



Event Reporting Self-Assessment

Final Report

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Event Reporting Self-Assessment Team

Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission

TABLE OF CONTENTS

	Page
EXECUTIVE SUMMARY	v
Background	
Purpose	
Results in Brief	
INTRODUCTION	1
Review Team Members	
Event Reporting Process	
Scope	
Task Topics	
Analysis and Methodology	
ANALYSIS AND REVIEW RESULTS:	
I. - WHY DO WE NEED TO COLLECT MATERIAL EVENT INFORMATION?	5
II. - HOW DOES NRC CURRENTLY COLLECT NRC LICENSEE AND AGREEMENTS STATES MATERIAL EVENT INFORMATION?	7
III. - HOW DOES NRC MAINTAIN NRC LICENSEE AND AGREEMENT STATE EVENT INFORMATION IN NMED?	12
IV. - SHARING RESULTS OF ANALYSES OF NATIONAL MATERIAL EVENT DATA	15
V.- REVIEW OF GUIDANCE DOCUMENTS AND IMPEP REPORTS TO IDENTIFY EVENT REPORTING CONCERNS	18
VI. - MATERIAL EVENT REPORTING REQUIREMENTS AND THE 2001 EVENT WORKING GROUP REPORT	28
VII. - DISCUSSION/MEETINGS WITH AGREEMENT STATES	32
a. Why do some states operate effectively and others operate with difficulty reporting event information to NRC?	
VIII. - DISCUSSION/MEETINGS WITH NRC REGIONS	35
a. Discuss concerns regarding closing out events and the effectiveness of the current process.	

IX. -	COMPILATION OF GOOD PRACTICES	36
X. -	FINDINGS AND CONCLUSIONS	37
XI. -	LIST OF RECOMMENDATIONS	40
X.	REFERENCE LIST	42

APPENDICES

APPENDIX A:	COMPILATION OF COMMENTS (AGREEMENT STATES AND NRC REGIONS)	45
APPENDIX B:	SURVEY QUESTIONNAIRE	59
APPENDIX C:	2003 NMED TRAINING SESSION ATTENDEE LIST	65
APPENDIX D:	SELF-ASSESSMENT ACTION PLAN	69

LIST OF TABLES

Table 1.	Sample 2002-2003 IMPEP Reviews (Event Evaluations)	22
Table 2.	Reporting Requirements That Reflects Recurring Information Identified as Missing from Event Reports	30
Table 3.	How Current Agreement States Report Events to NRC	33

EXECUTIVE SUMMARY

BACKGROUND

During the past 2 years, while conducting routine IMPEP reviews of Agreement State Programs, staff has placed increased attention and emphasis on Agreement State activities to report complete data on Agreement State licensee events for inclusion in the Nuclear Material Events Database (NMED). Results of these reviews, including recent reviews, indicate that State performance in this area continues to need improvement and that States continue to experience a number and range of difficulties in reporting event data. Representative concerns identified during IMPEP reviews include: variations between the process used by NRC and Agreement States for event reporting; variations in format and content of Agreement State event reports; timeliness in event reporting; and communication of the results of assessments of the data to regulators and licensees. In response, the NRC Office of State and Tribal Programs, in coordination with the Office of Nuclear Material Safety and Safeguards, formed a *Working Group* to conduct a self assessment of the *event reporting process* in February 2003.

PURPOSE

The team was tasked to provide recommendations that would support NRC's efforts to improve the event reporting process to increase timeliness, and ensure that technically accurate and complete material event reports are provided to NRC through an efficient and effective information collection process.

RESULTS IN BRIEF

A number of insights and findings were identified as a result of the assessment as follows:

- Results indicate that eight Agreement State programs submit hard copy event reports, 22 use NMED and submit NMED data e-files, and three submit data from their own database or spreadsheet file electronically to NRC NMED.
- States with the largest number of licensees, California, New York and Texas, do not use an electronic reporting system.
- The current NMED Local Data Entry program (MS Access), is performing satisfactorily and users commented that the program is easy to use.
- A similar process is followed by NRC and the Agreement States to respond, review and/or investigate the occurrence of a material event, conduct an inspection, and collect event information from licensees. The team determined that the process differs regarding the use of direct and indirect resources to compile and code (data entry) the event information into the NMED database. Rather than have NRC staff compile and code material event information into NMED, NRC decided it was more efficient and effective to secure a contractor to perform this function. The Agreement States use their own staff to conduct a similar compilation and summary abstract activity, and, in some instances, coding function for all radiation events, including AEA events, that have occurred under their jurisdiction, and maintain the records either manually, or code the data into their own database, or a Local NMED

database provided by NRC. The State sends the data to NRC; which is then entered into the NMED database by the NMED contractor.

- The event reporting process is working, but processes and support tools need to undergo periodic revisions based on regulatory and technological changes and developments to improve efficiency and effectiveness.
- Agreement States are providing timely notification of significant events, but need to improve quality and timeliness in providing NRC information on the results of follow-up investigations of significant events, such as those that meet the AO criteria.
- Approximately one-half of the Agreement States need to improve notification and timeliness for incidents and events that meet 30-60 day reporting requirements.
- NRC licensee event reporting is comparable to the 40-50% of Agreement States that generally report 30-60 day reportable events monthly resulting in a smaller number of periodic requests for additional or clarifying information.
- Some States are unable to provide monthly event information for the less-significant 30-60 day reportable events due to staffing issues, and/or ineffective or cumbersome internal quality control (Q/A) processes.
- Results indicated a need to revise IMPEP event reporting guidance to increase emphasis on timeliness and completeness of event report data.
- Results support continuing the policy of monthly reporting of 30-60 day reportable events and follow-up reports.
- Recurring requests for additional event information primarily involve requests for the make, model and/or serial number of equipment or a device, the root cause of a specific event or information on corrective actions.
- Specific information required to be reported is not consistent from one part of the regulation to the next; increased consistency and standardization for specific material reporting requirements could improve efficiency and reduce the number of NRC requests for additional event report information in specific areas.
- Results indicate a need to broaden the scope and frequency of periodic event analyses and provide timely distribution to increase communication and discussion of the results between NRC and the Agreement States.
- Tailoring NMED software updates closer to the software companies three year cycle for updating software programs could reduce some of the reported incompatibility problems. Several comments identified incompatibility problems between newer versions of software and older versions of NRC's NMED software program, in the past, that prohibited use of the Local NMED database program.
- Results indicated that the national website, which had not been updated since its inception about 5-6 years ago, could benefit from the inclusion of newer software technological advances. NRC initiated a recent update of the Local NMED database program that incorporated new technological advances and addressed user comments, with good results. NRC recently began a much needed update to incorporate technological advances to the national website NMED program, in September 2003, which is scheduled for completion mid-2004.
- Guidance documents need updating to incorporate rule revisions involving reporting requirements, and any new directives and programmatic or procedural changes related to the event reporting process since the last edition.
- Results indicate a need to explore the use of alternative training methods for NMED to increase the efficiency and effectiveness and address low participation during current traditional training. Alternative methods for exploration include video, CD-ROM, online tutorials, etc. in addition to traditional training methods. This would provide training to Agreement States that are unable to travel out-of-state.

RECOMMENDATIONS

A consolidated list of 16 recommendations is included in Section XI of the report on page 40.

INTRODUCTION

This report presents the results of a self-assessment of the *event reporting process* conducted by the Office of State and Tribal Programs in coordination with the Office of Nuclear Material Safety and Safeguards. The report presents the findings, conclusions and recommendations of the self-assessment team. The executive summary identifies the issues for consideration and assessment, and includes a summary of the findings. The introduction describes the event reporting process; the scope of the review; the tasks to be addressed that were developed based on the action plan, and presents a description of the analysis and methodology used to address the tasks. The report begins with an answer to the question, “why do we need to collect event information?,” followed by a description of the current *event reporting process*. The report also presents the results of discussions/ interview meetings with staff of the Agreement States and NRC Regions to further understand the issues for consideration and assessment. The Self-Assessment Action Plan is provided in Appendix D. The assessment was conducted by the following team members.

REVIEW TEAM MEMBERS

Patricia M. Larkins, Office of State and Tribal Programs, Leader
Terry Brock, Office of State and Tribal Programs
Michele Burgess, Office of Nuclear Material Safety and Safeguards

EVENT REPORTING PROCESS

The *event reporting process* describes the process or result of collecting and maintaining reports of incidents and events involving the operational use of nuclear materials reported to NRC by NRC licensees, Agreement States, and non-licensees. The process encompasses notification, evaluation, follow-up and closeout of radioactive material incidents and events (material events). The operational experience involving the use of material events is evaluated to identify any safety significant events and concerns, and causes. The reported information aids in understanding why the events occurred and in identifying any necessary actions to improve the effectiveness of the nuclear material regulatory program. The reports are recorded and maintained in NRC’s national website Nuclear Material Events Database (NMED), where they are classified based on event reporting requirements defined by Title 10 of the Code of Federal Regulations. To facilitate the collection of radioactive material events from the Agreement States, an NMED database software program was developed in Microsoft Access and provided to the Agreement States for local desktop and local area network (LAN) application as a tool to assist in collecting the information and submitting it to NRC for inclusion in the national database.

The following NRC offices participate in the *event reporting process* as follows; the Office of State and Tribal Programs (STP) participates through its responsibility as the primary contact for policy matters between the NRC and States including event reporting, the Office of Nuclear Material Safety and Safeguards (NMSS) responsibilities for regulation of NRC material licensees includes the assessment of all national material event information, and the Office of Nuclear Security and Incident Response (NSIR) directs the NRC program for response to incidents, and is the agency incident response coordinator providing interface with NRC licensees, the States, and other Federal agencies. *Significant event* notifications (reportable within 24 hours) are reported to the NRC Headquarters Operations Center, managed by NSIR.

SCOPE

The insights and recommendations documented in this report were developed by assessing the event collection and review processes and tools used to report material events (identified above), IMPEP review results, specific material reporting requirements, and event reporting guidance documents. Surveys and interviews were conducted with NRC and Agreement State technical staff involved in the event reporting process to capture more detailed information on actual experience. The team conducted a review of the following areas:

- Variances between the current event collection process for NRC licensees and Agreements States;
- IMPEP review reports of Agreements States and periodic meeting summary reports
- Event reporting guidance, including event reporting schedule;
- Specific regulatory reporting requirements involving recurring requests for information;
- The process used to communicate and disseminate results of event assessments and periodic event report data;
- National website NMED program and Local NMED database program;
- Responses to event reporting surveys and interviews with select NRC staff, and staff of the Agreement States; and
- Event reporting and NMED training.

TASK TOPICS

The following tasks were identified to be addressed by the self-assessment review team.

- Task 1. Document why do we need to collect material event information?
- Task 2. Conduct review of guidance documents and IMPEP reports for FY 2002 and periodic reports for June 2001 - September 2002 to identify event reporting concerns.
- a. Include an evaluation of experience and comments regarding current event reporting procedural guidance including monthly reporting ([SA-300](#)).
- Task 3. Review proposed revisions to Title 10 event reporting requirements identified in the Final Report of the Working Group on Event Reporting, April 2001.
- a. Review Agreement State comments on event reporting requirements
- Task 4. How does the agency maintain NRC and Agreement State licensee event information in NMED?
- Task 5. How do we currently collect NRC licensee and Agreement State material event information?
- a. Analyze NRC Licensee Event Information Collection Process
 - b. Agreement State Licensee Event Information Collection Process (Document and analyze variations between NRC and Agreement State event reporting data collection processes. Include variations in the data reported, format, method

used to report event data (electronic or hardcopy), personnel assigned responsibility to report event information (technical expertise), and process for reporting follow-up or close-out data to ensure a complete report)

- Task 6. Conduct a review of the current processes used to disseminate results of collective assessments and evaluative trending analyses of national material event data, including Generic Safety Issues (GSIs)
- a. Review evaluative analyses of (GSIs) formerly Generic Assessment Panel (GAP)
 - b. Review dissemination of collective assessments (current analyses, evaluations, and standardized reports of event report data for possible changes to ensure they meet regulatory agency and licensee needs)
- Task 7. Conduct discussions/meetings with Agreement States to determine why some States operate effectively and some operate with difficulty reporting event information to NRC .
- Task 8. Conduct discussion/meetings with regional staff regarding event reporting to seek comments on the current process. Document and analyze variations between NRC and Agreement State event reporting data collection processes. Include variations in the data reported, format, method used to report event data (electronic or hardcopy), personnel assigned responsibility to report event information, and process for reporting follow-up or close-out data to ensure a complete report.
- Task 9. Share any insights and recommendations developed as a result of this assessment with the Nuclear Materials Program (NMP) Pilot #3¹ working group for inclusion in their operation experience event evaluation process working group. The NMP pilot No. 3 working group plans to develop and test a joint NRC and Agreement State process for evaluating event report information for generic issues and subsequent regulatory actions.

¹Nuclear Materials Program (NMP) Pilot #3, is expected to examine the operating experience evaluation process and develop strategies and tools to make the processes more credible, predictable, and transparent. The pilot is expected to evaluate the successful and unsuccessful analyses of performance and trends (i.e., that may have led to generic communications) including methods to better communicate lessons learned, the results of evaluations, and insights.

ANALYSIS AND METHODOLOGY

The Event Self-Assessment Team's took the following actions to address the tasks identified above by the assessment team.

To complete the tasks the Self-Assessment team:

1. Reviewed previous event report evaluations, NRC material event publications, and pertinent Federal laws, statutory and regulatory reporting requirements.
2. Examined IMPEP review and periodic meeting reports for the last two years to identify any event reporting issues and concerns.
3. Developed a survey questionnaire to collect information on the format and method used to report event data, reporting schedule, effectiveness of monthly reporting, personnel assigned responsibility, FTE effort, and experience using the NMED Local Data Entry program and the National Website program.
4. Based on the survey questionnaire, the team conducted telephone interviews with staff of 14 Agreement States and all four NRC Regions on the current event reporting process including the NMED program. Interviews were conducted 5/12-6/30/03.
5. Analyzed survey responses and comments and provide responses, recommendations and conclusions to be included as part of the assessment in Appendix A.
6. Developed and presented event reporting training poster and flyer handout at the Organization of Agreement States meeting, held in Chicago, IL, October 14-18, 2003, to increase awareness and provide an alternative means of training support.
7. Although not specifically identified as part of the assessment, the team gained additional information regarding State experience and use of the NMED database while conducting event reporting training, that included the NMED program, which will be discussed further in Section III(a). Team members conducted training in the four Regions with both NRC and Agreement State staff participation. A special training session was conducted in Albany, NY, and hosted by the New York State Health and New York State Labor Department radioactive materials program. Training was conducted in the NRC Regions on June 17-18, 2003, July 8-9, 2003, July 22-23, 2003, August 19-20, 2003, and in New York State September 16, 2003.
8. Recommended a number of improvements in the event reporting process that are listed at the end of each section. A compilation of all 16 of the recommendations is provided in Section XI of the report.

ANALYSIS AND REVIEW RESULTS: Task Topics

I. WHY DO WE NEED TO COLLECT MATERIAL EVENT INFORMATION?

This section describes why we need to collect and maintain information on operational and occupational material event information, including the benefits derived from review of material event information and Federal and Congressional requirements for reporting of national material event data. Operating experience is an essential element in the regulatory process for ensuring that licensed activities are conducted safely. Reporting and assessing operating incidents and events helps to identify deficiencies in the safe use of Atomic Energy Act (AEA) radioactive material and to ensure that corrective actions are taken to prevent recurrence. A 1993 General Accounting Office (GAO) report identified the compilation and presentation of national materials data as an area for improvement and recommended that NRC take appropriate action to ensure that the information on radiation events is reported completely and accurately. As a result, the agency developed and implemented the Nuclear Materials Events Database (NMED) for use as a support tool in the collection and maintenance of historical information on the occurrence, follow-up and closeout of material events.

a. **BENEFITS**

1. Risk assessments and evaluations of material event reports are conducted by the NRC Office of Nuclear Material Safety and Safeguards (NMSS) to identify strengths and weakness in the materials licensing and inspection program.
 - a. NRC conducts reviews of all operating experience material event reports, from both NRC licensees and Agreement States, to identify safety concerns early, and to further evaluate individual safety concerns for any trends and patterns of repetitive events and failures that could become *generic safety issues (GSIs)*. The early identification of *GSIs* is important to provide notification to a class of licensees of the potential for system or equipment failure that could or will impact public health and safety. For example, a review of well-logging events involving breaching of the encapsulation of sealed well-logging sources resulted in modifications to 10 CFR Part 39 to prohibit licensees from removing sources from logging tools. The results of these assessments and evaluations are disseminated to affected licensees via NRC Information Notices (INs), NMED Quarterly reports and the NMSS Licensee Newsletter, NUREG/BR-0117.
 - b. The assessments are also used to support agency efforts to focus future time and resources on specific areas of need.
 - c. NRC shares information on *significant* material events with the international community through The International Nuclear Event Scale (INES). The INES was developed jointly by the International Atomic Energy Agency (IAEA) and the Nuclear Energy Agency of the Organization for Economic Co-operation and Development (OECD/NEA). Nuclear material events are reviewed against the INES Scale rating criteria, and abstract summaries of events

meeting the criteria are sent to INES for international public access through the INES Scale Internet Web-based database.

- d. Summaries of material events involving health and safety significance are included in the annual Abnormal Occurrence Report to Congress. Reliable information should be available to NRC, the Congress, and the States to identify any safety significant trends to determine if NRC and the Agreement States should evaluate the need for any revisions to regulatory programs.

b. REQUIREMENTS

1. There are Federal and Congressional mandates that require that NRC prepare specific reports of national material event information, as well as, agency policies to ensure that NRC collects national material event information to support the mandates and the agency in its mission to protect public health and safety and security.
 - a. The *Government Performance Results Act of 1993 (GPRA)*, requires all Federal Agencies to develop a strategic plan and measurable performance goals. NRC's strategic plan includes measurable outcome oriented performance goals linked to Agency programs and activities. An annual performance report to Congress is required that includes metric performance goals based on GPRA requirements. The metric goals are based on current and historical national material event reporting data from NMED. For example a metric goal may assess the number of significant events and incidents involving overexposures. The performance metrics identify how well we are doing in protecting public health and safety, in accordance with health and safety risk-informed and performance based regulatory programs.
 - b. Under the Energy Reorganization Act of 1974 (ERA), as amended, NRC is required to evaluate operational and occupational material event reports for both NRC and Agreement State licensees, and identify abnormal occurrences (AOs) that have occurred in licensed facilities, based on specific criteria. In addition, the ERA requires NRC to provide to Congress on an annual basis, information on significant events that meet the AO criteria. The report to Congress, NUREG-0090, *Abnormal Occurrence Report*, is publicly available. These events are maintained in NMED.
 - c. Under Section 274 of the AEA, Agreement States have assumed regulatory authority over byproduct source and certain quantities of special nuclear materials. The AEA directs NRC to cooperate with the States in the formulation of standards to protect employees or the general public against hazards of radiation and to assure that State and Commission programs will be coordinated and compatible. The Agreement Between the State and the USNRC includes provisions to keep each other informed of events and accidents. Under compatible regulations, Agreement State licensees are required to report the occurrence of incidents and events involving the use of nuclear materials to the appropriate regulatory agency. The AEA directs the Commission to periodically review actions taken by the States under the Agreements to ensure adequacy and compatibility with the provisions of the Act. NRC conducts periodic evaluations of Agreement State programs under the *Integrated Materials Performance*

Evaluation Program (IMPEP), which includes an evaluation of event response, reporting, follow-up, and close-out. (See NRC [Manual Directive 5.6](#) and STP Procedure [SA-100](#) (IMPEP))

- d.. Due to the importance of operational event information as an essential element in the regulatory process for ensuring that licensed activities are conducted safely, the Commission directed the staff to make Agreement State reporting of material events to NRC's NMED database an item of compatibility (see June 30, 1997, SECY-97-054). The implementing procedures are contained in STP Procedure SA-300.
- e. In 1998, a revision to the U.S. Code expanded the Federal Bureau of Investigation (FBI) criminal investigative jurisdiction to include byproduct material. The revision assigned lead responsibility for material events involving *theft or terrorist activities* to the FBI. (See All Agreement State Letter SP-98-038, May 5, 1998). NRC and the Agreement States are required to report any events involving the possible deliberate misuse of AEA radioactive material to the FBI.
- f. The States are encouraged to voluntarily report information on lost, stolen and abandoned sources (not covered under reporting requirements, including non-AEA and unlicensed material) as part of a joint NRC effort with the Conference of Radiation Control Program Directors (CRCPD).

II. HOW DOES NRC CURRENTLY COLLECT NRC LICENSEE AND AGREEMENT STATE EVENT INFORMATION?

NRC licensees are required to report material events to NRC under 10 CFR reporting requirements. The Agreement States require their licensees to report material AEA events to the Agreement State regulatory agency under compatible state reporting requirements. The Agreement States are required to report Agreement State licensee materials events to NRC as a matter of compatibility. The NRC publishes and distributes summary information on material events that occur nationally through Event Notifications (ENs), Morning Reports (MRs), and Preliminary Notifications (PN). The ENs are drafted by NRC/NSIR staff, MR's are drafted by NRC Region staff, and PNs are drafted by the HQ or Region staff, in coordination with the applicable Agreement State (where applicable), based on event notification information received from the licensee. A more detailed description of these processes appears below.

a. *Event Reporting Schedule* (based on 10 CFR reporting requirements):

1. NRC licensees and the Agreement States report the occurrence of a *significant event* (reportable within 24 hours) to the NRC Headquarters Operations Center. Significant event information is captured and publicly noticed in the NRC event notification database as a Preliminary Event Notification (EN). Public notification and distribution of event information is discussed further below in item (d) of this section.

2. NRC licensees report less significant events (reportable within 30-60 days) and follow-up event reports to the NRC Regions, which are captured in ADAMS (the agency's official document records system) and entered into NMED by the contractor.
3. The Agreement States report less significant events (reportable within 30-60 days) and follow-up event reports to NRC via the NMED contractor. The event reports are provided to the NMED contractor by electronic NMED data file, mail or Fax, and/or email non-NMED compatible database files. Event reports provided directly to the contractor are not available in ADAMS.

b. NRC Licensee Event Information Collection Process:

NRC collects event information from NRC licensees through material reporting requirements contained in 10 CFR regulations. The regulations require NRC licenses to report the occurrence of incidents and events involving the use of nuclear materials to the NRC.

1. NRC licensees telephone, mail or Fax material event reports to NRC. The information is entered into ADAMS.
2. The NMED contractor is responsible for retrieving NRC licensee event information directly from ADAMS and the NRC Website, and drafting the NMED abstract and other pertinent information necessary for a complete NMED record of all NRC licensee events. It is noted that INEEL has access only to the public ADAMS document collection.

c. Agreement State Licensee Event Information Collection Process:

1. Agreement State licensees are required to report the occurrence of incidents and events involving the use of nuclear materials to the appropriate Agreement State regulator, in accordance with compatible regulations. As a matter of compatibility, Agreement States are required to report the occurrence of material events to NRC.
2. Agreement State staff are responsible for drafting the abstract and other pertinent information necessary for a complete NMED record of all Agreement State material events.
3. Agreement States provide material event reports to the NRC NMED contractor via NMED program data file or other database or word processing file, by email, Fax or mail. Based on the results of a survey, and NMED contractor information: 22 Agreement States use the NMED local data entry program and send an NMED compatible electronic file to INEEL, eight Agreement States send in hard copy reports via Fax or mail, and three Agreement States send in a database file from their own database (incompatible to NMED) to report events to NRC.

d. Public Notification and Distribution Process for National Material Event Information:

1. *Event Notification (EN)*: The NRC Operations Center staff is responsible for drafting an *EN*, for all material events reported to the NRC Operations Center by both NRC licensees and the Agreement States. The *EN* contains an abstract summary of the initial event notification information provided by the NRC licensee or the Agreement State representative.
 - a. NRC licensee and Agreement State event notification information is immediately distributed internally to the appropriate Regional Duty Officer and NRC technical staff.
 - b. The *EN* is placed at the NRC external Website within one (1) day or less of receipt, for public availability.
 - c. NOTE: NRC delays posting of Agreement State *ENs* to the NRC public web site for 48 hours (2 business days), after notification to NRC, to permit States to complete the initial phase of their investigation. Agreement State event information is immediately available by contacting the specific Agreement State.
2. *Morning Reports (MR)*: The Region drafts a daily *MR* describing event notifications of interest received from NRC material licensees and the Agreement States. *MR's* are discussed each morning via teleconference with HQ Regional Coordinator staff, and *MR's* are immediately available to NRC management at the NRC internal Web site.
3. *Preliminary Notification (PN)*: Based on significance, a *PN* report containing a summary description of the event may be drafted by the applicable Region, for an event that could impact public health and safety.
 - a. A *PN* is usually drafted within a few hours of receipt of the event information, and posted to the NRC Website the next day for immediate public availability.
 - b. NOTE: NRC delays posting of Agreement State *PNs* to the NRC public web site for 48 hours (2 business days), after notification to NRC, to permit States to complete the initial phase of their investigation. Agreement State event information is immediately available by contacting the specific Agreement State.

e. NMED Contractor Event Review and Follow-up Process:

1. The NMED contractor, INEEL, conducts a daily review of the NRC Website, including ADAMS, to retrieve new EN, PN, and Morning Report documents and follow-up event reports entered that day, for entry into NMED national program.
 - a. Contractor developed abstract summaries of information contained in ENs, PNs, and MRs, are entered into NMED within two days of receipt.

- b. All other reports are entered within two weeks of receipt, including thirty-day licensee reports, inspection reports, and any follow-up reports (this includes both NRC and Agreement State reports).
- 2. The Agreement States are responsible for drafting their own material event NMED reports, and submitting them to the NMED contractor for entry into the national database.
- 3. *Feedback:* The NMED contractor provides an email response back to the Agreement State that the electronic (email) file has been received. A copy of the email record is retained by the contractor. No contractor receipt response provided for Fax or letter-mail documents.
- 4. ***Completeness Review of Event Information:*** Based on contract specifications, the NRC NMED contractor is responsible for conducting a completeness review of all material events. The NMED contractor is responsible for contacting both the Region and Agreement State staff directly via email for clarification of coding of event information needed for a complete NMED report (based on NRC guidance contained in STP procedure SA-300, *Reporting Material Events*, NMSS procedure *TI-2800-033* and the *NMED Coding Manual*). Upon receipt of updated information, including 30-60 day event reports, and any follow-up reports, the contractor is responsible for updating the data into the NMED national program.
 - a. *Pending Requests:* For information requests where the request has been pending greater than 60 days and the information is needed to determine whether the event is recordable; the contractor forwards the request to the NMSS NMED project manager for resolution. The Project Manager forwards overdue responses to NRC regional contacts or Regional State Agreements Officer for disposition.
 - b. *Complete Report Record:* The team found that there had been some confusion among some NMED users regarding the difference between the NMED terms “*Record Complete*” and “*Event Closed by State.*” In response, NRC provided clarification in the January 2003, “*NMED News*” newsletter (available at the NMED website), that defined the two terms as follows:
 - 1. The term “***record complete***” refers to an NMED record that contains all of the information specified by Section 3 of the *Handbook on Nuclear Material Event Reporting in the Agreement States, SA-300*. Additionally, the January 2002 issue of *NMED News* contains a detailed article on complete records.
 - 2. A “***closed event***” refers to an event that has been closed by the applicable Agreement State or NRC Region Office. In January 2003, the term was revised to “*Event Closed by Region/State*” to provide further clarification.

The team received a few comments expressing concern that the States are reporting to the NMED contractor rather than NRC or a preference for receiving follow-up questions from the NRC.

SECTION CONCLUSIONS

Based on the results of the review, the team concluded that a similar process is followed by NRC and the Agreement States to respond, review and/or investigate the occurrence of a material event, conduct an inspection, and collect event information from licensees. NRC Licensees send material event reports to the NRC Document Control Desk and the appropriate Region (both routes result in entry into NRC ADAMS), and Agreement State licensees send event reports to the appropriate Agreement State regulatory agency.

The team determined that the process differs regarding the use of resources to compile and code (data entry) the event information into the NMED database. Rather than have NRC staff compile and code material event information into NMED, NRC decided it was more efficient and effective to secure a contractor to perform this function. The contractor compiles event information from NRC inspection reports, investigations etc., retrieved from ADAMS, develops the abstract summary data, and codes the data into NMED. Rather than secure contractor resources, staff of the Agreement States conduct a similar compilation and summary abstract activity, and, in some instances, coding function for all radiation events, including AEA events, that have occurred under their jurisdiction, and maintain the records either manually, or code the data into their own database, or a Local NMED database provided by NRC. The States send the data to NRC, which is then entered into the National NMED database by the NRC contractor. Note: It appears that most Agreement State programs were already maintaining event report records in some form prior to becoming an Agreement State, although the State system may not have provided the level of detail now needed for NRC to meet Federal and Congressional mandates for national data in this area.

The team concluded that the information needs for a complete NRC report may be different from the information needs of an Agreement State for its own records. The team also concluded that under the *Agreement*, compatible event information should be provided by an Agreement State. Therefore, the team concluded that, although the additional information needs may place an additional burden on the Agreement States, the burden is reasonable if NRC deems the information is necessary to meet Federal and Congressional mandates and to protect public health, safety and security. The team also concluded that in providing several modes for Agreement State reporting of event information, FAX copy, email word processing file, NMED database file, or other database or spreadsheet format, no unfair burden exists regarding the reporting of event information to NRC and NMED.

The team concluded that NRC has responded to any confusion regarding NMED and the definition of a "complete record" and a "closed event." The team also concluded that the clarification should be included in event reporting guidance documents.

The team concluded, based on contract specifications, that NRC has designated the responsibility for conducting a completeness review of all material events and following up on incomplete information to the NMED contractor. The contractor is acting for the NRC.

RECOMMENDATIONS:

None

III. HOW DOES THE NRC MAINTAIN NRC LICENSEE AND AGREEMENT STATE MATERIAL EVENT INFORMATION IN NMED?

The NRC maintains a summary collection of historical information on the occurrence, description, and resolution of events involving the use of radioactive material in the United States (source, byproduct, special nuclear material, naturally occurring, and accelerator-produced radioactive material) in the *Nuclear Materials Events Database (NMED)*. NMED accommodates the sharing of NRC and Agreement State licensees material event data, as well as radioactive material event information submitted by nonlicensees. The data includes information on material events from January 1990 through the present. The database is maintained by the Office of Nuclear Materials Safety and Safeguards (NMSS) through a contract with Idaho National Engineering and Environmental Laboratory (INEEL). The NMED database currently exists in two platforms: 1) the national database at an Internet Website, and 2) as a local PC data entry program for specific Agreement States (individual desktop or LAN). The local program was designed to assist States in collecting event information and submitting that information to the national database.

a. NMED Local Data Entry Software Program

The team found the NMED Local Data Entry program is performing satisfactorily and users commented that the program is easy to use. The team also found that staff using the current version of the NMED Local Data Entry program commented that the program had been significantly improved from previous older versions. Current users identified no specific problems with loading the software on a LAN or a local PC. Most, generally found the program easy-to-use. The program includes pull down menu's with pick lists, and pop-up help flags for clarification, and a search subroutine. Most of the minor comments on the local data-entry program received during the teams interview discussions, have already been addressed in the latest version 5.1 of NMED. Of the 14 Agreements States interviewed, four had participated in NMED training in the last 3 years, and two additional States attended the Summer 2003 NMED training.

Training: NRC has continually conducted event reporting training covering revisions to SA-300 and NMED, at NRC Regional offices. Over the years, as an alternative option for those States unable to attend the training workshops held in the NRC Regions, NRC staff provided additional on-site training in Agreement States who acted as hosts. Invitations were sent out to adjacent States, NRC staff, and other Agreement and non-Agreement States for the training which was provided throughout the year based on specific requests for on-site training from Agreement States. The non-Agreement States have been invited to participate to facilitate the voluntary reporting of lost, stolen and abandoned non-AEA material to NMED. The team also found that searching the National Website NMED database prior to conducting an inspection is recommended in the Inspection Procedures course.

The team determined that many States were unable to participate in the five training sessions held in 2003. Many Agreement States identified an inability to travel out-of-state as the reason they were unable to participate in the training. For example, staff of the New York City Health Department were unable to attend the training in Albany, NY due to travel restrictions which included Albany, NY, because it involved an overnight hotel stay. Similarly, staff members from other States such as Tennessee and Maine were unable to

attend due to travel restrictions and asked for alternative methods of training. The team provided copies of the training handouts that included sample training exercises to help provide some alternative training support. Additionally, the NMED contractor also provided technical support to the Tennessee staff member. A review of the previous training attendance identified a similar attendance pattern. Based on comments and low attendee response to the five event reporting and NMED training sessions conducted by team members during 2003, in the four NRC Regions and in Albany, New York, the team concluded that more efficient and effective alternative methods of training should be explored. A list of the specific attendees is included in the report as Appendix C.

b. NMED National Website Database

The team found that most commenters interviewed by the team, stated that the NMED National Website database contained useful valuable information and was a good search tool. Some States and NRC Regions are using the NMED national program information to support licensing and inspections programs. Commenters also stated the current version could benefit from an upgrade to take advantage of newer technological search capabilities to simplify searches. Similar comments regarding upgrading the national Website program were made in the Final Report of the Working Group on Event Reporting, August 2001.

Team Response: The team found that this area is being addressed through a scheduled upgrade to the NMED National Website database begun in September 2003. We are aware that new developments in Web technology resulting in simplification of Internet users searches has taken place since the development and installation of the Web program approximately five years ago. The planned upgrade will incorporate new Web technology into the NMED national program. The upgrade is scheduled for completion Mid-2004.

c. NMED Data Queries

NMED data queries are provided by the NMED contract as part of technical support services. The team found that periodically Agreement State staff and NRC headquarters and Regional staff request that the contractor perform data queries, based on specific beginning and ending date parameters, and/or key words. NOTE: This feature is also included in the NMED Local Data Entry Program. Many of the requests coincide with an upcoming IMPEP review. A State or NRC Region may conduct their own review, or they may ask the contractor to perform the query. They may conduct their own data query and ask the contractor to conduct a similar query for comparative purposes. The data parameters used by both parties must be exactly the same or the results will vary. The team found that previous communication issues between some Agreement States, the Regions, and the NMED contractor, arose as a result of the use of different date parameters for requesting NMED contractor inquiries into the status of event report records that have been "closed out" in NMED.

d. NMED Upgrades/Modifications

NRC periodically upgrades the NMED software program to improve the overall intuitiveness of the program, eliminate unused or outdated data fields, incorporate changes recommended by the Agreement States, and keep abreast of technological changes. The team found that the first upgrade to the NMED software was initially sent to Agreement States in 1996, a second upgrade was completed in 2001, and a third upgrade was completed in June 2003. During that same time period Microsoft upgraded the Access software program several times, Access 96, 98, 2000, 2002, and 2004. The team found that in the past, some incompatibility problems occurred between the older NRC Access supported version of NMED and the more current version of Microsoft Access used by many of the Agreement States. The current 2003, 5.1 version of NMED is compatible with the most current version of Microsoft Access.

SECTION CONCLUSIONS:

The team concluded that some of the Agreement States were unable to participate in event reporting and NMED training due to travel restrictions.

The team concluded that the NMED (National and Local) is performing satisfactorily, based on comments received during discussion interviews and training sessions.

The team concluded that the use of different date and key word parameters by the State and the contractor will result in different output data and confusion. The team found that NRC has implemented a revised procedure to address these communication concerns. NRC has revised the NMED contractor procedures for processing requests for NMED technical support, including requests for specific data outputs covering specific periods of time, such as the four year period covered by an upcoming IMPEP review. The contractor will respond back to the requester in writing to clarify the exact type of query and the exact dates (beginning and ending) for the inquiry in writing to reduce the possibility of communication problems.

The team concluded that five years is too long a time period between updates of the NMED software program and may have contributed to the early incompatibility problems identified by some States.

The team concluded that NRC should continue to seek Agreement State input on significant proposed modifications to the Local Data Entry software program and the National Website NMED program. Modifications are generally made as a result of comments from NRC and Agreement State staff, and to incorporate new technological advances.

RECOMMENDATIONS:

- III-1. The team recommends that alternative training methods, such as video, CD-ROM or online methods, be evaluated to determine their feasibility and effectiveness, as an additional training tool to complement traditional training methods.**

- III- 2. The team recommends that NRC continue to upgrade the NMED software program on a schedule similar to the current two to three year scheduled upgrade between 2001 and 2003 to continue to improve the overall intuitiveness of the program, take advantage of technological advances in Microsoft Access software updates, and reduce the possibility of incompatibility problems.
- III-3. To keep abreast of technological changes in the regulatory process and technical areas that could impact the program, the team recommends that NRC continue to periodically survey the Agreement States for comments on the NMED Local Data Entry and National Website programs to determine changing needs and to solicit input for future upgrades, and share those comments with all users.

IV. SHARING RESULTS OF ANALYSES OF NATIONAL MATERIAL EVENT DATA

a. *Evaluative Analyses*

NRC conducts reviews of all operating experience material event reports, from both NRC licensees and Agreement States. Reviews should be conducted to:

- Identify safety significant concerns early
- Discover emerging trends or patterns of potential safety significance
- Assess the generic applicability of events
- Identify root causes
- Determine adequacy of corrective actions taken to address safety concerns
- Follow-up events to ensure complete information necessary to determine if an event meets the performance metric data goals for GPRA.

The NRC Office of Nuclear Material Safety and Safeguards staff conduct weekly reviews of new event notifications and follow-up event report information to identify safety significant concerns, including events that meet the NRC Strategic Plan performance goals and measures required under GPRA. Reviews are conducted to identify *significant* events for inclusion in the INES international events database. Identified individual safety concerns are further evaluated for any trends and patterns of repetitive events and failures that could become *generic safety issues (GSIs)*. The early identification of *generic safety issues (GSIs)* is important to provide notification to a class of licensees of the potential for system or equipment failure that could or will impact public health and safety. An event or condition could, by itself appear insignificant, but when compared with national information, could become a generic concern. In-depth analysis of event report data may result in the identification of actions that could lead to improvements in the effectiveness of NRC and Agreement State regulatory programs. Event analysis may also result in the issuance of Information Notices (INs) warning of possible safety concerns and assessment of the need for regulatory changes or revisions. The results of event analyses are provided to Agreement State regulators, the industry, and the public through various publications identified below. The team found that the 2002 Event

Working Group identified that “although the NMED Quarterly Report could be used to distribute assessment results, a monthly e-mail to Regional and Agreement State counterparts over the RadRap system would be a better feedback mechanism. It would be more timely and it would provide a mechanism for discussion and information exchange. The NMED Quarterly Report could be used to distribute information to licensees after all internal stakeholders have had a chance to review and comment on the e-mail reports.”

b. Dissemination of results of collective assessments

The team found that NRC's Office of Nuclear Regulatory Research publishes an annual report of safety significant events involving abnormal occurrences in the use of AEA radioactive material, NUREG-0090, Abnormal Occurrence Report, and the Office of Nuclear Material Safety and Safeguards (NMSS) publishes a quarterly NMED report that periodically presents information on the results of statistical analysis of event data and any significant or generic issues or concerns, to provide feedback on material event information provided by NRC licensees and the Agreement States. An NMED newsletter for users is also published quarterly by NMSS, that contains user hints, questions and answers (FAQ), coding changes, and information on software upgrades and available training. NMSS also publishes NUREG/BR-0127, NMSS Licensee Newsletter covering significant safety issues and events, generic issues (GSIs), and enforcement actions.

1. Based on results of event assessments, *Information Notices (INs)* are issued warning of possible safety concerns and assessment of the need for regulatory changes or revisions. INs are distributed to specifically impacted licensees and the Agreement States. INs are available at the NRC website.
2. NUREG-0090, *Abnormal Occurrence Report*. NUREG-series publications are available electronically at NRC's Public Electronic Reading Room at www.nrc.gov/NRC/ADAMS/INDEX.HTML. They may also be purchased through the Government Printing Office at: bookstore.gpo.gov
3. The *Nuclear Materials Events (NMED) Database Quarterly Report* is available in electronic form at the NMED Internet Website: <http://nmed.inel.gov>.
4. The newsletter, *NMED News: Nuclear Material Events Database*, is available at the NMED Internet Website: <http://nmed.inel.gov>.
5. The *NMSS Licensee Newsletter*, NUREG/BR-0117, is periodically published to provide information on generic and safety significant issues and events, and identifies any significant enforcement actions that have occurred during the period. The newsletter is distributed to NRC licensees, the Agreement States and selected NRC technical staff, and is available in NRC ADAMS.

During recent training on event reporting and NMED, staff emphasized the use and results of event assessments with examples such as,

1. Review of Radiography Overexposures (1997 to 2002), Addendum to NMED Quarterly Report, February 2003.

2. NUREG/CR - 6642, Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems. Historical NMED data was used, in part, to support risk ranking material activities and resource efforts identified in the report.
3. NUREG -1631, (Radiography) Source Disconnects Resulting from Drive Cable Failures, 1998.
4. Report on Irradiator Incident in Nebraska, resulted in modification to Reg. Guide 10.9 "Guide for the Preparation of Applications for Licenses for the Use of Gamma Irradiators;" follow-up letter to Information Notice.

The team found that since January 2002 the NMED Newsletter has been distributed via hard copy to Agreement and non-Agreement State Program Directors, and to NRC and State staff identified as user contacts for NMED and material events.

The team found that some Agreement States are using RADRAP to disseminate results of evaluations and assessments.

SECTION CONCLUSIONS:

The team concluded that, in general the results of most evaluations and assessments are disseminated or are available electronically to impacted licensees, the Agreement States and NRC staff. The team also concluded that broadening the scope and frequency of periodic event analyses could result in improvements in the possible early identification of trends or patterns and could improve communication and sharing of event information between NRC and the Agreement States. The Agreement States should also be encouraged to share the results of any event analyses with NRC. A monthly e-mail to Regional and Agreement State counterparts over the RadRap system would be a better feedback mechanism for the exchange of event analyses data. It would be more timely and it would provide a mechanism for discussion and information exchange. The NMSS Implementation Plan for the 2001 Event Working Group Report identified development of a plan to improve feedback including distribution of assessment results to State and Regional staff via the NMED Quarterly Report and the Rad Rap system.

RECOMMENDATIONS:

- IV-1. Opportunities for improvement should include broadening the scope and frequency of event analyses to increase timeliness and efficiency in the early identification of possible GSIs and trends and patterns, in addition to periodic email notification through a medium such as RADRAP of the availability of the results of an evaluation or assessment conducted by NRC or an Agreement State.**

V. REVIEW GUIDANCE DOCUMENTS AND IMPEP REPORTS TO IDENTIFY EVENT REPORTING CONCERNS: FY 2002-03 IMPEP Reports

a. *Procedural Guidance Review and Monthly Reporting (SA-300)*

The current procedural guidance document, STP Procedure SA-300, *Reporting Material Events*, states that *significant* event notifications (reportable within 24 hrs) should be sent to the NRC Operations Center within 24 hours of notification from the licensee. Further, guidance indicates that 30-60 day reportable event notifications, and any follow-up information on all events should be provided monthly to NRC.

b. *Timeliness*

The team found that the States are generally timely reporting *significant* events. The team found that a review of sample IMPEP reports indicated that a few significant events are not immediately identified or missed or are identified during the IMPEP review (3 of the 13 sampled IMPEP review reports (NY, OR, NE) identified unreported “significant” events (see Table 1). One other report (MD) identified unreported events but did not define the type of events and two of the States (OR and NE) indicated they were either caused by staffing shortages and/or NMED electronic transmission issues on the part of the State. Reporting guidance states that “significant” 24hour reportable event notifications should be provided to the NRC Operations Center within 24 hours of notification by an Agreement State licensee. The State has the option of notifying the Operations Center by telephone, Fax or E-mail. Therefore, NMED transmission problems would not be applicable to delays in reporting “significant” events. Based on interview discussions, the team found that some States were unable to provide monthly event information for the less-significant 30-60 day reportable events primarily due to staffing shortages, and an absence of or the need to improve internal quality control processes (QA) and competing work priorities (which also involves staff resources). Staff from Oregon stated during their last IMPEP review that staffing shortages and the lack of a QA process impacted their ability to provide timely and complete event report information. During interview discussions they stated that although the QA process has been improved, the time involved in the QA process results in delays in providing timely monthly event report information to NRC. Based on IMPEP review data and survey responses, approximately 40-50% of the Agreement States, generally provide 30-60 day reportable event information monthly.

Generally, most States supported monthly reporting of material events to maintain a current national collection of event information and to identify possible precursor events and generic issues. A few States with smaller programs, recommended a change to bi-monthly or quarterly reporting of the less-significant 30-60 day reportable events. Generally, the States found that it was more efficient to report monthly as staff maintain procedural expertise in entering data, and fewer events reduced the time necessary to collect background data. The States found that it involves more effort to collect information on a large number of events and to retrain staff on the process for entering event information, therefore providing event reports to NRC quarterly or annually was considered to be less efficient. We have not addressed the process of the State conducting an inspection and drafting an inspection report because the States choose to

provide event report summaries rather than copies of inspection reports. Whereas, the NRC licensee sends the 30-60 day reportable event notification directly to the NRC Region and the Region staff are responsible for timely entry of the information into ADAMS. The Region staff are also responsible for timely entry of inspection reports into ADAMS, which are downloaded by the NMED contractor for review. Historically, the team found that NRC licensees event reporting is comparable to the 40-50% of Agreement States that generally report 30-60 day reportable events and follow-up information monthly. Similar to those Agreement States, the NRC Regions receive a smaller number of periodic requests for additional or clarifying information from the NMED.

c. Completeness

Guidance contained in STP Procedure SA-300 and TI-200-033 clarifies the “Minimum Basic Information for a Complete Report.” The team determined that the technical quality and detail of event information continues to vary. The team found, based on comments from the NMED contractor, that recurring requests for additional event information primarily involve requests for the make, model and/or serial number of sources, devices and equipment (where applicable), the root cause of a specific event and/or information on corrective actions. The team also found that event report summaries of abnormal occurrences did not always provide sufficient clear detail on the results of dose analyses and investigations, including corrective actions. The issue regarding the make, model and/or serial number of sources, devices and equipment is explored further in Section VI. covering Material Event Reporting Requirements, of this report. During interview discussions a few States indicated they waited for the contractor to request follow-up information rather than automatically provide it as indicated in SA-300. The team determined that further emphasis needs to be placed on the importance and need to timely provide the results of follow-up investigations that discern the root cause, address corrective actions, and describe results of dose assessments. This could be accomplished through increased communication, such as informal periodic discussions between RSAO’s and the Agreement States, formal period meetings and IMPEP reviews, revisions to event reporting guidance documents, and periodic training on event reporting and NMED for IMPEP reviewers, and Agreement State staff. The team found that completeness of NRC licensees event reports is comparable to the 40-50% of Agreement States that generally report 30-60 day reportable events and follow-up information monthly. Similar to those Agreement States, the NRC Regions receive a smaller number of periodic requests for additional or clarifying information from the NMED.

d. NRC/NMSS Event Review

The team found that the NMSS Generic Assessment Panel (GAP), formerly responsible for the event review process has been discontinued. It has been replaced by an integral group of event reviewers, with direct contact to the specific material programs. The team also found, based on comments received during recent event reporting/NMED training sessions, that some States, primarily non-Agreement States, were unaware of the joint CRCPD/NRC effort to track lost, stolen and found radioactive material (including non-AEA and unlicensed material) through voluntary reporting of material that is not currently included under material event reporting requirements. The team found during the training sessions that further clarification is needed regarding the responsibility of Agreement and non-Agreement States to make the initial notification to the FBI for events involving the

possibility of deliberate misuse, theft, or terrorist activity involving AEA radioactive material.

e. FY 2002-03 IMPEP Report Review

The team conducted a sample review of IMPEP reports for FY2002-2003 and periodic meeting reports for June 2001-September 2002. The team found that the review criteria for this IMPEP indicator is contained in STP Procedure [SA-105](#), *Reviewing Common Performance Indicator #5, Response to Incidents and Allegations*, dated 1/6/00. SA-105 review criteria for incidents includes the following:

1. Assure that the level of effort in responding to an event is commensurate with potential health and safety significance
2. Confirm follow-up inspections are scheduled and completed, if necessary.
3. Confirm that Agreement State notification to NRC is performed in accordance with STP procedure SA-300, *Reporting Material Events*.
4. Confirm that NRC licensee notification to NMSS and NSIR is performed in a timely fashion.
5. Verify information provided by the Agreement States on events for NMED is *complete* and *accurate*.

The team found that SA-105, Section D. "Review Details" for events, addresses prompt reporting of "significant events", but needs to be updated to address timeliness for 30-60 day event notification, follow-up information, and completeness of NMED event records based on SA-300 guidance.

The team found that Appendix A to SA-105, "IMPEP Incident Reviewer Guidance Form," addresses criteria for response, investigation, and closeout. The criteria for prompt notification of significant events addresses timeliness, but needs to be updated to address timeliness for 30-60 day event notification, and follow-up information. The Reviewer Form also needs to be updated to address completeness of all NMED event records based on SA-300 guidance. The team concluded that SA-105 Review Details, and Appendix A, Reviewer Form should be revised to clarify information needed to "verify that information provided by the Agreement States on events for NMED is *timely, complete* and *accurate*," in accordance with SA-300 guidance. The inclusion of clarification of the terms "record complete" and "event closed" should also be considered in any revision to SA-105.

The team conducted a review of the findings for IMPEP *Common Performance Indicator #5, Response to Incidents and Allegations* identified in a sample of 2002-2003 IMPEP reports. The results of the review are contained in Table 1. below. The team found considerable variance in the level of detail provided in the report evaluations regarding use of and familiarity with SA-300 guidance, timeliness of event notifications (24 hour reportable and monthly reporting of 30-60 day reportable events), and completeness of NMED records. The review identified that timeliness and completeness were addressed in the reports about 50% of the time. Although the terms "*event closed*" and "*record*

complete" have been clarified in NMED Newsletters (see Section II(e)), the team determined that reviewers and some Agreement States could benefit from the inclusion of the definitions of the two terms and who is responsible for closing the event in NMED in SA-105 and SA-300.

The team determined that some confusion resulted from the inclusion of unverified statements in some draft reports regarding missing or incorrect data entries, or timely submission of information to an NRC office without subsequent verification before inclusion in the report, such as the statement "The NMED contractor did not capture all of the event data provided by the State." The team determined that the NMED reviewer may not be aware of historical or current event issues or concerns that have been or are under discussion with a State. Therefore such statements should be verified by the reviewer prior to inclusion in a report. As a result, the team proposed a revision to include contacting the NMSS NMED Project Manager and/or the STP Event Project Manager for information on any pending event area issues as part of the pre-IMPEP review and contacting these individuals during the on-site review or prior to completion of the draft report to try to clarify and/or resolve any event area issues prior to sending out the draft report.

The team also recognized from some Agreement State comments, that reporting delays may be due to staffing shortages and an absence of or the need to improve data entry Quality Assurance (see OR comments).

The team found that the NMED contractor maintains copies of all email requests sent to the NRC Regions and the Agreement States for additional information that is needed for a complete report (based on NRC guidance documents). After a period of 60 days has elapsed with no response to the request for additional information, the request for additional information is forwarded to the NRC Region for follow-up and resolution. The Region assigns the action to an NRC inspector or the Regional State Agreement Officer (RSAO), whichever is applicable. The contractor also maintains copies of email technical support discussions and can provide copies of email requests and discussions, when necessary.

The following Table 1., contains a description of the summary findings and recommendations compiled from a sample review of IMPEP reports for FY2002-2003. The last column contains the self-assessment team comments.

Table 1. SAMPLE 2002-2003 IMPEP REVIEWS (EVENT EVALUATION)

Date	Agreement State	Summary Finding	Recommendations	Comments
2002				
4/8-12	ALABAMA	--Office responsive to NMED contractor follow-up info requests. --24 hr and 30-60 day reportable events timely reported to NRC --NMED training helpful & latest version NMED very user-friendly	None Satisfactory	Timeliness addressed Completeness not documented in report
4/23-26	KANSAS	--4 of 44 events missing radionuclide or finding of unknown --Incomplete data found in some event reports, due to database entry made prior to having complete data --discussed flagging missing info. for completion prior to incident closeout	None: Satisfactory	Timeliness not documented in report Completeness addressed
6/24-28	MASS.	--1 unreported event --35 events were not timely reported (due by 2 weeks-2years) --11 incomplete events --9 events (2 reportable) apparently reported to NMED, but not found in NMED --Delays caused by staffing changes, and difficulty using the NMED program to enter data.	Satisfactory with Recommendations Recommend taking necessary steps to ensure that all reportable events are submitted and updated to NRC in accordance with SA-300.	Recommendations address findings Timeliness and completeness addressed.
7/15-19	OKLAHOMA	--All but one notification was made within the period required in SA-300.	None: Satisfactory	Timeliness addressed. Completeness not documented in report

Table 1. SAMPLE 2002-2003 IMPEP REVIEWS (EVENT EVALUATION)				
Date	Agreement State	Summary Finding	Recommendations	Comments
7/15-26	NEW YORK	--24 hr event reported 4 mos. late stated [alleged] timely sent to STP -- 3 late events, 1 unreported --inconsistent reporting of significant events due to philosophical differences ("no obligation to promptly report events that do not directly impact NRC licensees or licensees from other Agreement States.") --inconsistent reporting (1 of 4 events reported)	Satisfactory w/ Recommendations Ensure timely submittal of information to NRC and NMED and implement an effective procedure to identify, track, and review all incident reports.	Recommendations address findings Timeliness addressed. Completeness not documented in report NOTE: Reviewer should verify any apparent concerns such as "timely sent to STP or contractor" prior to inclusion in a draft and final report.
8/26-30	OREGON	---two 24 hr events unreported, one a year late --27 events reported late due to State computer problem (8 were reportable) --7 of 11 events need updated info.,i.e. contributing factors, corrective actions or closure information --Delays caused by staff shortages, loss of full-time IT/HP position, and absence of adequate data Q/A.	Satisfactory finding Recommendation: Ensure all reports through August '02 entered into NMED, correct missing NMED data; update and closeout events, resolve data transmission problems.	Finding not in accord with IMPEP evaluation findings and criteria-- was discussed with MRB and the Satisfactory finding was approved. Recommendation addresses findings Timeliness and completeness addressed

Table 1. SAMPLE 2002-2003 IMPEP REVIEWS (EVENT EVALUATION)

Date	Agreement State	Summary Finding	Recommendations	Comments
9/17-20	NEBRASKA	--14 events not in NMED (10 reportable) --9 lost Exit sign events and 1 stolen x-ray fluorescence device --noted many errors [alleged] in info. entered by NMED contractor i.e. wrong dates, event site, missing info.	Satisfactory finding. Recommend NRC NMSS review contractor's procedure for inputting NMED data and review database info. for accuracy & completeness.	Finding not in accord with evaluation findings and criteria Timeliness not documented in report. Completeness addressed. NMSS review conducted; many [alleged] NMED errors were due to NMSS procedural coding standards for NMED. State unable to find the [alleged] 9 lost exit sign events in response to Congressional inquiry. NOTE: Reviewer should verify any alleged concerns such as "NMED data entry errors" prior to including said statement in a draft and final report.
10/29-11/1	MAINE	--NMED event data missing in subcategory fields, e.g., device make, model & serial No., although, in most cases included in abstract. --New NMED incompatible with State LAN system, installed on stand-alone PC, now able to complete required fields. --State contacted NMED contractor to resolve missing data.	None Satisfactory	Timeliness not documented in report. Completeness addressed.
11/18-22	RHODE ISLAND	-2 incomplete incident files, misplaced during supervisor transition -all significant 24 hr and 30-60 day reportable events reported to NMED in a timely manner.	Satisfactory	Timeliness addressed Completeness not documented in report

Table 1. SAMPLE 2002-2003 IMPEP REVIEWS (EVENT EVALUATION)				
Date	Agreement State	Summary Finding	Recommendations	Comments
2003				
2/3-7	FLORIDA	--Team clarified what information should be reported to NRC for inclusion in NMED	None Satisfactory	Timeliness addressed Completeness not documented in report
6/9-13	S. CAROLINA	--data entered into NMED system	None Satisfactory	Timeliness and completeness, and significant and 30-60 day reporting not addressed. Reporting "significant" 24 hr events to Operations Center not addressed
7/21-25	MARYLAND	--found 4 events in local NMED but not in national NMED database --some local NMED events complete and closed out, but not in national NMED. --State will contact NMED contractor & resubmit the info. (other events & updates in NMED from same time period)	None Satisfactory	Timeliness and completeness addressed.
9/8-12	WASHINGTON	--events were appropriately reported to the NRC Operations Center and NMED.	None Satisfactory	Timeliness and completeness not documented in report (define appropriately)

SECTION CONCLUSIONS:

The team concluded that the technical quality and detail of event information continues to vary and increased emphasis needs to be placed on timely provision of the results of follow-up investigatory information to identify the root cause, corrective actions, and clarification of dose assessments results.

Based on the results of the review, the team recognized that the IMPEP event review evaluations could benefit from increased standardization to cover all of the major key areas, and should contain information identifying any issues, and, if known, the cause. Key areas could be identified through a standardized statement such as [*the team found that the State is reporting material events in accordance with SA-300; "significant 24 hour reportable events timely reported to the NRC Operations Center and all events, including those reportable in 30-60 days, were timely provided to NRC NMED. The*

team also found that the State provided completed event information in accordance with the guidance in SA-300, and all events were closed out or (explanation of delays) .”]

The team recognized the need to provide greater clarification of information on areas of concern regarding event reporting and NMED during IMPEP reviews, i.e. missing or incorrect data entries, or timely submission of information. Capturing more specific information early in the IMPEP process could result in timely resolution activities. Based on review results, the review team made a recommendation to revise the IMPEP review process for indicator No. 5, “Response to Incidents and Allegations,” to include contacting the NMSS NMED Project Manager and/or the STP Event Project Manager for information on any pending event area issues as part of the pre-IMPEP review. The revised process also includes contacting these individuals when event reporting or NMED software issues arise during the on-site review, preferably while on-site, or prior to completion of the Draft IMPEP report. The goal is to resolve any pending event reporting issues prior to sending out a Draft IMPEP report. The STP IMPEP Project Manager has begun implementation of the recommendation through a November 4, 2003 e-mail notification to all IMPEP reviewers, which will be added to the STP Website IMPEP Toolbox. NOTE: The revised process has been implemented in two recent IMPEP reviews, for LA and MD.

The team concluded that decreasing the frequency of reporting could result in increasing delays in the receipt of event information and could impact our ability to provide timely metric performance data to Congress as required under GPRA, and could impede early identification of generic or public safety implications that could impact public health and safety. The team concluded that although some States are unable to meet the monthly reporting schedule for 30-60 day reportable events and follow-up event information, most States generally support a national goal to collect material event information on a monthly basis.

The team concluded that STP Procedure SA-300 should be updated to incorporate revisions to regulatory and procedural requirements or processes impacting event reporting that have occurred since the last update, such as the recently revised 10 CFR Part 35. Additionally, the team concluded that additional emphasis needs to be placed on the joint CRCPD/NRC effort to track lost, stolen and found radioactive material (including non- AEA and unlicensed material) through voluntary reporting of material that is not currently included under material event reporting requirements; and further clarification is needed regarding NMED terms such as “*event closed by Region/State*” and “*record complete*” and who is responsible for closing out an event in NMED. Further clarification should be included regarding the responsibility of Agreement States to make the initial notification to the FBI for events involving the possibility of deliberate misuse, theft, or terrorist activity involving AEA radioactive material, based on comments received during event reporting training sessions. The team found that STP procedure SA-300 is scheduled for an update in 2004 and should incorporate comments from this report.

The team also concluded that development of alternative training methods should incorporate emphasis on the joint CRCPD/NRC effort, and FBI notification.

RECOMMENDATIONS:

- V-1. The team recommends increased emphasis on the importance and need to timely provide the results of follow-up investigations that discern the root cause, address corrective actions, and clarify the results of dose**

assessments. This could be accomplished through informal periodic discussions between RSAO's and the Agreement States, formal period meetings and IMPEP reviews, revisions to event reporting guidance documents, and periodic training on event reporting and NMED for IMPEP reviewers, and Agreement State staff.

- V-2. The team recommends inclusion of the revised process for indicator No. 5, "Response to Incidents and Allegations," a. Contacting the NMSS NMED Project Manager and/or the STP Event Project Manager for information on any pending event area issues as part of the pre-periodic meeting and pre-IMPEP review, and b. contacting these individuals when event reporting or NMED software issues arise during the on-site review, preferably while on-site, or prior to completion of the Draft IMPEP report, in the next revision of the STP procedure SA-105 covering Response to Incidents and Allegations.
- V-3. The team recommends including additional statements in the IMPEP guidance covering event reporting to address increased standardization to cover all of the major key areas, and to specifically identify any issues, and, if known, the cause. Key areas could be identified through a standardized statement such as [*"the team found that the State is reporting material events in accordance with SA-300; "significant 24 hour reportable events timely reported to the NRC Operations Center and all events, including those reportable in 30-60 days, were timely provided to NRC NMED." The team also found that the State provided complete event information in accordance with the guidance in SA-300, and all events were closed out or [explanation of delays] ."*]
- V-4. The team recommends that we continue the policy of monthly reporting of 30-60 day reportable events and follow-up event information. The team also recommends that NRC increase emphasis on the need to provide timely and complete event information.
- V-5. The team recommends incorporation of any revised regulatory or procedural event review processes, including revisions to Part 35 reporting requirements, and further clarification of NMED terms "event closed" and "record complete," and Agreement State and NRC responsibility to notify the FBI, into a revision to SA-300 and TI-2800-033 that provides guidance to the NRC Regions.
- V-6. Although the terms "event closed" and "record complete" has been clarified in NMED Newsletters the team recommends that reviewers and some Agreement States could benefit from the inclusion of the definitions of the two terms and who is responsible for closing the event in NMED in SA-105, Reviewing Common Performance Indicator #5, Response to Incidents and Allegations.
- V-7. The team recommends that CRCPD periodically remind States of the joint effort to track lost stolen and found material including notice through a medium such as RADRAP to ensure continued awareness of the effort in Agreement and non-Agreement States.

VI. MATERIAL EVENT REPORTING REQUIREMENTS AND THE 2001 EVENT WORKING GROUP REPORT

The team conducted a limited review of the material reporting requirements contained in various Parts of Title 10 of the Code of Federal Regulations (CFR) categorized by specific licensees. The team limited the review to specific areas of concern that the team found were contributing to or resulting in recurring requests for additional information from staff of NRC and the Agreement States, as identified below. The team conducted a summary review of the survey and discussion interview response comments from staff of the NRC and the Agreement States, regarding material reporting requirements. The team also reviewed the recommendations for improvement in NRC regulations reporting requirements identified in the April 2001 report of the Working Group on Event Reporting (2001 WG).

The team determined that the reporting requirements are scattered throughout the 10 CFR and difficult to find. The team found that the 2001WG came to the same conclusion. The team also found that some of the reporting requirements are conveniently presented as a subpart in some Parts of the 10 CFR as identified by the 2001WG. The team found that even so, some of the listings of requirements are incomplete in that the list may not contain all of the reporting requirements in that Part, as previously identified by the 2001WG. The team also determined, based on information provided by the NMED contractor, that recurring requests for additional event information primarily involve requests for the make, model and/or serial number of sources, devices and equipment (where applicable), the root cause of a specific event, and/or information on corrective actions. Additionally, clarification of the dose assessment results, are periodically necessary for "significant" abnormal occurrence (AO) material events. As a result, the team reviewed specific regulatory reporting requirements related to the areas identified by the NMED contractor, to discern whether information that has been identified as routinely missing from event reports received from NRC and Agreement State licensee event reports is clearly identified in the regulations.

The team found that specific information required to be reported is not consistent from one part of the regulation to the next. In addition, the specific details listed in STP Procedure SA-300 and NMSS Procedure TI -2800 -033 as the minimum basic information that should be provided for event report records, are not always reflected as specific reporting requirements in the regulations, as follows.

The team found that current regulatory reporting requirements such as 10 CFR Part 30.50, include requirements that the licensee event report present (a) a description of the event, (b) the probable cause, and (c) the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned. Current §31.5 requires the make, model and serial No., and a description of the event, and §34.101 requires the manufacturer and model No. , which is consistent with current guidance for a complete report (See Table 2. below).

The new Part 35.3067 requires the model and serial number for leaking sources (which is consistent with current guidance for a complete report).

Current regulatory reporting requirements such as 10 CFR Part 34.27, do not include a requirement that the licensee event report include item (c) above, the manufacturer and

model number (if applicable) of any equipment that failed or malfunctioned. Currently 10 CFR Part 39, Well Logging, §39.35 requires information on corrective actions, but does not mention make, model or serial No. of leaking sealed sources; and §39.77 requires a description of the well logging source, but does not specify make, model or serial No., which is not consistent with current guidance for a complete report. (See Table 2. below).

Based on discussions with staff of the NRC Regions and Agreement States, information on the make, model and/or serial number of sources, devices and equipment (where applicable), is not always provided by the licensee. It is sometimes necessary to make a follow-up request for the information. The team found that although the Agreement States generally receive information on the root cause and corrective actions from the licensees, they do not always provide that information to NRC. The team found that the effort to respond to additional requests for follow-up information has increased the burden time on Agreement States, and has resulted in additional effort in the NRC Regions and for the NMED contractor. Some Regions have implemented new procedures to request information on the manufacturer, model, and serial number of sources and equipment during inspections and added this information to inspection reports so that they will have the information available to complete the NMED report.

Table 2 below, presents in tabular form, specific reporting requirements identified above, that require written reports related to areas of concern, identified by the NMED contractor. These areas of concern have been identified as resulting in recurring requests for additional event information primarily involving requests for the make, model and/or serial number of sources, devices and equipment (where applicable), the root cause of a specific event and/or information on corrective actions. Recurring requests for additional information or clarification of the dose assessment has been identified for abnormal occurrence (AO) event reports.

Table 2. Reporting Requirements that Reflect Recurring Information Identified as Missing from Event Reports

10 CFR	Reporting Requirement	Agreement State Compatibility	Safety Significance	Working Group Recommendation	Self-Assess Team
Part 30 - Rules of General Applicability to Domestic Licensing of Byproduct Material					
30.50(c)(2)(i)	Written Report: "A description of the event, including the probable cause and the manufacture and model number (if applicable) of any equipment that failed or malfunctioned;" Report To: NRC Document Control Desk & NRC Region			None	
30.50(c)(2)(V)	Written report describing "Corrective actions taken or planned and the results of any evaluations or assessments" To: NRC Doc. Control Desk & NRC Region			None	
Part 31 - General Domestic Licenses for Byproduct Material					
31.5(c)(5)	(30 day report) Failure or damage to; or indication of possible failure of, or damage to the shielding, on-off mechanism, or indicator, or detection of 0.005 mCi of removable RAM. Written brief description of event and remedial action taken, and acceptance plan for unrestricted use, as necessary. Report to: MSS/GLTS	C	Low	Event W.G. Report stated "consider establishing Reports Section in Part 31 including this report plus a clear list of all the reports invoked by 31.2(a) and 31.5(c)(8)(13)(iii) Self-assessment recommends adding 31.5(c)(8)(ii)(A).	Agree w/01WG.
31.5(c)(8)(ii)(A) Device transfer	30 day Report: : "The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;" Rpt To: NMSS/GLTS			Not in Event W.G. Report	No recommendation
31.5(c)(8)(13)(iii) Device Registration	Manufacturer (or initial transferor) model No., serial No., radioisotope and activity (as indicated on label). Report To: MSS/GLTS			See Event W.G. Report comment above for Part 31.5(c)(5).	
Part 34 -Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations					
34.27(d) Leak testing and replacement of sealed sources	(5 day report) describing "equipment involved, the test results, and corrective actions taken." Report To: NRC Region.	C	Low	Event W.G. Report states Relocate or reference in Reports Section (Subpart F).	Agree w/01WG. Add make, model & serial # requirement.
Part 39- Licenses and Radiation Safety Requirements for Well Logging					
39.35(d)(2) Leak testing of sealed sources	(5 day report)describing "the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made." Report To: NRC Region	B	Low	Event W.G. Report stated compatibility inconsistent with other leak test requirements. Suggest change to "C" Relocate or reference in Reports Section (Subpart E)	Agreew/01WG. Add make, model & serial No. requirement.
39.77(d) (2) Notification of incidents and lost sources, abandonment procedures for...	(30 Day Report) "A description of the irretrievable well logging source involved including radionuclide and its quantity, chemical, and physical form; Report To: NRC Region				Add make, model & serial No. requirement.

SECTION CONCLUSIONS:

The team concluded that the various material reporting requirement subchapters could benefit from the establishment of a subsection in each Part of the 10 CFR that contains or references all reporting requirements in the Part, as identified by the 2001WG.

The team concluded that the various 10 CFR material reporting requirements schedules could benefit from a risk based review, and a review for inconsistency and standardization, where the information has been deemed essential to NRC needs. The current requirements include the following various reporting schedules: immediate reporting, prompt reporting, 4 hour report, 24 hour reporting, 2 day report, 30 day report and 60 day report. In some cases, similar requirements such as leak testing, have differing reporting schedules in different Parts of the 10 CFR. These type of inconsistencies were also identified by the 2001 Event Working Group Report.

The team concluded that 2001WG recommendation 2-3 to create a dedicated web page for basic reporting requirement information with electronic links to more detailed information, could benefit licensees and other users by providing one easily accessible site containing comprehensive guidance and information on reporting material events.

The team identified specific recommendations in Table 2 above, that reflects recurring information identified as missing from event reports. The team also indicated agreement with 2001WG recommendations for three of the reporting requirements. The team concluded that a joint NRC/Agreement State Working Group or Nuclear Materials Program Pilot No. 3, tasked with a much broader scope that includes conducting an overall comprehensive review of material operational experience, should conduct a follow on review of all the material reporting requirements, as well as ensure incorporation of the recommendations from this report into their assessment and any related guidance documents.

RECOMMENDATIONS:

- VI-1. The team recommends that Agreement State and NRC Region staff enhance the inspection report process and NRC/NMED reporting to ensure inclusion of information that has been identified by the NMED contractor as the primary source of requests for additional information. Steps taken should result in the inclusion of information on a. corrective actions taken, b. identification of the root cause, and c. the manufacturer, model and serial numbers of sources, devices, and equipment (where applicable).**

- VI- 2. The team recommends consolidating all reporting requirements in one subsection in each Part of the 10 CFR, similar to the new Part 35, which is consistent with the 2001 W.G. recommendation 2-2, as follows “establish a subsection in each Part of the 10 CFR that contains or references all reporting requirements in the Part. (Note: Agreement State regulations tend to be more consolidated than 10 CFR, but States should also consider the need to consolidate).”**

- VI-3. The team is recommending that a joint NRC/Agreement State working group or Nuclear Materials Program Pilot No. 3, tasked to examine operating experience, (1) conduct an evaluation of material reporting requirement inconsistencies and schedules, based on risk significance, for all reporting requirements including those identified above and in the 2001 Event Working Group Report, and (2) any information deemed essential to NRC needs should be reflected in revised regulations and revised guidelines.
- VI-4. The team supports 2001WG recommendation 2-3 to create a dedicated web page for basic reporting requirement information with electronic links to more detailed information.

VII. DISCUSSION AND INTERVIEWS (AGREEMENT STATES)

a. *Why Do Some States Operate Effectively and Some Operate with Difficulty Reporting Event Information to NRC (Include Timeliness and Completeness)?*

An initial survey request was sent to all 32 of the Agreement States to primarily collect information on the resources and effort involved in the preparation of a significant event report for notification to the NRC Operations Center, or a monthly report of 30 to 60 day event notifications. This information was used in the NRC NMED OMB clearance.

Based on the responses received, a discussion/interview survey was designed to collect more up-to-date general information from a sample of Agreement States on the current process and format used to report material events to NRC. The team contacted 14 Agreement States to further discuss the processes used to report material events and to capture more detailed information on their experience in using the current NRC guidance and tools used to implement, collect and manage the national collection of material event information. Interview discussions were conducted with the following 14 Agreement States: Arizona, Florida, California, Colorado, Georgia, Illinois, Iowa, Maryland, Nebraska, New Mexico, New York State Health, North Carolina, Tennessee, and Texas. We asked those contacted to cooperate with us to gain a better understanding of their event reporting processes and systems. The information would be used to support our efforts to simplify the current process through short- or long-term procedural or system modifications. We are providing a summary of the responses received. A copy of the Survey Questionnaire used during telephone discussions is included as Appendix B.

Based on the findings, the Agreement States provide material event information electronically by word processing application file, NMED local data-entry data file, non-NMED database or spreadsheet file, or by hard-copy Fax or mail.

Figure 1 below, identifies the method used by each Agreement State to provide material event information to NRC. NOTE: The States with the largest number of licensees, California, New York and Texas, do not use an electronic reporting system. (Highlight = States interviewed)

NOTE: All non-NMED submittals, including other electronic methods, are manually entered into NMED by INEEL.

Use Own database to send event data	Use NMED Local Data Entry program
<p>Florida Oregon Washington</p>	<p>Alabama Arizona (Beginning 4/03) Arkansas Colorado Illinois Iowa² Kansas Louisiana Maine Maryland Massachusetts Mississippi Nebraska Nevada</p>
Submit Hard Copy to NRC	<p>North Carolina (Duplication)³ North Dakota Ohio Oklahoma South Carolina Tennessee Utah Wisconsin</p>
<p>California Georgia Kentucky New Hampshire New Mexico New York⁴ Rhode Island Texas (Duplication)⁵</p>	
<p>TOTAL: 11 States 8,652 material licensees (52%)</p>	<p>TOTAL: 22 States 8,050 material licensees (48%)</p>

Table 3. How Current Agreement States Report Events to NRC.
(Discussions conducted with highlighted States)

² Iowa uses NMED to maintain local event data, but submits hard copies to NRC that are manually re-entered by INEEL.

³ Identified a duplication of effort in North Carolina. The program is entering event data in their own database and the NMED local data entry program.

⁴ New York State Health is currently developing their own proprietary database.

⁵ Identified a duplication of effort in Texas. The program is entering event data in their own database and the NMED local data entry program. Texas is working to try to combine the two programs.

b. Sample Summary Findings from Discussion Interviews

Most of the comments received were related to NMED such as query searches, newsletters and quarterly reports, the NMED contractor, or to NRC policy on reporting material events. A small sample summary of some of the key comments are provided below. A detailed description of the comments and team responses to the comments, as necessary, can be found in Appendix A to the report.

- Of the 14 States interviewed, four had participated in NMED training in the last 3 years, and two additional States attended the Summer 2003 NMED training. A listing of attendee for the 2003 NMED training is included as Appendix C.
- The team found that the effort to respond to additional requests for follow-up information has increased the effort for Agreement States, as identified in the NMED OMB clearance information, and has resulted in additional effort in the NRC Regions and for the NMED contractor.
- Some States indicated they are experiencing difficulty in providing timely 30-60 day event notifications and follow-up event report information.
- Based on Agreement State comments during the discussions, the current version of the NMED Local Data Entry program has been significantly improved from previous older versions.
- Current NMED users identified no specific problems with loading the software on a LAN or a local PC. Of the States interviewed, Maryland, North Carolina and Nebraska have the executable files on a LAN.
- Most NMED users generally found the program easy-to-use. Commenters stated that the program includes pull down menus with pick lists, and pop-up help flags for clarification which are helpful.
- Comments on the national website NMED program indicated that query searches are very useful and are being used to support the licensing and inspection programs in some States and NRC Regions.
- Most commenters stated that the NMED contractor provides helpful support.
- One comment stated they would prefer to report directly to NRC staff rather than a contractor.
- During the interview/discussions, the team identified a duplication of effort in two of the State's (North Carolina and Texas), and also found that New York State Health has begun development of a comprehensive database system that will encompass X-ray registration, radiation technology/materials, events, licensees, and physicians.
- One comment questioned the need for immediate notification of an event involving Tritium Exit signs. Why is this an immediate notification? Why not consider making it a 30 day reporting requirement?

- A few commenters indicated a need to improve NRC guidance on Abnormal Occurrences.
- A few comments indicated a need to revise event reporting guidance to update the reporting requirements table to include Part 35 revisions.
- Several comments asked for guidance on event closeout.

VIII. DISCUSSION/INTERVIEWS WITH NRC REGIONS

a. Concerns regarding responses to contractor requests for additional information, closing out events, and the effectiveness of the current process.

The review team conducted telephone interviews with staff from NRC Region I, II, III and IV. The team found that a similar process is followed by NRC and the Agreement States to respond, review and/or investigate the material events, conduct an inspection, and collect event information from licensees. The process differs regarding the use of resources to compile and code (data entry) the event information into the NMED database. NRC uses a contractor to perform this function. Therefore, the questions were focused on the process after the NMED contractor has developed an event report summary from the licensee event information collected in NRC ADAMS, i.e. ENs, PNs, MRs, inspection reports, licensee reports (LERs), etc. The NMED contractor is responsible for contacting Region staff directly via email for clarification of any event information needed for a complete NMED report, similar to the process for contacting Agreement States.

- The Region staff were primarily concerned with providing complete event report information and closing out event reports in NMED, based on discussion comments. Some Region staff are concerned about the detailed information needed for a complete report, similar to concerns previously expressed by the Agreement States.
- One Region staff member commented that Region maintenance of a Local NMED data entry program could be useful to Region staff.
- The team found that several Regions have implemented a revised process for tracking and responding to NMED contractor questions, to ensure actions are closed out. Currently, all Regions have assigned a technical staff member, Point of Contact (POC), the responsibility for tracking and responding to NMED contractor questions, to ensure actions are closed out. The POC coordinates the response with the inspector and the NMED contractor. In some Regions, NRC staff conduct a periodic review of all new NMED open items, similar to the process used by many Agreement States. Any open items are sent to the appropriate Branches for resolution. The revised process was recently established to ensure follow-up to NMED contractor questions for additional information or clarification and to ensure the NMED follow-up actions are closed. One Region has downloaded the national MS Access NMED program to keep track of open and closed Region events.

- In response to the teams inquiry regarding providing a monthly log of follow-up and closed out events to the NMED contractor, some Regions have implemented a process to send in a monthly log of follow-up and closed out events to the NMED contractor.
- The team found the Regions use NMED national Website data for review of Region events and find good quality event data.

IX. COMPILATION OF GOOD PRACTICES

During the assessment the team identified several good practices that had been implemented in Agreement State and NRC Region Programs, as identified below.

1. California:

The program used the NMED National Website database to query the national historical data to verify lost source claims from a TV newscast.

2. Colorado:

A radiography licensee questioned the corrective action recommendation from an inspection report. The NMED National Website database was used to query similar cases nationwide and to illustrate to the licensee the reasonableness of the prescribed corrective action when compared to the corrective actions of similar cases.

3. Maryland:

Use NMED National Website database for device history, and in the SS&D review process. Use NMED historical information for new licensees. Recently issued 2nd Gamma knife license and sent NMED historical gamma knife data history to new licensees. NOTE: Public access to NMED would be valuable for some licensees to gain historical perspective.

4. Region I

The team found that NRC Region I inspectors are required to query NMED for any open event issues, and to look at past history to identify past problems that should be focused on during the inspection.

Region I staff use NMED to identify loss gauges through the serial number.

5. Region III

The team found that NRC Region III inspection scheduling and planning process includes a query of NMED by the inspector, prior to conducting the inspection, for any open items for follow-up during the review, and to study the event history of the facility being inspected for any specific weaknesses in the program. The NMED data has been used by an Agreement State to provide a new gamma knife licensee historical operational information on AEA material events involving gamma knife devices at licensed facilities.

5. Region IV

The team found that the Monthly LER Package (summary table, forms, support information, closure status) that Region IV submits to NMSS for review is a useful tool for INEEL to be able to enter all information needed to complete each NMED entry, and to address the issue of closing events with INEEL.

Recommendations:

Based on Region comments, the team recommends that NRC consider the need to ensure that all references cited in the NMED database "Event Documents List" should be available in ADAMS.

X. FINDING AND CONCLUSIONS

- The team did not find that the variances between the event reporting process for NRC licensees and the Agreement States resulted in an unfair burden. Based on the results of the review, the team concluded that a similar process is followed by NRC and the Agreement States to respond, review and/or investigate the occurrence of a material event, conduct an inspection, and collect event information from licensees.

The team determined that the process differs regarding the use of resources to compile and code (data entry) the event information into the NMED database. Rather than have NRC staff compile and code material event information into NMED, NRC decided it was more efficient and effective to secure a contractor to perform this function. Rather than secure contractor resources, staff of the Agreement States conduct a similar compilation and summary abstract activity, and, in some instances, coding function for all radiation events, including AEA events, that have occurred under their jurisdiction, and maintain the records either manually, or code the data into their own database, or a Local NMED database provided by NRC. The State sends the data to NRC, which is entered into the National NMED database by the NRC contractor.

The team concluded that the information needs for a complete NRC report may be different from the information needs of an Agreement State for its own records. The team also concluded that under the *Agreement*, compatible event information should be provided by an Agreement State. Therefore, the team concluded that, although the additional information needs may place an additional burden on the Agreement States, the burden is reasonable if NRC deems the information is necessary to meet Federal and Congressional mandates and to protect public health, safety and security. The team also concluded that in providing several modes for Agreement State reporting of event information, FAX hard copy, email word processing file, NMED database file, or other electronic database or spreadsheet format, no unfair burden exists regarding the reporting of event information to NRC and NMED.

NOTE: The team found that the States with the largest number of licensees, California, New York and Texas, do not use an electronic reporting system, which could increase efficiency. Based on recent OMB NMED clearance data, the average time to provide event report information increased from 1 hour to 1.5 to 2 hours due to an increase in

the number of contractor requests for additional information. The team found the additional clarifying information is necessary to support performance metric data goals required by the Government Performance Results Act of 1993 (GPRA).

- The team also found that some recurring requests involve information that is not currently identified in some of the reporting requirements. The team is recommending a review of the need for the information and if deemed essential, a revisions of the regulatory reporting requirements to include the information, e.g., make, model and serial number of devices and equipment, and the root cause and corrective actions. The team concluded that this action could result in a reduction of the number of requests for additional information and reduce the burden on the Agreement States and NRC Regions staff to respond. The team found various reporting schedules from immediate to 60 days after the occurrence, and inconsistencies in the specific reporting schedules for similar type events throughout the reporting requirements. Based on the review results, the team is recommending a review of the current regulatory reporting requirements for risk significance to public health and safety by a joint NRC/Agreement State working group or the Nuclear Material Pilot No. 3 as part of their ongoing operational evaluation effort. The team concluded that risk-based reporting requirements could result in a reduction of the burden effort for reporting through development of more risk based reporting requirements and schedules, based on the risk significance of the occurrence of the event.
- The team found that, in general, most States are timely providing “*significant*” 24 hour reportable event notifications. The team identified that some States are experiencing difficulty in providing timely 30-60 day event notifications and follow-up event report information. It has been continually necessary for the NMED contractor to send follow-up information requests, pending beyond 60 days, to the Region staff for resolution. During interview discussions a few States indicated they waited for the contractor to request follow-up information rather than automatically provide it as indicated in SA-300. The team concluded that this area needs to be addressed through increased emphasis on the importance and need to timely provide the results of follow-up investigations that discern the root cause, address corrective actions, and clarify the results of dose assessments. This could be accomplished through revisions to event reporting and IMPEP guidance documents, informal periodic discussions between RSAO’s and the Agreement States, formal period meetings and IMPEP reviews, and periodic training on event reporting and NMED to IMPEP reviewers and other NRC staff involved in this area.
- The team found that NRC licensees event reporting is comparable to the 40-50% of Agreement States that generally report 30-60 day reportable events and follow-up information monthly. Similar to those Agreement States, the NRC Regions receive a smaller number of periodic requests for additional or clarifying information from the NMED.
- The team found that further clarification of the terms “*record complete*” and “*event closed by Region/State*”, and wider dissemination of the information would be beneficial to NRC Region and Agreement State staff.
- The team also found that most commenters agreed that monthly reporting was the most effective and efficient as staff maintain procedural expertise in entering data, and fewer

events reduced the time necessary to collect background data, even though they were not always able to meet the schedule. The team concluded that monthly reporting of material events should continue.

- The team determined that some States were unable to participate in the five event reporting/NMED training sessions held in 2003 due to travel restrictions. The team concluded that alternative training methods should be evaluated to continue to provide current training on event reporting to technical staff.
- The team concluded that the NMED Local Data Entry program is user friendly, technologically current, and has become a very useful tool for the Agreement States. Version 5.1 of the NMED Local Data Entry Program was released in September 2003. This version further streamlines data entry, upgrades the search function, and addresses a number of requests made by the Agreement States. The team found that the NMED National Website database is used by some Agreement States and the Regions to support inspection and licensing programs, but could use updating to incorporate IT technological advances. NRC has recently begun a planned scheduled update of the NMED National Website database with a planned release due mid-2004. To keep abreast of technological changes that could impact the program, the team is recommending that NRC continue to periodically survey the Agreement States for comments on NMED.
- The team identified the need to incorporate revisions to regulations and event reporting processes into the next revision of STP Procedure SA-300, Reporting Material Events.
- The identified the need to update IMPEP guidance documents, SA-105, and SA-100 to incorporate timeliness and completeness of event reports.

XI. LIST OF RECOMMENDATIONS

Section III. How does NRC maintain NRC licensee and Agreement State event information in NMED?

- III-1. The team recommends that alternative training methods, such as video, CD-ROM or online methods, be evaluated to determine their feasibility and effectiveness, as an additional training tool to complement traditional training methods. (P 15)
- III-2. The team recommends that NRC continue to upgrade the NMED software program on a schedule similar to the current two to three year scheduled upgrade between 2001 and 2003 to continue to improve the overall intuitiveness of the program, take advantage of technological advances in Microsoft Access software updates, and reduce the possibility of incompatibility problems.
- III-3. To keep abreast of technological changes in the regulatory process and technical areas that could impact the program, the team recommends that NRC continue to periodically survey the Agreement States for comments on the NMED Local Data Entry and National Website programs to determine changing needs and to solicit input for future upgrades, and share those comments with all users.

Section IV. Sharing results of analyses of national material event data.

- IV-1. Opportunities for improvement should include broadening the scope and frequency of event analyses to increase timeliness and efficiency in the early identification of possible GSIs and trends and patterns, in addition to periodic email notification through a medium such as RADRAP of the availability of the results of an evaluation or assessment conducted by NRC or an Agreement State. (p. 18)

Section V. Review guidance documents and IMPEP reports to identify event reporting concerns (FY 2002/03 IMPEP reports)

- V-1. The team recommends increased emphasis on the importance and need to timely provide the results of follow-up investigations that discern the root cause, address corrective actions, and clearly describe results of dose assessments. This could be accomplished through informal periodic discussions between RSAO's and the Agreement States, formal period meetings and IMPEP reviews, though revisions to event reporting guidance documents, and periodic training on event reporting and NMED. (p. 28)
- V-2. The team recommends inclusion of the revised process for indicator No. 5, "Response to Incidents and Allegations," a. Contacting the NMSS NMED Project Manager and/or the STP Event Project Manager for information on any pending event area issues as part of the pre-periodic meeting and pre-IMPEP review, and b. contacting these individuals when event reporting or NMED software issues arise during the on-site review, preferably while on-site, or prior to completion of the Draft IMPEP report, in the next revision of the STP procedure covering Response to Incidents and Allegations.
- V-3. The team recommends including additional statements in the INPEP guidance covering event reporting to address increased standardization to cover all of the major key areas,

and to specifically identify any issues, and, if known, the cause. Key areas could be identified through a statement such as “the team found that the State is reporting material events in accordance with SA-300; “significant 24 hour reportable events timely reported to the NRC Operations Center and all events, including those reportable in 30-60 days, were timely provided to NRC NMED.” The team also found that the State provided complete event information in accordance with the guidance in SA-300, and all events were closed out or [insert cause of delay] .”

- V-4. The team recommends that we continue the policy of monthly reporting of 30-60 day reportable events and follow-up event information. The team also recommends that NRC increase emphasis on the need to provide timely event information.
- V-5. The team recommends incorporation of any revised regulatory or procedural event review processes, including revisions to Part 35 reporting requirements, and further clarification of NMED terms “*event closed*” and “*record complete*,” and Agreement State and NRC responsibility to notify the FBI, into a revision to SA-300 and TI-2800-033 that provides guidance to NRC Regions..
- V-6. Although the terms “*event closed*” and “*record complete*” has been clarified in NMED Newsletters the team recommends that reviewers and some Agreement States could benefit from the inclusion of the definitions of the two terms and who is responsible for closing the event in NMED in SA-105, Reviewing Common Performance Indicator #5, Response to Incidents and Allegations.
- V-7. The team recommends that CRCPD periodically remind States of the joint effort to track lost stolen and found material including notice through a medium such as RADRAP to ensure continued awareness of the effort.

Section VI. Material event reporting requirements and the 2001 event working group report.

- VI-1. The team recommends that Agreement State and NRC Region staff enhance the inspection report process and NRC/NMED reporting to ensure inclusion of information that has been identified by the NMED contractor as the primary source of requests for additional information. Steps taken should result in the inclusion of information on a. corrective actions taken, b. identification of the root cause, and c. the manufacturer, model and serial numbers of sources, devices, and equipment (where applicable). (p32)
- VI- 2. The team recommends consolidating all reporting requirements in one subsection in each Part of the 10 CFR, similar to the new Part 35, which is consistent with the 2001 WG recommendation 2-2, as follows “establish a subsection in each Part of the 10 CFR that contains or references all reporting requirements in the Part. (*Note: Agreement State regulations tend to be more consolidated than 10 CFR, but States should also consider the need to consolidate.*)”
- VI-3. The team is recommending that a joint NRC/Agreement State working group or Nuclear Materials Program Pilot No. 3, tasked to examine operating experience, (1) conduct an evaluation of material reporting requirement inconsistencies and schedules, based on risk significance, for all reporting requirements including those identified above and in

the 2001 Event Working Group Report, and (2) any information deemed essential to NRC needs should be reflected in revised regulations and revised guidelines.

- VI-4. The team supports 2001WG recommendation 2-3 to create a dedicated web page for basic reporting requirement information with electronic links to more detailed information.

X. REFERENCE LIST

1. *Title 10 Code of Federal Regulations* contains all the regulations governing the Nuclear Regulatory Commission.
2. *The Government Performance Results Act of 1993 (GPRA)* is a Federal law that requires all Federal agencies to develop a strategic plan and measurable performance goals, based on the mission and goals of the agency. It also requires an annual report to Congress that addresses agency performance in meeting the performance goals and measures.
3. SECY-97-054, contains Commission policy on Agreement State reporting of events to NRC's NMED database as an item of compatibility for the Agreement States, dated June 30, 1997.
4. [Manual Directive 5.6](#), the "*Integrated Materials Performance Evaluation Program (IMPEP)*," contains the policy for conducting evaluations of NRC regional materials programs and Agreement State radiation control programs.
5. STP procedure [SA-100](#), "*Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*," contains the implementing procedures for conducting IMPEP reviews.
6. STP procedure [SA-200](#), *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, contains the 10 CFR compatibility categories for Agreement States.
7. STP procedure [SA-300](#), "*Reporting Material Events*," contains policy guidance on the process for notification, follow-up and closeout of material event reports to NRC and NMED. It also includes guidance on the identification of and report format for the mountain government "Abnormal Occurrences."
8. TI-2800-033, Temporary Instruction for Material Inspection Program
9. STP procedure [SA-105](#), *Reviewing Common Performance Indicator #5, Response to Incidents and Allegations*," contains guidance for IMPEP reviewers for evaluating notification, response, follow-up and closeout of events and allegations.
10. NUREG-0090, *Abnormal Occurrence Report*. NUREG-series publications are available electronically at NRC's Public Electronic Reading Room at www.nrc.gov/NRC/ADAMS/INDEX.HTML. They may also be purchased through the Government Printing Office at: bookstore.gpo.gov

11. The *Nuclear Materials Events (NMED) Database Quarterly Report* is available in electronic form at the NMED Internet Website: <http://nmed.inel.gov>.
12. The newsletter, *NMED News: Nuclear Material Events Database*, is available at the NMED Internet Website: <http://nmed.inel.gov>.
13. The *NMSS Licensee Newsletter*, NUREG/BR-0117, is periodically published to provide information on generic and safety significant issues and events, and identifies any significant enforcement actions that have occurred during the period. The newsletter is distributed to NRC licensees, the Agreement States and selected NRC technical staff, and is available in NRC ADAMS.

APPENDIX A

APPENDIX A

COMPILATION OF COMMENTS (Agreement States)

1. *NMED Local Data Entry Program*

- One commenter stated that follow-up event information is not provided to NRC until completion of the investigation which can result in delayed notifications to NRC.

Team Response: Timely updating of NMED on a monthly basis ensures that NRC and the Agreement States are aware of all events that could become a precursor to a more safety significant concern or that could contribute to the identification of a generic issue or concern involving recurring failures or defective systems, processes, equipment or devices.

- One commenter stated previous Internal software incompatibilities with MS Access 97 prevented installation of the NMED Local Data-Entry software program. MS Access has been upgraded, and based on positive comments from other States already using the software, staff successfully installed the 4.2 version of the NMED program.
- The local data entry program requires a lot of information for some fields that may not be useful to NRC.

Team Response: Based on similar comments from other NMED users, NRC conducted a review and removed unnecessary fields from the latest NMED local data-entry program version 5.1 (September 2003). The fields in question may have been addressed in the new version. We recommended trying the new revised version 5.1, and indicated that we would appreciate any comments.

- Commenter liked the pop-up help information that appears when you hover over a field title in the NMED Local Data Entry Program.
- Commenter stated the NMED local data entry program was very user-friendly; CD walks you through with simple steps, and the questions help you add things you might not have included if you were doing it manually. Commenter found the program an improvement over manually drafting an event report, and each report is now standardized.
- Commenter stated they are using the NMED local program, but do not plan to provide event reports electronically. Plan to continue Faxing hard copy NMED reports to NRC/STP Director.
- Commenter stated that early on, in the past, they did not always receive E-mail confirmation that event file information had been received by NMED contractor, so they stopped using NMED. Due to uncertainty, rather than send an electronic

transfer file, the program staff print out the NMED event report and FAX a hard copy to the Director, STP (in accordance with SA-300 for hard copy event reports).

Team Response: Team suggested trying to send an electronic NMED local program event report transfer file with the new version. During the early implementation process, the contractor may not have consistently E-mailed a receipt response. Current procedures include providing an E-mail response to all submissions received via E-mail, notifying the sender that the NMED .mdb file was received and that the file was readable. The NMED contractor does not routinely provide receipt verification to information submitted via Fax, letter, or diskette. If the sender wishes to verify receipt, they should telephone the contractor.

- Four more commenters stated the NMED local data entry program is a useful database tool and simple to use. The 4.2 version is outstanding, compared to the earlier versions.
- One commenter indicated they had been using version 4.2 about 1.5 years. Commenter expressed interest in receiving the new version 5.1 when it becomes available.
- Commenter stated NMED Coding Guidance included within the software, is very good; use it all the time. Use SA-300 for information on IMPEPs.
- Two commenters stated that overall, the help support provided by the contractor is excellent.
- Two commenters indicated completeness of NMED data records is very good, find everything during the quality assurance (Q/A) review.
- One commenter suggestions for improvement for the (NMED Local Data Entry) to simplify the ability to convert the abstract into a "word processing file." Sometimes they lose the last sentence of the abstract when generating the word file. They have to "print to file" and then save as a "Word" document.

Team Response: This suggestion has already been addressed in version 4.2.

- Comment received to simplify the editing ability. As you page through and cursor to the next button for each page, you may eventually have to click on the field to go forward. Maintain the next button for all page through.

Team Response: The NMED Version 4.1 allowed easier navigation through the screens via a menu tree so users can go directly to the screen of interest. The new version 5.1 improves and streamlines the screens.

- Comment received to simplify sorting records. Opening screen for event record listing currently sorted by Item No. only. How about including a sort by name or City. The current process results in a user going through the 1999 records to get to

the most current events. NRC staff responded “would reverse order sorting help?” Yes, if we could resolve the year 2000 concerns.

Team Response: The new NMED Version 5.1 includes sorting of the opening screen for event record by item No., licensee name, license No., city, or event type in ascending or descending order. It also sorts records .

- Comment received that the LAS event type includes too many types of events, of which some should have their own category.

Team Response: The number of event types or classes is intentionally few in number and broad in scope (currently only 10). Further distinctions are made through key words, cause, or reporting requirement.

- Manufacturer pick list is not complete, i.e., missing BEBIG brachytherapy unit, understand it has now been added.

Team Response: Manufacturers would not appear on the pick list until the first events related to that entity is added to NMED. As soon as the event is added, the manufacturer appears on the pick list.

- Commenter stated cannot always find model Nos. for Novoste equipment

Team Response: This will be considered during the upcoming national website redesign.

- Commenter suggested improvement for Searches -- provide automatic ending for State listing rather than having to scroll through the whole list of States, i.e. type “NE” and the cursor automatically scrolls to “Nebraska.”
- Commenter suggested improvement for data entry program: LAS coding page, provide full definition in a pop-up, “Loss of material includes...” Click Next-Add pop-up “Next go to Event type.” It’s not easy to know what to do next.
- Commenter stated Reference Documents did not contain the State ID No., such as NE ID number.
- One commenter asked if they could receive information on structural development of the NMED tables.

Team Response: We can provide this type of information to users at their request.

- One commenter stated that their program needs to reduce event reporting data entry duplication of effort to gain efficiencies to support effort to become self sufficient by 2004.

Team Response: NRC staff and the NMED contractor are available to help with any efforts to consolidate your event information into one single system that is compatible with NRC's NMED program.

- NMED Quarterly Report: Staff indicated they do not receive hard copies of the NMED quarterly report, but they are useful when they get a chance to read them at the website. Staff find the NMED newsletter useful and want to continue receiving a hard copy.
- One commenter was unaware of the NMED quarterly and monthly reports generated by INEEL, and didn't see the utility in those reports.
- One commenter stated that the NMED Newsletter and Quarterly reports contain useful and helpful information.

2. NMED National Website database comments:

- The NMED National Website database is a good database. Recommend use by all Agreement States.
- The completeness of data is good at the NMED national website
- Unable to identify previously sent event reports that have not yet been closed out, in the NMED national program at the NRC website.

Team Response: This capability was added to the Nation Website in August 2003.

- One commenter did not use the NMED national website for any national searches. Only go to national website program for quality assurance (Q/A) of State data.
- Commenter did not use the NMED National Website database. Use own database information. Used the NMED national program for about 45 seconds, found it was not as simplistic as assumed, and did not use it. Commenter stated that any Internet search would have to provide results in a few seconds or the commenter will not use it. Commenter did identify that they were not very knowledgeable of the option choices and how to use them. For example, a query for "scrapyard" =orphan source or transportation did not result in a find.

Team Response: About two years ago, the national database was migrated to a faster server. Most searches take less than ten seconds for typical users, with the maximum of 20 seconds for complex searches returning many records. This is a good response time for a complicated system with over 14,000 records. The users system and Internet connection is typically the limiting factor for response time.

- Commenter expressed interest and expectation that NRC conducts event trending analysis and that NRC will send out Information Notices to State programs when an issue is identified, rather than use NMED National Website database.

Team Response: NRC conducts event assessment trending analyses. These are disseminated to state's and others through a variety of vehicles. The type of vehicle chosen is based on the appropriate type of notification warranted, i.e., INs, NUREG-series reports, NMSS and NMED newsletters, NMED quarterly report, etc.

- Two commenters identified the need to simplify searches: Performing searches on the NMED National Website database are not as simplistic as the average Internet search, but can find information with persistence. Sometimes have to find data via circular route rather than standardized reports. Primarily use "Other criteria" for searches. Found gamma knife through search under "events with a specific system", related to key word list (which can be limited). Searches using standard report for "Specific serial No." are useful.

Team Response: NRC began a scheduled upgrade of the NMED National Website database in September 2003 with an estimated completion date of early 2004. We are aware that new developments in Web technology resulting in simplification of Internet user searches have taken place since the development and installation of the Web program approximately three years ago. The planned upgrade will incorporate new Web technology into the national NMED program. The NMED contractor staff are available to assist with searches.

- Two commenters stated NMED National Website database is a very useful tool, and has a lot of useful information. Recommend that all the States use the national NMED information.
- Two more commenters stated that queries of the NMED National Website database provide "very valuable" information.
- One commenter identified no problems with national NMED program at the NRC website. The completeness of information was good. Commenter stated that staff have an understanding of the assumptions and limitation of a database. The commenter provided the following example of limitations of a database. Based on the information provided by various States, searches using "nuclide" went very well -- searches using "Model No." were not as fluid (one individual's model No. may be another's serial No.).

3. Policy Issues

- One commenter stated that currently their material licensee event reports do not include the root cause, or corrective actions. Licensee event reports also do not include make or model No. for events involving gauges or equipment, based on current reporting requirements. Upon receipt of a request for follow-up information from INEEL, they have to call the licensee to get this additional information.

Team Response: The team found that the specific information required to be reported is not consistent throughout the 10 CFR. The team found that recurring requests for additional information include the make, model No. and serial No. (Where applicable), root cause, and the identification of corrective actions. The self-assessment team is recommending that NRC conduct an evaluation of the reporting requirements based on risk significance, consistency and the need for the information, to ensure that the make and model No., root cause, and the identification of corrective actions are included in the specific reporting requirements (where applicable), if deemed necessary for public health, safety and security. Current 10 CFR Parts 30.50, 31.5, and 34.101 require that the licensee provide this information. When reporting under similar regulations licensees should be providing the information.

- Comment received on STP procedure SA-300, Reporting Material Events. Commenter stated that the procedure is not very useful for defining what is an AO. The AO criteria is confusing. Commenter indicated the need for a full description of what is an unusual event. Commenter couldn't discern between the 7 options identified in the AO criteria.

Team Response: We will provide additional clarifying information for an unusual event in the next revision of SA-300. We will forward your comments on the AO criteria to the appropriate NRC office.

- Commenter expressed concern that the NMED contractor does not always understand technical issues described in event reports. Would prefer follow-up questions coming from the NRC staff.

Team Response: The NRC contractor codes event based on NRC developed coding guidance criteria. The team did not find evidence of contractor failure to understand technical issues. In addition, NRC has modified its procedure regarding requests for information. In the past, the contractor handled all requests for additional information and follow-up information. Under revised procedures, the contractor will respond back to the requester in writing to clarify the exact type of question or query and the exact dates for the inquiry (begin and end) in writing to reduce the possibility of communication issues.

- Commenter expressed concerns regarding the NMED contractor recoding information sent in the State's transfer file without consulting the State first. For

example, a recent transfer file included an irradiator event identified as “not reportable.” The State was concerned that the NMED contractor made an assumption and changed it to “reportable” under Part 36.83 (a) (1), source stuck in an unshielded position. The commenter indicated that additional information in their files supported the statement that it was unreportable. See NMED item No.030369.

Team Response: The NRC has assigned the NMED contractor the responsibility to review, code, maintain, and support the NMED database. As part of that effort, the contractor conducts a completeness review, including the applicable reporting requirement, based on the 10 CFR rules. A complete report should provide enough information to determine whether an event is reportable. The event report should clarify why an event was identified as “not reportable,” when the event conditions such as a “source stuck in an unshielded position” could be identified as reportable.

It is acknowledged that at times, the contractor does recode information received from the Agreement States. This is sometimes necessary in order to maintain consistency with standard definitions and coding practices. In an effort to maintain open clear communication with the States, the contractor informs the States of such changes. If the State believes the change was an error, the State should contact the contractor to explain, supplying any additional information as necessary.

- Commenter expressed concern regarding events that are closed from a State perspective, but are not closed by the NMED contractor, INEEL in the NMED national website database. The events could become an issue during IMPEP reviews. This can occur when the review team runs an NMED query and finds “open events,” when from the State perspective, they have closed those events and provided all possible information.

Team Response: The NMED contractor will mark any record closed at the direction of an Agreement State or NRC Region. The Agreement State or Region need only send a request to the contractor, or indicate closed if they use the NMED transfer file.

- Commenter expressed concern regarding the amount of time it takes to correspond with the NMED contractor, INEEL, in response to E-mail questions soliciting more information for an event.
- Monthly Reporting: Commenter stated the monthly reporting schedule to NRC is reasonable; 90% in the system within 30 days. Follow-up reports -- don't make the 30 days until they have enough information on complex significant reports such as an AO.
- One commenter stated that reporting monthly is a reasonable schedule.

- Commenter suggested reporting material events to NRC on an every other month schedule. Also recommend NRC send out a bi-monthly reminder to the States. Due to the need for quality assurance (Q/A) of event reporting information prior to sending to NRC and competing priorities, States may find it difficult to meet the monthly requirement schedule. But, the commenter agrees that monthly reporting is more valuable in maintaining current data, and it helps the user to maintain proficiency in using the NMED program.

Team Response: The team concluded that bi-monthly reporting would not be as effective as monthly reporting. The non-standard schedule could result in confusion and contribute to further notification delays.

- Commenter expressed concerns that the NMED contractor does not always understand technical issues described in event reports. Would prefer follow-up questions coming from the NRC staff.

- Team Response: The team provided clarification that event reporting guidance contained in SA-300 covers reporting to NRC. The NRC contractor has been designated by NRC to review, collect, support and maintain NRC/NMED event report information. As part of that effort, the contractor conducts a completeness review, including the applicable reporting requirement, based on the 10 CFR rules. A complete report should provide enough information to determine whether an event is reportable, based on SA-300 guidance.

- The NMED is a very useful tool, but should not be a matter of adequacy and compatibility.
- Commenter expressed concern regarding reporting to NMED contractor rather than NRC.

Team Response: The team provided clarification that event reporting guidance contained in SA-300 covers reporting to NRC. The NRC contractor has been designated by NRC to review, collect and maintain NRC event report information.

- Comment received that public access to NMED would be valuable for some licensees to gain historical perspective.

Team Response: This is under consideration by NRC materials staff.

- Concerns regarding NMED contractor, INEEL recoding information different from the information provided in the transfer file. For example, an incident took place in Alliance, Nebraska, but the record was changed by INEEL from the site of the event to the address for the licensee.

Team Response: The NRC data entry coding manual designates coding the event under the licensees name and official address. The site of the event is identified in the site of event field. NRC plans to

post a copy of the NMED Coding Manual at the NRC NMED Website.

- The commenter provided the following example: Discussions took place with the NMED contractor as to the appropriate coding category for an event involving a Novoste Beta Cath system with a missing gold marker string. The NMED contractor, notified the commenter that they were going to code the event as “defective or failed equipment,” and that, in accord with current policy, the contractor usually adds this type of event to several fields - both loss of material and equipment problem. The commenter did not agree that the coding category fit the event. The commenter indicated that the marker string was missing not defective or failing during use. The coding categories are too limited.

Another example where the State disagreed with the NMED contractor involved a Gamma knife event. The event did not involve radioactive material, but did involve an equipment problem; the helmet hoist did not engage. The commenter indicated that they deliberated several times with the NMED contractor as to whether it was a reportable event. The NMED contractor agreed it was a reportable event.

Another example involved the loss of an exit sign. Generally, you are not immediately aware of the Exit sign loss. A couple of years may have passed by the time it has been identified as missing.

Team Response: NRC and the contractor have detailed guidance and coding criteria that the contractor uses to code events. Given the unique nature of some events, some level of interpretation and professional judgment may be required when coding events. It is acknowledged that there will be occasions where the State and contractor interpretation may differ, or where the State may have additional clarifying information. In addition, when there is a significant question by the contractor regarding how to code an event, the contractor will consult with NRC headquarters.

- One commenter discussed GL Reporting Requirements. The commenter indicated that 1/3 of their events involved lost Exit signs. Why is this an immediate notification requirement? Why not 30 day?

Team Response: The reporting requirement schedules are determined by the appropriate regulations. The team is recommending further review of material reporting requirements based on risk significance, consistency and need for the information.

COMPILATION OF COMMENTS (NRC REGIONS)

- The review team conducted telephone interviews with staff from NRC Region I, II, III and IV. The questions were focused on the process after the NMED contractor has developed an event report summary from the event information provided by the NRC licensee and entered the event report information into NMED. The NMED contractor is responsible for contacting Region staff directly via email for clarification of any event information needed for a complete NMED report, similar to the process for contacting Agreement States.
- The team found that several Regions have implemented a revised process for tracking and responding to NMED contractor questions, to ensure actions are closed out. Currently, all Regions have assigned a technical staff member, Point of Contact (POC), the responsibility for tracking and responding to NMED contractor questions, to ensure actions are closed out. The POC coordinates the response with the inspector and the NMED contractor. In some Regions, NRC staff conduct a monthly review of all new NMED open items, similar to the process used by many Agreement States. Any open items are sent to the appropriate Branches for resolution. The revised process was recently established to ensure follow-up to NMED contractor questions for additional information or clarification and to ensure the NMED follow-up actions are closed.
- The regions provided examples of follow-up information questions. Some questions involve identification of the source, make and model No., or serial number. The Region found through contractor follow-up questions, that the NMED contractor enters events into NMED that may have been discovered while on-site conducting an inspection. The event may have been a lab spill that is mentioned in the inspection report, but has been closed out, as all enforcement issues have been closed.
- In response to our inquiry regarding providing a monthly log of follow-up and closed out events to the NMED contractor, some Regions have implemented a process to send in a monthly log of follow-up and closed out events to the NMED contractor.
- The team found the Regions use NMED national Website data for review of Region events and find good quality event data. There have been a few instances when Region staff had to discuss whether or not an event was reportable and whether or not it was an immediate or a thirty-day report with the NMED contractor. The Region staff found the contractor was very responsive.
- The only output that the Region suggests as useful would be a quarterly report of incomplete NMED entries for this region. The NMED database is scanned monthly, but items that are incomplete sometimes escape being readily noticed.

Team Response: Currently we have one standardized administrative event status report. A monthly report of all requests for additional information still pending after 60 days is prepared for NRC management for events where the information is needed to determine whether the event is reportable. In addition, the Website was upgraded in August 2003 to allow users to identify records that have not been closed out.

- One Region indicated that while the NMED database “Event Documents List” contains a reference document list, Region staff understand a referenced ML _____ No. ID, but sometimes found they could not identify the referenced document and could not find it in an ADAMS search. For example, see NMED 000152, Department of the Army. Under the “Events Document List” subheading “Report ID and Entry Date,” it includes LTR0000217. Region staff were unable to locate the reference in ADAMS, and commented that all references should be available in ADAMS.
- Another comment concerned the narratives under each event type in NMED; and stated that some information needs to be updated by the NMED contractor, especially the medical event section. The example record outlined requirements for old part 35, and the Region stated that they needed to reflect new part 35.

Team Response: The regulatory citations for each event reflect the regulations in place at the time of the event. It is not appropriate to update the citations as regulations change. Under the event type the new Part 35 definition has recently been added.

APPENDIX B

SURVEY QUESTIONNAIRE AGREEMENT STATE EVENT REPORTING QUERY (Final)

We recently sent out an email query on staff time involved in providing event information to NRC.

We are contacting several Agreement States by telephone for further discussion in the event reporting area, and would like to include you in those discussions. We need your assistance to help us evaluate the efficiency and effectiveness of the current event reporting process (policy, procedures, NMED database). We are interested in your experience to date and any comments or concerns that you may have regarding the current event reporting process. We are also interested in any ideas or comments that you may have for improving the event reporting process. The interest and focus in this area has increased. We are experiencing increased demands for incident and event information, such as the annual performance report to Congress based on Strategic Plan performance goals and nuclear material event target metric data, which is required under the Government Performance Results Act (GPRA), and increased general public interest in the use and control of nuclear material.

We have developed a discussion template to help us in our evaluation of the efficiency and effectiveness of the current process and tools used to collect, maintain, and review material event information. We would like to ask that you would cooperate with us to gain a better understanding of your event reporting processes and systems. This information will help support our efforts to simplify the current process through short- or long-term procedural or system modifications. Our goal is to reduce the number of problems that some Agreement States may be experiencing in this area, and to increase the use of compatible automated IT systems, including NMED.

QUESTIONS: How do you report-- Method and Process

- A. Method used to report event data; is it a form of 1, 2, or 3? (1. Electronic Format-File Type, 2. Non-NMED database, 3. Use NMED Local Data-entry Program)

- 1. ELECTRONIC FORMAT-TYPE OF FILE** (word processing file via email (MS Word98, WordPerfect 8, etc.); paper Fax copy, etc.

If you use a word processing format, go to Box 1, for additional questions.

Agreement State:	
Box 1	Format Used: Word Processing File via Email
Additional Questions	<ol style="list-style-type: none"> 1. What is the process used to develop and send an event report to NRC via NMED contractor, or the Operations Center? For example, do you maintain a basic event tracking outline in a spreadsheet _____ or word processing program? Do you extract some information from the tracking outline and other information from manual files? Do you send the completed report to NRC via email or Fax? ____ How do you send to OPs Center? ____ If not, please describe your process? 2. Personnel assigned responsibility to report event information , i.e. technical expertise (clerical, administrative, scientific)? Have they attended NMED training and when? 3. Process for reporting follow-up or close-out data to ensure a complete report. 4. Can you provide an estimate of the amount of time (FTE effort) necessary to provide an event notification? _____ 5. Go to General questions box 4

2. NON-NMED DATABASE

If you use a Non-NMED database, go to Box 2, for additional questions.

Box 2	Format Used: Non-NMED database
Additional Questions	<ol style="list-style-type: none"> 1. What database program and what version are you using, e.g., MS Access 2000. 2. Are the fields compatible to the NMED data fields_____; (is it one-to-one)? 3. Is the field size, type, and character length compatible to the NMED database format? 4. Personnel assigned responsibility to report event information (technical expertise, i.e. technical expertise (clerical, administrative, scientific)? Have they attended NMED training and when)? 5. Process for reporting follow-up or close-out data to ensure a complete report. 6. Can you provide an estimate of the amount of time (FTE effort) necessary to provide an event notification? _____ 7. Go to General questions box 4

3. USE NMED LOCAL DATA ENTRY PROGRAM

If you use the NMED LOCAL data entry program, go to Box 3, for additional questions.

Box 3	Use NMED local data entry program
Additional Questions	<ol style="list-style-type: none"> 1. What version of NMED program do you use? 2. Is it on your Network _____ or a local PC _____ ? Any incompatibility problems incurred? 3. Do you complete both the basic and detailed NMED screens? Any comments? 3. Do you send event reports via the NMED program transfer file? If not, what method do you use? Why? 4. Personnel assigned responsibility to report event information, i.e. technical expertise (clerical, administrative, scientific)? Have they attended NMED training and when? 5. Process for reporting follow-up or close-out data to ensure a complete report. 6. Can you provide an estimate of the amount of time (FTE effort) necessary to provide an event notification? _____ 7. Go to General questions box 4
Box 4	GENERAL QUESTIONS FOR ALL METHODS OF REPORTING
	<ol style="list-style-type: none"> 1. Do you receive? review? use? any outputs from the NMED national program at the NRC website? Are there any that would be useful or helpful for you that you would want to see? 2. Do you have any comments on reporting monthly? If so, if not monthly , what frequency would you recommend? Why? 3. How would you rate NMED on a scale of 1-10 for the following (what <u>specifics</u> of good/problems) where 1 = poor; and 10 = excellent: <ul style="list-style-type: none"> - reliable access - ease of searches - usefulness/range/scope of searches - completeness of database (events not missed) - completeness of records (complete info for each record) - timely/accurate (up-to-date information) - applicability to A/S programs/operations (in what way) - ease of data upload/submittals - Are there any frustrations/concerns (w/relative magnitude)? Why? - Are there any fields causing the (biggest) problems? Why? (this is where we can see if there are any we can make optional to provide some relief until we get the results of Mike's group) - What relief/assistance/solutions can you propose?

APPENDIX C

2003 NMED Training Session Attendee List

Session	Name	Agency	Phone	Email
RI	Michael Snee	OH	614-644-2727	MSNEE@gw.odh.state.oh.us
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APPENDIX D

Date: February 13, 2003

EVENT REPORTING PROCESS SELF-ASSESSMENT REVIEW ACTION PLAN

SUBJECT: REVIEW EVENT REPORTING PROCESS TO ADDRESS PERIODIC COMMENTS ON SCOPE, SCHEDULE, COMPLETENESS OF DATA, NMED REPORTING, AND THE EVALUATION OF EVENT REPORTING DATA.

I. OBJECTIVE: Identify strengths and weaknesses of the event reporting process, and recommend changes to ensure that technically accurate and complete material event reports are provided to NRC in accordance with 10 CFR or compatible Agreement State reporting requirements through an efficient and effective information collection process. This effort may result in clarification or revision of procedural guidance and/or tools used to implement, collect and manage the national collection of material event information.

II. SCOPE OF REVIEW ACTIVITIES

A. ANALYSIS AND REVIEW: PRE-INTERVIEWS

1. Why do we need to collect material event information, i.e. benefits, burdens, requirements?

Task II.A.1. Schedule: Larkins - Draft to be completed by 3/03/03

2. How do we currently collect NRC licensee and Agreement State material event information. Document and analyze variations between NRC and Agreement State event reporting data collection processes. Include variations in the data reported, format, method used to report event data (electronic or hardcopy), personnel assigned responsibility to report event information (technical expertise), and process for reporting follow-up or close-out data to ensure a complete report.

Task II.A.2. Schedule: Brock, Burgess - Draft to be completed by 3/03/03

3. Guidance document review to be conducted concurrently with Task 1 and 2 (*complete list at end of action plan*).
 - a. Review all procedural guidance documents necessary to gain an understanding of the current process, e.g. App. A, item 1-4.
 - b. Review IMPEP reports for FY 2002 and periodic reports for June 2001 - September 2002 to identify event reporting concerns.

Larkins completed review

- c. Include an evaluation of experience and comments regarding current procedural guidance for Agreement States to provide material event reports to NRC on a monthly reporting schedule (SA-300).
- d. Review proposed revisions to event reporting requirements identified in the Final Report of the Working Group on Event Reporting, April 2001.

Task II.A.3.a.,b.,c.,d. Schedule: Larkins, Brock, Burgess -Draft to be completed by 3/12/03

Larkins completed review

- 4. a. Review current process used to disseminate results of collective assessments and evaluative trending analyses of national material event data.

Task II.A.4.a. Schedule: Burgess - Draft to be completed by 3/14/03

Task II.A.4.b Schedule: Brock - Draft to be completed by 3/14/03

- 5. Review current analyses, evaluations, standardized reports, for possible changes to ensure they meet regulatory agency and licensing needs. (Not done under this self-assessment as this is part Nuclear Material Pilot No. 3 Working group task)

B. DISCUSSIONS AND INTERVIEWS

- 1. Discussions/Meetings with Agreement States to determine why some States operate effectively and some operate with difficulty reporting event information to NRC (include timeliness and completeness).
 - a. Sample draft query: Data reported (AEA only, non-AEA ,LAS only or all non-AEA events)
 - Schedule used to report event data to NRC for inclusion in NMED
 - Data format: Method used to report event data (electronic format-type of file, i.e NMED file, identify other software and version (are the fields compatible to the NMED data fields); hardcopy format - (word processing file via email (MS Word98, WordPerfect 8, etc.); paper Fax copy, etc.
 - Personnel assigned responsibility to report event information (technical expertise), and;
 - Process for reporting follow-up or close-out data to ensure a complete report.
 - How do they use the NMED data as a tool?
 - Should we use NMED data to generate draft AO reports?
 - Analysis of why some States operate with difficulty and why some operate successfully.
 - b. Identify 5 Agreement States (2 successful, 4 non-successful) based on analysis and review results
 - c. Establish standard set of query questions.

d. Conduct Joint conference calls with Agreement States.

Task II.B.1.a,b,c Schedule: Larkins, Brock, Burgess
Questions to be completed by 3/18/03

Task II.B.1.d . Schedule: Larkins, Brock, Burgess
Interviews to be conducted 3/19-4/19/03
Draft to be completed by 5/25/03

2. Discussion/meetings with NMSS, regional staff, and the NMED contractor, INEEL, regarding event reporting. Document and analyze variations between NRC and Agreement State event reporting data collection processes. Include variations in the data reported, format, method used to report event data (electronic or hardcopy), personnel assigned responsibility to report event information, and process for reporting follow-up or close-out data to ensure a complete report.

- a. Establish standard set of query questions
- b. Identify three Regions and staff, e.g., IMPEP team members, RSAO's, NMED Project Mgr. ,etc.
- c. Conduct Regional and NMED contractor (INEEL's coding practices) interviews

Task II. B.2.a.b. Schedule: Draft to be completed by 3/28/03

II. B.2.c. Schedule: Brock, Region 1; Burgess, Region II, IV.
Team discussions/interviews conducted: 5/20-7/30/03
Draft to be completed by: 8/29/03

C. ANALYSIS AND REVIEW: Post-Interview

1. Evaluate experience and comments regarding current procedural guidance for Agreement States, including providing material event report's to NRC on a monthly reporting schedule (SA-300), and recommend any necessary specific procedural guidance changes.

Task II.C.1. Schedule: Larkins, Burgess
To be completed by: 8/20/03

2. Based on comments and review of proposed revisions to event reporting requirements identified in the Final Report of the Working Group on Event Reporting, April 2000, recommend any necessary specific rule changes.

Task II.C. 2. Schedule: Larkins
To be completed by: 10/15/03

3. Review current analyses, evaluations, standardized reports, and other uses of event report data, including AO report criteria, for possible changes to ensure they meet regulatory agency and licensee needs. Include communication and distribution of outputs to users.

Task II.C. 3. Schedule: Larkins
Draft to be completed by: 10/15/03

4. Coordination any insights and recommendations with the Nuclear Materials Program (NMP) Pilot #3, operational experience event evaluation process working group. The Pilot No. 3 working group is tasked to develop and test a joint NRC and Agreement State process for evaluating event report information for generic issues and subsequent regulatory actions.

III. CONCLUSIONS

IV. RECOMMENDATIONS

Draft Self-Assessment Report to be Completed by: 11/3/03
Management Review to be Complete by: 12/29/03
Final Self-Assessment Report to be Completed by: 3/22/04