STP Procedure SA-300, Reporting Material Events

Sent to Agreement States (STP-05-064), Regions and NMSS for comment: August 30, 2005. Minor editorial comments received from the Regions, OGC, NSIR, and NMSS were made to the procedure, as appropriate, and are not documented in this comment resolution paper

Event Reporting Procedure

1. Section III. *"Background"*

   Comment: Insert, "The reported information is critical for initiating a timely and effective response to security-related events." (NSIR)

   Response: The section has been revised as suggested.

2. Section I.V. *"Roles and Responsibilities"*

   Comment: Section I.V.F., Last sentence, add "and NMSS" after STP. (Region I)

   Response: NMSS has been added to Section I.V.F., "Roles and Responsibilities."

   Comment: Discuss the role of NSIR. In particular, add to item A: "The NSIR's Operations Center receives notifications of significant events. NSIR staff participates in review and evaluation of security-related material events." (NSIR)

   Response: The suggested text was added.

3. Section V.B.1. "*Reports of Significant Events Received from Agreement States by Phone"*

   Comment:

   a. This guidance suggests that an Regional Agreement State Officer (RSAO) inform three people (Project Manager, Director and Deputy Director) of an event. One point of contact should be adequate. *(*Region III*)*

   b. Who is the Project Manager? What project does this refer to? (NMSS)

   Response: The intent of informing the Event Project Officer (or her backup) and Director and Deputy Director is to ensure that all involved parties are fully informed of significant events. Note: the term *Event Project Officer* was added to more clearly define which project manager is being referred to.

   Comment: Move this [the definition of significant event] to the 1st place the word "significant" is used? (Section IV. b) Also, page 21 defines significant in a different way. Suggest need to define clearly what "significant" means here and not use the term on page 21, if it means something different there. Then throughout document, check uniform use of the term "significant." Suggest replacing phrasing of "requiring 24-hour notification" to "requiring notification within 24 hours" since there could be some confusion as to the exact meaning of the first phrasing. (NMSS)

Response: Section V.B.1 is the first place the word significant is used, as such, *significant* is appropriately defined at this location. We agree with your “phrasing” suggestion and will define “significant” consistently throughout the document.

4. Section V.B.2. *“E-mail, FAX, or Written (Hard Copy) Event Reports”*

   Comment: The "NRC Operations Center" is the group. The "Headquarters Operations Officer" is the individual. In 10 CFR, the direction is to make reports to the "NRC Operations Center." Suggest the use of Op Center and HOO throughout the document be checked to ensure appropriate use. (NMSS)

   Response: We agree with this comment and will revise SA-300, accordingly.

5. Section V.B.3. *"Electronic Event Reports"*:

   Comments:

   a. References to "PC Diskette" should be changed to "electronic storage media" since computer disks are used less in favor of compact disks. (Region I)

   b. Electronic event reports may be submitted on CDs as well as the media indicated. (RIII)

   Response: Section V.B.3. has been revised, adding the new reference.

6. *Section V. B.4 "Event Review for Safety Significance and Identification of Possible Generic Concerns":*

   Comment: This section should be modified to reflect that States are requested to update NMED on a monthly basis until the event is closed. *(*Region I*)*

   Response: Section V.B.4.c. has been modified reflect monthly updates, as requested.

   Comment: The term “LER” is not normally used by States and should be eliminated from the procedure. (Region III)

   Response: We agree with the comment, and procedural references to “LER” in section V.B.4.c. has been eliminate and replaced with “*Event Report*.”

   Comment: In section V.B.4.c., replace “...receipt of the initial record.” with, “...the date it was reported to the regulatory agency.”

   Response: The section has been revised as requested.

   Comment: In section V.B.4.d., add "the Region" to those offices that participate in the identification and review of potential AO events. (Region I)

   Response: We agree with the comment, the section has been revised to include the Regions.

Event Reporting Handbook

1. *"Abstract"*

Comment: Although we have been standardly changing occurrences of "misadministration" to "medical event" in all NRC documents, given that the audience is Agreement States, consider whether to continue use of the term "misadministration" to accompany the term "medical event" throughout the document. Given use of the term "medical event" is a category D compatibility item, the Agreement States are not required to adopt the word "medical event" and may choose to continue using the term "misadministration." (NMSS)

Response: The intent of this comment is valid. However, for Agency consistency, the term *"medical event"* will be used in SA-300. No changes will be made to the procedure based on this coment.

Comment: Insert "…safety- and security-significant events". (NSIR)

Response: Inserted, as requested.

2. *Section 1. "Introduction"*

Comment: The first use of the acronym "NARM" should be eliminated. (Region III, NMSS)

Response: The section has been revised as suggested.

3. *Section 1.1 "Why do we collect event information?"*

Comment: This section should be modified to indicate that event information is reported to Congress annually and used to demonstrate that the agency and the States are meeting the safety and security goals and the corresponding strategic outcomes in the NRC's strategic plan. (Region I)

Response: Modified, as requested.

4. Section 1.5 *"Reporting Lost, Stolen and Abandoned Sources"*

Comment: Reverse order of paragraphs 1 & 2. 10 CFR 20.2201 requirements pre-date 9/11/01 however the current structure of this section makes it read as if 20.2201 was in reaction to 9/11. (NMSS)

Response: We agree with this comment and will re-arranged the order of paragraphs 1 and 2 in Section 1.5.

5. *Section 1.6 "Reporting Theft or Terrorist Activity Events"*

Comment: Section 1.6 should be clarified to indicate if the State should (or it is really "shall") contact their local FBI office, FBI Headquarters, another FBI group, or their local law enforcement agency (LLEA). In the past, there have been occasions where the State contacted their local FBI office or LLEA but NSIR and/or FBI Headquarters felt that this was not adequate. (Region I)

Response: Section 1.6 was revised to reflect guidance that Agreement State Agencies are required to immediately report events to the NRC Operations Center involving high-risk sources in *quantities of concern* that exceed the International Atomic Energy Agency's (IAEA) Category II thresholds. This includes intentional use of radioactive materials that could be used in an unauthorized malevolent manner that could to serious consequences (including theft or terrorist activities) to the FBI. Agreement States should coordinate with the NRC, their communications with other local, Federal and State Agencies, to ensure that shared information is accurate and consistent.

Comment: Add to the FBI notification section: "The NRC Operations Center should also be notified immediately of any actual or attempted theft, sabotage, or diversion of "risk-significant" radioactive material or devices." (NSIR)

Response: Section 1.6 was revised to addressed actual, attempted theft, sabotage, or diversion of "risk-significant," also referred to as high-risk sources in *quantities of control*.

Comment: The handbook should provide clear direction regarding the type and at what quantity of material the State shall contact the FBI. Is it an environmental standard of Pu-239; portable gauge; shipment of I-125 seeds for a single prostate procedure; Mo-99/Tc-99m generator; or only those isotopes and quantities that are of concern (i.e., IAEA Category 2 sources or higher)? In all examples above, the State was asked by the NRC if they had contact the FBI. (Region I)

Response: According to NSIR, Agreement State Regulatory Agencies should notify the FBI in all cases of actual theft, sabotage, diversions and possible terrorism of radioactive material, regardless of the quantity of involved. And, Agreement States are required to notify the NRC Headquarters Operations Center immediately in any event involving source quantities equal to or in excess of IAEA Category II sources and in all cases involving theft or terrorist activity. A list of those sources containing radioactive material quantities of concern can be found in Section 1.6 (Table 3, Radionuclides of Concern) and in Appendix P to 10 CFR Part 110, "High-Risk Radioactive Material, Category 2." Sections 1.5 and 1.6 outline event reporting guidelines concerning high-risk sources. See also comment above.

6. *Section 2.2, "Initial NMED Record for Significant Events"*

Comment:

a. The example event ID numbers used throughout the handbook appear to be inconsistent with the description which requires an eight digit number. (Region III).

b. Insert and cross-out suggested NMSS describing Event Identification Numbers. (NMSS)

Response: We agree with the comments and revised Sections 2.2 and 2.4 describing the Event Identification Number, for consistency.

7. Section 4, *"NRC Publication and Distribution of Event Notifications"*

Comment: Modify section 4.1, "Event Notifications (ENs)," to indicate that the NRC will withhold Agreement State reports from public release for at least 48 hours. (Region I)

Response: Section 4.1 has been revised accordingly.

Comment: Section 4.2, *"Preliminary Notifications*." Preliminary notifications are normally issued the same business day of the notification (or next business day if reported after hours or on the weekend), not within two hours. (Region I)

Response: Section 4.2 has been revised accordingly. (Region I)

8. *Section 5.1,* "*NRC Review of Material Events for Safety Significance and Generic Assessment"*

Comment: The last two paragraphs distinguish between significant and non-significant events and indicate that NRC staff may contact the State for significant events and the RSAO may contact the State for non-significant events. This contradicts Section I.V.F. of the procedure which indicates that the RSAO is the principal point of contact for the State. States have consistently given feedback to the NRC that they want one point of contact for the NRC since it is common for multiple NRC offices to contact the State for information or updates regarding a particular event. These two paragraphs should be simplified to provide one point of contact for the State regarding event information coordination. (Region I)

Response: Section 5.1 was revised to show that the RSAO will normally contact the Agreement States for event follow-up action.

Comment: Security related events would be reviewed by NSIR's Division of Nuclear Security. Strike "materials" from "NRC materials staff." (NSIR)

Response: We agree with the comment and have deleted *"materials"* from the sentence.

9. *Section 5.2, "Followup Review of 'Significant' Events"*

Comment: The title of this section should be modified to reflect that the paragraph discusses the actions that the NRC may take in response to a significant event. *Region I*

Response: The title was revised, as requested.

10. *Section 6, "Abnormal Occurrence Guidelines and Criteria"*

Comment: In light that the AO criteria will be revised in the near future and few events out of the hundreds of events reported annually by the States are AO's, this section should be modified as follows: (Region I)

a. Delete Section 6.2 since it provides only additional information.

b. Delete pages 25-35.

c. Add references directing States to refer to Management Directive 8.1 on the NRC and STP web sites for AO criteria and writeup information.

Response: The intent of the comments are valid. However, for quick reference to the Agreement States, the AO criteria is included with SA-300 since the section provides guidelines for reporting events classified as AOs. Section 6.2 provides the regulatory statute for AO event reporting and deleting pages 25-35 would delete the criteria from SA-300 in it's entirety. For these reasons, no changes were made to the procedure in response to items a and b. Regarding item c. the procedure will refer the States to ADAMs and the NRC public website for the current AO criteria and write-up information.

Comment: Ensure that the abnormal occurrence criteria is consistent with the approved recommendations of the AO working group, including the gonadal exposure identified in items 1.A and IV and new language proposed to capture significant security events. (RIII, NSIR)

Response: As per SRM-SECY-05-0137, dated October 24, 2005, the Commission approved the proposed revised AO criteria and has directed the staff to publish the revised criteria for public comment. After final Commission review of the new criteria, SA-300 will be revised.

Comment: It appears that the AO Criteria, as stated in the NRC's Handbook on Nuclear Material Event Reporting in the Agreement States (dated April 24, 2001) and Draft Revision (dated August 30, 2005) for Medical Licensees has not kept up with the changes to 10 CFR 35, specifically, 10 CFR 35.3045(a)(3).

The AO criteria defines a medical misadministration as an event that results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; and represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical, or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

10 CFR 35.3045(a)(3) requires report and notification of a medical event when a dose to the skin or an organ or tissue other than the treatment that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive. Also, the NMED data entry requires the fields entitled "% Dose Exceeds Prescribed" or "% Dose Is Less Than Prescribed," these fields do not accurately reflect the event reported. [Refer NUREG/BR-0117, No. 05-02, July 2005; article entitles, "Understanding 10 CFR 35.3045(a)(3) Wrong Treatment-Site Reportable Medical Event.]

STP-05-064, Opportunity to Comment on the Draft Revision to STP Procedure 300, "Reporting Materials Events (August 30, 2005), for medical licensees under AO Criteria proposes only to change the word "misadministration" to "event." (Utah)

Response: The intent of this comment is valid. However, medical events and AOs are not the same and are not defined by the same thresholds. A medical event could be classified as an AO if it exceeds specific criteria as established by Section 208 of the Energy Reorganization Act. Separately, 10 CFR Part 35 outlines the requirements for medical event classification and reporting. Because medical events and AOs are defined by different regulatory statutes, the two cannot be combined for one classification. For these reasons, no changes will be made to the procedure which would change the definition of an AO. See also, the response above regarding SRM-SECY-05-0137.

Comment: All three examples are medical events. Consider including a non-medical event to show the difference between the kinds of details included in a report related to medical use vs. industrial use. (NMSS)

Response: All three events are <u>not</u> medical events. The first event is a nuclear pharmacy overexposure and is classified as an AO event under criterion I.A.1., “Human Exposure to Radiation from Licensed Material.” Radiography events would also be classified under the same criteria. No additional examples of AOs will be provided based on this comment.

11. *Glossary*

Comment: Replace "DPC " with ADAMS. There are also a number of terms missing that should be added including: AO, INL, CRCPD, AEA, ERA, FBI, NRP, STP etc. (Region I)

Response: We will insert ADAMS in the glossary, the remaining terms are already defined within the text of SA-300, as they are mentioned, and will not be added to the glossary.

12. Table 1,"Regulatory Reporting Requirements"

Comments:

a. The *“Significant Reporting Category”* is defined as reportable within 24 hours to the Operations Center, but on pages 16 & 17 have 5-day reports listed in this column (and a 5-day report in 30-60 day column). (NMSS)

b. Suggest changing the “Reporting Requirement” heading to “Brief Summary of “Reporting Requirement” (NMSS)

c. Delete reference to Part 21 reporting requirements. Part 21 is not a matter of compatibility with Agreement States. (NOTE: Region I made an identical comment regarding Part 21 during the previous draft revision of this procedure in 2001) (Region I)

d. The original reference of 34.27(d) is correct. (Region I)

e. Delete reference to 35.67. The reporting requirement is correctly given (i.e., 35.3067) (Region I)

f. Move 39.77(b) to the significant reporting category and change the notification time to 24 hours. (Region I)

g. Change the notification time for 39.77 (c) and (d) to 30 days. (Region I)

h. Move the references for 40.60 and 70.50 to the corresponding 30.50 requirements since the reporting requirements and notification times are the same. Agreement States normally have these requirements similarly combined. Delete references to 40.60 (c) and 70.50 (c), since they specify the contents of the licensee's report. (Region I)

I. Add a new line for transportation, specifically, 10 CFR 71. Section 10 CFR 71.5 references 49 CFR 171.15 which requires the immediate reporting of the following transportation events (Compatibility B requirement): (Region I)

> 49 CFR 171.15 (a)(1) requires the immediate reporting of incidents involving hazardous materials (which include radioactive materials) that result in an individual's death, injury requiring hospitalization, carrier or property damage in excess of $50,000, evacuation of the general public for at least one hour and the closure of one or more major transportation facility or roadway for at least one hour.
>
> 49 CFR 171.15(a)(2) requires the immediate reporting of fire, breakage, spillage, or suspected radioactive contamination occurs involving the shipment of radioactive material.

Response: We agree with the comments, with the exception of the items a. and f. In response to item a, as the referenced in the title, the table contains, "....current 10 CFR material reporting requirements for which Agreement States should have compatible regulations. In reference to item f, the format of the table is to separate all the compatible regulatory citations (e.g., Parts 35, 36, 39, etc.) by rows even if the notification requirement is repeated within another row. No changes will be made to the *Regulatory Reporting Requirement* table based on these comments.

13. *Table 2, "Examples of Reportable Events" (table):*

Comment: Delete the reference to Table 3 in the title. There are no references to Tables 1 and 2 in the handbook. Modify the medical event example to include a device that is currently used for radiation therapy (i.e., Gamma Knife, HDR). Teletherapy units are rarely used any more and have been replaced, usually by linear accelerators. (Region I)

Response: We agree with the comments. However, after re-formatting of SA-300, Table 3 of the handbook remained labeled as Table 2. The examples included in the *Examples of Reportable Events* table were revised to include an HDR event.

Comment: Double check regulatory citation to ensure accuracy with current regulations (NMSS)

Response: The citations were double checked and changed as appropriate.

Comment: Delete the irradiator [event] example. (NMSS)

Response: The intent of the table is to give a variety of examples for reporting similar events. Deleting the irradiator event would decrease the number of examples given. No changes to the table will be made based on this comment.

Comment: The medical event example involving the wrong treatment site needs to state the actual dose to the treatment site so it is clear that the actual dose is delivered to the treatment is greater than the prescribed dose. (NMSS)

Response: The example states that the administration resulted in a partial treatment of the intended site. Given that a partial dose was delivered, the dose to the treatment would be less the prescribed dose. In this example, the focus is the dose to the wrong treatment site. No changes to this example will be made based on this comment.

14. *Table 4, "Minimum Basic Event Information for a Complete Report":*

Comment:

a. This table should be modified to be consistent with other NRC guidance (i.e., IMC 2800). Region I has reviewed and concurs with the changes suggested by the NMED Project Manager. (*Region I)*

b. Add suggested text to Section 3.2. Record Complete in NMED,"*...a specified minimum set of information. This minimum set is defined on the NMED website under "Help."* Note: This [text] change is needed because the table in Section 3 and the criteria that Idaho National Laboratory (INL) is using does not exactly match. NMSS staff is forwarding to STP (separately) a suggested rewrite that could be adopted for both SA-300 Section 3 and for INL criteria. (NMSS)

Response: We agree with the comments, this table was revised to be consistent with Inspection Manual Chapter 2800 and the minimum information necessary for INL to complete NMED record.

15. References

Comment: "FRP" is defined. Should this be "NRP" instead? The FRERP was replaced by the Nuclear/Radiological Incident Annex to the National Response Plan (FRP). (Region I, NMSS, NSIR)

Response: We agree with the comment, the procedural reference to "FRP' was an error.

16. *"Event Reporting Schedule for Agreement States" (Handy Reference)*

Comment:

a. This reference needs to have a reference to Section 1.5 of the Handbook to ensure that the States have adequate background to make the correct and timely notification to the NRC. (Region I)

b. The table on page 44, "Event Reporting Schedule for Agreement States," does not include the immediate 4 hour notification for category 1 and 2 sources, but is

mentioned on page 5 of the "Event Reporting Handbook." We recommend that the 4 hour immediate notification be added to the table. (Region IV)

Response: We agree with the comments, and will revise the *"Event Reporting Schedule for Agreement States," (handy reference table)* to include immediate notifications (within 4-hours).

17. General Comments
Throughout document replace "radioisotope" and "isotope" with the word "radionuclide." (NMSS)

Response: We agree with this comment and will revise the procedure accordingly.

Although, not specifically requested during the comment period, information was added to the Event Reporting Handbook on NRC's Annual Agency Action Review Meeting (AARM). In accordance with SECY-02-216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse License Performance," Agreement State events will be considered, along with other materials licensees, for discussion during the AARM. The revised Management Directive and Handbook 8.14, "Agency Action Review Meeting," describes STP's participation in the AARM and its role as the leader of discussion on Agreement State licensees, as necessary.