March 21, 2014

Mr. Michael Snee, Chief
Bureau of Radiation Protection
Ohio Department of Health
246 North High Street
Columbus, OH 43215

Dear Mr. Snee:

On February 18, 2014, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Ohio Agreement State Program. The MRB found the Ohio program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 12, of the enclosed final report contains a summary of the IMPEP team's findings. The review team made no recommendations in regard to program performance by the Ohio Agreement State Program during this review, and closed a recommendation concerning the development and implementation of a staff training and qualification program from the 2008 IMPEP review. In addition, the team identified Ohio's establishment of the Bureau Medical Event Review Team for reviewing medical and other possible overexposure events as a good practice. Based on the results of the current IMPEP review, the next full review of the Ohio Agreement State Program will take place in approximately 5 years, with a periodic meeting tentatively scheduled for June 2016. The next IMPEP review was extended by one year because of Ohio's sustained high level of performance.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

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

Enclosure:
Ohio Final IMPEP Report

cc: Jennifer Opila, Colorado
Organization of Agreement States
Liaison to the MRB

Michael Bear, Interim Branch Chief
Ohio Emergency Management Agency

Mr. Michael Snee, Chief
Bureau of Radiation Protection
Ohio Department of Health
246 North High Street
Columbus, OH 43215

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Letter to M. Snee from Michael F. Weber dated March 21, 2014

SUBJECT: OHIO FY2014 FINAL IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE OHIO AGREEMENT STATE PROGRAM

DECEMBER 10–13, 2013

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Ohio Agreement State Program. The review was conducted during the period of December 10-13, 2013, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Minnesota.

Based on the results of this review, Ohio's performance was found satisfactory for all performance indicators reviewed. The review team did not make any recommendations regarding program performance by the State and determined that the one recommendation from the 2008 IMPEP review be closed.

The review team identified a good practice by the State regarding its creation of a board to review all medical events and any other events involving potential overexposures in order to formulate a comprehensive and informed response by all board members.

Accordingly, the review team recommends that the Ohio Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The review team recommends that the next IMPEP review take place in approximately five years.

1.0 INTRODUCTION

This report presents the results of the review of the Ohio Agreement State Program. The review was conducted during the period of December 10-13, 2013, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Minnesota. 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 NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of November 1, 2008 to December 13, 2013, were discussed with Ohio managers on the last day of the review.

A draft of this report was provided to Ohio for factual comment on January 6, 2014. The State responded to the findings and conclusions by email dated January 14, 2014. A copy of the State's response is included as an Attachment to this report. A Management Review Board (MRB) met on February 18, 2014, to consider the proposed final report. The MRB found the Ohio Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

The Ohio Agreement State Program is administered by the Bureau of Radiation Protection (the Bureau) which is located within the Division of Prevention (the Division). The Division is part of the Department of Health (the Department). Organization charts for the Department and the Bureau are included as Appendix B.

At the time of the review, the Ohio Agreement State Program regulated 608 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Ohio.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Bureau on April 2, 2013. The Bureau provided its response to the questionnaire on December 10, 2013. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML13281A503.

The review team's general approach for conduct of this review consisted of (1) examination of the Bureau's response to the questionnaire, (2) review of applicable Ohio statutes and regulations, (3) analysis of quantitative information from the Bureau's database, (4) technical review of selected regulatory actions, (5) field accompaniments of six inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the Ohio Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to the recommendation made during the previous review.

Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on October 31, 2008, the review team made one recommendation regarding the Ohio Agreement State Program's performance. The status of the recommendation is as follows:

> "The review team recommends that the State document and implement a training and qualification program that, at a minimum, contains a statement of policy, minimum qualifications for staff training, and supervisory verification for ensuring this policy is implemented. (Section 3.1)"
>
> Status: The State developed and implemented a training and qualification program for technical staff members. Supervisors maintain a folder for each employee, which contains the training policy, and has records of training, supervisory accompaniments, and approvals for specific types of inspections and licensing actions. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC regional and Agreement State radioactive materials programs. These indicators are (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Considerations central to the evaluation of this indicator include the Bureau's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Bureau's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Bureau is located in the Department offices in Columbus and is headed by the Bureau Chief. The Bureau is divided into three programs: the Nuclear Material Safety Program, the X-ray Program, and the Technical Support Program. Each program is managed by an administrator. The Agreement State program is implemented by the Nuclear Material Safety Program and a portion of the Technical Support Program. The Nuclear Material Safety Program functions as the licensing and inspection group for radioactive materials. The Technical Support Program is responsible for oversight of staff training and houses the Bureau's radiation safety officer program.

At the time of the review, there were 24 technical staff members with various degrees of involvement in the radioactive materials program, totaling approximately 20.3 full-time equivalents (FTE). No technical positions were vacant at the time of this review. Nine

technical staff members were hired during the five-year review period, including people with industry and medical experience. Seven employees left the program during the review period for other positions in Ohio government and industry, or retirement. The vacancies were promptly filled. Two employees are currently working remotely for the program from other State offices. The review team determined that staffing levels were adequate for the Agreement State program.

The Bureau has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The review team suggested that the Program may wish to use the recently issued IMC 1248, "Formal Qualifications Programs for Federal and State Materials and Environmental Management Programs," which has an expanded qualification journal component.

The Bureau uses a combination of self-study and formal training, such as the NRC courses, and on-the-job experience to qualify staff as both inspectors and license reviewers. New staff members are trained in licensing and inspection by performing simple licensing and inspection activities and gradually working toward more technical activities. All new staff members perform licensing actions and inspections with a senior-level staff member providing support and guidance until they are approved by their supervisor to work independently. An individual is approved to perform independent actions after the supervisor has observed or reviewed the individual's performance on several licensing actions or inspections of a given license type.

The State uses "Ohio Train", which is a State-wide web-based system, to electronically track each staff member's training history. Monthly training sessions on current topics are widely attended by staff. The review team noted that Department and Bureau managers enthusiastically support training opportunities for staff members.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Ohio's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Bureau's questionnaire response relative to this indicator, data gathered from the Bureau's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that Ohio's inspection frequencies for all types of radioactive material licenses are at the same frequency as similar license types listed in IMC 2800, "Materials Inspection Program".

The Bureau conducted 508 Priority 1, 2, and 3 inspections during the review period, none of which were performed overdue based on the inspection frequencies established in IMC 2800.

In addition, the Bureau performed 63 initial inspections during the review period, none of which were conducted overdue. The Bureau performs an initial inspection at the time of license delivery and requires the licensee to notify them when they receive materials at which time they will perform another inspection.

The review team evaluated the Bureau's timeliness in providing inspection findings to licensees. A sampling of 25 inspection reports indicated that four of the inspection findings were communicated to the licensees beyond the Bureau's goal of 30 days after the inspection (from 4 to 75 days overdue)

During the review period, the Bureau granted 380 reciprocity permits, 122 of which were candidate licensees based upon the criteria in IMC 1220. The review team determined that the Bureau exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the five years covered by the review period.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Ohio's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 25 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 11 Bureau inspectors and covered inspections of various license types, including medical broad scope, medical institutions-therapy (including high dose rate remote afterloader, permanent/temporary implant brachytherapy), medical-diagnostic, portable gauges, industrial radiography, gamma knife, nuclear pharmacy, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensee's radiation safety programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to licensees, unresolved safety issues, the effectiveness of corrective actions taken to resolve previous violations and discussions held with licensees during exit interviews.

The inspection procedures utilized by the Bureau are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then reviewed and signed by the Manager. Supervisory accompaniments were conducted annually for all inspectors.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. The Bureau issues to the licensee, either a letter indicating a clear

inspection or a Notice of Violation (NOV), in letter format, which details the results from the inspection. When the Bureau issues an NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 30 days. All findings are reviewed by the Program Manager.

The review team noted that the Bureau has an adequate supply of survey instruments to support its inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, was observed to be available. The Bureau also has portable multi-channel analyzers located in offices across the State. Instruments are calibrated at least annually, or as needed, with National Institute of Standards and Technology traceable sources. The Bureau uses a database to track each instrument, its current location, and next calibration date.

Accompaniments of six Bureau inspectors were conducted by two IMPEP team members during the week of September 9, 2013. The inspectors were accompanied during health and safety inspections of source manufacturing, industrial radiography, portable gauges, nuclear pharmacy, medical therapy including high dose rate remote after loader/gamma knife/unsealed radioiodine therapy/permanent implant brachytherapy, etc., and medical diagnostic licenses. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health and safety and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Ohio's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 27 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 6 new licenses, 3 renewals, 3 decommissioning or termination actions, and 15 amendments. Files reviewed included a cross-section of license types, including broadscope, medical diagnostic and therapy (including high dose rate remote afterloader, unsealed radioiodine therapy, temporary/permanent implant brachytherapy), gamma knife, industrial radiography, research and development, nuclear pharmacy, gauges, and manufacturers. The casework sample

represented work from 12 license reviewers. A list of the licensing casework evaluated with case-specific comments is provided in Appendix D.

The review team discovered one amended license issued for a facility with a gamma knife included an authorized medical physicist who was added to the license without proper documentation to verify the training, experience, and preceptor attestation. Specifically, the documentation submitted did not meet the educational requirements. The review team brought this to the attention of the Bureau, who immediately contacted the licensee and determined this specific authorized medical physicist could be qualified through the same educational requirements he met to be on a license in 2011 for high dose rate afterloader. The Bureau then added the appropriate documentation to the file for the gamma knife amendment to show the authorized medical physicist meets the educational requirements.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Requests for licensing deficiencies clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. License reviewers use the Bureau's licensing guides and NRC NUREG-1556 series guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

The supervisors perform a technical and supervisory review on all licensing actions before issuance to the licensee. The Bureau Chief signs all licenses. Licenses are issued for a five year period under a timely renewal system.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Bureau's licensing procedures and/or NUREG-1556 guidance documents, the State's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Bureau performs pre-licensing checks of all new applicants. The Bureau's pre-licensing review methods incorporate the essential elements of the NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. The Bureau hand-delivers all new licenses to the licensee's location of material use. At that time a pre-licensing site visit, which includes an evaluation of the applicant's radiation safety and security programs, is performed.

The review team examined the Bureau's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The review team analyzed the Bureau's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Bureau requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Bureau's implementation of its procedure for the control of sensitive information. This procedure addresses the identification, marking, control, handling, preparation, transportation, transmission, and destruction of documents that contain sensitive information related to the Increased Controls. While on site, the review team evaluated the Bureau's handling and storing of sensitive documents. The team noted that while files containing Increased Controls documents were appropriately protected, segregated from other files, and maintained in a manner to limit access; the actual licenses in those files were not marked as containing sensitive information. The team discussed this issue with Bureau management who committed to address this in their procedure for the handling of documents containing sensitive, security information and also committed to marking these documents as such.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Ohio's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Bureau's actions in responding to incidents and allegations, the review team examined the Bureau's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Ohio in the Nuclear Material Events Database (NMED) against those contained in the Bureau's files, and evaluated the casework for 27 radioactive materials incidents. A list of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Bureau's response to 13 allegations involving radioactive materials, including 4 allegations referred to the State by the NRC during the review period.

The review team examined the Bureau's implementation of its incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, and reporting of incidents. When notification of an incident or an allegation is received, a program supervisor determines the appropriate level of initial response. If the incident involves a medical event or other potential exposure event, the Bureau Medical Event Review Team (BMERT) is assembled. The BMERT is chaired by the Radiation Protection Bureau Chief and is composed of administrators from the Nuclear Materials Safety, Technical Support, and X-Ray Sections, the Supervisor overseeing the incident, the Office of General Counsel, and other personnel as requested. Participation by both radioactive material and x-ray program representatives allows the Bureau a comprehensive view of radiation use in the State. The process has resulted in the identification of crosscutting issues amongst the represented sections who regulate the same licensees, but different activities such as linear accelerators and brachytherapy. The BMERT also tracks escalated enforcement and allegation cases. The review team identified, and the MRB agreed, this as a good practice by the State.

The review team identified approximately 208 radioactive material incidents listed in Ohio's RADMAT database for the review period, 59 of which required reporting. Twenty non-reportable incidents were also reviewed for reportability and found to be correctly categorized as non-reportable by the Bureau. The review team selected 27 reportable radioactive material incidents for evaluation. These incidents included the several types of events: lost radioactive material, overexposure, medical event, equipment failure, damaged

equipment, leaking source, and contamination. The Bureau's responses to the incidents were found to be complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the potential health and safety significance of the event. Inspectors were dispatched for onsite investigations when appropriate. Ohio places a high priority on on-site responses as evidenced by an on-site response in 22 of the 27 incidents evaluated during this review. Enforcement and other regulatory actions were taken as appropriate. The actions taken in response to incidents were documented in Ohio's RADMAT database. If the incident met the reportability thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED in a prompt manner.

In evaluating the effectiveness of the Bureau's response to allegations, the review team evaluated the completed casework for 13 allegations, including 4 that NRC referred to the State during the review period. The review team concluded that the Bureau took prompt and appropriate actions in response to concerns raised. The review team noted that the Bureau documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Bureau notified the concerned individuals of the conclusion of its investigations. The review team determined that the Bureau adequately protected the identity of concerned individuals.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Ohio's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program.

4.1 Compatibility Requirements

4.1.1 Legislation

Ohio became the 31st Agreement State in 1999. Legislative authority to create an agency and enter into an Agreement with the NRC is granted in Ohio Revised Code, Section 3748.03. The Department is designated as the State's radiation control agency. The Department Director has designated the Bureau Chief to administer the Agreement State program for the Department. The review team noted that three new pieces of legislation in the Ohio Revised Code were passed since the last review affecting the Agreement State program or its authority. These included Chapter 3748 regarding overall legislation for the program, Chapter 3747 regarding low level radioactive waste act, and Chapter 119 regarding due process for license termination; however, none of these changes affected the radioactive materials program.

4.1.2 Program Elements Required for Compatibility

The Ohio Regulations for Control of Radiation are found in various chapters of Section 3701 of the Ohio Administrative Code. These rules apply to all ionizing radiation, whether emitted from radionuclides or machine sources. Ohio requires a license for possession and use of all radioactive material. These rules are subject to review every five years to decide whether to continue the rule as it exists or modify it.

The review team examined the procedures used in the Department's regulatory process and found that regulations are drafted by staff and presented to the Radioactive Materials Committee of the Radiation Advisory Council (the Council). The regulations are posted on the Department's web site and electronically sent to interested stakeholders for a 30- to 45-day comment period. Concurrently, the proposed rules are sent to the NRC for a compatibility review. Any comments received from the NRC, stakeholders, or the public are evaluated, and the regulations are revised, as necessary. The revised regulations are submitted to the Council for a recommendation for adoption. The formal rule adoption process begins with submittal to the Ohio Public Health Advisory Board, which places the review of the proposed rules on its calendar, holds a public hearing, and then submits the proposed rules to the Joint Committee on Agency Rules Review (JCARR). The JCARR is composed of State legislators and senators. After JCARR completes its review of the proposed rules and if it takes no action against the rule, the Director of Health signs the rule into enactment after it receives final approval by the Common Sense Initiative-Small Business Initiative of the Governor's Office. The legislation process takes approximately one year from submittal to finalization.

The review team evaluated the Bureau's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status sheet that FSME maintains. The team found that Ohio submitted eight proposed regulation amendments for the NRC review during the review period. None were submitted overdue. Ohio is current on all rulemaking. These amendments are as follows:

- Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 (72 FR 55864, 73 FR 42671) due for adoption November 30, 2010.

- Occupational Dose Records, Labeling Containers and Total Effective Dose Equivalent, Parts 19 and 20, (72 FR 68043) due for adoption February 15, 2011.

- Medical Use of Byproduct Material—Authorized User Clarification, Part 35 (74 FR 33901) due for adoption September 28, 2012.

- "Decommissioning Planning", Parts 20, 30, 40, 70, (76 FR 35512) due for adoption December 17, 2015.

- "Licenses, Certifications, and Approvals for Materials Licensees", Parts 30, 36, 39, 40, 70, and 150, (76 FR 56951) due for adoption November 14, 2014.

- "Change of Compatibility of 10 CFR 31.5 and 31.6", (77 FR 3640), due for adoption January 25, 2015.

  Advance Notification to Native American tribes of Transportation of Certain Types of Nuclear Waste (77 FR 34194) due for adoption August 10, 2015.

- Physical Protection of Byproduct Material, 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71 and 73 (78 FR 16922, due for adoption March 19, 2016

A complete list of regulation amendments can be found on the NRC website at the following address: http://nrc-stp.ornl.gov/rss_regamendents.html.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Ohio's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.2 Sealed Source and Device Evaluation Program

In reviewing this indicator, the review team uses three subelements to evaluate the Bureau's performance regarding the Sealed Source and Device (SS&D) Evaluation Program. These subelements are (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 State SS&D evaluation activities, the review team examined the information provided in response to the IMPEP questionnaire and evaluated the SS&D registry sheets and supporting documents processed during the review period. The team also evaluated SS&D staff training records, certain reported incidents involving products authorized in Ohio SS&D registrations, the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations.

4.2.1. Technical Staffing and Training

The Bureau had three qualified SS&D reviewers with full signature authority during the review period. The Bureau had two SS&D reviewers-in-training and one qualified SS&D reviewer leave the Bureau during the review period.

The Bureau currently has two qualified reviewers. Both individuals have completed the NRC SS&D Workshop. The Bureau plans to designate two new reviewers-in-training to be trained in-house with oversight from the senior SS&D reviewers. The Bureau intends to send the new reviewers-in-training to the NRC SS&D Workshop in 2014.

4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated all of the 35 SS&D actions that the Bureau processed during the review period. The actions reviewed were for 2 new, 29 amended, and 4 inactivated SS&D registrations. The casework reviewed represented the efforts of all three SS&D reviewers. The casework review included all supporting documentation, licenses, and inspections associated

with the distributors of the SS&Ds. A list of SS&D casework examined, with case-specific comments, can be found in Appendix F.

Analysis of the casework and interviews with the managers and staff confirmed that the Bureau's policy is to follow the recommended guidance from the NRC's SS&D Workshop and the Bureau's SS&D Evaluation and Registration procedure, NMS-LIC-03, which is equivalent to NRC's NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses - Applications for Sealed Source and Device Evaluation and Registration". Appropriate review checklists were used to ensure that all relevant materials were submitted and evaluated. The checklists were retained in the SS&D files along with other documents that identified the responsible reviewers. The review team confirmed that pertinent American National Standards Institute standards, NRC Regulatory Guides, and applicable references were available and used appropriately in performing the SS&D reviews.

The registration files contained all correspondence, engineering drawings, photographs, radiation profiles, and details of the licensees' quality assurance and quality control programs. However, the review team found that in 10 of the 35 case files reviewed, the drawings provided by the licensee were missing dimension labels. This issue was discussed with the Bureau, who indicated that they would review those registrations. The review team determined that overall the registrations clearly summarized the product evaluations to provide license reviewers with adequate information to license the possession and use of the products. Deficiency letters clearly stated regulatory positions. The review team determined that the evaluations were of high quality with health and safety issues properly addressed. The Bureau enforces the requirements of SS&D registrations through license conditions in the specific licenses issued to the distributors of SS&D products.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Based upon the Bureau's response to the questionnaire, interviews with the Bureau's managers and staff, and the review team's searches of NMED, the review team determined that there were incidents or defects that the Bureau reported during the review period that involved SS&D products registered in Ohio. The review team determined that the Bureau analyzed the events, reviewed the issues, and followed up on the incidents in accordance with procedures established by the Bureau in NMS-LIC-03 which includes generic fault considerations when evaluating SS&D incidents. The review team concluded that the Bureau is routinely evaluating the root causes of defects and incidents involving SS&D evaluations and is taking appropriate actions.

The review team noted that the Bureau routinely monitors incidents reported to the NRC and to NMED and identified incidents or defects associated with SS&D products registered in Ohio for further investigation and review. The review team concluded that the Bureau evaluates the root causes of defects and incidents involving SS&D evaluations and takes appropriate actions.

The review team did not identify any allegations received by the Bureau related to defects or failures of SS&D products registered in Ohio during the review period.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Ohio's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low Level Radioactive Waste Program (LLRW)

Although Ohio has LLRW disposal authority, the NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put a regulatory program in place that meets the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Ohio. Accordingly, the review team did not review this indicator.

4.4 Uranium Recovery Program

Although Ohio has authority to regulate uranium recovery activities, the NRC has not required States to have a program for licensing a uranium recovery facility until such time as the State has such a facility. When an Agreement State has been notified or becomes aware of the need to regulate a uranium recovery facility, it is expected to put a regulatory program in place that meets the criteria for an adequate and compatible uranium recovery program. There are no plans for a uranium recovery facility in Ohio. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Ohio's performance was found satisfactory for all performance indicators reviewed. The review team did not make any recommendations and determined that the recommendation from the 2008 IMPEP review be closed. One good practice was identified during the review, as detailed in Section 3.5.

Accordingly, the review team recommended, and the MRB agreed, that the Ohio Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. 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.

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Michelle Beardsley, FSME	Team Leader Status of Materials Inspection Program Compatibility Requirements
James Lynch, Region III	Technical Staffing and Training Technical Quality of Incidents and Allegations Inspection Accompaniments
Sherrie Flaherty, Minnesota	Technical Quality of Licensing Actions
Joseph Nick, Region I	Technical Quality of Inspections Inspection Accompaniments
Stephen Poy, FSME	Sealed Source and Device Evaluation Program

APPENDIX B

OHIO ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML13281A813

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Scott Process Systems, Inc. License No.: 03320770000
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 1/14/13 Inspectors: PB/SK

File No.: 2
Licensee: Medical Physics Consultants License No.: 03225990000
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 1/16/13 Inspector: CL

File No.: 3
Licensee: Janx Integrity Group License No.: 03320990002
Inspection Type: Special, Announced Priority: 1
Inspection Date: 12/31/12 Inspectors: SK/PB

File No.: 4
Licensee: Kanawha Scales & Systems License No.: 03214130000
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 12/26/12 Inspector: SD

File No.: 5
Licensee: Case Western Reserve University License No.: 01100180011
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 12/11/12 Inspector: SD

File No.: 6
Licensee: Navitus Engineering, Inc. License No.: 31210800002
Inspection Type: Initial, Announced Priority: 5
Inspection Date: 10/24/12 Inspector: PB

File No.: 7
Licensee: Northrup Grumman Systems License No.: 032140310003
Inspection Type: Initial, Announced Priority: 5
Inspection Date: 10/3/13 Inspector: PB

File No.: 8
Licensee: Desert NDT License No.: 03320990009
Inspection Type: Special, Announced Priority: 1
Inspection Date: 9/12/13 Inspector: SK

File No.: 9
Licensee: Halliburton Energy Services License No.: 31210990018
Inspection Type: Initial, Unannounced Priority: 5
Inspection Date: 6/25/13 Inspector: CS

File No.: 10
Licensee: VEGA Americas Corporation License No.: 03214310002
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 5/3/12 Inspector: SD

File No.: 11
Licensee: Morrow County Hospital License No.: 02121600000
Inspection Type: Initial, Unannounced Priority: 5
Inspection Date: 1/31/13 Inspectors: CG/RB

File No.: 12
Licensee: The Cleveland Clinic Foundation License No.: 02110180013
Inspection Type: Special, Announced Priority: 2
Inspection Date: 10/8/13 Inspector: AC

File No.: 13
Licensee: Ohio State University License No.: 02110250037
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 12/4/12 Inspectors: AC/SD/CG/RB

File No.: 14
Licensee: Jewish Hospital LLC License No.: 02120310029
Inspection Type: Initial, Announced Priority: 3
Inspection Date: 1/3/13 Inspector: DC

File No.: 15
Licensee: Chetan Patel MD LLC License No.: 02201440002
Inspection Type: Initial, Unannounced Priority: 5
Inspection Date: 11/4/09 Inspector: SD

File No.: 16
Licensee: Fisher-Titus Medial Center License No.: 02120400001
Inspection Type: Special, Announced Priority: 3
Inspection Date: 8/27/10 Inspector: AC

File No.: 17
Licensee: Christ Hospital License No.: 02120310008
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 6/14/11 Inspectors: SD/KA

File No.: 18
Licensee: University Hospitals of Cleveland License No.: 02110180077
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 4/17/12 Inspectors: AC/CG/SD

File No.: 19
Licensee: Unicon Physics, Inc. License No.: 03220310040
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 1/21/10 Inspector: PB

File No.: 20
Licensee: Sen Tek Corporation License No.: 03214250002
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 12/26/12 Inspector: CL

File No.: 21
Licensee: Progress Services, Inc. License No.: 03320530004
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 9/10/13 Inspector: SK

File No.: 22
Licensee: Team Industrial Services License No.: 03320990000
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/9/13 Inspector: SK

File No.: 23
Licensee: Coca Cola Refreshments License No.: 00006GL0279
Inspection Type: Initial, Announced Priority: N/A
Inspection Date: 8/21/13 Inspector: PB

File No.: 24
Licensee: Johns Manville License No.: 00006GL0047
Inspection Type: Initial, Announced Priority: N/A
Inspection Date: 5/29/13 Inspector: PB

File No.: 25
Licensee: Worthington Steel License No.: 00006GL0218
Inspection Type: Initial, Announced Priority: N/A
Inspection Date: 4/24/13 Inspector: PB

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1
Licensee: Flower Hospital License No.: 02120490004
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 9/9/13 Inspector: AC

Accompaniment No.: 2
Licensee: Cardinal Health (Nuclear Pharmacy Services) License No.: 02500490001
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 9/10/13 Inspector: CG

Accompaniment No.: 3
Licensee: Mercy St. Charles Hospital License No.: 02120490017
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 9/11/13 Inspector: RB

Accompaniment No.: 4
Licensee: URS Corporation License No.: 31210180083
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 9/9/13 Inspector: CS

Accompaniment No.: 5
Licensee: Progress Services, Inc. License No.: 03320530004
Inspection Type: Routine, Announced, Special Priority: 1
Inspection Date: 9/10/13 Inspector: SK

Accompaniment No.: 6
Licensee: Fluke Biomedical License No.: 03211180000
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 9/11/13 Inspector: PB

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: TSS Technologies, Inc — License No.: 03362009000
Type of Action: New — Amendment No.: 0
Date Issued: 2/3/11 — License Reviewer: LB

File No.: 2
Licensee: Desert NDT, LLC — License No: 03320990009
Type of Action: New — Amendment No.: 0
Date Issued: 9/26/13 — License Reviewer: SK

File No.: 3
Licensee: Cardinal Health — License No.: 02500310032
Type of Action: New — Amendment No.: 0
Date Issued: 12/9/11 — License Reviewer: CG

File No.: 4
Licensee: OSU Mobile — License No.: 02220250000
Type of Action: New — Amendment No.: 0
Date Issued: 4/16/11 — License Reviewer: CG

File No.: 5
Licensee: UH AHUSA Medical Center — License No.: 02120180103
Type of Action: New — Amendment No.: 0
Date Issued: 9/29/10 — License Reviewer: SD

File No.: 6
Licensee: St, Elizabeth Boardman Health Center — License No.: 02120510001:
Type of Action: Amendment — Amendment No.: 12
Date Issued: 8/20/13 — License Reviewer: AC

File No.: 7
Licensee: Gamma Med — License No.: 02500510004
Type of Action: Renewal — Amendment No.: 9
Date Issued: 9/2/11 — License Reviewer: SD

File No.: 8
Licensee: Tri State Urologic Services — License No.: 02200310050
Type of Action: New — Amendment No.: 0
Date Issued: 10/11/13 — License Reviewer: DC

File No.: 9
Licensee: Fairview Hospital License No.: 02120180101
Type of Action: Renewal Amendment No.: 15
Date Issued: 9/27/13 License Reviewer: DC

File No.: 10
Licensee: Oncology/Hematology Care, Inc. License No.: 02230310001
Type of Action: Amendment Amendment No.: 15
Date Issued: 9/18/13 License Reviewer: RB

File No.: 11
Licensee: Cleveland State University License No.: 01110130017
Type of Action: Amendment Amendment No.: 9
Date Issued: 4/30/12 License Reviewer: SD

File No.: 12
Licensee: Ohio University License No.: 01100050003
Type of Action: Amendment Amendment No.: 22
Date Issued: 9/26/12 License Reviewer: SD

File No.: 13
Licensee: University Hospitals of Cleveland License No.: 02110180077
Type of Action: Amendment Amendment No.: 24
Date Issued: 2/12/10 License Reviewer: AC

File No.: 14
Licensee: Team Industrial Services License No.: 03320990000
Type of Action: Amendment Amendment No.: 18
Date Issued: 6/2/11 License Reviewer: PB

File No.: 15
Licensee: Hi-Tech Testing Services License No.: 03320770023
Type of Action: Amendment Amendment No.: 1
Date Issued: 12/10/12 License Reviewer: SK

File No.: 16
Licensee: MISTRAS Group License No.: 03320460000
Type of Action: Renewal Amendment No.: 18
Date Issued: 9/26/13 License Reviewer: PB

File No.: 17
Licensee: Triad Isotopes License No.: 02500250072
Type of Action: Termination Amendment No.: 39
Date Issued: 12/17/12 License Reviewer: KA

File No.: 18
Licensee: Elite Inspection License No.: 03320990005
Type of Action: Termination Amendment No.: 6
Date Issued: 11/18/09 License Reviewer: KVA

File No.: 19
Licensee: Deaconess Hospital License No.: 02120310012
Type of Action: Termination Amendment No.: 17
Date Issued: 2/8/11 License Reviewer: KVA

File No.: 20
Licensee: Viewray Incorporated License No.: 03214180005
Type of Action: Amendment Amendment No.: 6
Date Issued: 8/19/11 License Reviewer: CS

File No.: 21
Licensee: Phillips Medical Systems License No.: 03214180003
Type of Action: Amendment Amendment No.: 41
Date Issued: 6/8/12 License Reviewer: SD

File No.: 22
Licensee: Akron Gamma Medical License No.: 02120780000
Type of Action: Amendment Amendment No.: 32
Date Issued: 5/14/12 License Reviewer: AC

File No.: 23
Licensee: Jewish Hospital, LLC License No.: 02120310029
Type of Action: Amendment Amendment No.: 23
Date Issued: 10/15/12 License Reviewer: DC

File No.: 24
Licensee: Jewish Hospital, LLC License No.: 02120310029
Type of Action: Amendment Amendment No.: 25
Date Issued: 2/8/13 License Reviewer: DC

Comment:
AMP added to the license without proper documentation of educational requirement.

File No.: 25
Licensee: Nationwide Children's Hospital License No.: 02110250012
Type of Action: Amendment - Variance Amendment No.: 18
Date Issued: 5/28/13 License Reviewer: AC

File No.: 26
Licensee: Advanced Medical Systems, Inc License No.: 03900180000
Type of Action: Amendment Amendment No.: 12
Date Issued: 3/20/13 License Reviewer: JC

File No.: 27
Licensee: Mercy Hospital – Mt. Airy License No.: 02120310000
Type of Action: Amendment Amendment No.: 14
Date Issued: 11/25/13 License Reviewer: RB

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Community Regional Medical Center — License No.: 02120480002
Date of Incident: 12/10/08 — NMED No.: 080891
Investigation Date: 12/22/08 — Type of Incident: Contamination
Type of Investigation: Site

File No.: 2
Licensee: University Hospitals of Cleveland — License No.: 02110180077
Date of Incident: 12/15/08 — NMED No.: 090443
Investigation Date: 3/19/09 — Type of Incident: Equipment Failure
Type of Investigation: Site

Comment:
The licensee did not report the incident. It was discovered during an inspection by the Bureau.

File No.: 3
Licensee: Urology Center — License No.: 02200310002
Date of Incident: 5/11/09 — NMED No.: 090497
Investigation Date: 6/12/09 — Type of Incident: Medical Event
Type of Investigation: Site

File No.: 4
Licensee: Acuren Inspection, Inc. — License No.: 03320990006
Date of Incident: 6/26/09 — NMED No.: 090572
Investigation Date: 6/26/09 — Type of Incident: Equipment Failure
Type of Investigation: Telephone

File No.: 5
Licensee: PetroChem Inspection Services — License No.: 03320990001
Date of Incident: 6/9/09 — NMED No.: 090612
Investigation Date: 7/1/09 — Type of Incident: Equipment Failure
Type of Investigation: Site

File No.: 6
Licensee: Meridian Automotive Systems, Inc. — License No.: N/A
Date of Incident: 8/25/09 — NMED No.: 090694
Investigation Date: 8/26/09 — Type of Incident: Lost RAM
Type of Investigation: Site

File No.: 7
Licensee: Scott Process Systems, Inc. — License No.: 03320770000
Date of Incident: 10/6/09 — NMED No.: 090852
Investigation Date: 11/18/09 — Type of Incident: Damaged Equipment
Type of Investigation: Telephone

File No.: 8
Licensee: The Jewish Hospital License No.: 02120310029
Date of Incident: 1/21/10 NMED No.: 100049
Investigation Date: 2/4/10 Type of Incident: Medical Event
Type of Investigation: Site

File No.: 9
Licensee: The Jewish Hospital License No.: 02120310029
Date of Incident: 12/28/09 NMED No.: 100053
Investigation Date: 2/4/10 Type of Incident: Medical Event
Type of Investigation: Site

File No.: 10
Licensee: JANX Integrity Group License No.: 03320990002
Date of Incident: 4/9/10 NMED No.: 100178
Investigation Date: 4/19/10 Type of Incident: Overexposure
Type of Investigation: Site

File No.: 11
Licensee: Ohio State University Medical Center License No.: 02110250037
Date of Incident: 4/16/10 NMED No.: 100209
Investigation Date: 4/21/10 Type of Incident: Overexposure
Type of Investigation: Site

File No.: 12
Licensee: Tiffin Mercy Hospital License No.: 02120750001
Date of Incident: 12/10/08 NMED No.: 100480
Investigation Date: 5/4/10 Type of Incident: Medical Event
Type of Investigation: Site

Comment:
The licensee did not report the incident. It was discovered during an audit conducted by the Bureau.

File No.: 13
Licensee: Cleveland Clinic Foundation License No.: 02110180013
Date of Incident: 9/27/10 NMED No.: 100483
Investigation Date: 9/28/10 Type of Incident: Medical Event
Type of Investigation: Telephone

File No.: 14
Licensee: Clinton Memorial Hospital License No.: 02120140000
Date of Incident: 5/20/09 NMED No.: 100501
Investigation Date: 9/10/10 Type of Incident: Medical Event
Type of Investigation: Site

Comment:
The licensee did not report the incident. It was discovered during an inspection by the Bureau.

File No.: 15
Licensee: Riverside Methodist Hospital License No.: 02120250070
Date of Incident: 4/6/10 NMED No.: 100510
Investigation Date: 7/28/10 Type of Incident: Medical Event
Type of Investigation: Site

Comment:
The licensee did not report the incident. It was discovered during an inspection by the Bureau.

File No.: 16
Licensee: Cleveland Clinic Foundation License No.: 02110180013
Date of Incident: 10/26/10 NMED No.: 100543
Investigation Date: 11/3/10 Type of Incident: Medical Event
Type of Investigation: Site

File No.: 17
Licensee: Private Individual License No.: N/A
Date of Incident: 10/31/11 NMED No.: 110599
Investigation Date: 11/1/11 Type of Incident: Lost RAM
Type of Investigation: Site

File No.: 18
Licensee: University of Toledo License No.: 0211049006
Date of Incident: 12/19/11 NMED No.: 120050
Investigation Date: 1/12/12 Type of Incident: Medical Event
Type of Investigation: Site

File No.: 19
Licensee: Trinity Medical Center License No.: 02120420003
Date of Incident: 8/24/12 NMED No.: 120498
Investigation Date: 9/25/12 Type of Incident: Leaking Source
Type of Investigation: Site

File No.: 20
Licensee: Acuren Inspection, Inc. License No.: 03320990006
Date of Incident: 7/24/12 NMED No.: 120522
Investigation Date: 9/5/12 Type of Incident: Equipment Failure
Type of Investigation: Site

File No.: 21
Licensee: Southern Ohio Medical Center License No.: 02300740000
Date of Incident: 11/21/12 NMED No.: 120696
Investigation Date: 12/6/12 Type of Incident: Equipment Failure
Type of Investigation: Telephone

File No.: 22
Licensee: University of Toledo License No.: 02110490006
Date of Incident: 11/27/12 NMED No.: 130001
Investigation Date: 12/19/12 Type of Incident: Medical Event
Type of Investigation: Site

File No.: 23
Licensee: Akron General Medical Center License No.: 02120780000
Date of Incident: 3/19/13 NMED No.: 130142
Investigation Date: 3/29/13 Type of Incident: Medical Event
Type of Investigation: Site

File No.: 24
Licensee: Private Individual License No.: N/A
Date of Incident: 4/19/13 NMED No.: 130216
Investigation Date: 4/21/13 Type of Incident: Lost RAM
Type of Investigation: Site

File No.: 25
Licensee: Cleveland Clinic Foundation License No.: 02110180013
Date of Incident: 5/9/13 NMED No.: 130438
Investigation Date: 10/8/13 Type of Incident: Medical Event
Type of Investigation: Site

File No.: 26
Licensee: Wittenberg University License No.: 01120120000
Date of Incident: 1/9/13 NMED No.: 130460
Investigation Date: 1/23/13 Type of Incident: Leaking Source
Type of Investigation: Telephone

File No.: 27
Licensee: Mount Carmel Health System License No.: 02120250034
Date of Incident: 10/25/13 NMED No.: 130530
Investigation Date: 11/14/13 Type of Incident: Medical Event
Type of Investigation: Site

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registry No.: OH-0522-D-120-B — SS&D Type: (D) Gamma Gauge
Applicant Name: Ohmart/VEGA — Type of Action: Amendment
Date issued: 11/3/08 — Reviewers: KVA, KB

File No.: 2
Registry No.: OH-0298-S-102-S — SS&D Type: (H) General Neutron Source/ (W) Well Logging
Applicant Name: Frontier Technology Corporation — Type of Action: Amendment
Date issued: 4/3/09 — Reviewers: KB, SD

File No. 3
Registry No.: OH-0522-D-120-B — SS&D Type: (D) Gamma Gauge
Applicant Name: Ohmart/VEGA — Type of Action: Amendment
Date issued: 5/8/09 — Reviewers: KVA, SD

File No.: 4
Registry No.: OH-8211-D-801-G — SS&D Type: (W) Self Luminous Light Source
Applicant Name: Best Lighting Products, Inc. — Type of Action: Inactivation
Date issued: 8/5/09 — Reviewers: KVA, SD

File No.: 5
Registry No.: OH-0522-D-120-B — SS&D Type: (D) Gamma Gauge
Applicant Name: Ohmart/VEGA — Type of Action: Amendment
Date issued: 8/20/09 — Reviewers: KVA, SD

Comment:
Drawing/diagram not included in the registration certificate.

File No.: 6
Registry No.: OH-0522-S-109-S — SS&D Type: (D) Gamma Gauge
Applicant Name: Ohmart/VEGA — Type of Action: Amendment
Date issued: 8/24/09 — Reviewers: KB, SD

File No.: 7
Registry No.: OH-0522-D-102-B — SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation — Type of Action: Amendment
Date issued: 9/01/09 — Reviewers: KVA, SD

File No.: 8
Registry No.: OH-8208-S-801-S SS&D Type: (AD) Photo Emitting Teletherapy
Applicant Name: Advanced Medical Systems Type of Action: Inactivation
Date issued: 9/22/09 Reviewers: KVA,SD

File No.: 9
Registry No.: OH-8208-D-802-S SS&D Type: (AD) Photo Emitting Teletherapy
Applicant Name: Advanced Medical Systems Type of Action: Inactivation
Date issued: 11/13/09 Reviewers: KVA, KB

File No.: 10
Registry No.: OH-8208-D-803-S SS&D Type: (AD) Photo Emitting Teletherapy
Applicant Name: Advanced Medical Systems Type of Action: Inactivation
Date issued: 11/13/09 Reviewers: KVA, KB

File No.: 11
Registry No.: OH-1090-D-103-B SS&D Type: (E) Beta Gauge
Applicant Name: Automation and Control Tech. Type of Action: Amendment
Date issued: 2/16/10 Reviewers: KVA, SD

File No.: 12
Registry No.: OH-0522-D-120-B SS&D Type: (D) Gamma Gauge
Applicant Name: Ohmart/VEGA Corp Type of Action: Amendment
Date issued: 10/14/10 Reviewers: KVA, SD

File No.: 13
Registry No.: OH-0522-D-112-S SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 11/01/10 Reviewers: KVA, SD

File No.: 14
Registry No.: OH-1033-D-101-B SS&D Type: (D)Gamma Gauge, (E)Beta Gauge
Applicant Name: IRM Group, Inc. Type of Action: Amendment
Date issued: 11/05/10 Reviewers: SD, KVA

File No.: 15
Registry No.: OH-0522-D-120-B SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 1/7/11 Reviewers: KVA, SD

File No.: 16
Registry No.: OH-0522-D-116-S SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 2/4/11 Reviewers: KVA, SD

File No.: 17
Registry No.: OH-1090-D-103-B SS&D Type: (E) Beta Gauge
Applicant Name: Automation and Control Tech. Type of Action: Amendment
Date issued: 11/1/11 Reviewers: SD, KVA

File No.: 18
Registry No.: OH-0522-D-120-B SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Type of Action: Amendment
Date issued: 7/5/12 Reviewers: SD,KVA

File No.: 19
Registry No.: OH-0109-S-125-S SS&D Type: (R) Gas Source
Applicant Name: ABB, Inc. Type of Action: Amendment
Date issued: 7/17/12 Reviewers: SD, KVA

File No.: 20
Registry No.: OH-0109-S-126-S SS&D Type: (T) Other
Applicant Name: ABB, Inc. Type of Action: Amendment
Date issued: 7/17/12 Reviewers: SD, KVA

File No.: 21
Registry No.: OH-1346-D-101-S SS&D Type: (AD) Teletherapy (AE) Gamma Device
Applicant Name: ViewRay, Inc. Type of Action: New
Date issued: 8/17/12 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

File No.: 22
Registry No.: OH-0522-D-102-B S&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 10/29/12 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

File No.: 23
Registry No.: OH-0522-D-111-S SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 11/20/12 Reviewers: SD, KVA

File No.: 24
Registry No.: OH-0109-D-121-B SS&D Type: (D)Gamma Gauge, (E)Beta Gauge
Applicant Name: ABB, Inc. Type of Action: Amendment
Date issued: 11/30/2012 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

File No.: 25
Registry No.: OH-0109-D-122-B SS&D Type: (D)Gamma Gauge, (E)Beta Gauge
Applicant Name: ABB, Inc. Type of Action: Amendment
Date issued: 12/3/12 Reviewers: SD, KVA

File No.: 26
Registry No.: OH-0109-D-123-B SS&D Type: (D)Gamma Gauge, (E)Beta Gauge
Applicant Name: ABB, Inc. Type of Action: Amendment
Date issued: 12/3/12 Reviewers: SD, KVA

File No.: 27
Registry No.: OH-0109-D-124-B SS&D Type: (D)Gamma Gauge, (E)Beta Gauge
Applicant Name: ABB, Inc. Type of Action: Amendment
Date issued: 12/3/12 Reviewers: SD, KVA

File No.: 8
Registry No.: OH-0109-S-127-S SS&D Type: (T) Other Beta Gauge
Applicant Name: ABB, Inc. Type of Action: Amendment
Date issued: 12/3/12 Reviewers: SD, KVA

File No.: 29
Registry No.: OH-0109-S-128-S SS&D Type: (T) Other Beta Gauge
Applicant Name: ABB, Inc. Type of Action: Amendment
Date issued: 12/3/12 Reviewers: SD, KVA

File No.: 30
Registry No.: OH-1219-D-104-S SS&D Type: (Y) Calibrator
Applicant Name: Thermo Eberline LLC Type of Action: New
Date issued: 12/14/12 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

File No.: 31
Registry No.: OH-1219-D-102-S SS&D Type: (Y) Calibrator
Applicant Name: Thermo Eberline LLC Type of Action: Amendment
Date issued: 12/14/12 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

File No.: 32
Registry No.: OH-0522-D-111-S SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 3/5/13 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

File No.: 33
Registry No.: OH-0522-D-112-S SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 3/7/13 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

File No.: 34
Registry No.: OH-0522-D-102-B SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 3/26/13 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

File No.: 35
Registry No.: OH-0522-D-111-S SS&D Type: (D) Gamma Gauge
Applicant Name: VEGA Americas Corporation Type of Action: Amendment
Date issued: 5/29/13 Reviewers: SD, KVA

Comment:
Missing dimension labels on the attached diagrams/drawings.

ATTACHMENT

January 14, 2014 Email from Michael Snee
Ohio's Response to the Draft Report
ADAMS Accession No.: ML14027A002