January 4, 2005

MEMORANDUM TO: Martin J. Virgilio, Deputy Executive Director
for Materials, Research and State Programs

Paul H. Lohaus, Director
Office of State and Tribal Programs

Jack R. Strosnider, Director
Office of Nuclear Material Safety and Safeguards

Karen D. Cyr, General Counsel

***/RA By Dennis M. Sollenberger***

FROM: Josephine M. Piccone, Deputy Director ***Acting for/***
Office of State and Tribal Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE OHIO RADIATION CONTROL PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Attachment 1) documenting the IMPEP review of the Ohio Radiation Control Program. The review of the Ohio program was conducted by an interoffice team during the period of October 25-29, 2004. The team issued a draft report to Ohio on November 29, 2004 for factual comment. Ohio responded to the findings and conclusions of the review by E-mail dated December 14, 2004, from Michael Snee, Administrator, Technical Support Program, Bureau of Radiation Control, Ohio Department of Health (Attachment to the proposed final report).

The review team found Ohio's performance to be satisfactory for all performance indicators reviewed. Accordingly, the review team recommends that the Ohio Agreement State program be found adequate to protect public health and safety and compatible with NRC's program.

The MRB meeting to consider the Ohio report is scheduled for **Tuesday, January 11, 2005, from 1:00 p.m. to 3:00 p.m., in One White Flint North, Room O-3B4**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is attached (Attachment 2).

If you have any questions prior to the meeting, please contact me at 301-415-2325 or John Zabko at 301-415-2308.

Attachments:
As stated

cc: See next page

cc: Dr. J. Nick Baird, Director
Ohio Department of Health

Robert E. Owen, Chief
Bureau of Radiation Protection
Ohio Department of Health

Michael Snee, Administrator
Technical Support Program
Bureau of Radiation Protection
Ohio Department of Health

Carol O'Claire, State Liaison Officer
Supervisor, Radiological Branch
Ohio Emergency Management Agency

Steve Collins, IL
OAS Liaison to the MRB

cc: Dr. J. Nick Baird, Director
Ohio Department of Health

Robert E. Owen, Chief
Bureau of Radiation Protection
Ohio Department of Health

Michael Snee, Administrator
Technical Support Program
Bureau of Radiation Protection
Ohio Department of Health

Carol O'Claire, State Liaison Officer
Supervisor, Radiological Branch
Ohio Emergency Management Agency

Steve Collins, IL
OAS Liaison to the MRB

Distribution:
DIR RF DCD (SP07) PDR (YEST)
AMcCraw, STP
LMcLean, RIV
JLynch, RIII
SSeeley, Maine
XYin, NMSS
ISchoenfeld, OEDO
CMiller, NMSS/IMNS
RStuckmeyer, NMSS/IMNS
STreby, OGC

**DOCUMENT NAME: E:\Filenet\ML050100301.wpd**
**To receive a copy of this document, indicate in the box:** "**C**" = Copy without attachment/enclosure "**E**" = Copy with attachment/enclosure "**N**" = No copy

| OFFICE | STP | | STP:DD | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| NAME | JGZabko:gd | | JMPiccone | | | | | | | |
| DATE | 01/4/05 | | 01/4/05 | | | | | | | |

**ML050100297 Pkg.** **OFFICIAL RECORD COPY**

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF OHIO AGREEMENT STATE PROGRAM

October 25-29, 2004

# PROPOSED FINAL REPORT

U.S. Nuclear Regulatory Commission

**ATTACHMENT 1**

## 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 October 25-29, 2004, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Maine. 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 a 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 May 19, 2001 to October 29, 2004, were discussed with Ohio management on October 29, 2004.

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

The Ohio Agreement State program is administered by the Bureau of Radiation Protection (the Bureau). The Bureau is part of the Division of Prevention, within 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 program regulated 767 specific licenses, authorizing Agreement materials, naturally occurring radioactive materials, and accelerator-produced materials. The review focused on the 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 non-common performance indicators was sent to the Bureau on August 26, 2004. The Bureau provided a response to the questionnaire on September 30, 2004. A copy of the questionnaire response may be found on the NRC's Agencywide Document Access and Management System (ADAMS) using the Accession Number ML042800450.

The review team's general approach for conduct of this review consisted of: (1) examination of Ohio's response to the questionnaire; (2) review of applicable Ohio statutes and regulations; (3) analysis of quantitative information from the Bureau's licensing and inspection database; (4) technical evaluation of selected licensing and inspection actions; (5) field accompaniments of six Ohio inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Ohio Agreement State program's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP review and the team's conclusions regarding close-out of the recommendations. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings and recommendation.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on May 18, 2001, recommendations were made and the results were transmitted to Dr. J. Nick Baird, Director, Ohio Department of Health, on August 22, 2001. The review team's evaluation of the current status of the recommendations is as follows:

RECOMMENDATION FOR THE STATE:

1. The review team recommends that the Bureau develop formal training and qualification requirements for SS&D reviewers. (Section 4.2.2 of the 2001 report)

   Current Status: The Bureau developed a formal training and qualification program. Training and qualifications are documented for each sealed source and device (SS&D) reviewer. This recommendation is closed.

RECOMMENDATION FOR THE NRC:

1. The MRB recommends that NRC staff revise NRC guidance so that the differences between safety analysis summary documentation for certificates for specifically licensed verses generally licensed devices are clarified. (Section 4.2.1 of the 2001 report)

   Current Status: NUREG-1556, Vol. 3, was revised in the Spring of 2004. The revision included detailed instructions so that the differences between safety analysis summary documentation for certificates specifically licensed and generally licensed (GL) devices are apparent. This recommendation is closed.

## 3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State 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

Issues 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 Bureau management and staff, and considered any possible workload backlogs.

The Bureau, headed by the Bureau Chief, regulates approximately 767 specific licenses with approximately 25 full time equivalents (FTE) assigned to implement the radioactive materials licensing and inspection programs. The Bureau is divided into four programs: the Nuclear Materials Safety Program; the Environmental Radiation Safety Program; the Technical Support Program; and the X-Ray Program. Each Program is managed by an administrator. The Nuclear Materials Safety Program consists of the Medical Section and the Industrial Section,

both of which are managed by section supervisors. These two sections are responsible for the routine licensing and inspecting of most materials facilities within the State. The SS&D Evaluation Program is under the Industrial Section of the Nuclear Materials Safety Program, and three staff members conduct the reviews. The Environmental Radiation Safety Program consists of the Radiological Assistance Section and the Decommissioning Section, which are also managed by section supervisors. The Decommissioning Section conducts license terminations and partial site releases including the contaminated sites transferred from the NRC. The Environmental Radiation Safety Program is also responsible for all low-level radioactive waste activities. The Technical Support Program is responsible for oversight of the training and quality assurance programs as well as for writing rules and developing procedures. The Agreement State program is implemented by the Nuclear Materials Safety Program, a portion of the Decommissioning Section in the Environmental Radiation Safety Program, and the Technical Support Program. The technical staff positions are classified as Health Physicist I, II, or III, with Health Physicist III being the senior-level technical position. Technical staff perform both inspection and licensing functions.

Eight staff members left the Bureau and ten staff members were hired during the review period. There are currently two vacant positions in the Agreement State program. One position is for a Health Physicist II in the Industrial Section of the Nuclear Materials Safety Program and the other position is a senior-level position in the Technical Support Program. Vacant positions are posted quickly by the Bureau. Bureau management indicated that vacant senior-level positions are typically filled internally. This allows the Bureau to recruit candidates outside the Bureau to fill junior positions. The review team noted that the Bureau had stable funding during the review period due to dedicated revenue from licensee fees.

The qualifications of the staff were determined from the questionnaire, training records, and interviews of personnel. The staff are well qualified from an education and experience standpoint. All staff have at least a Bachelor's degree in the sciences, or equivalent training and experience.

The Bureau has a documented training and qualifications program for technical staff that is modeled after NRC's Manual Chapter (MC) 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Area." The Bureau uses a combination of self-study, formal training (such as NRC courses), and on-the-job experience to qualify both inspectors and license reviewers. Most senior-level technical staff members have taken the NRC courses deemed appropriate for their tasks. New staff members plan to attend appropriate required courses when available. The review team noted that it may take several years for a new staff member to receive all the required training due to limitations on out-of-State travel. However, the team noted that the Bureau is making commendable efforts to provide the required training to the staff in-house. Last year, the Bureau hosted four NRC courses: Licensing Practices and Procedures (G-109); Inspection Procedures (G-108); Inspecting for performance (G-304); and the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM). In addition, the Bureau hosted the Root Cause/Incident Investigation Workshop (G-205) following the IMPEP.

New staff are trained in licensing and inspections 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. Every individual's qualification journal, contains documentation that the individual has met the minimum qualifications and received their supervisor's approval to perform independent inspections and/or license reviews for the license types listed on the sheet.

The Radiation Advisory Council (the Council) of the State of Ohio, as constituted under State law, is comprised of medical and industrial stakeholders as well as a member of the public. All members of the Council are appointed by the Governor. The Council has the responsibility to advise and consult with the Bureau on the development of rules and the administration, implementation and enforcement of these rules. The Council also provides advice and guidance on the development of inspection criteria, procedures, and guidelines to be used by the Bureau. No evidence of any conflict of interest issues was identified.

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

### 3.2 Status of Materials Inspection Program

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

The review team's evaluation of the Bureau's inspection priorities revealed that inspection frequencies for each type of license were the same or more frequent than similar license types listed in the NRC MC 2800, with three exceptions: Teletherapy; Source Material Possession Only - Permanent Shutdown; and Special Nuclear Material Possession Only (Non-Fuel) - Permanent Shutdown. These categories have an inspection priority less frequent than NRC; however, during the review period, Priority 1, 2, and 3 licenses were inspected at intervals in accordance with frequencies consistent with NRC MC 2800. The Bureau can only change these priorities through rulemaking. The Bureau has included these changes with the next scheduled rule revision, which is already in process.

At the time of the review, there were no overdue inspections. The Bureau conducted 344 routine inspections and 43 reciprocity inspections of candidate licenses during the review period. The Bureau exceeded the minimum 20 percent criteria prescribed in NRC MC 1220 by inspecting 50 percent of candidate licenses. Initial inspections were scheduled and generally conducted within six months of license issuance and all were performed within 12 months.

The Bureau currently utilizes an Oracle-based data tracking system, but will be moving to a Microsoft.net system. The current tracking system is able to archive the inspection history of each licensee. This feature enhances the Bureau's management of the inspection program by facilitating access and review of the inspection history of its licensees by inspectors. The new system will offer a wider variety of options available to the Bureau to interact more efficiently within the Bureau and with other programs across State government.

The timeliness of the issuance of inspections findings was evaluated by the team's review of inspection casework. In all cases, the response letters and inspection reports to the licensee regarding the inspection results were sent within 30 days of the inspection date. Inspection finding letters to licensees generally were dated within 2-15 calendar days after the inspection date. The team noted that at the request of Ohio's licensees, a complete copy of the inspection report is sent to the licensee for their files.

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

### 3.3 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 17 radioactive materials inspections conducted during the review period. The casework included work performed by 11 of the Bureau's materials license inspectors, and covered a variety of license types including: academic broad; medical (broad scope, private practice, and institutional); mobile high dose remote afterloader (HDR); mobile nuclear medicine; teletherapy; nuclear pharmacy; industrial radiography; pool irradiator; decommissioning services; manufacturing and distribution-broadscope; and research and development. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments, as well as the results of the inspection accompaniments.

Based on the casework reviewed, the review team noted that the routine inspections covered all aspects of the licensees' radiation programs. The review team found that inspection reports were generally very 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 the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were frequently performed for larger and complex licensees and for training purposes. The review team noted in the review of the documentation and in discussions with staff, that although independent and/or confirmatory measurements had been conducted, their documentation of these surveys was often inconsistent and in five cases was missing from the document. The Bureau indicated that they would review this area and modify future reports as necessary and since the IMPEP have commenced reviewing all inspection reports to ensue proper documentation of inspector surveys.

Completed inspection reports were signed by the appropriate section supervisor and the appropriate program administrator. Supervisory accompaniments are being conducted annually for all inspectors; however, there is currently no formal method for capturing the overall evaluation of the inspector's performance during their inspection. The Bureau committed to review the procedures on documenting an inspector's performance during accompaniments and make any changes deemed necessary and since the IMPEP have implemented a new form to document inspector performance on accompaniments.

The inspection findings were appropriate and prompt regulatory actions were taken, as necessary. The Bureau normally issues Compliance letters, Observations letters, or Notices of Violations, as it deems appropriate. Violations of minor safety or environmental concerns, which are at or below the level of significance equivalent to NRC's Severity Level IV violation,

are documented in the inspection report and generally issued to the licensee as Observations. The licensee is required to respond to the noted Observations within 30 days. Notices of Violations are routinely issued for licensees with repeat violations and those, which are elevated above the Observation level. In addition, the Bureau has the ability to impose an administrative penalty when it is deemed that the licensee has had a significant breakdown in operations that affects overall health and safety. A “General Statement of Policy - Enforcement Actions” procedure has been established and implemented, which explains the enforcement program. All inspection findings are clearly stated and documented in the report, and reviewed by the appropriate section supervisor and the appropriate program administrator, before being sent to the licensee with the appropriate letter detailing the results of the inspection. Escalated enforcement actions are reviewed and sent from either the Bureau Chief or Department Director, depending upon the situation.

The Bureau has adequate numbers and types of radiation survey instruments to support their efforts. The review included a check of survey instruments and equipment monitoring, including calibration frequency and repairs. Each inspector is assigned a Ludlum 3 survey meter. A staff member in the Technical Support Program is responsible for sending survey instruments out to the Ohio Emergency Management Agency for calibration and/or repair; however, the neutron detectors are sent to the manufacturer for calibration and/or repair. The Department’s Laboratory performs sampling analysis for the Bureau, as needed.

Six Bureau inspectors were accompanied during inspections by a review team member during the weeks of October 4, 2004 and October 11, 2004. Inspection accompaniments included: medical institution/HDR, nuclear pharmacy, fixed industrial radiography, gauge manufacturing and distribution, teletherapy, and a pool irradiator. These accompaniments are identified in Appendix C. During the accompaniments, each inspector demonstrated appropriate performance based inspection techniques and knowledge of the regulations. The inspectors were trained, prepared, and thorough in their audits of the licensees radiation safety programs. Overall, each inspector utilized good health physics practices. Interviews with licensee personnel were performed in an effective manner, and the inspections were adequate to assess radiological health and safety at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends 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 interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 15 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate 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 files were also evaluated for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions which were completed during the review period by 12 different license reviewers. The cross-section sampling focused on the new licenses, amendments, renewals, and license terminations issued during the review period. The sampling included the following types of licenses: academic; pool irradiator; service provider; industrial radiography; research and development; portable gauges; source manufacturing and distribution; nuclear pharmacy; medical private practice; and medical institution. Licensing actions evaluated included two new licenses, three renewals, six amendments, and four termination files. A listing of the casework licenses evaluated with case specific comments may be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. The exemptions noted in the questionnaire response were determined to be appropriate and well documented by license conditions. A review of termination actions found that terminated licensing actions were well documented, showing appropriate transfer records or appropriate disposal methods and records, confirmatory surveys, and survey records.

The Bureau modified their policy for overnight storage of portable gauges after experiencing multiple losses of gauges from licensee employee vehicles parked at residences. The policy requires that gauges be returned to the licensee facility or secured at a temporary job site. If such storage is a hardship for the licensee, vehicle storage is allowed, with certain provisions, including notification of the Bureau.

Section supervisors assign licensing actions to license reviewers based on that individual's qualifications for the particular license type. Each licensing action is entered into the Bureau database, RADMAT, an Oracle-based database. Licensing actions are also tracked in a separate Microsoft Access database. This database has milestones so that supervisors may easily track the status of a given licensing action. A new web-based database is being developed which would replace the aforementioned databases and provide an interactive licensing process. The new database is anticipated in 2006.

When a licensing action is completed by a reviewer, the entire package is given to their section supervisor and then to the appropriate program administrator for approval. All licensing actions are signed by the Bureau Chief, for the Department Director. License reviewers are responsible for the handling and mailing of completed licensing actions. Licenses are issued for a five-year term.

The Bureau utilizes the Department's regulatory guides (NMS-LIC), which are based on NRC's NUREG-1556 series guides. Standard license conditions, similar to those used by NRC, are utilized by reviewers. The review team noted consistent use of guidance documents and standard license conditions.

The Bureau appropriately requires certain licensees to maintain financial assurance for decommissioning. Surety instruments are maintained in a locked cabinet in the secure license file room. The Industrial Section Supervisor has the responsibility for control of the documents. The review team evaluated the contents of several financial assurance folders which were found to be in good order.

The review team noted good communication between inspectors and license reviewers. In fact, for some complex licensing actions, license reviewers, who are also inspectors, performed an inspection of the license prior to renewal of the license. This inspection provided the reviewer with a more in-depth understanding of the licensee's program, which aided in an effective licensing action.

The Bureau actively licenses a number of major long-term decommissioning projects. One site, contaminated with depleted uranium, was decommissioned and released in 2003. In addition to their own decommissioning efforts, Bureau inspectors also routinely accompany and provide assistance to NRC inspection teams at the Battelle-West Jefferson decommissioning site, for which the NRC retained jurisdiction after Ohio became an Agreement State.

Based on the IMPEP evaluation criteria, the review team recommends 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 and reviewed the incidents reported for Ohio in the Nuclear Material Events Database (NMED) against those contained in the Bureau's casework and license files, and supporting documentation, as appropriate, for 10 incidents. A list of the incident casework reviewed is included as Appendix E. The team reviewed the Bureau's response to the 30 allegations received during the review period involving radioactive materials including 16 allegations referred to the Bureau by NRC.

The review team discussed the Bureau's incident and allegation procedures, file documentation, the Bureau's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center with the Bureau managers and selected staff. During the review period, each incident meeting the criteria for reporting to the NMED system was reported to NRC and the NMED contractor for entry into NMED, as required.

Responsibility for initial response and follow-up actions to material incidents and allegations rests with the Bureau staff. The Department provides a 24-hour emergency number for anyone to report emergencies involving hazardous materials. The Bureau has a duty call list that is staffed by the Bureau's seven supervisors. When a radiological incident is reported after work hours, they are contacted by cell phone. When the Bureau is notified of an incident during working hours, the sections supervisors, the administrators, and/or the Bureau Chief determine the approach to be taken regarding the incident. The review team found that the Bureau's responses to incidents and allegations were complete and comprehensive. The level of effort was commensurate with the health and safety significance of the event. Inspectors were dispatched for investigations when appropriate and the Bureau took suitable enforcement action when indicated.

The review team found a good correlation between the Bureau's response to the questionnaire and the incident information in the casework. The review team also queried the incident information reported on the NMED system for Ohio which identified 25 reported incidents during this review period. The ten incidents selected for evaluation included three medical events, two

events involving lost/stolen gauges, two leaking sources, one event involving exposure to a member of the public, and two equipment failures.

The review of incident casework and interviews with staff revealed that incidents are promptly evaluated for the need for investigations. For those incidents not requiring investigations, copies of reports were in the incident and inspection files. In response to incidents, the Bureau took prompt, appropriate action. The review team found that the Bureau's responses were prompt and well-coordinated. The evaluation of the casework indicated that incident reports were thorough and well-documented. All incident reports were reviewed and signed by the appropriate level of management.

The evaluation of the 30 allegation cases indicated that the Bureau took prompt and appropriate action in response to the allegers' concerns. Through review of the casework and interviews with staff, the review team determined that the Bureau provided feedback to allegers either verbally or in writing when possible. Any alleger requesting anonymity is informed that every effort will be made to protect his/her identity, but cannot be guaranteed. All interviewed staff were knowledgeable of the Bureau's allegation procedure. There were no performance issues identified from the review of allegation files and documentation.

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

## 4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in evaluating 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

Along with their response to the questionnaire, the Bureau provided the review team with the opportunity to review copies of legislation that affects the radiation control program. 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 Director has designated the Bureau Chief to administer the Agreement State program for the Department. The review team noted that no new legislation was passed since last review, which would affect the Agreement State program or its authority.

#### 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 produced by machines. Ohio requires a license for the possession and use of all radioactive material including naturally occurring materials, such as certain isotopes of

radium, and accelerator-produced radionuclides. Ohio also requires registration of all machines designed to produce x-rays or other ionizing radiation.

The review team examined the procedures used in the Department's regulatory process and found that regulations are drafted by the staff and presented to the State's Radiation Advisory Council (Council). The regulations are posted on the Department web site with a 45-day comment period. At this point, the proposed rules are sent to the NRC for a compatibility review. Any comments received by the NRC, stakeholders or the public are evaluated, and the regulations are revised as necessary. The revised regulations are submitted to the Radiation Advisory Council for a recommendation for adoption. The formal rule adoption process begins with submittal to the Public Health Council which places the review of the proposed rules on their calendar, hold a hearing, and then submit them to the Joint Committee on Agency Rules Review (JCARR). After JCARR completes its review of the proposed rules and takes no action against the rule, the Public Health Council is able to take final actions to enact the rule. The rule becomes final after it is filed with several State rule codification agencies. The minimum amount of time for a rule to become final is ten days after such filing.

The 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 Office of State and Tribal Programs' (STP) State Regulation Status Sheet. During the previous IMPEP review, it was noted that the Bureau had adopted all required NRC regulations by reference during the negotiation of the Agreement. Since then, the Bureau has replaced many of the NRC regulations incorporated by reference with State-specific regulations. All regulations required to be adopted are currently in effect.

For the following two amendments, the NRC reviewed the State's proposed regulations for these amendments and determined that if the proposed regulations are adopted without significant changes, they would meet the NRC's compatibility and health and safety requirements:

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 1629) that became effective April 5, 2002.

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendment (67 FR 20249) that became effective April 24, 2002.

The team identified the following regulation changes and adoptions that will be needed in the future, and Bureau management indicated that the regulations would be addressed in upcoming rulemaking, incorporation by reference, or by adopting alternate legally binding requirements:

- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendment (68 FR 57327) that became effective December 3, 2003.

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that became effective October 1, 2004.

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

## 4.2 Sealed Source and Device (SS&D) Evaluation Program

In assessing the Ohio SS&D evaluation program, the review team examined the information provided in response to the IMPEP questionnaire. The team evaluated SS&D registry sheets issued during the review period and the supporting document files. The team also evaluated SS&D staff training records, certain reported incidents involving products authorized in Ohio SS&D sheets, the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations. Three sub-indicators were used to evaluate the Bureau's performance regarding their SS&D Evaluation Program. These sub-indicators were (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

### 4.2.1 Technical Staffing and Training

Presently, the SS&D Evaluation Program is under the Industrial Section of the Nuclear Materials Safety Program, and three staff members conduct the reviews. One of the three reviewers works in the Decommissioning Section and acts as a backup SS&D reviewer. One previously qualified and experienced SS&D reviewer left the Bureau during the review period. The review team evaluated the qualifications of the individuals authorized and currently performing SS&D evaluations. All reviewers were qualified through implementation of the newly developed Formal Training and Qualification Journal for SS&D Reviewers. All have regulatory experience and have attended the NRC SS&D Workshop. The review team noted that SS&D reviewers have degrees in engineering, environmental science, or equivalent training and experience.

### 4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated 12 of the 51 SS&D evaluation amendments, inactivations, and new registrations the Bureau completed during the review period, representing the work of four SS&D reviewers. The cases selected were representative of the Bureau's licensees and SS&D reviewers. A list of SS&D casework examined along with case-specific comments may be found in Appendix F.

The team's review of the casework and interviews with the staff confirmed that the SS&D reviewers used "Consolidated Guidance - Application for Sealed Source and Device Evaluation", which is Ohio's version of NUREG-1556, Vol. 3, and the American National Standards Institute (ANSI)/Health Physics Society (HPS) standards. All pertinent ANSI/HPS standards, regulatory guides, and applicable references were confirmed to be available and were used when performing SS&D reviews. The appropriate review checklist was used to assure relevant materials had been submitted and reviewed. The checklists were retained in all of the registration files examined.

The registration files contained all correspondence, engineering drawings, radiation profiles, and results of tests conducted by the applicant. The files were well organized in a consistent manner. Deficiency letters clearly stated regulatory positions and health and safety issues were properly addressed. The Bureau handles proprietary information by creating a blue folder for

any proprietary or trade secret information. If a request to view SS&D files is received, the legal department will conduct a review of the SS&D file to determine if material is suitable for public review. The review team determined that product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of likely accidents.

The review team recommends that a good practice be found in the Ohio SS&D Evaluation Program. Whenever an SS&D casework is completed, the updated SS&D registration is always tied to the applicant's material license. When a sealed source and/or a device is introduced in an applicant's product line, a design or radioactive source strength is modified, or an error is corrected, these actions are reflected in applicant's license. This practice provides an excellent reference to help license reviewers, inspectors, and investigators better understand SS&D issues, especially when an SS&D related enforcement action is necessary.

Overall, the quality of the evaluations was high, but a few minor issues were identified during the review, as noted in App F. The review team discussed the issues with Bureau management and the SS&D review staff, and the Bureau committed to correcting the errors.

#### 4.2.3 Evaluation of Defects and Incidents Regarding SS&D

Three incidents or defects related to SS&D issues were reported to the Bureau during the review period concerning devices registered by the Bureau and are noted in Appendix E, file numbers 2, 3, and 6. There were no generic design or performance issues identified from the review of SS&D incident files and documentation. The Bureau provided a timely and adequate response in the investigation and resolution of the events. No allegations related to SS&Ds were reported during the review period.

Based on the IMPEP evaluation criteria, the review team recommends that Ohio's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

### 4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

Although Ohio has LLRW disposal authority, 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, they are expected to put in place a regulatory program which will meet 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 Uranium Recovery authority, 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, they are expected to put in place a regulatory program which will meet 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 and 4 above, the review team found Ohio's performance to be satisfactory for all performance indicators reviewed. Accordingly, the review team recommends that the Ohio Agreement State Pogram be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full review should take place in approximately four years. The review team made no recommendations regarding the performance of the Ohio Agreement State Program.

GOOD PRACTICE:

> The review team recommends that a good practice be found in the Ohio SS&D evaluation program. Whenever SS&D casework is completed, the updated SS&D registration is tied to the applicant's material license. When a sealed source and/or a device is introduced in an applicant's product line, a design or radioactive material strength is modified, or an error is corrected, all these actions are reflected in applicant's license. This practice provides an excellent reference in helping license reviewers, inspectors, and investigators better understand SS&D issues, especially when an SS&D related enforcement action is necessary. (Section 4.2.2)

LIST OF APPENDICES


| | |
|---|---|
| Appendix A | IMPEP Review Team Members |
| Appendix B | Ohio Organization Charts |
| Appendix C | Inspection Casework Reviews |
| Appendix D | License Casework Reviews |
| Appendix E | Incident Casework Reviews |
| Appendix F | Sealed Source and Device Casework Reviews |
| Attachment | December 14, 2004 Email from Michael Snee<br>Ohio's Response to Draft IMPEP Report |

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

| **Name** | **Area of Responsibility** |
| --- | --- |
| Linda McLean, Region IV | Team Leader<br>Technical Quality of Incident and Allegation |
| Aaron McCraw, STP | Technical Staffing and Training<br>Compatibility Requirements |
| Shawn Seeley, State of Maine | Status of Materials Inspection Program<br>Technical Quality of Inspections<br>Inspector Accompaniments |
| James Lynch, Region III | Technical Quality of Licensing Actions<br>Inspector Accompaniments |
| Xiaosong Yin, NMSS | Sealed Source and Device Evaluation Program |

APPENDIX B

OHIO ORGANIZATION CHARTS

ADAMS: ML042800450
PAGES 26-30

# APPENDIX C

## INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Knox Community Hospital License No.: 02120430001
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/16/02 Inspectors: AC, JA

Comment:
Independent surveys were not recorded.

File No.: 2
Licensee: Advanced Cardiovascular Specialists License No.: 02201230000
Inspection Type: Initial Priority: 3
Inspection Date: 10/7/04 Inspector: AC

File No.: 3
Licensee: Cardinal Health License No.: 02500580000
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 9/30/04 Inspector: LS

Comments:
a) Independent surveys were not recorded.
b) Survey instrument was not recorded.

File No.: 4
Licensee: Mercy Hospital–Fairfield License No.: 02120310032
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 11/13/03 Inspector: JA

Comment:
Independent surveys were not recorded.

File No.: 5
Licensee: Premier Physicians Center - Mobile License No.: 02220180000
Inspection Type: Routine, Unannounced Priority: 2 and 3
Inspection Date: 9/30/04 Inspector: CC

Comments:
a) Independent surveys were not recorded.
b) Survey instrument was not recorded.

File No.: 6

Licensee: Cardinal Health
License No.: 02500180000
Inspection Type: Routine, Unannounced
Priority: 1
Inspection Date: 7/2/04
Inspectors: CC, MC

Comment:
Survey instrument was not recorded.

File No.: 7
Licensee: Cooperheat – MQS, Inc.
License No.: 03320990000
Inspection Type: Routine, Unannounced
Priority: 1
Inspection Dates: 6/22-24/04
Inspectors: KB, MR

File No.: 8
Licensee: Mount Carmel Health System
License No.: 02120250034
Inspection Type: Routine, Unannounced
Priority: 1
Inspection Date: 10/12/04
Inspector: AC

Comment:
Independent surveys were not performed.

File No.: 9
Licensee: Cancer Treatment Partner
License No.: 02300780008
Inspection Type: Routine, Unannounced
Priority: 3/NRC 5
Inspection Date: 10/6/04
Inspector: DC

File No.: 10
Licensee: ABB, Inc
License No.: 03211250000
Inspection Type: Routine, Unannounced
Priority: 1/NRC 2
Inspection Date: 10/15/04
Inspector: KV

Comment:
Survey instrument was not recorded.

File No.: 11
Licensee: Sterigenics
License No.: 03521250000
Inspection Type: Routine, Unannounced
Priority: 1/NRC 2
Inspection Date: 10/13/04
Inspector: KB

File No.: 12
Licensee: Scott Process Systems, Inc.
License No.: 03320770000
Inspection Type: Routine, Unannounced
Priority: 1
Inspection Date: 10/7/04
Inspector: SD

File No.: 13
Licensee: University of Cincinnati
License No.: 02110310010
Inspection Type: Routine, Unannounced
Priority: 1/NRC 2
Inspection Dates: 5/22-24/04
Inspectors: AC, LS, CC

File No.: 14
Licensee: The Ohio State University
License No.: 02110250037
Inspection Type: Routine, Unannounced
Priority: 1/NRC 2
Inspection Dates: 2/18-20/04
Inspectors: DC, LS, CC

File No.: 15
Licensee: Solutient Technologies, LLC
License No.: 03219770000
Inspection Type: Routine, Announced
Priority: 2/NRC 3
Inspection Date: 10/30/03
Inspector: CM

Comment:
Survey instrument was not recorded.

File No.: 16
Licensee: Proctor & Gamble
License No.: 03610090000
Inspection Type: Routine, Announced
Priority: 2/NRC 3
Inspection Date: 7/30//03
Inspectors: SD, WH

File No.: 17
Licensee: Cardinal Health 419, LLC
License No.: 03211180000
Inspection Type: Routine, Unannounced
Priority: 1/NRC 2
Inspection Date: 10/20/04
Inspectors: KB, MR

Comment:
Survey instrument was not recorded.

## INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Sterigenics License No: 03521250000
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/13/04 Inspector: KB

Accompaniment No.: 2
Licensee: Mount Carmel East Hospital License No: 02120250034
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/12/04 Inspector: AC

Comment:
No independent measurements were taken.

Accompaniment No.: 3
Licensee: Regional Nuclear Pharmaceuticals License No: 02500250001
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/14/04 Inspector: JA

Accompaniment No.: 4
Licensee: ABB Industrial, Inc. License No: 03211250000
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/15/04 Inspector: KV

Accompaniment No.: 5
Licensee: Cancer Treatment Center Partners License No.: 02300780008
Inspection Type: Routine Priority: 3
Inspection Date: 10/6/04 Inspector: DC

Accompaniment No.: 6
Licensee: Scott Process Systems, Inc. License No.: 03320770000
Inspection Type: Routine Priority: 1
Inspection Date: 10/7/04 Inspector: SD

January 4, 2005
APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Knox Community Hospital
Type of Action: Renewal
Date Issued: 10/8/03
License No.: 02120430001
Amendment No.: 3
License Reviewer: AC

File No.: 2
Licensee: Cardinal Health
Type of Action: Renewal
Date Issued: 2/10/04
License No.: 02500180000
Amendment No.: 6
License Reviewer: DC

File No.: 3
Licensee: ABB, Inc.
Type of Action: Amendment
Date Issued: 3/12/02
License No.: 03211250000
Amendment No.: 4
License Reviewer: KB

File No.: 4
Licensee: Crystal Clear Imaging, LLC
Type of Action: Amendment
Date Issued: 3/28/03
License No.: 02200120002
Amendment No.: 2
License Reviewer: JA

File No.: 5
Licensee: Baker Inspection Group, LLC
Type of Action: New
Date Issued: 8/5/04
License No.: 03320770014
Amendment No.: 0
License Reviewer: MR

File No.: 6
Licensee: GE Reuter-Stokes, Inc.
Type of Action: Amendment
Date Issued: 2/2/04
License No.: 03214780011
Amendment No.: 4
License Reviewer: KV

File No.: 7
Licensee: Aultman Hospital
Type of Action: Amendment
Date Issued: 2/2/04
License No.: 02120770003
Amendment No.: 16
License Reviewer: LS

cc: See next page
Comment:
The maximum allowed possession limit is incorrect.

MEMORANDUM TO: Martin J. Virgilio, Deputy Executive Director
for Materials, Research and State Programs

Paul H. Lohaus, Director
Office of State and Tribal Programs

Jack R. Strosnider, Director
Office of Nuclear Material Safety and Safeguards

Karen D. Cyr, General Counsel

***/RA By Dennis M. Sollenberger/***
***Acting for:***

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE OHIO RADIATION CONTROL PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Attachment 1) documenting the IMPEP review of the Ohio Radiation Control Program.

The review of the Ohio program was conducted by an interoffice team during the period of October 25-29, 2004. The team issued a draft report to Ohio on November 29, 2004 for factual comment. Ohio responded to the findings and conclusions of the review by E-mail dated December 14, 2004, from Michael Shee, Administrator, Technical Support Program, Bureau of Radiation Control, Ohio Department of Health (Attachment to the proposed final report).

The review team found Ohio's performance to be satisfactory for all performance indicators reviewed. Accordingly, the review team recommends that the Ohio Agreement State program be found adequate to protect public health and safety and compatible with NRC's program.

The MRB meeting to consider the Ohio report is scheduled for **Tuesday, January 11, 2005, from 1:00 p.m. to 3:00 p.m., in One White Flint North, Room O-3B4**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is attached (Attachment 2).

If you have any questions prior to the meeting, please contact me at 301-415-2323 or John Zabko at 301-415-2308.

Attachments:
As stated

File No.: 8
Licensee: NUCON International, Inc.
Type of Action: Renewal
Date Issued: 5/5/03
License No.: 03225250036
Amendment No.: 3
License Reviewer: SD

File No.: 9
Licensee: Denison University
Type of Action: Termination
Date Issued: 9/26/02
License No.: 01129460000
Amendment No.: 1
License Reviewer: JD

File No.: 10
Licensee: Wyle Laboratories
Type of Action: Termination
Date Issued: 3/29/02
License No.: 03510460000
Amendment No.: 4
License Reviewer: JD

File No.: 11
Licensee: Dayton Testing Laboratory, Inc.
Type of Action: Termination
Date Issued: 7/21/03
License No.: 31210580010
Amendment No.: 2
License Reviewer: SD

File No.: 12
Licensee: Mallinckrodt, Inc.
Type of Action: Amendment
Date Issued: 10/23/04
License No.: 02500310002
Amendment No.: 8
License Reviewer: CC

File No.: 13
Licensee: Multi-Dimensional Imaging, Inc.
Type of Action: Termination
Date Issued: 3/22/04
License No.: 03214180000
Amendment No.: 1
License Reviewer: SD

File No.: 14
Licensee: Isomedix Operations, Inc.
Type of Action: Amendment
Date Issued: 10/6/04
License No.: 03521250028
Amendment No.: 3
License Reviewer: KB

File No.: 15
Licensee: Best Lighting Products, Inc.
Type of Action: New
Date Issued: 8/26/04
License No.: 03214460000
Amendment No.: 0
License Reviewer: WH

# APPENDIX E

## INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: BBC&M Engineering
Date of Incident: 9/14/04
Investigation Date: 9/14/04
License No.: 31210-25-0006
NMED Number: 04063
Type of Incident: Stolen Device
Type of Investigation: Phone, Written report

File No.: 2
Licensee: ABB, Inc.
Date of Incident: 5/14/04
Investigation Date: N/A
SS&D No.: OH-0109-D-121-B
NMED Number: N/A
Type of Incident: Equipment Failure
Type of Investigation: Phone, Written report

File No.: 3
Licensee: Ohmart/Vega Corp.
Date of Incident: 7/22/03
Investigation Date: N/A
SS&D No.: OH-0321-231-0036
NMED Number: 030631
Type of Incident: Leaking Source
Type of Investigation: Phone, Written report

File No.: 4
Licensee: The Cleveland Clinic
Date of Incident: 2/18/04
Investigation Date: 3/12/04
License No.: 02110-18-0013
NMED Number: 040178
Type of Incident: Medical Event
Type of Investigation: Inspection

File No.: 5
Licensee: University of Cincinnati (University Hospital)
Date of Incident: 5/10/04
Investigation Dates: 5/10-11/04
License No.: 02110-31-0010
NMED Number: 04032
Type of Incident: Medical Event
Type of Investigation: Inspection

File No.: 6
Licensee: Scott Process Systems, Inc
Date of Incident: 1/8/03
Investigation Date: N/A
License No.: 03320-77-0000
NMED Number: 030154
Type of Incident: Equipment Failure
Type of Investigation: Phone, Written report

File No.: 7
Licensee: Battelle Memorial Institute
Date of Incident: 0/1/04
Investigation Date: N/A
License No.: 03610-25-00001
NMED Number: 040767
Type of Incident: Leaking Source
Type of Investigation: Phone, Written report

File No.: 8
Licensee: Premcor Refining Group
License No.: 3120-10-20001
Date of Incident: 8/18/04
NMED Number: 040597
Investigation Date: 8/19/04
Type of Incident: Overexposure
Type of Investigation: Investigation, Inspection

File No.: 9
Licensee: Southwest General/Ireland Cancer Center
License No.: 02120-18-0001
Date of Incident: 12/22/03
NMED Number: 040003
Investigation Date: 12/29/03
Type of Incident: Medical Event
Type of Investigation: Investigation, Inspection

File No.: 10
Licensee: Solar Testing Laboratories, Inc.
License No.: 31210-18-0065
Date of Incident: 4/18/03
NMED Number: 030334
Investigation Date: N/A
Type of Incident: Stolen Device
Type of Investigation: Phone, Written report

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENTS IS INCLUDED FOR COMPLETENESS ONLY; MOST COMMENTS, SUCH AS INCONSISTENT S&SD REGISTRY ISSUANCE DATE ISSUE, HAVE BEEN DISCUSSED WITH THE BUREAU AND APPROPRIATE ACTIONS ARE EXPECTED.

File No.: 1
Registry No.: OH-0109-D-121-B
SS&D Type: (D) Gamma Gauge/(E) Beta Gauge
Manufacturer: ABB Inc.
Model No.: TG-4
Date Issued: 1/2/04
Type of Action: Amendment
SS&D Reviewers: KV, SD

Comments:

a) Format: Amended in Its Entirety was under Issuance Date instead of under the Title.
b) Inconsistent issuance date and review date, issued on 1/27/04, second reviewer signed on 2/9/04.

File No.: 2
Registry No.: OH-0522-S-900-S
SS&D Type: (T) Other
Manufacturer: Ohmart/VEGA
Model Nos.: LAB-23601(s), 111(s), 355(s), 244(s), 238(s), 454(s)
Date Issued: 1/2/04
Type of Action: Inactivation
SS&D Reviewers: KV, SD

Comment:
Inconsistent issuance date and review date, first reviewer signed 1/23/04, second reviewer signed on 1/2/04.

File No.: 3
Registry No.: OH-1211-D-101-G
SS&D Type: (W) Self Luminous Light Source
Manufacturer: Best Lighting
Model No.: SLXTU NCHYY
Date Issued: 7/13/04
Type of Action: New
SS&D Reviewers: KV, SD

Comment:
Inconsistent issuance date and review date, issued on 1/23/04, second reviewer signed on 1/26/04.

File No.: 4
Registry No.: OH-1075-D-102-S
SS&D Type: (B) Medical Radiography
Manufacturer: Hitachi Medical Systems
Model Nos.: Sceptre and ART Series
Date Issued: 1/21/03
Type of Action: New
SS&D Reviewers: KV, GC

Comments:
a) Inconsistent isotope authorization. On the first page isotope stated as Cs-137, however, attachment 1 provided labeling information for GE/GA-68.
b) Inconsistent radiation profile. In the text the maximum radiation level was for Cs-137, however, in attachment 2, the maximum radiation level was for Ge/Ga-68.

File No.: 5
Registry No.: OH-0522-D-114-B SS&D Type: (D) Gamma Gauge
Manufacturer: Ohmart/VEGA Model Nos.: MTDS Series
Date Issued: 8/6/04 Type of Action: New
SS&D Reviewers: KV, KB

Comment:
Inconsistent issuance date and review date, issued on 8/6/04, second reviewer signed on 8/9/04.

File No.: 6
Registry No.: OH-1090-D-104-B SS&D Type: (E) Beta Gauge
Manufacturer: Automation & Control Model No.: FAM-1
Date Issued: 8/26/04 Type of Action: Amendment
SS&D Reviewers: KV, KB

File No.: 7
Registry No.: OH-1189-D-101-B SS&D Type: (D) Gamma Gauge/(E) Beta Gauge
Manufacturer: SENTEK Corp. Model No.: TX-1
Date Issued: 5/30/04 Type of Action: New
SS&D Reviewers: KV, SD

Comment:
In attachment 3, “the actual size and color” was used. However, the color has been changed when the original was copied for the registration.

File No.: 8
Registry No.: OH-0522-S-108-S SS&D Type: (D) Gamma Gauge
Manufacturer: Ohmart/VEGA Model No.: A-58755
Date Issued: 7/31/01 Type of Action: Correction
SS&D Reviewers: KV, GC

File No.: 9
Registry No.: OH-0522-D-102-B SS&D Type: (D) Gamma Gauge
Manufacturer: Ohmart/VEGA Model Nos.: SH-x & SH-Fx Series
Date Issued: 7/31/01 Type of Action: Amendment
SS&D Reviewers: KV, GC

Comment:
a) Inconsistent issuance date and review date, issued on 7/31/01, second reviewer signed on 8/3/01.
b) Format: Amended in Its Entirety was under Issuance Date instead of under the Title.

File No.: 10
Registry No.: OH-1177-D-101-G SS&D Type: (E) Beta Gauge
Manufacturer: UPA technology Model No.: Micro-Derm
Date Issued: 3/9/04 Type of Action: Amendment
SS&D Reviewers: KV, SD

Comment:
When the registration was amended for the maximum activity, however, the maximum radiation level was not amended accordingly.

File No.: 11
Registry No.: OH-0522-D-110-B
Manufacturer: Ohmart/VEGA
Date Issued: 4/19/04

SS&D Type: (D) Gamma Gauge
Model No.: SHGL
Type of Action: Amendment
SS&D Reviewers: KV, SD

File No.: 12
Registry No.: OH-0104-D-104-S
Manufacturer Phillips Medical Systems
Date Issued: 4/8/04

SS&D Type: (B) Medical Radiography
Model No.: MOSAIC
Type of Action: Amendment
SS&D Reviewers: KV, SD

**ATTACHMENT**

December 14, 2004 Email from Michael Snee
Ohio's Response to Draft IMPEP Report

ADAMS: ML050030045

**Agenda for Management Review Board Meeting**
**January 11, 2004, 1:00 p.m. - 3:00 p.m., O-3B4**

1. MRB Chair convenes meeting. Introduction of MRB members, review team members, Ohio representatives, and other representatives participating through telephone bridge or video conferencing.

2. Consideration of the Ohio IMPEP Report.

   A. Presentation of Findings Regarding Ohio Program and Discussion.
      - Technical Staffing and Training
      - Status of Materials Inspection Program
      - Technical Quality of Inspections
      - Technical Quality of Licensing Actions
      - Technical Quality of Incident and Allegation Activities
      - Compatibility Requirements
      - Sealed Source and Device Evaluation Program

   B. MRB Consultation/Comments on Issuance of Report.
      - Adequacy and Compatibility Rating
      - Recommendation for Next IMPEP Review

   C. Comments

4. Status of IMPEP Reviews and Heightened Oversight/Monitoring Activities

5. Establishment of Precedents/Lessons Learned

6. Adjournment

Invitees:

Martin Virgilio, EDO
Paul Lohaus, STP
Jack Strosnider, NMSS
Karen Cyr, OGC
Steve Collins, IL
Robert E. Owen, OH
Josephine Piccone, STP
Osiris Siurano, STP
Linda McLean, R IV
Aaron McCraw, STP
Shawn Seeley, ME
James Lynch, R III
Xiaosong Yin, NMSS
John Zabko, STP

**ATTACHMENT 2**