December 27, 2005

MEMORANDUM TO: Jack R. Strosnider, Director
Office of Nuclear Materials Safety and Safeguards

FROM: Martin J. Virgilio, Deputy Executive Director ***/RA/***
for Materials, Research, State and Compliance Programs

Barbara Hamrick, Chair ***/RA by Janet R. Schlueter for/***
Organization of Agreement States, Inc.

SUBJECT: FINAL REPORT FOR THE INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE NRC SEALED SOURCE AND DEVICE EVALUATION PROGRAM

On December 20, 2005, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report of the U.S. Nuclear Regulatory Commission's (NRC) Sealed Source and Device (SS&D) Evaluation Program. The MRB found the NRC SS&D Evaluation Program to be adequate to protect public health and safety.

Section 4.0, page 5, of the enclosed final report summarizes the results of the review and presents the one recommendation made by the review team. Based on the letter to the review team leader, Karl Von Ahn, State of Ohio, dated November 21, 2005, from Charles L. Miller, Director, Division of Industrial and Medical Nuclear Safety, which described your actions taken in response to the findings in the draft report, no additional information is required. The MRB accepted the team's recommendation to conduct the next IMPEP review in four years.

If you have any questions, please contact Karl Von Ahn, RRPT, Health Physicist, Bureau of Radiation Protection, Ohio Department of Health at (614) 644-2727.

We appreciate your staff's efforts during the IMPEP review period, especially during the time of the team's visit.

Enclosure:
As stated

cc: Charles L. Miller, Director, IMNS, NMSS
Thomas Essig, Chief, MSIB, IMNS, NMSS

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NRC SEALED SOURCE AND DEVICE PROGRAM

September 19 – 23, 2005

FINAL REPORT

ORGANIZATION OF AGREEMENT STATES

1.0 INTRODUCTION

This report presents the results of the review of the Nuclear Regulatory Commission's (NRC) Sealed Source and Device (SS&D) Evaluation Program. The review was conducted during the period of September 19 – 23, 2005, by a review team comprised of technical staff from the Commonwealth of Massachusetts, the State of Ohio, and NRC's Region I. Members of the review team are listed in Appendix A. The review was conducted in accordance with the February 26, 2004, NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of September 15, 2001 to September 23, 2005, were discussed with NRC management on September 23, 2005.

A draft of this report was issued to NRC's Office of Nuclear Material Safety and Safeguards (NMSS) for factual comment on October 21, 2005. Charles L. Miller, Director, Division of Industrial and Medical Nuclear Safety (IMNS) responded by letter dated November 21, 2005. The Management Review Board (MRB) met on December 20, 2005 to consider the proposed final report. The MRB found the NRC SS&D Evaluation Program adequate to protect public health and safety.

IMNS administers the SS&D Evaluation Program through the Materials Safety and Inspection Branch (MSIB). Section A (the Section), within MSIB, is responsible for conducting safety evaluations of SS&Ds that contain radioactive material regulated by NRC. An organizational chart is shown in Appendix B. The Section also conducts generic safety reviews of incidents and accidents where the failure of a source or device is suspected of being a contributing factor. The Section maintains a catalog of SS&D registration certificates for those sources and devices that have been determined to meet acceptable design criteria for licensing and use by individuals. The Section controls and allocates the vendor designation numbers for the registration certificates issued by the NRC and the Agreement States. The Section also distributes copies of completed registration certificates to the 33 Agreement State programs that license the use of the same devices.

In preparation for the review, a questionnaire addressing the non-common performance indicator, SS&D Evaluation Program, was sent to NRC on May 24, 2005. NRC provided a response to the questionnaire on August 9, 2005. A copy of the questionnaire response can be found on the NRC's Agencywide Document Access and Management System (ADAMS) using the accession number ML052220363.

The review team's general approach for conducting the review consisted of: (1) an examination of NRC's response to the questionnaire; (2) a review of selected safety evaluation casework, (3) a review of staffing and training, (4) a review of incident and allegation files, and (5) interviews with the staff and management to answer questions or to clarify issues. The review team evaluated the information it gathered against the IMPEP performance criteria for this non-common performance indicator and made a preliminary assessment of the NRC's SS&D evaluation program.

The NRC's response to recommendations made following the previous IMPEP review are discussed in Section 2.0 below. The results of the current review are presented in Section 3.0 below. Section 4.0 below summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to performance by the Section.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review which concluded on September 14, 2001, all prior recommendations were closed, and no additional recommendations were made.

3.0 NON-COMMON PERFORMANCE INDICATOR - SEALED SOURCE AND DEVICE EVALUATION PROGRAM

The IMPEP process identifies five common and four non-common performance indicators to be used when reviewing Regional and Agreement State programs. This review was limited to evaluating the non-common performance indicator, SS&D Evaluation Program.

In conducting this review, three sub-indicators were used to evaluate the NRC's performance regarding their SS&D Evaluation Program. These sub-indicators were: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

3.1 Technical Staffing and Training

Presently, the SS&D Team Leader and four staff members conduct reviews. All but one individual is fully qualified to independently review and sign registry sheets. One licensing assistant provides support to the program. Since the last review, seven individuals have joined the SS&D group with three individuals still conducting reviews. Two of the five current staff members conducted reviews throughout the entire review period. Staff turnover was the result of individuals taking assignments in other parts of the NRC. There are currently no vacancies in the program.

All current staff members spend only a portion of their time conducting SS&D reviews. During the last two fiscal years, the highest time expenditure by any individual was 0.3 full-time-equivalents (FTE). According to the questionnaire submitted by the NRC, the FTE expenditure on the SS&D program decreased during the review period from a high of 2.45 FTE in FY 2002 to 1.1 FTE (as of July 15, 2005) in FY 2005.

The review team evaluated the qualifications and qualification journals of two of the three individuals who completed the training and were certified to independently review and sign registry sheets during the review period. The team also reviewed the qualifications and qualification journal for the individual currently in the training process. The qualification procedure used for NRC SS&D reviewers is found in NRC Manual Chapter (MC) 1246A16 "Technical Reviewer Qualification Journal Byproduct Materials Sealed Source and Device Reviewers." The review team determined that training requirements in MC 1246A16 are consistent with SS&D training performance criteria in MD 5.6.

New staff members are required to complete all training requirements in MC 1246A16 and participate in the full review of 20 cases. Typically, the required SS&D casework includes sources, irradiators, radiography equipment, consumer products, gauges and medical devices. Once the staff member has completed training and casework, the staff member is evaluated by an SS&D review board, typically consisting of the SS&D Team Leader, Section Chief and Branch Chief, prior to being certified to independently review applications and sign registry sheets.

Based on interviews with staff and review of casework, the review team concluded that the training program was effective in ensuring the SS&D program maintains a qualified staff. The review team also concluded that staffing levels were adequate based on the timeliness of the reviews and the high quality and thoroughness of the casework produced by the technical staff.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that NRC's performance with respect to the sub-indicator, Technical Staffing and Training, was satisfactory.

3.2 Technical Quality of the Product Evaluation Program

The team evaluated the SS&D technical quality in accordance with the guidance provided in MD Handbook 5.6 and State and Tribal Program (STP) Procedure SA-108 "Reviewing the Non-Common Performance Indicator, Sealed Source and Device (SS&D) Evaluation Program" dated June 20, 2005. Twenty-four case files were selected for review that included work performed by all reviewers. The cross-section sampling included the more complex evaluations completed by Section staff over the review period. The reviewed SS&D actions included new certificates, amendments, transfers, and inactivations. The SS&D certificates issued by the NRC that were evaluated by the review team are listed with case-specific comments in Appendix C.

The official copies of documentation for the SS&D reviews are maintained in ADAMS. The Section did have some back-up original paper copies from the last case review. On two occasions, the paper copy records had to be accessed since the items were not included in ADAMS. On one occasion, the file scanned into ADAMS did not have the engineering document unfolded when it was scanned. The scanning and/or recording of documents into ADAMS was not of consistent quality.

The selected SS&D registration certificates and case files were reviewed for accuracy, appropriateness for authorization, tie-down statements, and overall technical quality. The casework was evaluated for timeliness, adherence to good radiation safety practice, acceptable engineering practices, reference to appropriate regulations, evaluation of safety evaluation reports, manufacturing Quality Assurance/Quality Control, supporting documents, peer and supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and other supporting data.

Analysis of the casework and interviews with staff and engineering technical support professionals confirmed that the NRC generally follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, Revision 1 issued in April 2004. All applicable and pertinent American National Standards Institute (ANSI) standards, NUREG-1556 Series, NRC Regulatory Guides, and applicable references were confirmed to be available and were used appropriately in performing the SS&D reviews. Appropriate review checklists were generally used to assure that all relevant materials were submitted and reviewed for new registrations and major amendments, or a note to file indicating why a checklist was not used. The checklists were retained in the case files. Registrations clearly summarized the product evaluation and provided license reviewers with adequate information on areas requiring additional attention to license the possession, use, and distribution of the products. The team determined that product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of likely accidents.

The registration document as written did not follow the format as recommended in NUREG-1556 Volume 3, Revision 1 in the cases identified in Appendix C. These formatting issues did not adversely impact the technical quality or content of the review. The review team recommends that the Section adhere more closely to the document format and contents in the guidance as identified in the current NUREG-1556, Volume 3.

Documents were missing in three of the cases reviewed from the ADAMS files. Electronic records issues were identified from scanning into, or conversion to, electronic files in four of the cases reviewed. These are identified in Appendix C. The review team is cognizant that document processing after the registrations are completed is beyond the scope of this review. However, the team advised, and the Section acknowledged, there should be a mechanism implemented by the Section to ensure that the document packages in ADAMS are a complete and accurate representation of the materials submitted for inclusion in ADAMS.

Dual units were not used in one case. The SS&D team leader's interpretation of Commission paper "Final Policy Statement – Conversion to the Metric System" (SECY-96-098) permitted solely using custom units if the licensee uses custom units. The policy statement permits using only the units that the licensee uses if the document only pertains to a specific licensee. The policy statement also states documents applicable to all licensees, or a class of licensees that may operate in metric units will use dual units. NUREG-1556 Volume 3, Revision 1, references this policy statement for the use of dual units within SS&D registrations. Whether the SS&D registration is a document that pertains to one specific licensee or to more than one is subject to interpretation. It is the team's view that the registration document pertains to the registrant, license reviewers, and user licensees, which constitute a category of licensees that may use metric units, and therefore the use of dual units should be used in the SS&D registration. This was discussed with the SS&D team leader who agreed to review and reconsider the issue at a later date.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that NRC's performance with respect to the sub-indicator, Technical Quality of the Product Evaluation Program, was satisfactory.

3.3 Evaluation of Defects and Incidents Regarding SS&Ds

In evaluating the effectiveness of the NRC's actions in response to the evaluation of defects and incidents involving SS&Ds, the review team examined NRC's response to the questionnaire, reviewed incident reports in the Nuclear Material Events Database (NMED) and evaluated reports and supporting documentation for incidents involving SS&Ds. A list of the incident casework examined with case specific comments is included in Appendix D. The team also reviewed the NRC's response to two allegations involving SS&D manufacturers.

The review team found that the NRC's response to SS&D incidents was complete and comprehensive. Responses were prompt, well coordinated with the appropriate NRC Regional Office or Agreement State and the level of effort commensurate with the health and safety significance. As necessary, SS&D technical staff conducted on-site investigations and took suitable follow-up actions.

The NRC SS&D program evaluates and resolves defects and incidents involving SS&Ds in a number of different ways. On a daily basis, any event reported to the NRC involving equipment or device related problems are forwarded to the SS&D Team Leader by the NMED Project

Manager. 10 CFR Part 21 reports involving materials device and source defects are also provided to the Team Leader. The Team Leader will evaluate the event to determine if it is a generic issue based on the criteria in MD 6.4 “Generic Issue Program.” If a generic issue is identified, the NRC will issue a generic communication to licensees and Agreement States. The type of generic communication used is based on the purpose of the communication and urgency of the issue. For example, NMSS issued an Information Notice in 2005 regarding the recently identified safety issues by NRC and the State of Wisconsin, involving manual brachytherapy source jamming.

The Section also evaluates and responds to Technical Assistance Requests (TARs) from NRC Regions or Agreement States involving specific safety or regulatory issues related to SS&Ds. The type of TARs reviewed by the SS&D program included training requirements for TheraSphere brachytherapy sources, leak test requirements, vibrational limitations for a gauging device that failed and the temperature limitation for brachytherapy seeds molded into strands.

The data in NMED was used by the program for evaluating potential generic issues related to both specific devices and for broad trends. The Program requested that the NMED contractor conduct an analysis of leaking electron capture devices manufactured by an NRC license against other manufacturers. A broad review of NMED data was undertaken by the SS&D program in 2005 to identify potential generic issues. The result of this review identified a number of potential generic issues for additional action. The review team noted that the Section is recommending that this evaluation continue to be conducted on a semiannual basis. At the time of the review, the Section Chief and Team Leader indicated that Division management has not responded to this recommendation.

Two allegations were received by the NMSS allegation program related to SS&D issues. Both allegations required coordination with Regional offices and Agreement States to resolve. The review team reviewed the correspondence by the NMSS allegation coordinator and discussed the issues with the SS&D Team Leader. The results of the investigations were provided to the appropriate alleger. The team concluded that the investigation of the allegations was thorough and the allegations were handled in accordance with NRC’s allegation policy in MD 8.1.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that NRC’s performance with respect to the sub-indicator, Evaluation of Defects and Incidents Regarding SS&Ds, was satisfactory.

4.0 SUMMARY

As noted above, the review team recommended and the MRB agreed that the NRC’s performance in the sub-indicators, Technical Quality of the Product Evaluation Program, Technical Staffing and Training and Incidents and Allegations Regarding the SS&Ds were satisfactory. Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that NRC’s performance with respect to the indicator, Sealed Source and Device Evaluation Program, was satisfactory. Accordingly, the review team recommended and the MRB agreed that the NRC’s overall performance for the SS&D Program is adequate to protect health and safety. Based on the results of the current IMPEP review, the next review should take place in approximately four years.

Below is the one recommendation, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the Section.

RECOMMENDATION:

The review team recommends that the Section adhere more closely to the document format and contents in the guidance as identified in the current NUREG-1556, Volume 3. (Section 3.2)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

SS&D REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Karl Von Ahn, Ohio	Team Leader Technical Quality of Product Evaluations
Joshua Daehler, Massachusetts	Technical Quality of Product Evaluations
Duncan White, NRC Region I	Technical Staffing and Training Evaluation of Defects and Incidents Regarding SS&Ds

APPENDIX B

Nuclear Regulatory Commission's Office of Nuclear Material Safety
and Safeguards' Materials Safety and Inspection Branch Organization Chart

ADAMS: ML052220379

APPENDIX C

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No: 1 (NRC Case # 05-04)
Applicant: International Isotopes Idaho, Inc — Registry No: NR-1235-S-101-S
SS&D Type: Irradiator and Teletherapy Source — Date Issued: 3/17/05
Use Codes: (AD) Photon emitting Teletherapy Units; (J) Gamma Irradiation, Category I; (K) Gamma Irradiation, Category II; (L) Gamma Irradiation, Category III — Type of action: New

Comment:
A review checklist was missing from ADAMS, the NRC's official records system.

File No: 2 (NRC Case # 02-36)
Applicant: IMS Systems, Inc. — Registry No: NR-1120-D-104-S
SS&D Type: Tube Wall Thickness Gauge — Date Issued: 3/27/03
Use Code: (D) Gamma Gauges — Type of action: New

Comments:
a) The Diagram section of the registration should reference "attachments 1 through 5" instead of "attachments 1 and 5."
b) The header of each Attachment of the registration should not specify the Device Type as recommended by NUREG-1556, Vol. 3.
c) The header of each Attachment of the registration should specify the total number of attachments as recommended by NUREG-1556, Vol. 3.
d) The Description section of the registration specifies that the mechanical shutter status flag of green indicates that the shutter position is open, whereas the applicant's letter (ML022470349) specifies that the mechanical shutter status flag of green indicates that the shutter is closed.

File No: 3 (NRC Case # 05-08)
Applicant: SABIA, Inc. — Registry No: NR-1195-D-104-S
SS&D Type: Material Analyzer — Date Issued: 5/10/05
Use Code: (H) General Neutron Source Applications — Type of action: New

Comments:
a) The header of each Attachment of the registration should not specify the Device Type as recommended by NUREG-1556, Vol. 3.
b) The header of each Attachment of the registration should specify the total number of attachments as recommended by NUREG-1556, Vol. 3.
c) The registration identifies a distributor who's facility is in California, a facility that is under Agreement State jurisdiction for SS&D reviews.

File No: 4 (NRC Case # 03-07)
Applicant: MDS Nordion Registry No: NR-0220-D-128-S
SS&D Type: Gamma Irradiator Date Issued: 4/2/03
Use Code: (K) Gamma Irradiation, Category II Type of action: New

Comment:

The header of each Attachment of the registration should specify the total number of attachments as recommended by NUREG-1556, Vol. 3.

File No: 5 (NRC Case # 03-36)
Applicant: Draeger Safety, Inc. Registry No: NR-1199-D-101-E
SS&D Type: Gas Detector Date Issued: 11/12/03
Use Code: (N) Ion Generators, Chromatography Type of action: New

Comments:

a) The header of each Attachment of the registration should not specify the Device Type as recommended by NUREG-1556, Vol. 3.
b) The header of each Attachment of the registration should specify the total number of attachments as recommended by NUREG-1556, Vol. 3.

File No: 6 (NRC Case # 04-16)
Applicant: Ingersoll-Rand Company, LCN Division Registry No: NR-1214-D-101-E
SS&D Type: Smoke Detector Date Issued: 6/28/04
Use Code: (P) Ion Generators, Smoke Detectors Type of action: New

File No: 7 (NRC Case # 04-49)
Applicant: Met One Instruments Registry No: NR-1124-D-102-E
SS&D Type: Aerosol Detector Date Issued: 12/8/04
Use Code: (T) Other Type of action: Amendment

Comments:

a) The header of each Attachment of the registration should specify the total number of attachments as recommended by NUREG-1556, Vol. 3.
b) Applicant's letter dated October 12, 2004, a reference in the registration, was missing from ADAMS, the NRC's official electronic records system.

File No: 8 (NRC Case # 04-07)
Applicant: Mills Biopharmaceuticals, Inc Registry No: NR-1081-S-101-S
SS&D Type: Therapeutic Seed Source Date Issued: 3/22/04
Use Code: (V) General Medical Use Type of action: Amendment

Comments:

a) The header of each Attachment of the registration should not specify the Source Type as recommended by NUREG-1556, Vol. 3.
b) The header of each Attachment of the registration should specify the total number of attachments as recommended by NUREG-1556, Vol. 3.

File No: 9 (NRC Case # 02-28)
Applicant: TRUGLO, Inc. Registry No: NR-1180-D-101-E
SS&D Type: Bow and Gun Sights Date Issued: 11/12/02
Use Code: (W) Self-Luminous Light Source Type of action: New

Comments:
a) The header of each Attachment of the registration should not specify the Device Type as recommended by NUREG-1556, Vol. 3.
b) The header of each Attachment of the registration should specify the total number of attachments as recommended by NUREG-1556, Vol. 3.
c) The registration found in ADAMS, the NRC's official records system, was poorly formatted to include a diagram that intersected the Issuing Agency section of the registration; vertical instead of horizontal text in the Issuing Agency section of the registration; and the Description section of the registration began on page 1 instead of page 2 of the registration.

File No: 10 (NRC Case # 04-39)
Applicant: SABIA, Inc. Registry No: NR-1195-D-103-S
SS&D Type: Materials Analyzer Date Issued: 11/2/04
Use Code: (H) General Neutron Source Applications Type of action: New

Comment:
The registration identifies a distributor whose facility is in California, a facility that is under Agreement State jurisdiction for SS&D reviews.

File No: 11 (NRC Case # 03-23)
Applicant: Montesino Technologies Registry No: NR-1193-D-101-G
SS&D Type: Thickness Measuring Device Date Issued: 9/9/03
Use Code: (E) Beta Gauges Type of action: New

Comments:
a) The text formatting on the cover page was not consistent with NUREG-1556, Vol. 3, Rev. 1 Appendix D.
b) Under conditions of normal use, temperature ranges given only in °C.
c) Under "external radiation levels," the doses were listed in uSv with a custom unit equivalent in mR. Sievert is a unit of dose equivalent, and so is the custom unit of Rem. Roentgen is unit of exposure in dry air and is not a defined unit of measure in NRC regulations. (Note: the same error exists in NUREG-1556, Vol. 3, Rev. 1 Appendix D.)
d) The review checklist was missing from the ADAMS files. A hard copy from unofficial files was found for the team member and added to ADAMS.
e) The dose rate was measured with a Victoreen 450B (ion chamber) for a beta emitting radionuclide. The equivalent window density thickness was not requested to identify if the dose rates reported were shallow or deep doses.
f) The application described safety features of red and green indicator lights. The red and green indicator lights were not identified as safety features in the device registration as suggested in section 12.3 of NUREG-1556, Vol. 3, Rev. 1.
g) A reference document, letter dated August 14, 2003, was missing from the ADAMS file. An unofficial copy was found, and electronically pasted into ADAMS.
h) The expected working life of ten years was indicated in the application. However, the

device registration did not indicate the expected working life as suggested in NUREG-1556, Vol. 3, Rev. 1, Section 12.6.

File No: 12 (NRC Case # 04-56)
Applicant: MDS Nordion Registry No: NR-0220-D-113-S
SS&D Type: Glass Microsphere Date Issued: 1/24/05
Use Code: (AF) Other Medical Uses Type of action: Amendment

File No: 13 (NRC Case # 03-30)
Applicant: MDS Nordion Registry No: NR-0220-S-129-S
SS&D Type: Irradiator Source Date Issued: 7/2/03
Use Code: (I) Gamma Irradiator Category I Type of action: New

Comments:
a) The source diameter and wall thickness were listed, but the description did not indicate if the diameter was an inner or outer diameter.
b) The cover page listed the SI units of activity as a exponential number instead of using the typical prefix as suggested in the NUREG-1556, Vol. 3, Rev. 1 guidance for number formatting.
c) This registration was the one of the first in a series of over 50 conversions from one manufacturer to another, some of which were inactivated, and others maintained as active registrations. Two months after the release of this registration, an inactivated registration NR-0220-S-830-S superseded the NR-0619-S-124-U registration, but should have indicated that it superseded the distributed NR-0220-S-129-S registration, which superseded the NR-0169-S-124-U upon its issuance. The NRC SS&D team leader indicated that the NR-0220-S-129-S registration was a working copy that should not have been released.

File No: 14 (NRC Case # 05-31)
Applicant: Smith's Detection, Inc Registry No: NR-0163-D-101-G
SS&D Type: Ion Mobility Spectrometer Date Issued: 5/31/05
Use Code: (N) Ion Generator, Chromatography Type of action: Amendment

Comments:
a) The copy in ADAMS was an unsigned copy, but the corresponding document showing on the SS&D web-site is signed.
b) On the first page, the "Distributor" section should be listed before the "Manufacturer" section as identified in the NUREG-1556, Vol. 3, Rev. 1 Appendix D sample registration.
c) In the description, on page 2, second paragraph, last sentence, two numbers were identified in the format of "#.## x 10E-y." This is not a standard scientific or engineering number format.
d) The registration states that the leak test may be performed "by persons specifically or generally licensed." This may potentially mislead a general licensee to perform a wipe test analysis, which must be done a specific licensee, although a general licensee may collect a leak test sample to send out for analysis.
e) Attachment 2 and Attachment 3 in the ADAMS copy of the registration had images that were so dark that the details were hard to identify.

File No: 15 (NRC Case # 04-02)
Applicant: Environics Registry No: NR-1160-D-101-E
SS&D Type: Gas & Aerosol Detector Date Issued: 12/2/03
Use Code: (N) Ion Generator, Chromatography Type of action: Amendment

File No: 16 (NRC Case # 03-15)
Applicant: General Dynamics Registry No: NR-1167-D-101-E
SS&D Type: Gas Detector Date Issued: 3/18/03
Use Code: (P) Ion Generators, Smoke Detectors Type of action: Amendment

Comments:
a) The first page formatting alignment was not consistent with the suggested sample document format in NUREG-1556, Vol. 3, Rev. 1, Appendix D.
b) The registration revision was treated as a name change, although the document stated, "amended in its entirety." Therefore, a reviewer checklist was not generated.

File No: 17 (NRC Case # 04-24)
Applicant: Trilux Technology Registry No: NR-8145-D-801-E
SS&D Type: Illuminated Sight Assembly Date Issued: 3/23/04
Use Code: (R) Gas Source Type of action: Inactivation

Comments:
a) The first page formatting alignment was not consistent with the suggested sample document format in NUREG-1556, Vol. 3, Rev. 1 Appendix D.
b) The document heading does not indicate "Supersedes NR-1028-D-101-E" as indicated in NUREG-1556, Vol. 3, Rev. 1, Section 13.4.
c) The following sections were added to the exempt device registration and are not identified in sample registration format in NUREG-1556, Vol. 3, Rev. 1 Appendix D: "Labeling," "Diagram," ""Conditions of Normal Use," "Prototype Testing," "External Radiation Levels," "Quality Assurance and Control," "Limitations and Conditions of Use," and "Safety Analysis Summary."

File No: 18 (NRC Case # 02-16)
Applicant: Powertronic Systems Registry No: NR-1065-D-101-E
SS&D Type: Gas Detector Date Issued: 6/13/02
Use Code: (P) Ion Generator, Smoke Detector Type of action: Amendment

Comments:
a) The first page formatting alignment was not consistent with the suggested sample document format in NUREG-1556, Vol. 3, Rev. 1 Appendix D.
b) Reviewer's signatures were replaced with "/RA/" in the ADAMS registration copy. The review team questioned the use of the typed notation in lieu of an actual signature for an official copy of record. The NRC SS&D team leader indicated that this was considered acceptable as an original signature.

File No: 19 (NRC Case # 04-36)
Applicant: Draximage Registry No: NR-1121-S-101-S
SS&D Type: Brachytherapy Source Date Issued: 7/7/04
Use Code: (AA) Manual Brachytherapy Type of action: Amendment

Comments:
a) The first page formatting alignment was not consistent with the suggested sample document format in NUREG-1556, Vol. 3, Rev. 1 Appendix D.
b) The Use Code on first page was incorrectly identified as "V." NUREG-1556, Vol. 3, Rev. 1 Appendix C indicates that the Use Code "V" had been discontinued as of October 24, 2002. The appropriate use code should have been "AA."
c) The beginning of page 4 did not indicate the continuation of the subheading with "Conditions of Normal Use - continued" as indicated in the suggested format in NUREG-1556, Vol. 3, Rev. 1 Appendix D.
d) The calculated radiation levels were tabulated as "mR/hr/mCi." Dual units were not used, nor were dose rates for maximum source activity. The radiation unit of "R," for Roentgen, is not a defined unit of radiation exposure in the NRC regulations.
e) The section entitled "FDA Approval Summary" was not included. The FDA approval information was referenced in the safety summary. NUREG-1556, Vol. 3, Rev. 1 section 12.11 identifies that the "FDA Approval Summary" section be used to identify the FDA PMA/510k information.
f) No checklist was identified in the file, or a file notation that one was not needed or used.
g) The old changes from a prior amendment were still in boldface print. The suggested formatting notation in NUREG-1556, Vol. 3, Rev. 1 is that only changes in the current amendment or corrected page be in boldface font.

File No: 20 (NRC Case # 04-25)
Applicant: Trijicon Registry No: NR-0418-D-101-E
SS&D Type: Luminous Gun Sight Date Issued: 3/12/05
Use Code: (W) Self Luminous Light Source Type of action: Amendment

Comments:
a) The cover page identified Trijicon Inc as the "Distributor." No "Manufacturer" was identified. The cover page should have listed "Trijicon, Inc" as both the manufacturer and distributor in accordance with NUREG-1556, Vol. 3, Rev. 1.
b) The "Use Code" was incorrectly changed from "W - Self Luminous Light Source" to "R - Gas Source." The "Use Code" was corrected in a corrected copy issued April 14, 2004 in response to the applicant identifying model number typos.
c) The text formatting on the cover page was not consistent with NUREG-1556, Vol. 3, Rev. 1 Appendix D.

File No: 21 (NRC Case # 04-44)
Applicant: Smith's Detection Registry No: NR-0163-D-101-G
SS&D Type: Ion mobility Spectrometer Date Issued: 10/8/04
Use Code: (N) Ion Generator, Chromatography Type of action: Amendment

Comments:
a) The text formatting on the cover page was not consistent with NUREG-1556, Vol. 3, Rev. 1 Appendix D.

b) On the first page, the “Distributor” section should be listed before the “Manufacturer” section as identified in the NUREG-1556, Vol. 3, Rev. 1 Appendix D sample registration.
c) In the description, on page 2, second paragraph, last sentence, two numbers were identified in the format of “#.## x 10E-#.” This is not a standard number format.
d) Under the section “External Radiation Levels” on page 8, states ...” a copy of the leak test results is to be delivered along with the a copy of the general license....” This is potentially misleading in that it appears the distributor issues the general license instead of the regulatory agency.
e) Attachment 2 and Attachment 3 in the ADAMS copy of the registration had images that were so dark that the details were hard to identify.

File No: 22 (NRC Case # 02-27)
Applicant: Savage Systems, Inc. Registry No: NR-1183-D-101-E
SS&D Type: Archery Sights Date Issued: 12/6/02
Use Code: (W) Self Luminous Light Source Type of action: New

Comments:
a) The text formatting on the cover page was not consistent with NUREG-1556, Vol. 3, Rev. 1 Appendix D.
b) The following sections were added to the exempt device registration and are not identified in sample registration format in NUREG-1556, Vol. 3, Rev. 1 Appendix D: “Labeling,” “Diagram,” “”Conditions of Normal Use,” “Prototype Testing,” “External Radiation Levels,” “Quality Assurance and Control,” “Limitations and Conditions of Use,” and “Safety Analysis Summary.”
c) Under “Prototype Test,” the registration states that the sealed sources meet ANSI N540 standards (currently N43.4-2000). The ANSI standard provides a rating system for source classification, not defining adequacy for particular use. The adequacy reference should have been to similarly constructed devices.

File No: 23 (NRC Case # 04-01)
Applicant: MDS Nordion Registry No: NR-0220-D-102-S
SS&D Type: Gamma Irradiator Date Issued: 2/25/04
Use Code: (J) Gamma Irradiator, Category I Type of action: Amendment

Comments:
a) The text formatting on the cover page was not consistent with NUREG-1556, Vol. 3, Rev. 1 Appendix D.
b) The reference letter dated September 18, 2003, did not have the engineering diagrams opened when the documents were scanned into ADAMS. Therefore, these diagrams could not be used. Subsequent engineering diagrams were submitted in a letter dated November 24, 2003 in response to staff requests for additional information, and these provided the engineering diagrams of record.

File No: 24 (NRC Case # 05-29)
Applicant: International Isotopes Laboratory Registry No: NR-1235-S-102-S
SS&D Type: Medical Reference Source Date Issued: 5/25/05
Use Code: (X) Medical Reference Source Types of actions: New, Conversion

Comments:
a) The text formatting on the cover page was not consistent with NUREG-1556, Vol. 3, Rev. 1 Appendix D.
b) Dual units of activity were not included on the cover page.

APPENDIX D

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM

File No.: 1
Licensee: Advance Care
Site of Incident: New York Hospital
Date of Incident: 8/10/04
Investigation Dates: 8/04 - 4/05
NRC License No.: 06-30764-01
Incident Log No.: NMED
Type of Incident: Equipment Failure and Leaking Source

File No.: 2
Licensee: Berthold Technologies
Site of Incident: Monsanto Corporation, Luling, LA
Date of Incident: 6/29/03
Investigation Dates: 6/04 - 7/04
Tennessee License No.: R-01082-D02
NMED No.: 030565
Type of Incident: Equipment Failure

File No.: 3
Licensee: Agilent Technologies
Sites of Incidents: Various
Dates of Incidents: Various
Investigation Dates: 6/05
NRC License No.: 07-28762-02G
Incident Log No.: Various NMED reports
Type of Incidents: Leaking sources

ATTACHMENT

November 21, 2005 letter from Charles L. Miller,
NRC's Response to the Draft IMPEP Report

ADAMS: ML053260020

ATTACHMENT 2

RESOLUTION OF COMMENTS
RESPONSE TO NRC COMMENTS FROM THE DRAFT 2005 IMPEP REPORT

The NRC staff responded to the draft IMPEP report in a letter dated November 21, 2005, with comments included as an attachment. In response to the NRC letter, minor edits to the report were made where appropriate. The remaining NRC staff responses to the draft IMPEP report are listed below.

Appendix C - File 11

IMPEP team comment: Under "conditions of normal use," vibration is not defined; only stated that there were no device failures in the past.

NRC Response: In our view, the conditions of use, which includes the vibration environment encountered by the device, were sufficiently supported by operational history, an acceptable method by NUREG-1556, Vol. 3, Section 10.5; thus, no change to the registration certificate is needed.

IMPEP team response: The team agrees with the NRC response, the sample device registration in Appendix D to NUREG-1556 Vol. 3 lists ranges of vibration in the section "Conditions of Normal Use." The operational history stands in support of the durability testing identified in the section "Prototype Testing." The comment was removed and does not appear in the proposed final report.

Appendix C - File 13

IMPEP team comment: The registration was listed as amended in entirety, but was handled as name change for a December 1, 1969 registration NR-0169-S-124-U by updating only the first page information. However, the vendor code and product code were both changed, making it a new registration that should have been reviewed and updated in its entirety.

NRC Response: (1) NRC handles name/address changes as amendments because we add the correspondence, requesting the change, for traceability to the references, i.e. to the last page in the registration and, consequently, the signatures must also be updated on the last page. NRC will clarify this practice in the next revision of NUREG-1556, Vol. 3.

NRC Response: (2) NRC does not conduct a full safety review of old registrations for administrative changes, such as for this one issued 36 years ago, because the safe operational history of the product demonstrates product safety sufficiently.

IMPEP team response: The comment was removed and does not appear in the proposed final report.

IMPEP team comment: the source diameter and wall thickness were listed, but the description did not indicate if the diameter was an inner or outer diameter.

NRC Response: Note 2 above applies.

IMPEP team response: The team agrees with the NRC's policy, however, the team believes that it would be prudent to correct any editorial errors that are found regardless of the circumstance. The comment remains in the proposed final report.

IMPEP team comment: excluding the first page, only the references section was updated. The rest of the registration was missing the subsections entitled "Labeling," "Diagram," "Conditions of Normal Use," "Prototype Testing," "External Radiation Levels," "Quality Assurance and Control," Limitations and/or Other Conditions of Use," and "Safety Analysis Summary."

NRC Response: Note 2 above applies.

IMPEP team response: The comment was removed and does not appear in the proposed final report.

Appendix C - File 14

IMPEP team comment: In the description, on page 2, second paragraph, last sentence, two numbers were identified in the format of "#.## x 10E-y." This is not a standard scientific or engineering number format.

NRC Response: The values, expressed in dual units, are related to each other and, as shown in the text one following the other, are consistent with the context, i.e. 400 microns = 1.31E-3 inch and 200 microns = 0.66E-3 inch. The reviewers did discuss, during the safety evaluation, the best method to show the half values in dual units, and decided on the representation as shown. No change is warranted.

IMPEP team response: The issue identified was the combining of the scientific number formats of *[number]* E *[exponent]* and *[number]* x10$^{[exponent]}$. The team acknowledges that the comment was not specific in this regard in the draft report. The comment remains in the proposed final report however, this comment is editorial in nature and the NRC may address this in any way they believe is prudent.

Appendix C - File 15

IMPEP team comment (a): Reviewer's signatures were replaced with "**/RA/**." The NRC SS&D team leader indicated that this was considered acceptable as an original signature.

NRC Response: The NRC Office of the General Council made a determination that **/RA/** is to replace the signatures on electronic documents, see "ADAMS Desk Reference Guide," March 1, 2005, Page 8-4.

IMPEP team response: The comment was removed and does not appear in the proposed final report.

Appendix C - File(s) 16 and 18

IMPEP team comment (b): Reviewer's signatures were replaced with "**/RA/**" in the ADAMS registration copy. The review team questioned the use of the typed notation in lieu of an actual signature for an official copy of record. The NRC SS&D team leader indicated that this was considered acceptable as an original signature.

NRC Response: The NRC Office of the General Council made a determination that **/RA/** is to replace the signatures on electronic documents, see "ADAMS Desk Reference Guide," March 1, 2005, Page 8-4.

IMPEP team response: The comment was removed and does not appear in the proposed final report

Appendix C - File 20

IMPEP team comment (d): The cover page headings of "Isotope" and "Maximum Activity" list multiple maximum activities for tritium for the device registration, with the different activities for different device models. The per model activity limits is appropriate for the "Description" section of the registration, with the maximum activity of all the models for a particular isotope listed on the cover page.

NRC Response: The registration certificate was issued for a line of products with 11 differing configurations. Each configuration was approved for a different maximum activity level. For ease of use and for quick reference, we chose to show these varying maximum activity levels on the front page. In view of the complexity of the various configurations, we think that the registration certificate serves its intended purpose effectively and we do not see a need for a change.

IMPEP team response: The comment was removed and does not appear in the proposed final report.

Appendix C - File 21

IMPEP team comment (c): In the description, on page 2, second paragraph, last sentence, two numbers were identified in the format of "#.## x 10E-#." This is not a standard number format.

NRC Response: (1) The comment is identical to the one in File 14.

NRC Response: (2) The values, expressed in dual units, are related to each other and, as shown in the text one following the other, are consistent with the context, i.e. 400 microns = 1.31E-3 inch and 200 microns = 0.66E-3 inch. The reviewers did discuss, during the safety evaluation, the best method to show the half values in dual units, and decided on the representation as shown. No change is warranted.

IMPEP team response: The issue identified was the combining of the scientific number formats of *[number]* E *[exponent]* and *[number]* x10$^{[exponent]}$. The team acknowledges that the comment was not specific in this regard in the draft report. The comment remains in the proposed final report however, this comment is editorial in nature and the NRC may address this in any way they believe is prudent.

IMPEP team comment: The registration states that the leak test may be performed "by persons specifically or generally licensed." This may potentially mislead a general licensee to perform a wipe test analysis, which must be done by a specific licensee, although a general licensee may collect a leak test sample to send out for analysis.

NRC Response: The SS&D registration certificates are not intended to provide detailed procedures and qualification requirements either for operation or maintenance. The operating manual, reviewed during the safety evaluation, serves that purpose. Therefore, we do not see a need to change the document to be more specific.

IMPEP team response: The comment was removed and does not appear in the proposed final report.