NOTE: The NRC comments on the Draft Report are shown in the text as high-light for additions and comments, and as strike-out+high-light for deletions.

Organization of Agreement States

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NRC SEALED SOURCE AND DEVICE EVALUATION PROGRAM

October 19-23, 2009

DRAFT REPORT

Enclosure

1.0 INTRODUCTION

This report presents the results of the review of the U.S. Nuclear Regulatory Commission's (NRC) Sealed Source and Device (SS&D) Evaluation Program. The review was conducted during the period of October 19-23, 2009, by a review team comprised of technical staff members from the NRC, the State of Florida, and the Commonwealth of Massachusetts. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and the February 26, 2004 NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of September 24, 2005, to October 23, 2009, were discussed with NRC managers on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The SS&D Evaluation Program is administered by the Licensing Branch (the Branch) in the Division of Materials Safety and State Agreements (the Division). The Division is part of the Office of Federal and State Material and Environmental Management Programs (the Office). Organization charts for the Office and the Division are included in Appendix B.

At the time of the review, the SS&D Evaluation Program maintained authority for performing SS&D evaluations in areas licensed by NRC and also in areas licensed by the Agreement States of Arkansas, Iowa, Minnesota, New Jersey, Oklahoma, New Mexico, North Dakota, Oregon, Pennsylvania, Rhode Island, Utah, Virginia, and Wisconsin.

In preparation for the review, a questionnaire addressing the non-common performance indicator SS&D Evaluation Program was sent to the Branch on August 6, 2009. The Branch provided its response to the questionnaire on September 30, 2009. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML092730651.

The review team's general approach for conduct of this 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 staff and managers. The review team evaluated the information gathered against the established criteria for the non-common performance indicator and made a preliminary assessment of the SS&D Evaluation Program's performance.

Section 2.0 of this report covers the NRC's actions in response to recommendations made during the previous review. The results of the current review are presented in Section 3.0. Section 4.0 summarizes the review team's findings and recommendations. The review team's recommendations are comments that relate directly to program performance by the NRC. A response is requested from the NRC to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on September 23, 2005, the review team made one recommendation in regard to program performance. The status of the recommendation is as follows:

> 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 of the 2005 IMPEP report)
>
> Current Status: The Branch (formerly the Section) issued a set of Policy and Guidance Directives in April 2006 that included direction for staff to follow the guidance of NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses – Applications for Sealed Source and Device Evaluation and Registration". Interviews with staff confirmed that staff follows guidance from the current revision of NUREG-1556, Volume 3. As evidenced by fewer format and content issues averaged per completed registration discovered during this review period of less than one as compared to that discovered during the last review period of greater than two, the review team determined that the Branch adheres more closely to the document format and contents in the guidance as identified in the current NUREG-1556, Volume 3. This recommendation is closed.

3.0 PERFORMANCE INDICATOR

IMPEP identifies five common performance indicators and four non-common performance indicators to be used in reviewing Agreement State and NRC Programs. This review was limited to evaluating the non-common performance indicator, SS&D Evaluation Program.

In reviewing this performance indicator, the review team used three subelements to evaluate the Branch's performance regarding the SS&D Evaluation Program. These subelements were: (1) Technical Staffing and Training, (2) Technical Quality of the Product Evaluation Program, and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Branch's SS&D evaluation activities, the review team examined information contained in the Branch's response to the IMPEP questionnaire for this indicator and performed searches of the National Material Events Database (NMED). The review team evaluated 13 SS&D evaluations and supporting documents processed during the review period. The review team noted the staff's use of guidance documents and procedures, interviewed staff members involved in SS&D evaluations, and verified the use of regulations and inspections to enforce commitments made in the applications.

3.1 Technical Staffing and Training

At the time of the review, the SS&D Team Leader and four staff members were conducting SS&D reviews. Three individuals ~~of these individuals~~ were fully qualified to independently review and sign registry sheets. There is one additional Branch staff member who was fully qualified to independently review and sign registry sheets; however, this individual was not conducting reviews at the time of the IMPEP. One licensing assistant provides administrative support to the program. Since the last review, the program has been through two

reorganizations, four individuals (three fully qualified and one in training) have left the SS&D group, and two individuals have joined the group. Three 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 were no vacancies in the SS&D group at the time of the review.

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 0.30 full-time equivalents (FTE). According to the Branch's questionnaire response, the FTE expenditure on the SS&D program during the review period was 1.02 FTE for FY 2006, 1.01 FTE for FY 2007, 1.01 FTE for FY 2008, and 1.60 FTE for FY 2009.

The review team evaluated the qualifications of and the respective documentation for the individuals who were certified to independently review and sign registry sheets during the review period. The review team also evaluated the qualifications of and the respective documentation for the two individuals currently in the training process. The qualification procedure used for NRC SS&D reviewers is found in the NRC Inspection Manual Chapter (IMC) 1246 Appendix A, Section XVI, "Technical Reviewer Qualifications Journal - Byproduct Material Sealed Source and Device Reviewers."

New staff members are required to complete the training requirements in IMC 1246, Appendix A, Section XVI and participate in the review of 20 cases. Depending on the casework available during the training period, the required SS&D casework includes sources, irradiators, radiography equipment, consumer products, gauges and medical devices. Once the staff member has completed the training and casework, the staff member is evaluated by an SS&D review board prior to being certified to independently review applications and sign registry sheets.

Based on interviews with staff, a review of casework, and a review of the required training courses, the review team concluded that the training program is effective in developing a competent and qualified staff. The review team also concluded that staffing levels were adequate based on the Branch's current and projected workload.

Based on the IMPEP evaluation criteria, the review team recommends that NRC's performance with respect to the subelement, Technical Staffing and Training, be found satisfactory.

3.2 Technical Quality of the Product Evaluation Program

The review team evaluated 13 SS&D registrations that were completed by the Branch during the review period. At the time of the review, the Branch had 236 active SS&D registrations of which 46 registrations were for exempt products. The questionnaire response provided by the Branch supported that at least 166 SS&D registration cases were completed during the review period. Casework selected for review included work performed by four fully qualified staff members and consisted of a cross section sampling of new, amended, inactivated, and corrected registrations. The review team performed their review using the official records in ADAMS. A list of SS&D casework examined, with case-specific comments, can be found in Appendix C.

Analysis of the casework and interviews with staff members confirmed that the Branch staff follows the recommended guidance from NRC's SS&D Workshop and NUREG-1556, Volume 3, Revision 1. The review team confirmed that all applicable and pertinent American National Standards Institute standards, NUREG-1556 Series guides, NRC Regulatory Guides, and applicable references were available and used appropriately in performing the SS&D reviews.

A case file is created for each applicant's request. This case file will contain all documents received and generated by this request and includes the applicant's request, Branch's requests for additional information, applicant replies, e-mails, the signed registry certificate issued to the applicant, etc. Once the case file is closed, the information is made an official agency record in ADAMS. The process for document management is described in one of the Branch's Policy and Guidance Directives. The ADAMS documents available for review contained all photographs, engineering drawings, and radiation profiles required to evaluate the source or device; however, the review team found several instances where the NRC's official records in ADAMS were missing documents that contained commitments made by the licensee that should be enforceable via inspection in case of violation. The review team found that 4 of the 13 case files evaluated were missing critical information in ADAMS. Of these four files, a total of eight documents were missing from ADAMS or incorrect documents were placed in ADAMS in their stead. At the time of discovery by the review team, the commitments made under these four registrations were not legally enforceable based upon the NRC's official records. The review team noted that the information missing in three of the four files was added to ADAMS during the on-site review, because the paper copies of the application and commitments were still available. As a general practice, all paper copies of the cases completed during the review period are destroyed following the IMPEP review. The review team noted that the Branch's Policy and Guidance Directive for document management requires a final quality check of ADAMS documents for each case file to be performed by the SS&D Team Leader; however, that final check was not consistently performed. The review team recommends that the NRC evaluate the implementation and effectiveness of the Branch's Policy and Guidance Directives and ensure that all of the required documents needed to enforce the provisions of the registration certificate are made part of the NRC's official records in ADAMS, including those cases closed during this review period.

With one exception noted in the next paragraph, the registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license the possession and use of the product. Requests for additional information clearly stated regulatory positions. The review team found that the registry evaluations were of high quality with health and safety issues properly addressed.

The review team found that one SS&D registration had been amended in its entirety twice after a health and safety waste disposal issue involving the discovery of long-lived radioactive contaminants was identified and documented in NRC Information Notice (IN), IN 2007-10, "Yttrium-90 Theraspheres® and Sirspheres® Impurities". Neither amended registration incorporated the information to provide license reviewers with adequate information to license the possession and use of the product. The registration currently identifies only one radionuclide, a short-lived radionuclide, contained in the product and specifies in the Limitations and/or Other Considerations of Use Section of the registration, in part, that disposal is to be determined by the licensing authority. The review team discussed with Branch management the benefit of including information about the long-lived contaminants in the registration to alert license reviewers and allow license reviewers to make informed licensing decisions regarding

disposal of the product. For example, license reviewers may find that a decay-in-storage method of disposal is appropriate for a short-lived radionuclide but may find that such disposal method is not appropriate for a long-lived radionuclide. The Branch's management committed to add the information to the registration at the next time that the holder of the registration requests for an amendment of the registration. The review team found that immediate amendment of the registration was not critical because the NRC has widely distributed IN 2007-10 to communicate the waste disposal issues to its license reviewers.

The staff uses Section 10.7 and Appendix G of NUREG-1556, Volume 3, Revision 1, to review details of the applicant's quality assurance and quality control (QA/QC) program. The review team determined that the staff's evaluation of applicant developed QA/QC programs was adequate and consistent with Section 10.7 and Appendix G of NUREG-1556, Volume 3, Revision 1. The review team did not evaluate the NRC's practice of evaluating implementation of applicant QA/QC programs as it is handled by the Regional offices and, therefore, was out of the scope of this review. The review team was provided a copy of NRC Inspection Procedure 87125 for the inspection of Materials Processor/Manufacturer Programs and verified that inspectors are provided guidance to evaluate the implementation of QA/QC programs, as committed to by the licensee during the application process, during inspections.

Based on the IMPEP evaluation criteria, the review team recommends that the NRC's performance with respect to the subelement, Technical Quality of Product Evaluation Program, be found satisfactory.

3.3 Evaluation of Defects and Incidents Regarding SS&Ds

Based upon the Branch's response to the questionnaire, interviews with Branch staff, review of incident files maintained by the SS&D Team Leader and the review team's searches of NMED, the review team determined that one product registered by the NRC exhibited a generic defect during the review period. The SS&D registration for the product is identified in Appendix D of this report. The generic defect was reported by the distributor of the product to the NRC, and the Branch took appropriate action to include evaluation of a design change to mitigate the defect and evaluation of corrective actions proposed by the distributor to modify products already distributed. The review team noted that the design change is described in the report made by the distributor but that the SS&D registration had not been amended to include the design change. The SS&D Team Leader explained that the Branch evaluated whether the Description section of the registration should be amended and decided that a change in the Description section was not warranted. The review team also noted that, unrelated to the specific design change made, a picture submitted with the distributor's report contained different information than that contained in diagrams made part of the registration. Specifically, the on and off indicators of the product were position reversed.

The review team discussed with Branch management the benefit of adding the distributor's report containing the design change to the registration and also for resolving the on and off indicator discrepancy. The Branch's management committed to add the design change information as a reference to the registration, and to resolve the on and off indicator discrepancy. Subsequent to the on-site portion of the review, the NRC issued an amendment of Registration Certificate NR-1195-D-103-S, dated December 14, 2009, which reflected the design change.

In addition to evaluating incidents and defects of products registered by the NRC, the Branch also evaluates defect and incidents of additional sealed source and device products registered by Agreement States that are used by NRC licensees. The Branch accomplishes these evaluations by performing generic assessments of product incident information that is received by the Branch daily through NRC's Operations Center and also through periodic analysis of events reported to NMED. The Branch performs generic assessments in accordance with criteria contained in MD 6.4 "Generic Issues Program" dated July 29, 2005. If a generic issue is identified, the NRC will issue a generic communication to licensees and Agreement States. Examples of generic communications resultant from Branch assessments or participation by Branch staff during the review period included IN 2007-35, "Varian Medical Systems Varisource HDR Events: Iridium-192 Source Pulled from Shielded Position"; IN 2009-5, "Contamination Events Resulting from Damage to Sealed Radioactive Sources During Gauge Dismantlement and Non-Routine Operations"; IN 2009-15, "Varian Medical Systems Varisource High Dose-Rate Remote Afterloader Events: Source Retraction Problems"; and IN 2009-18, "Performance of Required Shutter Checks and Reporting of Gauge Shutter Failures".

The review team concluded that the Branch is routinely evaluating the root causes of defects and incidents involving SS&D evaluations and is taking appropriate actions.

There were no allegations completed by the NRC during the review period related to defects or failures of SS&D products registered by the NRC.

Based on the IMPEP evaluation criteria, the review team recommends that the NRC's performance with respect to the subelement, Evaluation of Defects and Incidents Regarding SS&Ds, be found satisfactory.

4.0 SUMMARY

As noted in Section 3.0, the review team found the NRC's SS&D Evaluation Program performance to be satisfactory for all three subelements; therefore, based on the IMPEP evaluation criteria, the review team recommends that the NRC's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory. Overall, the review team recommends that the NRC's SS&D Evaluation Program be found adequate to protect public health and safety. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately 4 years.

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

> The review team recommends that the NRC evaluate the implementation and effectiveness of the Branch's Policy and Guidance Directives and ensure that all of the required documents needed to enforce the provisions of the registration certificate are made part of the NRC's official records in ADAMS, including those cases closed during this review period. (Section 3.2)

LIST OF APPENDIXES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Joshua Daehler, Massachusetts	Team Leader Evaluation of Defects and Incidents Regarding SS&Ds
Monica Orendi, FSME	Technical Staffing and Training
Michael Stephens, Florida	Technical Quality of the Product Evaluation Program

APPENDIX B

NRC ORGANIZATION CHARTS

ADAMS: ML092730280

APPENDIX C

SEALED SOURCE & DEVICE CASEWORK REVIEWS

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

File No.: 1
Registry No.: NR-0220-D-131-S
Applicant Name: MDS Nordion
Date Issued: 9/18/09
SS&D Type: (AF) Other Medical
Type of Action: Amendment
Reviewers: UB, JJ

Comment:

A Reviewer Note (as described in NUREG-1556 Vol. 3, Rev. 1, Section 12.10) was not added to the Limitations and/or Other Considerations of Use section to address waste disposal issues with this device. NRC staff committed to issue an amendment for NR-0220-D-131-S to add a Reviewer's Note indicating that disposal issues should be handled in accordance with Information Notice 2007-10, "Yttrium-90 Theraspheres® and Sirspheres® Impurities."

NOTE: Please add the statement above to the comment.

File No.: 2
Registry No.: NR-1289-D-101-S
Applicant Name: MDS Nordion
Date Issued: 8/14/08
SS&D Type: (AA) Manual Brachytherapy
Type of Action: Amendment
Reviewers: NA, TH

Comments:

a) Leak test frequency on page 1 says "Not Applicable (See Description)" where it is not discussed and the Limitations and/or Other Considerations of Use section specifies leak tests every 6 months.

b) Limitation and/or Other Considerations of Use section indicates to avoid storage in excessive heat or humidity but does not indicate what is considered excessive.

c) ADAMS was missing a report dated March 5, 2008 that was referenced in reviewer's letter dated May 6, 2008 (ML092930407). Subsequent to the on-site portion of the review, the NRC staff located the report in ADAMS (ML081270170) and placed it in the case file.

NOTE: Please add the statement above to the comment.

File No.: 3
Registry No.: NR-0348-D-806-B
Applicant Name: Agilent Technologies
Date Issued: 7/7/08
SS&D Type: (N) Ion Generators, Chromatography
Type of Action: Inactivation
Reviewers: TH, NA

File No.: 4
Registry No.: NR-0220-D-131-S
SS&D Type: (AF) Other Medical

Applicant Name: MDS Nordion
Date Issued: 10/3/08
Type of Action: Amendment
Reviewers: UB, JJ

Comments:

a) A Reviewer Note (as described in NUREG-1556 Vol. 3, Rev. 1, Section 12.10) was not added to the Limitations and/or Other Considerations of Use section to address waste disposal issues with this device.

b) Current active SS&D registration dated October 3, 2008 was not available in ADAMS under the case number folder. Subsequent to the on-site portion of the review, the NRC staff determined that the document was in the folder, but it was incorrectly profiled with a security classification which made it invisible to the review team. The NRC staff re-profiled the document to be in compliance with the other content of the SS&D folder.

NOTE: Please add the statement above to the comment.

File No.: 5
Registry No.: NR-1124-D-101-S
Applicant Name: Department of Army
Date Issued: 9/5/06
SS&D Type: (AF) Other Medical
Type of Action: Amendment
Reviewers: TH, JJ

Comment:

Custom user evaluation was contrary to recommendations of NUREG-1556, Vol. 3, Rev. 1. Custom users are typically limited to 2-3 users at most and are identified by name and address (See NUREG-1556, Vol. 3, Rev.1, Sections 5.2; 10.1; and 15; and Appendix D). The registration listed the users as "All U.S. Federal Government Agencies" without regard to name of specifically licensed user(s) and what address. The submitted documentation indicated that product would be distributed to over 50 sites in the U.S.

NOTE: Please delete the comment above because the device distribution was expanded to "All U.S. Federal Government Agencies" for national security reasons as requested by the U.S. Department of the Army in letter dated February 25, 2000 (ML010390070), during the previous review cycle. The Branch Chief authorized the NRC staff to use the expanded distribution in an e-mail (ML010390174) dated April 19, 2000, by stating "…[attached] procedure specifies the definition of 'custom user' for U.S. Army registration certificates. This procedure is to be used as a supplement to NUREG-1556/Vol. 3."

File No.: 6
Registry No.: NR-0163-D-101-G
Applicant Name: Smith Detection, Inc.
Date Issued: 3/28/08
SS&D Type: (N) Ion Generators, Chromatography
Type of Action: Amendment
Reviewers: UB, JJ

File No.: 7
Registry No.: NR-0195-D-103-S
Applicant Name: SABIA, Inc.
SS&D Type: (H) General Neutron Source Application
Type of Action: Amendment

Date Issued: 10/20/08
Reviewers: NA, JJ

File No.: 8
Registry No.: NR-1302-D-101-B
SS&D Type: (D) Gamma Gauge
Applicant Name: Endress & Hauser
Type of Action: New
Date Issued: 8/24/08
Reviewers: TH, NA

Comment:

The References section of the registration listed the following items that were not in the official records ADAMS under this case file: application dated November 14, 2007; letters dated April 28, 2008 and May 29, 2008; and e-mails dated ~~July~~ June 2, 2008 and August 15, 2008. Two of the five missing documents were entered into ADAMS as official records during the on-site portion of the review. Subsequent to the on-site portion of the review, the NRC staff located in ADAMS the following missing documents and placed them in the case folder: application, dated November 14, 2007 (ML093360429); letter dated April 28, 2008 (ML0929304560); e-mail dated June 2, 2008 (ML0824211691); and e-mail dated Aug.15, 2008 (ML0929304510).

NOTE: Please add the statement above to the comment

File No.: 9
Registry No.: NR-0122-D-101-B
SS&D Type: (E) Beta Gauge and (D) Gamma Gauge
Applicant Name: Beta Control of America
Type of Action: Amendment
Date Issued: 1/26/06
Reviewers: NA, UB

Comment:

Radiation profiles for new isotope and the increased activity of an existing isotope were listed at distances 50/100 centimeters instead of 5/30/100 centimeters as recommended in NUREG-1556, Vol. 3, Rev. 1.

NOTE: Please delete the comment above because the content of NUREG-1556, Vol. 3, Rev. 1, "is designed to provide guidance to applicants," i.e., not requirements (see Abstract, Page iii). In this case, the NRC staff deemed sufficient to list the radiation profiles at 50/100 centimeters vs. the traditional 5/30/100 centimeters. The staff's determination was based on the facts that the device is a beta-gauge with low penetration radiation and the dose rate values were at background levels. Furthermore, the radiation profiles for three of the five isotopes, authorized to be used in the device, where radiation was measurable above background, are listed at 5/30/100 centimeters; while for two isotopes, radiation is not measurable above background at 50/100 centimeters.

File No.: 10
Registry No.: NR-1235-S-101-S
SS&D Type: (J),(K),(L),and(M) Gamma Irradiation Categories
Applicant Name: International Isotopes Idaho
Type of Action: Corrected
Date Issued: 1/30/07
Reviewers: NA, JJ

File No.: 11
Registry No.: NR-1265-D-101-E
SS&D Type: (W) Luminous Light Sources
Applicant Name: Hess Fine Arts
Type of Action: New
Date Issued: 9/26/06
Reviewers: TH, JJ

File No.: 12
Registry No.: NR-0348-D-111-B
SS&D Type: (N) Ion Generators, Chromatography
Applicant Name: Agilent
Type of Action: Amendment
Date Issued: 6/30/09
Reviewers: JJ, UB

File No.: 13
Registry No.: NR-1307-D-102-S
SS&D Type: (J) Gamma Irradiation, Category I
Applicant Name: Best Theratronics, Ltd.
Type of Action: Amendment
Date Issued: 7/30/08
Reviewers: NA, JJ

Comment:

The official record ADAMS under this case file contained an unsigned registry sheet that was also missing the term /RA/. The document was entered into ADAMS as official records during the on-site portion of the review to list it as /RA/.

APPENDIX D

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Registry No.: NR-1195-D-103-S
Licensee: SABIA, Inc.
NRC License No.: 11-27727-01

NMED Item Number: 060169
Type of Incident: 10 CFR 21.21(d)(1)(ii), Generic defect
Investigation Dates: 1/06-2/07