UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 26, 2015

MEMORANDUM TO: Catherine Haney, Director
Office of Nuclear Material Safety
and Safeguards

FROM: Michael F. Weber ***/RA/***
Deputy Executive Director for Materials, Waste, Research,
State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Michael A. Welling, Chair ***/RA/***
Organization of Agreement States

SUBJECT: FINAL REPORT FOR THE INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE U.S. NUCLEAR REGULATORY COMMISSION'S (NRC) SEALED SOURCE AND DEVICE (SS&D) EVALUATION PROGRAM

On March 5, 2015, the Management Review Board (MRB) met to consider the proposed final IMPEP report of the NRC SS&D Evaluation Program. The MRB found the NRC SS&D Evaluation Program 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 results of the current review, the next IMPEP review of the NRC SS&D Evaluation Program will take place in approximately 5 years.

We appreciate the courtesy and cooperation extended to the IMPEP team during the review, and we applaud your staff's efforts during the IMPEP review period.

Enclosure:
Final NRC SS&D Evaluation
Program IMPEP Report

cc: See next page

CONTACT: Lisa Dimmick, NMSS/MSTR
301-415-0694

cc: Raymond Manley, MD
Organization of Agreement States
Liaison to the MRB

Hipolito Gonzales, Branch Chief
Materials Licensing Branch

Tomas Herrera, Team Leader
Sealed Source & Device Team
Materials Licensing Branch

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Program IMPEP Report

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CONTACT: Lisa Dimmick, NMSS/MSTR
301-415-0694
Distribution: (SP01) see next page

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DATE	3/9/15	3/10/15	03/10/15	03/11/15	3/24/15	3/10/15	3/26/15

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Memo to C. Haney from M. Weber and M. Welling dated: March 26, 2015

SUBJECT: NRC SS&D EVALUATION PROGRAM FY2015 FINAL IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE U.S. NUCLEAR REGULATORY COMMISSION
SEALED SOURCE AND DEVICE EVALUATION PROGRAM

DECEMBER 8–11, 2014

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the U.S. Nuclear Regulatory Commission (NRC) Sealed Source and Device (SS&D) Evaluation Program. The review was conducted during the period of December 8-11, 2014, by a review team composed of technical staff members from the NRC and the States of Tennessee and Ohio.

Based on the results of this review, the review team found the NRC's performance to be satisfactory for all three of the sub-elements of the SS&D performance indicator.

The review team made one recommendation regarding program performance by the Materials Safety Licensing Branch regarding obtaining missing historical documents from SS&D registrations transferred from the State of Georgia. The review team determined that the recommendation from the 2009 IMPEP review regarding missing information from case files should be closed.

Accordingly, the review team recommended, and the Management Review Board (MRB) agreed, that the NRC SS&D Evaluation Program is adequate to protect public health and safety. The review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately five years.

1.0 INTRODUCTION

This report presents the results of the review of the Nuclear Regulatory Commission (NRC) Sealed Source and Device (SS&D) Evaluation Program. The review was conducted during the period of December 8–11, 2014, by a review team composed of technical staff members from the NRC and the States of Ohio and Tennessee. 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 October 24, 2009, to December 11, 2014, were discussed with NRC managers on the last day of the review.

A draft of this report was issued to the Office of Nuclear Material Safety and Safeguards (NMSS) on January 9, 2015, for factual comment. The Materials Safety Licensing Branch (MSLB) responded to the findings and conclusions of the review by electronic mail dated January 27, 2015. A copy of MSLB's response is included as an attachment to this report. The Management Review Board (MRB) met on March 5, 2015, to consider the proposed final report. The MRB found the NRC SS&D Evaluation Program adequate to protect public health and safety.

The SS&D Evaluation Program (the Program) is administered by the Materials Safety Licensing Branch (the Branch) in the Division of Material Safety, State, Tribal, and Rulemaking Programs (the Division). The Division is part of the Office of Nuclear Material Safety and Safeguards (the Office). Organization charts for the Office and the Division are included in Appendix B.

At the time of the review, the Program maintained authority for performing SS&D evaluations in areas licensed by the NRC and also in areas licensed by the Agreement States of Arkansas, Georgia, 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 Program was sent to the Branch on August 19, 2014. The Branch provided its response to the questionnaire on November 5, 2014. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML14297A407.

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 NRC's performance.

Section 2.0 of this report covers the NRC's actions in response to a recommendation 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.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on October 23, 2009, the review team made one recommendation in regard to the NRC's performance as follows:

> "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 2009 IMPEP Report)"

Current Status: The Branch developed and implemented Policy and Guidance Directives to ensure that the required documents were included in ADAMS. The review team found that documents from the Branch's casework were appropriately entered in ADAMS. The review team recommended, and the MRB agreed, that this recommendation be closed.

3.0 PERFORMANCE INDICATORS

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

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

To assess the Branch's SS&D evaluation activities, the review team examined the information provided in response to the IMPEP questionnaire and evaluated 28 SS&D registration certificates and supporting documents processed during the review period. The team also evaluated SS&D staff training records, reported incidents involving products authorized by the NRC SS&D registration certificates, and the Branch's use of guidance documents and procedures. The team interviewed the staff currently conducting SS&D evaluations.

3.1. Technical Staffing and Training

At the time of the review, the SS&D Team Leader and two staff in the Branch were fully qualified to independently review and sign SS&D registration certificates. Another qualified SS&D reviewer is assigned to another branch in the Division and supports the Branch for SS&D reviews during peak workloads. One licensing assistant provides administrative assistance to the Program. In the interim period between reviews, four qualified reviewers left the Branch due to other opportunities in the agency and/or retirement, and two staff joined the Branch. One of those staff is currently progressing through the qualification process. There were no vacant positions at the time of the onsite IMPEP review. There were no organizational changes during the review period until the merger the NMSS and the Office of Federal and State, Materials, and Environmental Programs in October 2014. With the merger, the Division and Branch responsible for the Program were not significantly impacted.

All current qualified SS&D staff members spend only a portion of their time conducting reviews. During the last two fiscal years (FY), the highest time expenditure by an individual was 0.8 Full-Time Equivalents (FTE). According to the Branch's response to the IMPEP questionnaire, the FTE expenditure on the Program during the review period was 2.5 FTE for FY 2010, 1.3 FTE for FY 2011, 1.8 FTE for FY 2012, 1.5 FTE for FY 2013, and 2.5 FTE for FY 2014. The increase in FTE for FY 2014 is largely attributed to the State of Georgia's transfer of its SS&D evaluation program to the NRC.

The review team evaluated the qualifications of and the respective documentation for the individuals who were qualified to independently review and sign SS&D registration certificates during the review period. The review team also evaluated the qualifications of the one candidate in the qualification process. The qualification procedure used for the NRC SS&D reviewer is found in NRC Inspection Manual Chapter (IMC) 1248, Appendix D, "Technical Reviewer Qualification Journal, Byproduct Material Sealed Source and Device Reviewer." All other previously qualified staff were qualified to IMC 1246, Section XVI, "Technical Reviewer Qualification Journal, Byproduct Material Sealed Source and Device Reviews."

Based upon the review team's 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 competent and qualified staff. The review team concluded that staffing levels were adequate based upon the Branch's current and projected workload.

Based upon the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that the NRC's performance with respect to the sub-element, Technical Staffing and Training, be found satisfactory.

3.2 Technical Quality of the Product Evaluation Program

The review team evaluated 28 SS&D registration certificates that were completed by the Branch during the review period. The questionnaire response provided by the Branch indicated that the Branch evaluated 230 SS&D registrations during the review period. The casework selected for review by the IMPEP team included work performed by fully qualified staff members and consisted of a cross section sampling of new, amended, inactivated, and corrected registrations. The review team performed its review using the official records in ADAMS. Appendix C contains a listing of SS&D casework examined with case-specific comments.

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 "Consolidation Guidance About Materials Licenses: Application for Sealed Source and Device Evaluation and Registration." 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. The IMPEP team noted that NUREG-1556, Volume 3, Revision 2 has been out for public comment since May 2013. The draft Revision 2 incorporates the many rule changes that have occurred since Revision 1 was published. The Branch staff is cognizant of these discrepancies, and applies the current regulations as applicable.

To process a SS&D registration certificate, the Branch creates a case file for each applicant's request. This case file contains all documents received and generated by the request and includes the application, the 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 ADAMS documents available for the casework reviewed contained all photographs, engineering drawings, and radiation profiles required to evaluate the source or device.

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 comments noted in Appendix C do not reflect deficiencies in the health and safety evaluations of the products.

During the review period, the State of Georgia returned its SS&D program to the NRC. The Georgia program transferred 58 active registration certificates. The NRC is in the process of converting the certificates to NRC documents. The IMPEP team observed, on four occasions, that the State of Georgia registration certificates were amended and converted to NRC registration certificates, but the case files in ADAMS did not contain all the historical documents listed in the "references" section of the registration certificates. The Branch had identified some supporting documents were missing from the Georgia SS&D transfer and added a note to the file indicating that they were missing. The review team noted that the commitments made under these registrations may not be legally enforceable based upon the incomplete official records. The review team recommended, and the MRB agreed, that the Branch develop and implement a mechanism to obtain missing historical documents referenced in the SS&D registration certificates transferred from the State of Georgia.

In the 2009 IMPEP review, the team found that a registration certificate had been amended without including a reviewer note addressing disposal issues specified in IN 2007-10, "Yittrium-90 Theraspheres® and Sirspheres® Impurities." The Branch committed to adding a reviewer note to the SS&D registration certificate. At the time of the current review, the team found that the SS&D registration certificate number NR-0220-D-131-S had been amended for a name change, however the reviewer note was not included with the revised registration certificate. Since the on-site portion of the current review on December 12, 2014, the Branch has issued an amended page 8 to the registration certificate to include the reviewer note.

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 NRC's Regional offices and, therefore, was out of the scope of this review.

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

3.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team reviewed five allegation cases involving SS&D's and found the NRC's evaluation and disposition of the allegations was timely, effective, and in accordance with its prescribed allegations process. There were no allegations completed by the NRC related to defects or failures of SS&D products registered by the NRC.

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 Nuclear Materials Events Database (NMED), the review team determined that one product registered by the NRC exhibited a potential defect during the review period. The potential defect investigated was regarding a contaminated source in a Gammacell 40 irradiator. The Branch conducted an in-depth review of the incident and issued Information Notice 2010-24 "Notice of Possible Source Leakage During Non-Routine Maintenance on a Gammacell 40 Irradiator" dated November 18, 2010. The results of the review did not require an amendment to the device registration certificate.

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". If the NRC identifies a generic issue, it will issue a generic communication to licensees and Agreement States.

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.

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

4.0 SUMMARY

As noted in Section 3.0, the NRC's performance was found satisfactory for all three sub-elements under this performance indicator; therefore, based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that the NRC's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory. Overall, the review team recommended, and the MRB agreed, that the NRC's SS&D Evaluation Program is adequate to protect public health and safety. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately five years. Below is the review team's recommendation, as mentioned in the report, for evaluation and implementation by the Branch:

> The review team recommends that the Branch develop and implement a mechanism to obtain missing historical documents referenced in the SS&D registration certificates transferred from the State of Georgia. (Section 3.2)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

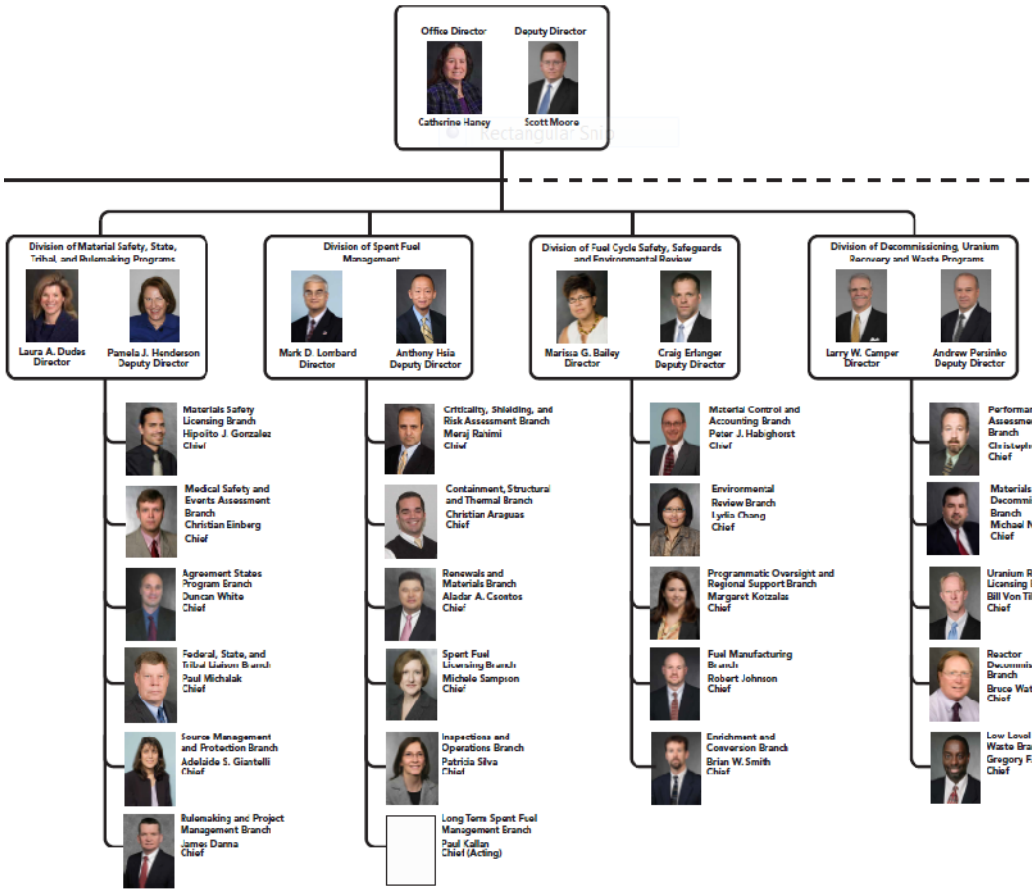
Name	**Area of Responsibility**
Joe O'Hara, NMSS/MSTR/ASPB	Technical Staffing and Training Evaluation of Defects and Incidents Regarding SS&Ds (Allegations component)
Ron Parsons, Tennessee	Technical Quality of the Product Evaluation Program
Karl Von Ahn, Ohio	Team Leader Technical Quality of the Product Evaluation Program Evaluation of Defects and Incidents Regarding SS&Ds (Incidents component)

APPENDIX B

NRC ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML14297A409

Office of Nuclear Material Safety and Safeguards



Division of Material Safety, State, Tribal, and Rulemaking Programs (MSTR)				
MSTR - M/S T-8-E-18	**Division Phone #: 415-3340**		ROOM	PHONE
Dudes	**Laura**	**Director**	**T-8D48**	**415-0146**
Henderson	**Pamela**	**Deputy Director**	**T-8E01**	**415-5949**
Cool	Donald	Senior Level Advisor	**T-8E27**	**415-6347**
Holahan	E. Vincent	Senior Level Advisor	T-8F34	415-7510
Ashkeboussi	Nima	Technical Assistant (Starting date 1/15/15)	T-8E3	415-
Rajapakse	Champa	Administrative Assistant	T-8D44	415-7438
Tyler	Cynthia	Administrative Assistant	T-8A33	415-1648
Johnson (Contractor)	Sandrea	Administrative Assistant	T-8D42	415-0435
Pringle (Contractor)	Marcia	Administrative Assistant	T-8A31	415-8722
Source Management and Protection Branch (SMPB)			ROOM	PHONE
Giantelli	**Adelaide**	**Branch Chief**	**T-8F26**	**415-3521**
Decicco	Joseph	Senior Health Physicist	T-8F10	415-7833
Eusebio	Linda	Source Protection Analyst	T-8H10	415-5017
Goldberg	Paul	Project Manager	T-8F14	415-7842
Killian	Michelle	Health Physicist	T-8C26	415-6711
Lee	William	Health Physicist	T-8F11	415-8024
Lukes	Kim	Health Physicist	T-8I05	415-6701
Quinones	Ernesto	Senior Project Manager	T-8C02	415-0271
Randall	Angela	Project Manager	T-8F15	415-6806
Smith	George	Senior Project Manager	T-8H10	415-7201
Wu	Irene	Project Manager	T-8F17	415-1951
Agreement State Programs Branch (ASPB)			ROOM	PHONE
White	**Duncan**	**Branch Chief**	**T-8E23**	**415-2598**
Beardsley	Michelle	Health Physicist	R1	610-337-6942
Casby	Marcia	Training and Travel Coordinator	T-8J04	415-6525
Dimmick	Lisa	Senior Health Physicist	T-8F31	415-0694
Doolittle	Beth	Senior Project Manager	T-8E06D	415-6424
Katanic	Janine	Health Physicist	RIV	817-200-1151
Meyer	Karen	Regulation Review Specialist	T-8B03	415-0113
O'Hara	Joseph	General Engineer	T-8F40	415-6854
Poy	Stephen	Mechanical Engineer	T-8F16	415-7135
Spackman	David	Health Physicist	T-8F41	415-6389
Taylor	Torre	Senior Health Physicist	T-8F07	415-7900
Medical Safety and Events Assessment Branch (MSEB)			ROOM	PHONE
Bollock	**Douglas**	**Branch Chief** (Rotation to MSEB until 2/28/15)	**T-8E11**	**415-6609**
Einberg	**Christian**	**Branch Chief** (Rotation to MSTR Front Office until XX/XX/XX)	**T-8F20**	**415-5422**
Abogunde	Maryann	Health Physicist	T-8A15	415-6474
Burgess	Michele	Senior Regional Coordinator	T-8C24	415-5868
Cockerham	Ashley	Health Physicist	N/A	240-888-7129
Daibes-Figuera	Said	Health Physicist	T-8A26	415-6863
Fuller	Michael	Medical Team Leader	T-8F18	415-0520
Gabriel	Sandra	Health Physicist	N/A	301-801-3889
Hawkins	Sarenee	Allegations Coordinator	T-8A25	415-7562
Holiday	Sophie	Health Physicist	T-8F9	415-7865
Howe	Donna-Beth	Senior Health Physicist	T8E33	415-7848
McIntosh	Angela	Regional Program Coordinator	T-8D27	415-5030
Rivera-Capella	Gretchen	General Scientist	T-8F39	415-5944
Sun	Robert	Project Manager	T-8D16	415-3421
Materials Safety Licensing Branch (MSLB)			ROOM	PHONE
Gonzalez	**Hipolito**	**Branch Chief**	**T-8E15**	**415-5637**
Arribas-Colon	Maria	Project Manager	T-8J07	415-6026
Herrera	Tomas	SSD Team Leader	T-8D32	415-7138
Kime	Traci	Licensing Assistant	T-8E14	415-8140
McMurtray	Anthony	Senior Project Manager	T-8D32	415-2746
Reber	Eric	General Engineer	T-8I04	415-5608
Rodriquez-Luccioni	Hector	Project Manager	T-8A05	415-6004
Sepulveda	Lymari	General Engineer	T-8C30	415-5619
Struckmeyer	Richard	Health Physicist	T-8F36A	415-5477
Valentin-Rodriquez	Celimar	General Engineer (NSPDP)	T-8B05	415-7124

Wagner	Katie	General Engineer	T-8D40	415-6202
Xu	Shirley	Health Physicist	T-8I08	415-7640
Federal, State, and Tribal Liason Branch (FSTB)			ROOM	PHONE
Michalak	**Paul**	**Branch Chief**	**T-8D19**	**415-5804**
Easson	Stuart	Project Manager	T-8I09	415-5134
Firth	James	Project Manager	T-8C4	415-6628
Flannery	Cindy	Senior Health Physicist	T-8F7A	415-0223
Lynch	Jeffery	Project Manager	T-8B01	415-5041
McGrady-Finneran	Patricia	Project Manager	T-8I01	415-2326
Mroz	Sara	Senior Liaison Program Manager (Acting) (Rotation to FSTB until 1-13-15	T-8D30	415-1692
O'Sullivan	Kevin	Senior Liaison Program Manager	T-8F24	415-8112
Ryan	Michelle	Project Manager	RIII	630-829-9724
Talley	Sandra	Senior Liaison Project Manager	T-8F08A	415-8059
Rulemaking and Project Management Branch (RPMB)			ROOM	PHONE
Danna	**James**	**Branch Chief**	**T-8E05**	**415-7422**
Bhalla	Neelam	Senior Project Manager	N/A	415-0978
Carrera	Andrew	Health Physicist	T-8D28	415-1078
Comfort	Gary	Senior Project Manager	T-8E19	415-8106
Cox	Vanessa	Project Manager	T-8A7	415-8342
Horn	Merri	Senior Project Manager	3WFN-14A42	301-287-9167
Lohr	Edward	Health Physicist	T-8G1	415-0253
MacDougall	Robert	Project Manager	T-8C6	415-5175
Mattsen	Catherine	Senior Project Manager	T-8D33	415-6264
Maupin	Cardelia	Senior Project Manager	T-8D23A	415-2312
McDaniel	Keith	Senior Project Manager	T-8I7	415-5252
Sahle	Solomon	Health Physicist	T-8F35	415-3781
Tanious	Naiem	Project Manager	T-8J01	415-6103
Trussell	Gregory	Financial Project Manager	T-8E10	415-6445
Young	Thomas	Senior Project Manager	T-8E17	415-5795

Last Revised-1/5/15

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APPENDIX C

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registry No.: NR-505-D-101-E — SSD Type: (W) Self Luminous light source
Applicant Name: Marathon Watch Co. — Type of Action: Amendment
Date Issued: 7/30/12 — Reviewers: SP, UB

File No.: 2
Registry No.: NR-1302-D-101-B — SSD Type: (D) Gamma Gauge
Applicant Name: Endress & Hauser — Type of Action: Amendment
Date Issued: 9/29/14 — Reviewers: LS, TH

File No.: 3
Registry No.: NR-1302-D-103-S — SSD Type: (D) Gamma Gauge
Applicant Name: Endress & Hauser — Type of Action: Amendment
Date Issued: 12/10/14 — Reviewers: MAC, TH

File No.: 4
Registry No.: NR-1138-D-101-S — SSD Type: (K) Gamma irradiator Category II
(J) Gamma irradiator Category I
Applicant Name: Hopewell — Type of Action: Amendment
Date Issued: 8/21/14 — Reviewers: TH, MAC

Comments:
1) Source model CDC.800 should be CDC.811.
2) Source model CKC.P6 is not referenced in the registration certificate, but it is still used in the device although it is not currently distributed in new devices.

File No.: 5
Registry No.: NR-1180-D-101-E — SSD Type: (W) Self Luminous light source
Applicant Name: Truglo — Type of Action: Amendment
Date Issued: 6/12/14 — Reviewers: LS, MAC

File No.: 6
Registry No.: NR-1235-S-104-S — SSD Type: (X) Medical Reference Sources
Applicant: International Isotopes Inc. — Type of Action: Amendment
Date Issued: 2/20/13 — Reviewers: MAC, SP

Comments:
1) Omitted BM09 Series in description and external radiation levels since it was discontinued.
2) Should retain information in the registration certificate and state that the BM09 series is no longer distributed but still may be approved for licensing purposes.

File No.: 7
Registry No.: NR-1370-D-101-S SSD Type: (D) Gamma Gauge
Applicant Name: RAM Services Type of Action: Amendment
Date Issued: 7/28/14 Reviewers: LS, TH

File No.: 8
Registry No.: NR-0497-D-108-S SSD Type: (AC) Photon emitting Remote Afterloaders
Applicant Name: Elekta Inc. Type of Action: Amendment
Date Issued: 5/27/14 Reviewers: LS, JJ

Comment: Missing files in ADAMS dated February 12, 1999 and Aug 4, 2003 were not received from GA transfer.

File No.: 9
Registry No.: NR-0167-D-101-E SSD Type: (P) Ion generators, smoke detectors
Applicant Name: BRK Brands, Inc. Type of Action: Amendment
Date Issued: 10/17/13 Reviewers: JJ, TH

File No.: 10
Registry No.: NR-0716-D-801-S SSD Type: (D) Gamma Gauges
Applicant Name: Scan Technologies Type of Action: Amendment
Date Issued: 10/16/14 Reviewers: SP, TH

File No.: 11
Registry No.: NR-0269-S-103-S SSD Type: (AE) Gamma Stereotactic Radiosurgery Units
Applicant Name: Elekta Type of Action: Amendment
Date Issued: 8/12/14 Reviewers: LS, TH

File No.: 12
Registry No.: NR-0155-D-126-S SSD Type: (W) Self Luminous Applications
Applicant Name: Department of the Army Type of Action: Amendment
Date Issued: 3/1/13 Reviewers: UB, JJ

Comment: First page should state “Custom Device” not “Custom Source” since the SS&D registration certificate was changed to “Safety Evaluation of a Device”.

File No.: 13
Registry No.: NR-8261-D-801-S SSD Type: (D) Gamma Gauges
Applicant Name: Krones Inc. Type of Action: Amendment
Date Issued: 11/6/12 Reviewers: JJ, UB

File No.: 14
Registry No.: NR-1286-D-102-E SSD Type Device: (W) Self Luminous Light Sources
Applicant Name: Isolite Type of Action: New Registration
Date Issued: 5/10/12 Reviewers: UB, LS

Comment: The first page should state “Custom Device” not “Custom Source” since the SS&D registration certificate is for a device.

File No.: 15
Registry No.: NR-1195-S-106-S SSD Type: (H) General Neutron source applications
Applicant Name: Sabia, Inc. Type of Action: Inactivation
Date Issued: 11/17/11 Reviewers: JOD, UB

File No.: 16
Registry No.: NR-0657-D-101-E SSD Type: (P) Ion generators, smoke detectors
Applicant Name: Universal Security Instruments, Inc. Type of Action: Amendment
Date Issued: 12/10/10 Reviewers: JJ, UB

File No.: 17
Registry No.: NR-0571-D-101-G SSD Type: (D) gamma gauge, (E) Beta gauge
Applicant Name: Honeywell Inc. Type of Action: Amendment
Date Issued: 10/8/14 Reviewers: MAC, TH

Comment: Historical documents were missing from ADAMS that are listed in the SS&D registration; there was a memo to file that the documents were not received from Georgia during the SS&D transfer.

File No.: 18
Registry No.: NR-1289-S-101-S SSD Type: (AA) Manual brachytherapy
Applicant Name: Eckert & Ziegler Type of Action: Amendment
Date Issued: 9/4/14 Reviewers: MAC, TH

Comments:
1) SS&D listed the leak test frequency as “not applicable” however a leak test is required for I-125 (one of multiple radionuclides).
2) Sealed source is strand of individual sources, the individual sealed source models were not identified in the SS&D.

File No.: 19
Registry No.: NR-1124-D-102-E SSD Type: (T) Other
Applicant Name: Met One Instruments Type of Action: Amendment
Date Issued: 8/14/14 Reviewers: JH, MAC

File No.: 20
Registry No.: NR-1348-D-101-S SSD Type: (H) General Neutron Source Application
Applicant Name: PanAnalytical Type of Action: Amendment
Date Issued: 8/26/14 Reviewers: SP, TH

Comment: Missing June 3, 1999 document in ADAMS.

File No.: 21
Registry No.: NR-1370-D-102-G SSD Type: (E) Beta gauges
Applicant Name: RAM Services Type of Action: New
Date Issued: 7/8/14 Reviewers: MAC, SP

Comment: Sealed source model KAC.D4 containing Kr-85 has ANSI N43.6 classification of 33331 instead of the minimum classification of 33332 as referenced by the ANSI standard for use in a beta gauge. The source's registration stated that the source was approved for use in a device. The reviewer should have placed a note to the file and in the SS&D identifying the reason why the source was approved for use in the device.

File No.: 22
Registry No.: NR-571-D-107-B SSD Type: (D) Gamma gauge, (E) Beta gauge
Applicant Name: Honeywell International Type of Action: Amendment
Date Issued: 8/4/14 Reviewers: MAC, TH

Comment: Device with device housing attached was not included in diagrams to aid others in being able to recognize device.

File No.: 23
Registry No.: NR-1375-S-101-S SSD Type: (H) General Neutron, (T) Other
Applicant Name: Babcock & Wilcox Type of Action: New
Date Issued: 10/7/13 Reviewers: MAC, SP

Comments:
1) Distances listed in SS&D table for radiation levels was listed as 5, 10 and 30 cm versus standard 5, 30, and 100 cm. The data in the table was for the combined gamma and neutron doses at 5, 30, and 100 cm. The table heading was in error.
2) Cover page listed the maximum activity for Cf-252 as 1.80 Ci instead of 1.08 Ci for the Model BWSSI source.

File No.: 24
Registry No.: NR-0497-D-114-S SSD Type: (AC) photon-emitting remote afterloader
Applicant Name: Elekta Type of Action: Amendment
Date Issued: 5/27/14 Reviewers: LS, JJ

File No.: 25
Registry No.: NR-1267-D-102-E SSD Type: (P) Ion Generator, Chemical Agent Detector
Applicant Name: RapiScan Type of Action: Amendment
Date Issued: 4/28/14 Reviewers: MAC, JJ

Comments:
1) Reviewer note added under a newly added section “Limitations and other conditions of use”. This section is not applicable to exempt devices.
2) References section of SS&D included “August 24, 2014” when SS&D was issued April 28, 2014. Referenced document should have been April 24, 2014.

File No.: 26
Registry No.: NR-1302-D-102-G SSD Type: (D) Gamma Gauge
Applicant Name: Endress & Hauser Type of Action: New
Date Issued: 12/5/12 Reviewers: JJ, UB

File No.: 27
Registry No.: NR-155-D-126-S SSD Type: (N) Ion generators, chromatography
Applicant Name: Department of the Army Type of Action: Amendment
Date Issued: 4/30/13 Reviewers: UB, JJ

File No.: 28
Registry No.: NR-0220-D-131-S SSD Type: (AF) Other medical use
Applicant Name: Nordion Type of Action: Amendment
Date Issued: 3/17/11 Reviewers: UB, JJ

ATTACHMENT

January 27, 2015 Email from Tomas Herrera
NRC SS&D Response to the Draft Report
ADAMS Accession No.: ML115027A320

From: White, Duncan
To: Meyer, Karen
Cc: Dimmick, Lisa
Subject: FW: Draft SSD IMPEP Report - Response
Date: Tuesday, January 27, 2015 1:11:12 PM

SS&D response.

From: Herrera, Tomas
Sent: Tuesday, January 27, 2015 12:37 PM
To: White, Duncan
Cc: Dimmick, Lisa; Gonzalez, Hipolito; Henderson, Pamela; Dudes, Laura
Subject: Draft SSD IMPEP Report - Response

Good Afternoon Duncan,

We reviewed the draft report and only identified one clarification for consideration. On page 2 under Technical Staffing and Training, 4th sentence it states that "In the interim period between reviews, four qualified reviewers have left the Branch due to promotions and/or retirement…"

To clarify in my response in the questionnaire, I identified that John O'Donnell had left due to a promotion. This was actually a lateral, an opportunity had opened for him to move back to Texas to Region IV. Also, in the questionnaire I did not include Steve Poy as "having left the program" because he has still assisted us from time to time depending on the SSD workload. I'm not sure if this should be characterized or not, because he was due branch reorganizations, and move as a lateral.

Please let me know if you have any questions.

Thank you,
Tomas