actual rule text presented in 10 CFR, in order to know the complete criteria used to determine if an event is reportable.

Response: We agree with this comment. The handbook was revised accordingly.

Comment 16: Handbook, Section.1.4 - Suggest including contact information (email or whatever) for the NMED Project Manager.

Response: We agree with this comment. The handbook was revised accordingly.

Comment 17: Handbook, Section 2.3 - Change “National Response Plan” to “National Response Framework”. Suggest also that this paragraph include a brief reference to how a state would request federal assistance (with an “Assistance Request Form (ARF)” through the states’ emergency management organization).

Response: We agree with this comment. The handbook has been revised to change “National Response Plan” to “National Response Framework” In Section 2.5 Also, the handbook indicates how a State would request federal assistance in regards to a nuclear material incident/event (i.e., contact NRC’s Operation Center).

Comment 18: Handbook, Section 2.4.e, first sentence - Suggest changing the url for inl to an NRC url in case contractors change in the future.

Response: Please see response to Texas’s Comment 13 above. No changes were made to the handbook in response to this comment.

Comment 19: Handbook, Section 2.5 - Suggest rewording “should provide” and “should be provided” to “must provide” and “must be provided”, to remove ambiguity.

Response: We appreciate the comment; however use of the word “must” connotes regulatory requirements normally reserved for licensees. The procedure and

handbook are guidance documents for the Agreement States. There is not a specific regulatory requirement that the Agreement States must provide follow-up information. Therefore, we use the word “should” instead of “must.” However, in an effort to gather comprehensive event information we ask that follow-up information be provided to the NRC. No changes were made to the handbook in response to this comment.

Comment 20: Handbook, Section 2.5 a. - On occasion, NRC Headquarters has asked for follow up information (via the RSAO) regarding specific incidents in Texas. Texas staff has routinely updated in the information for these incidents in the NMED database, in accordance with SA-300, yet Texas Staff receive questions from NRC staff through informal communications prior to them looking in NMED. The NRC should work in conjunction with NMED in order to obtain updated information on an event, and should not burden State personnel to double report information.

Response: We appreciate and acknowledge this comment; however this comment is outside the scope of the revision of this procedure. No changes were made to the procedure or handbook in response to this comment.

Comment 21: Handbook, Section 3.2 - Add a statement(s) at the end of the section clarifying that if an event is not designated as “complete” it does not indicate that there is a need for further investigation because the information may be impossible to obtain. For example, if a source is melted, it may be impossible to retrieve a source serial number, but there would not be a need for further investigating (i.e. the record would be considered closed by the state, but not complete).

Response: We appreciate, but disagree with this comment. The term “closed” is described in Section 3.1 of the handbook and should be used for the circumstance described in this comment. No changes were made to the handbook in response to this comment.

Comment 22: Handbook, Section 4.1 - Many of the initial reports that Texas makes to NRC Headquarters are preliminary, and due to certain circumstances, the publication of an Event Notification by the NRC may need to be withheld. This section should be amended to include information on how State personnel can request that the NRC not publish certain information in the EN due to the natures of its confidentiality.

Response: We appreciate, but disagree with the comment. For Event Notifications, the Agreement States should try to provide only publicly available information when initially notifying the NRC. If non-public information needs to be provided to meet the requirements for reporting, then the Agreement States should let the NRC know that the information should not be released, and should indicate what information and why it should not be released. Please note that the NRC generally holds the event information for at least 3 business days before it is made public. No changes were made to the handbook in response to this comment.

Comment 23: Handbook, Section 4.2 - Clarify the criteria used by NRC to determine if an event report necessitates a PN by the NRC.

Response: The NRC determines if an event reported by the State meets the criteria for a Preliminary (PN). Also, the NRC (not the Agreement States) prepares and issues the PNs. Since the NRC determines what events should be considered PNs, the criteria for what makes up a PN are not included in this procedure. The criteria that NRC uses to determine if an event report should be made a PN may be found in NRC Inspection Manual Chapter 1120 (i.e., see http://pbadupws.nrc.gov/docs/ML0912/ML091210017.pdf). No changes were made to the handbook in response to this comment.

Comment 24: Handbook, Section 4.2 - The reporting State should be copied on the PN.

Response: We appreciate, but disagree with the comment. NRC does not copy the States on PNs, but the Agreement State is informed if a PN is going to be issued for one of their events. The PNs are published on the NRC website at http://www.nrc.gov/reading-rm/doc-collections/event-status/prelim-notice/. No changes were made to the handbook in response to this comment.

Comment 25: Handbook, Section 4.2, last sentence - Suggest that the scope of allowable inquiry be stated to prevent tying up Agreement States' investigatory staff with frivolousness.

Response: We appreciate, but disagree with the comment. If the NRC request additional information from the State, the information requested is needed for a specific purpose, and should not be considered frivolousness. No changes were made to the handbook in response to this comment.

Comment 26: Handbook, Section 5.1, last sentence - Reword to say "Events of interest include:"

Response: We agree with the comment, but revised the sentence to clarify the types of events are "Generic or Significant" events.

Comment 27: Handbook, Section 5.1., third paragraph (begins "If necessary, NRC…") - Suggest adding language to clarify that NRC staff should be sensitive to the reporting State's personnel time and not burden state personnel with persistent inquiries, subsequently inhibiting the state's response to the incident. Often requests for subsequent information are made by NRC staff before adequate time to conduct a thorough investigation has been allowed.

Response: We agree with the comment and have deleted the third paragraph and clarified last sentence in the second paragraph to address the concern.

Comment 28: Handbook, Section 5.1, fourth paragraph - This paragraph essentially states that it is NRC policy to follow up on events not warranting immediate or 24-hour reporting within 30 or 60 days of the event. This policy seems to be counterintuitive to both the efficient investigatory efforts by the states and the health and safety of the public. Events necessitating immediate or 24-hour reporting are generally more complex and carry greater risk to the health and safety of the public. Therefore, the NRC should allow more time for the states to

conduct their investigations without interruption for these more significant events, rather than the less significant ones.

Response: We appreciate, but disagree with the comment. It should be noted that the NRC understands that some significant events require more time to investigate, however the information on significant events may be needed earlier than 30-60 days in order to ensure appropriate actions have been or need to be taken to prevent such an event. No changes were made to the handbook in response to this comment.

Comment 29: Handbook, Section 6.2, second sentence - Identify the staff who is performing the action (NRC, state, or both should continue to follow-up?).

Response: We agree with the comment. The sentence was revised to indicate that the Agreement States should be performing this action.

Comment 30: Handbook, 6.2, next to last sentence - "States are encouraged to share with NRC and the other States any findings…" Can't States share with NRC who will then share with the other states? Most states, because they aren't allowed to have deficit spending, have limited resources. Furthermore, as the NRC routinely issues Preliminary Notices to all states regarding these types of events. It would be helpful if the NRC described in this section what process is used by NRC to evaluate trends and data before they issue information notices to all states.

Response: We agree with the first point of this comment. The sentence was revised to indicate that the States can provide the information to the NRC and we will share it with all of the Agreement States. The second point of the comment, the process the NRC uses to evaluate trends is outside the scope of this procedure. No changes were made to the handbook in response to this portion of the comment.

Comment 31: Handbook, Section 7.3 - Suggest changing the "shoulds" to a more affirmative word (shall? must?).

Response: We appreciate, but disagree with the comment. The identification of abnormal occurrences (AOs) and the States reporting of AOs is not a regulatory requirement. No changes were made to the handbook in response to this comment.

Comment 32: Handbook, Section 7.4 - Suggest changing the "shoulds" to a more affirmative word.

Response: See response to Texas' Comment 31 above.

Comment 33:`Handbook, Section 7.4 - When reviewing AO's, the State of Texas will not be including patient information that is confidential and not available for release to the public. This section should include a disclaimer stating that information considered confidential should not be included because it will potentially be made public by the NRC.

Response: We agree with this comment and note that NRC does not request or ask for patient information. Section 7.4 was revised to indicate that Agreement States should refrain from providing confidential, personal privacy, and/or security related information unless the information is necessary to describe the AO, and properly mark the event report to indicate that sensitive information has been provided.

Comment 34: Handbook, Section 7.4 - Discussion on AO's does not include a timeframe for submittal of an AO write-up. Suggest inclusion of same.

Response: We appreciate, but disagree with this comment. The NRC has a goal of receiving the AO event information within 30 to 60 days. This time frame falls in line with what is expected for providing event report information. However, we understand that more time may be needed to get the necessary information required for the AO write-up. No changes were made to the handbook in response to this comment.

Comment 35: Appendix A, NRC Regulatory Reporting Requirements Table - The "Brief Summary of Reporting Requirement" correlating to10 CFR Part 20.2201(a)(1)(i) is incorrect. The rule specifically states:

> Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that **it appears to the licensee that an exposure could result** to persons in unrestricted areas.

Essentially there are two criteria presented in the rule that must be met in order to necessitate immediate reporting. The material must be both 1,000 times greater than the appendix C quantity and it must pose a risk of exposure to those in unrestricted areas. On occasion, it has been determined that a device containing a quantity of radioactive material greater than 1,000 the appendix C value has been lost. Yet, because the device is designed in such a way that the likelihood of exposure to persons is minimal, it does not necessitate immediate reporting. Therefore, this field should be changed in the table to properly represent the rule that it cites by including both criteria.

Response: We agree with the comment, and the procedure was revised accordingly.

Comment 36: Appendix A, NRC Regulatory Reporting Requirements Table - The "Brief Summary of Reporting Requirement" correlating to10 CFR Part 20.2201(a)(1)(ii) is incorrect. The rule specifically states:

> Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in appendix C to part 20 that **is still missing** at this time.

Essentially there are two criteria presented in the rule that must be met in order to necessitate 30 day reporting. The material must be both 10 times greater than the appendix C quantity and it must still be missing 30 days after the initial discovery. Therefore, this field should be changed in the table to properly represent the rule that it cites by including both criteria.

Response: We agree with the comment, and the procedure was revised accordingly.

Comment 37: Appendix A, NRC Regulatory Reporting Requirements Table – The "Brief Summary of Reporting Requirement" correlating to 10 CFR 34 Part 31.5(c)(5) should be amended. It has been determined, through informal communications with NRC personnel and obscure NRC guidance documents, that component failures of generally licensed devices are not to be reported within 30-days, as the table clearly states. Rather, these incidents have been determined to be included under the umbrella of 10 CFR Part 30.50(b)(2), requiring 24-hour reporting. Because it has been decided by the NRC that these incidents fall under the 24-hour reporting requirement and not the 30 day one, a reference to 10 CFR Part 30.50(b)(2) should be included in the "Brief Summary" of 10 CFR 34 Part 31.5(c)(5) so that when using this as a reference, State personnel will know to refer to the 24-hour reporting requirement.

Response: We appreciate but disagree with the comment. Defining interpretations of any particular regulation is outside the scope of this handbook. However, for clarity, the text under the 10 CFR 31.5(c)(5) reporting requirement was revised to include references to other reporting requirements Part 21 and 30.

Comment 38: Appendix A, NRC Regulatory Reporting Requirements Table - The "Brief Summary of Reporting Requirement" correlating to10 CFR 34 Part 34.101(a) should be amended. It has been determined, through informal communications with NRC personnel and obscure NRC guidance documents, that industrial radiography source disconnects, inability to retract sources, and component failures of the radiography device are not to be reported within 30-days, as the table clearly states. Rather, these incidents have been determined to be included under the umbrella of 10 CFR Part 30.50(b)(2), requiring 24-hour reporting. Because it has been decided by the NRC that these incidents fall under the 24-hour reporting requirement and not the 30 day one, a reference to 10 CFR Part 30.50(b)(2) should be included in the "Brief Summary" of 10 CFR 34 Part 34.101(a) so that when using this as a reference, State personnel will know to refer to the 24-hour reporting requirement.

Response: We appreciate the comment, however 10 CFR 30.50 is a broad requirement and is not specific to radiography, and 10 CFR 34.101(a) does apply to this type of circumstance. However, for clarity, the text under the 10 CFR 34.101(a) reporting requirement was revised to include references to other reporting requirements in Part 21 and 30.

Comment 39: Appendix C - Is Thomas W. Smith still the correct staff member to receive notices by mail?

Response: We agree with this comment. The procedure was revised to provide the appropriate NRC mailing address to receive notices.

Comment 40: Appendix D - Suggest putting fax number in the grey box at the top of the form for easy reference.

Response: We agree with this comment. The procedure was revised accordingly.

Comment 41: Appendix H, Section II, regarding evaluation of AO reporting criteria *For Commercial Nuclear Power Plant Licensees* - This entire section should be completely removed. If one were to refer to Section II of the procedure titled "Objectives," one would see that the scope of this document is clearly "to provide guidance for use by the Agreement States on reporting [radioactive] material events to NRC" and "to provide guidance to NRC staff in the collection, coordination, and preliminary review of [radioactive] material events reported by the Agreement States." Because Agreement states do not have regulatory authority over nuclear power plants, they would not be reporting events involving their incidents. Ere go, this section is superfluous and should be removed.

Response: We agree with this comment. The AO criteria have been completely removed from the procedure, and the procedure now references the Abnormal Occurrence Report to Congress (NUREG-0090) website for the AO criteria.

Comment 42: Appendix H, entire set of AO criteria - Through informal communications with NRC personnel, it has been learned by the State of Texas that the criteria used to evaluated AO's is derived from information presented in the Nuclear Regulatory Commission Guides (NUREG's). Texas has also learned that AO criteria is periodically updated in the NUREG's, however, it is neither kept current in the SA-300 document nor are the states informed by the NRC when the information in the NUREG's changes. Hence, the failure to report an event as an AO can result because State personnel may not be aware that the accurate information is actually kept, or that it has been updated in the NUREG's. Consequently, it is recommended that, while the examples and templates should remain in the SA-300 document, the specific criteria used to evaluate AO's be completely removed from the SA-300 document, and that information be replaced with the specific references to the appropriate NUREG's.

Response: We agree with the comment. See response to Texas' Comment 41 above.

Comment 43: A general comment to NRC staff reviewing events reported by Agreement States to NMED. It has been learned by the State of Texas, that after a report has been submitted to NMED, NMED personnel change the reporting requirement the state personnel have cited based on instructions established for them (NMED personnel) by the NRC. While it is understandable that human error may yield some clerical mistakes in citing the correct reporting criteria, by allowing NMED to change the citation without notification to the Agreement State personnel, Agreement States may appear to not report events within the correct reporting timeline. For instance, if State personnel were to report something under what they thought was a 30-day reporting timeline, but it had been determined by the NRC that they were going to include these types of events under a 24-hour reporting timeline, NMED could change the reporting citation without notification to the reporting state's personnel. Because NMED would not notify the reporting entity, the reporting state would not know that they were reporting the event

using the wrong reporting timeline. However, had NMED notified the State personnel that the reporting citation would be changed in NMED because NRC had chosen to include these events under the 24-hour reporting timeline instead of the 30-day one, the aforementioned, hypothetical state could have starting inquiring sooner into the matter. This would have subsequently allowed the state to more readily correct their event reports. Therefore, NMED should not be allowed to make changes to the reporting criteria of a reported incident without notification to the Agreement State person reporting the incident for resolution.

Response: We appreciate and acknowledge the comment; however the comment is outside the scope of the procedure and handbook. No changes were made to the procedure or handbook in response to this comment.

Comment 44: In the email dated March 10, 2010, Texas provided 63 comments. The following comments were considered editorial in nature, Comments 5, 6, 7, 8, 9, 10, 13, 14, 15, 17, 21, 25, 26, 28, 44, 45 48, 50, 51.

Response: We agree with the majority of the comments (excepting only comments 13, 21, 25, and 50). The procedure was revised accordingly.

OREGON

Comment 1: Section III.A – Add text, "…the Agreement States, report, to NRC those incidents and events reported to them by their licensees, or other reporting party that involve the use of nuclear materials."

Response: We agree with the comment, however the text was revised to use "or non-licensees," instead of "other reporting party," for additional clarity.

Comment 2: Section V.C.4(a) – Add/remove text,
"…for additional information on events that ~~pose or could~~ pose risks to health and safety, security and~~/or~~ the environment."
"…a few days of notification of the event occurrence ~~of the event~~ based on the safety significance."

Response: We agree with portions of this comment. In some events there may be sufficient information to suggest a possible risk; however additional information is needed to make that assessment. The words "could pose" have been retained to illustrate that in some cases, NRC may be asking for additional information to clarify such a situation. The procedure was changed to reflect the remaining portion of your comment to change "occurrence of the event" to "event occurrence."

Comment 3: Handbook, Section 1.3 – Add/Remove text,
"Agreement States shall~~should~~ report to NRC all events reported to their s~~S~~tate by reporting parties ~~State licensees~~ following ~~under~~ s~~S~~tate regulations equivalent to NRC's reporting requirements.

"~~The~~ States are encourages to voluntarily report an occurrence that the s~~S~~tate believes might be of safety significance, generic interest or concern, ~~or~~ involves media interest, (event if that occurrence is not able to be tracked to a specific reporting requirement). These can be occurrences that actually happened (event) or occurrences ~~something~~ that may happen…"

"…this type the s~~S~~tate should identify the situation and provide…"

Response: We agree with portions of this comment. The term "should" was replaced with "shall" for the first sentence in Section 1.3. The text was revised to address Oregon's comment regarding who reports event information to the States. The capitalization of "State" is consistent with the NRC style manual and was not changed.

Comment 4: Handbook, Section 2.1 – Add/Remove text,
"Agreement States shall~~should~~ report required events ~~requiring notification~~ within 24 hours to the NRC Operations Center."

"Information ~~should be~~ is initially reported…"

"…An example of a ~~fax~~, facsimile page…"

"States ~~should~~ assign an Event Report Identification Number for ~~to~~ each reportable event."

"…event information to ~~that should~~ be provided for completing ~~to complete~~ an event report."

"…please provide as much information ~~as is known~~ possible at the time…"

Response: We agree with one portion of the comment, but disagree with the remaining suggestions. The term "should" was replaced with "shall" for the first sentence in Section 2.1. Note, for the first sentence in the comment, the term "required events" cannot be used for this sentence as all "required events" are not required to be reported within 24 hours. This clarification has been added to the text. The term "fax" is a commonly used term and therefore was not changed to "facsimile." We did not change the wording regarding completing an event, to acknowledge the fact that although the goal is to have this set of minimum information in an event report, it is possible in some cases that all of the information will not be able to be obtained. The remaining editorial suggestions were not adopted in the handbook.

Comment 5: Handbook, Section 2.1 – Should the term incident or event be used in the sentence, "Follow-up information for the event (incident or event?) may also be provided…"

Response: We appreciate the comment; however NRC regulations use the term "incident" and "event" interchangeably throughout the regulations. Both terms are used in this procedure. No changes were made to the handbook in response to this comment.

Comment 6: Handbook, Section 2.6 – Remove text
"…material of all types ~~(including non-AEA and unlicensed material)~~ found in both…"

"…Reporting Material Events~~"~~ to report any lost..."

Response: We appreciate but disagree with the comment This clause in the text makes it clear that "material of all types" includes not only byproduct material but also any non-AEA material or unlicensed material. No changes were made to the handbook in response to this comment.

Comment 7: Handbook, Section 5.1 – In reference to "significant impact on ~~public~~ health and safety…", clarification needed to state who's safety/health is addressed in that statement.

Response: We agree with this comment and have revised the handbook to keep "public" health and safety throughout the handbook.

Comment 8: Handbook, Section 5.1 – Add/remove text

"NRC staff will ~~may~~ contact an Agreement State~~s~~ for additional information…"

"…safety, security, and~~/or~~ the environment."

"…or a designee will ~~may~~ contact an Agreement State~~s~~ for additional event…"

"…for follow-up information will ~~may~~ also be sent routinely…"

Response: We appreciate but disagree with the comment. The word "may" instead of "will" is used because NRC staff does not contact Agreement States for every event that is reported (e.g., depends on the information that is already provided by the Agreement State). No changes were made to the handbook in response to this comment.

Comment 9: Handbook, Section 6.1 – Add/remove text

"Agreement States will be responsible to ~~should~~ review events occurring within their jurisdiction, or ~~related to~~ products registered in their jurisdiction, ~~to identify any events that may involve generic concerns or issues, or could have significant impact on health and safety, security, and/or the environment~~."

Response: We appreciate but disagree with the comment. This text is to emphasize to the Agreement States that they should also be reviewing events for generic concerns or issues, or events that could have significant impact on public health and safety, security, and/or the environment. No changes were made to the handbook in response to this comment.

Comment 10: Handbook, Section 7.4 – Add/remove text,

"...indicate whether or not the s~~S~~tate was satisfied..."

"...enforcement actions, penalties given to the licensee ~~and/or individual(s~~) or their agents."

"...identified as open if the s~~S~~tate expects additional action(s).."

Response: We appreciate but disagree with the comment. The use of the word "individual(s)" is consistent with NRC's regulatory scheme and appropriate as the term "agent" can have different meanings, which would not apply in this case. No changes were made to the handbook in response to this comment.

Comment 11: In summary, the majority of the comments contained in the document from Oregon were editorial in nature.

Response: We agree with some of the editorial comments. Where it was appropriate and consistent with the style of FSME procedures, the procedure and handbook were revised.

II. **Sent to the NRC Offices for Comment**: January 12, 2010

Comments/Dated:

Region III – 2/19/2010 (email)
Region IV/Staff A – 3/11/2010 (email)
Region IV/Staff B – 3/11/2010 (email)
OGC – 1/25/2010 (email)
NSIR – 3/23/2010 (email)
NSIR/DPR – 2/20/2010 and 3/23/2010 (email)
FSME/DWMEP – 1/13/2010 (email)

FSME/MSSA/LB – 2/4/2010 (email)
FSME/DILR/ILB – 2/22/2010 (email)
FSME/DILR – 2/19/2010 (email)

Response to/Resolution of Comments:

REGION III:

Comment 1: Handbook, Section 2.4 (and elsewhere) - States are instructed to submit reports to the RMSB Branch Chief or directly to NMED. Suggest rewording this instruction to promote direct input into NMED, as this is a more efficient methodology.

Response: We agree with this comment. Only reports that are not electronic should be provided to the RMSB Branch Chief. All other reports should be provided to NMED directly via the local Agreement State software to the "Upload" function on the NMED website. The procedure has been revised to clarify this point.

Comment 2: Handbook, Appendix B "Examples of Reportable Events" - Suggest removing the teletherapy unit malfunction example and replacing it with a more frequent type of event, such as an industrial radiography source retraction failure.

Response: We agree that a different example should be used instead of a teletherapy event. The handbook was revised accordingly.

Comment 3: Handbook, Appendix I "Sample AO Write-Ups" - Example 2, second paragraph, fifth sentence, change "prescribe" to "prescribed"

Response: See response to Texas' Comment 41 above. This appendix has been removed from the procedure, and now NUREG-0090 (AO Report to Congress) website is referenced for examples of AO write-ups.

Comment 4: Handbook, Appendix I "Sample AO Write-Ups" - Suggest that another Abnormal Occurrence example be included, for a seed implant medical therapy event, which has been a commonly seen type of Abnormal Occurrence.

Response: See the response to Region III's Comment 3 above.

Comment 5: Handbook, Appendix J "Glossary of Terms and References" - The definition of "RSAO" includes a reference to the now defunct Office of State and Tribal Programs.

Response: We agree with this comment. The procedure was revised accordingly.

REGION IV/STAFF A

Comment 1: Recommend that the AO Criteria web site be listed in the procedure rather than the actual document. This way the latest criteria will be available for use.

Response: We agree with the comment. See response to Texas' Comment 41 above.

REGION IV/STAFF B

Comment 1: For at least the last two years Region IV has not used the PN process to update event information. We have asked the States to update the HOO instead of using a PN. This not only updates the actual event notifications, but it receives wide distribution. We request that the State update the HOO, make sure they are aware it is not a requirement, and also ask them to include the HOO on the NMED closure of an event when they make that closure by email. The HOO then updates the EN and again widely distributes it. Is it possible to formally use this approach instead of using PNs?

Response: We appreciate the comment, however; PNs should be handled differently than an EN. See the response to Texas' Comment 23 above. No changes were made to the handbook in response to this comment.

Comment 2: On the table on Pages 21-24, should we include reporting requirements for the new Part 37?

Response: We appreciate, but disagree with the comment. 10 CFR Part 37 has not been published as of the date of this document. No changes were made to the handbook in response to this comment.

Comment 3: States often don't realize what exactly falls under 10 CFR 30.50(b)(2) and what should be reported under this regulation (it's not clear). You should include a subheading under this section (clearly indicating these reports are examples under 10 CFR 30.50) to show what 30.50 reporting mean to NRC.
Some examples include:

(1) Gauge Shutter Malfunctions
(2) Gauge Shielding Failures
(3) Radiography Source Disconnects
(4) Radiography Cameras Failing to Fully Retract (INC Camera Issue) to the fully shielded position.

Response: We appreciate but disagree with the comment. Defining interpretations of any particular regulation is outside the scope of this handbook. No changes were made to the handbook in response to this comment.

Comment 4: In the medical report examples, get rid of medical events involving teletherapy units. Nobody has these any longer and we never receive reports involving these treatment units.

Response: We agree with this comment. See the response to Region III's Comment 2 above.

OGC

Comment 1: Handbook, Section 2 – Clarify the discussion of what it terms the "immediate" reporting requirements. The actual requirement (e.g. 40.60(a)) states that specified events should be reported to NRC no later than 4 hours after discovery. Doing so will better distinguish Section 2 from Section 2.1, which discusses events that must be reported within 24 hours after discovery. Provided this comment is addressed, OGC has NLO to the subject guidance.

Response: We agree with the comment. The term "immediate reporting" was removed and the handbook was revised to state events requiring reporting "within 24 hours."

OFFICE OF NUCLEAR SECURITY AND INCIDENT RESPONSE (NSIR)

Comment 1: Added paragraph to 2.1 – "If these events meet the criteria for transmittal to the IAEA under its International Nuclear and Radiological Event Scale (INES), then the FSME coordinator will work with the U.S. National Officer for INES (an NSIR staff member) to develop an Event Rating Form (ERF) for the event for subsequent approval and transmittal to IAEA (see section 2.3). Any updated information should be subsequently provided in follow-up reports (see Section 2.6)

Response: We agree with the intent of the comment. Section 2.6 was added to the procedure to capture the Agreement States role for reporting events to INES. Portions of the above comment were used for drafting this section of the procedure as appropriate.

Comment 2: Red line changes provided in draft document - Added some text on INES as a new Section 2.3. NRC is also required to send this in to IAEA within 48 hours (using the 24 hour reporting requirement they have to NRC, but that level of detail is not provided here). The FSME policy & procedure was referenced and the website address for the User's Manual was provided. I didn't provide the references for the All Agreement State letter or the IN that went out last year to the States on use of the INES scale. This info may also be added to App A and C. The table of contents has been updated to reflect the new section.

Response: We agree with the intent of the comment. See Response to NSIR Comment 1 above.

OFFICE OF NUCLEAR SECURITY AND INCIDENT RESPONSE/DIVISION OF PREPAREDNESS AND RESPONSE (NSIR/DPR)

Comment 1: Section V.C.4.b – Add to the end of the paragraph: In addition, the NRC Headquarters Operations Officer may contact the Agreement State for clarification or additional information relevant to the 24 hour reports submitted to the Operations Center.

Response: We appreciate the comment, but note that Section V.C.4.a. addressed this comment by saying, "NRC staff may contact the Agreement States for additional information …" However, Section V.C.4.a. was revised to specifically mention that NRC's Operations Center staff could contact the Agreement States. Section V.C.4.b. was not revised as the NRC Headquarters Operation Officer is not generally notified of events that are not considered to pose a risk to public health and safety. No changes were made to the procedure in response to this comment.

Comment 2: Handbook, Section 1, paragraph 1, line 7 - Add "radioactive" between "of" and "material."

Response: We agree with intent of this comment; however the word "nuclear" was used. See the response to Washington's Comment 1 above.

Comment 3: Handbook, Section 1.1, paragraph 2, line 4 - Delete s in https:

Response: We agree with this comment. The procedure was revised accordingly.

Comment 4: Handbook, Section 2.3, paragraph 1, line 3 - Add to the end of the first sentence: "in accordance with the National Response Framework and the Nuclear Radiological Incident Annex." Delete the rest of the paragraph.

Response: We agree with the comment however this paragraph/section (now Section 2.5) was completely revised to include NRC's current role in the National Response Framework.

Comment 5: The document should recognize that the HOO may call the Agreement State if they need additional information to complete the Event Notification.

Response: We agree with this comment. Where appropriate, the procedure was revised.

Comment 6: Region 4 has started requiring the Agreement States to report events that the State does not feel is reportable but falls into our suspicious activities (SID) reporting criteria. These suspicious activity reports (SIDs) have been going on for several years in the reactor and some NMSS facilities. Staff indicated that SA-300 requires this reporting. I am not sure that the NRC has worked out a process for handling SID reports from the Agreement States and that the NRC has explained the process requirements to the States.

Response: We appreciate the comment; however it is outside the scope of this procedure and handbook. SA-300 is a procedure and therefore it cannot be used to require the Agreement States to report SIDs. The reporting of SIDs is not a matter of compatibility or is a regulatory requirement at this time. Therefore, the States cannot be required to report these events. At this time, the NRC has not provided specific guidance for reporting SIDS. No changes were made to the procedure or the handbook in response to this comment.

OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL PROGRAMS/DIVISION OF WASTE MANAGEMENT AND ENVIRONMENTAL PROTECTION (FSME/DWMEP)

Comment 1: Based on this revision, FSME/DWMEP has no role in any Agreement State notification of any Materials event. That may not be accurate 100% of the time. DWMEP suggests that you add to Section IV – Roles and Responsibilities – under Paragraph B that the RMSB BC will also coordinate with other FSME organizations (or other text that accomplishes the same idea), which is similar to what is already in Paragraph B as the RMSB BC coordinating with NMSS, NSIR, RES, and NRC Regions. (As always, the coordination is “as appropriate” based on the event being discussed.)

Response: We agree with this comment. The procedure was revised accordingly.

OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL PROGRAMS/DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS/LICENSING BRANCH (FSME/MSSA/LB)

Comment 1: There have been some ongoing issues regarding reporting certain radiography equipment events under both 30.50(b)(2) and 34.101. 34.101(a) states, "In addition to the reporting requirements specified in § 30.50 and under other sections of this chapter, such as § 21.21...." HQ has taken the position that if a radiography source cannot be secured in its fully shielded position, or a component (critical to safe operation of the device) fails to properly perform its intended function which results in the source not being secured in its fully shielded position, it meets the 30.50(b) twenty-four hour reporting requirement. I would suggest that the SA-300 revision should make clear, perhaps in Appendix A, this connection between the reporting requirements and, perhaps, include an example in Appendix B. I would also suggest you perhaps consider revising

Appendix A to include other similar cross references, for example 34.101(b) requires that the information specified in that paragraph be included in any report of an overexposure submitted under 10 CFR 20.2203 when it involves failure of radiography equipment safety components.

Response: We agree with this comment. See the response to Texas' Comment 38 above.

OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL PROGRAMS/DIVISION OF INTERGOVERNMENTAL LIAISON AND RULEMAKING/INTERGOVERNMENTAL LIAISON BRANCH (FSME/DILR/ILB)

Comment 1: Handbook Section 7.2 (second paragraph) - The sentence that begins with "As specified in Section 208…" was a bit confusing to me. It seems inconsistent to have a limit of "15 days" as well as "as soon as possible" in the same sentence and that the sentence should end after "…public as reasonably possible."

Response: We agree with this comment. The procedure was revised accordingly.

OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL PROGRAMS/DIVISION OF INTERGOVERNMENTAL LIAISON AND RULEMAKING (FSME/DILR)

Comment 1: Isn't the AO reporting criteria Management Directive (8.1) being revised? Just wanted to ensure consistency – also the MD is only mentioned in the reference appendix and not within the text.

Response: We agree with the comment. Management Directive 8.1 has been revised. We have ensured that the information provided in this text is in line with the revised management directive. Also, the management directive was reference in the introduction of Section 7.1 of this handbook.

Comment 2: Handbook, Section 7.2, paragraph 3 - The sentence that begins "As specified" is a little awkward.

Response: We agree with the comment. The sentence has been revised.

Comment 3: Several of the comments contained in the document from FSME/DILR were editorial in nature.

Response: We agree with the majority of those comments. The procedure was revised accordingly.