

August 22, 2001

J. Nick Baird, M.D.
Director
Ohio Department of Health
246 North High Street
Columbus, OH 43266

Dear Dr. Baird:

On August 9, 2001, 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 Nuclear Regulatory Commission's program.

Section 5.0, page 12, of the enclosed final report presents the IMPEP team's single recommendation for the State of Ohio. We received your June 29, 2001 letter which described your staff's actions taken in response to the recommendation in the draft report. We request no additional information.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
for Materials, Research
and State Programs

Enclosures:
As stated

cc: Roger Suppes, Chief
Bureau of Radiation Protection
Ohio Department of Health

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

Richard M. Fry, North Carolina
OAS Liaison to the MRB

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cc: Roger Suppes, Chief
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bcc: Chairman Meserve
Commissioner Dicus
Commissioner McGaffigan
Commissioner Merrifield

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DCD (SP01)
PDR (YES√)

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STP-AG-31

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF OHIO AGREEMENT STATE PROGRAM

May 14 -18, 2001

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Ohio radiation control program. The review was conducted during the period May 14-18, 2001, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Georgia. 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 November 5, 1999, NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period August 31, 1999 to May 18, 2001 were discussed with Ohio management on May 18, 2001.

A draft of this report was issued to Ohio for factual comment on June 13, 2001. The State responded in a letter dated June 29, 2001. The Management Review Board (MRB) met on August 9, 2001 to consider the proposed final report. The MRB found the Ohio radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Ohio Agreement State program is administered by the Bureau of Radiation Protection (the Bureau), Division of Prevention, 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 702 specific licenses authorizing Agreement 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 indicators was sent to the Bureau on March 8, 2001. The Bureau provided a response to the questionnaire on April 19, 2001. A copy of the questionnaire response is included as Appendix G of the proposed final report and can be found on the NRC's Agencywide Documents Access and Management System (ADAMS) using the accession number ML011620625.

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 licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of five 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 non-common indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below, Status of Items Identified in Previous Reviews, is not applicable to the State as this was the initial program review. 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 recommendations. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The State of Ohio became an Agreement State on August 31, 1999. The Agreement includes byproduct material as defined in Section 11e.(1) and 11e.(2), source and limited quantities of special nuclear materials, low-level radioactive waste disposal (LLRW), and sealed source and device (SS&D) evaluations.

This was the initial program review. A management orientation meeting was held with the Bureau on June 7, 2000. The purpose of the meeting was to discuss the status of the program and the initial program activities following the transfer of authority. No attempt to evaluate the performance of the program was made at that meeting.

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) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

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

The review team's evaluation of the Bureau's inspection priorities revealed that inspection for each type of license were the same or more frequent than similar license types listed in the NRC Inspection Manual Chapter (IMC) 2800. Core licensees were inspected at intervals in accordance with frequencies consistent with IMC 2800 procedures. At the time of the review, there were no overdue inspections for core licensees. The Bureau is in the process of changing over from an ACCESS data base to a new Oracle data tracking system. The present ACCESS data tracking system is not able to capture or archive the inspection history of each licensee. The review team discussed the flexibility of the new Oracle data base to capture and maintain a history of the inspection dates for each licensee. This feature would enhance the Bureau's management of the inspection program by facilitating access and review of the inspection history of its licensees. Bureau management indicated that they believe the new data base system has these features and they will ensure that this capability is available to the Bureau.

The Bureau conducted 391 inspections since the effective date of the Agreement, and approximately 70 new licenses were issued during this time. Forty-two reciprocity inspections were conducted and more than 50% of the industrial radiography reciprocities were inspected during the review period. Initial inspections were generally conducted within 6 months of the new license approval/issuance date. The review team discussed with the staff the importance

of properly documenting in the inspection files justification whenever the initial inspection for a new licensee has been extended, such as the licensee does not yet possess any radioactive material. Inspectors were not consistently documenting this information in the file.

Of the 14 inspection files reviewed by the team, the response letter to the licensee regarding inspection results was sent within 30 days of the inspection date. Inspection finding letters to licensees were dated within 2 to 19 calendar days after the inspection date.

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.

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 14 radioactive materials inspections conducted during the review period. The casework included 11 of the Bureau's materials license inspectors, and covered inspections of various types including: medical (broad scope, private practice and institutional), mobile high dose remote afterloader (HDR), mobile nuclear medicine, teletherapy, nuclear pharmacy, industrial radiography, pool irradiator, portable and fixed gauges, and reciprocity (including source loading services) inspections. 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 casework, the review team noted that the routine inspections covered all aspects of the licensees' radiation programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that 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 performed when appropriate and for training purposes.

Inspection reports were signed by the appropriate supervisor and the Administrator Supervisory accompaniments were adequately documented in the inspection reports. Inspectors are qualified to perform a certain type of inspection once they have been accompanied by a Senior Health Physicist/Supervisor at least three times on that particular type of inspection. The inspectors's Supervisor must sign off for each area and for the overall final approval and qualification.

The inspection findings were appropriate and prompt regulatory actions were taken as necessary. The Bureau normally issues Compliance letters, Observations, or Notice of Violations, as it deems appropriate. Violations of minor safety or environmental concerns which are below the level of significance of Severity Level IV are documented in the inspection report and issued to the licensee as a letter of Observations. The licensee is required to respond to the noted Observations within 30 days. An administrative penalty is assessed with a Notice of Violations. A "General Statement of Policy - Enforcement Actions" procedure has been established and implemented which explains the enforcement program.

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 Services Unit is responsible for sending survey instruments out to the Ohio Emergency Management Agency for calibration and repairs, however, the multichannel analyzers are sent to the manufacturer for servicing. The Department's Laboratory performs sampling analysis for the Bureau, as needed.

Five Bureau inspectors were accompanied during inspections by a review team member during the week of April 30, 2001 through May 4, 2001. Inspection accompaniments included: medical institution/HDR, nuclear pharmacy, fixed industrial radiography, and pool irradiator. These accompaniments are identified in Appendix C.

During the accompaniments, each inspector demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance based inspections. The inspectors were trained, prepared, and thorough in their audits of the licensees' radiation safety programs. Overall, each inspector utilized good health physics practices, their interviews with licensee personnel were performed in an effective manner, and their 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.

3.3 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 responses relative to this indicator, interviewed Bureau management and staff, and considered any possible workload backlogs.

The Bureau desires that all technical staff have the equivalent of a bachelor's degree in the sciences. The personnel regulations did not allow the Bureau to require a bachelors degree. The new class plan currently being processed in the personnel office would require a bachelors degree. The technical staff positions are classified as Health Physicist I, II, or III.

The Bureau, headed by the Bureau Chief, has approximately 702 licenses with a total of 23.5 full time equivalent (FTE) assigned to implement the materials licensing and inspection program. The Bureau is divided into four sections: Nuclear Material Safety Section; Environmental Radiation Safety Section; Technical Services Section; and X-ray Section. Each Section is managed by an Administrator. The Nuclear Materials Safety Section has the medical and the non-medical programs managed by program supervisors. This included the routine licensing and inspection of most of the materials facilities. The Environmental Radiation Section has the radiological assistance program and the decommissioning program is managed by program supervisors. The decommissioning program conducts license terminations and partial site releases including the contaminated sites transferred from NRC. The Technical Services Section conducts the SS&D evaluations with assistance from staff in the other sections. The Agreement State program is implemented by the Nuclear Material Safety Section, a portion of the decommissioning program in the Environmental Radiation Safety Section, and the Technical Services Section. Technical staff perform both inspection and licensing functions.

The Bureau has had limited staff turnover. Since entering into the Agreement, three staff members have left the program and three staff members have been hired. There are currently two vacant positions in the materials program with an additional position that became vacant on June 15, 2001. Vacant positions are quickly posted. The Office of Personnel is evaluating the candidates for the first two vacancies. A request for posting has been sent to the Office of Personnel for the other position. In addition, the Bureau has submitted a reclassification plan for the Bureau staff to the Office of Personnel. This plan would provide an increase in the overall salary scale as well as additional career opportunities within current grade structure. The Bureau request also included two additional positions (one for regulation and guidance development, one for training and quality assurance activities). As part of this plan, the Bureau began a revision of the training and qualification requirements. The Bureau is fully supported by fees and has had ample funding for training and travel needs.

The Bureau has a documented training and qualifications program for technical staff that is modeled after NRC's IMC 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Area." The technical staff is well qualified from an educational and experience standpoint. Staff has attended the basic courses as part of the transition to an Agreement State. The Bureau staff has a wide variety of work experience in licensed facilities which has helped the Bureau. The review of staff training documentation was difficult because the different Bureau sections kept different records to demonstrate staff qualification. Also, in the Nuclear Materials Safety Section there were many pages of qualifications with no clear supervisor approval that the individual had met the minimum qualification. The review team discussed and the Bureau management agreed to consider the desirability of establishing consistent summary documentation for staff qualifications as part of the revision to the training requirements discussed above.

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.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 18 specific licenses. Licensing actions were evaluated for thoroughness, completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality.

Casework was evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, or other supporting documents, consideration of enforcement history on renewals, peer or supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and supporting data. Pre-licensing visits are conducted for broad scope licensees and radiography licensees adding new vaults to their facility. For medical licensees, the pre-licensing visit is dependent upon the scope of the licensing request.

The licensing casework was selected to provide a representative sample of licensing actions which were completed during the review period. The sampling included the following types: HDR (including mobile); medical (broad scope, private practice and institutional); broad scope

research and development; mobile nuclear medicine; broad scope manufacturing and distribution; fixed gauges; industrial radiography; and portable gauges. Types of licensing actions included three new licenses, five renewals (including one denial and one exemption), six amendments, and four terminations (including one bankruptcy and one partial site decommissioning of a facility). A list of the licenses evaluated with case-specific comments can be found in Appendix D.

The licenses transferred from NRC to the Bureau are being reissued as Department licenses when the licensee requests the combination of their existing NARM (Naturally-Occurring and Accelerator-Produced Radioactive Material) license and the transferred NRC byproduct material license, or when the transferred NRC byproduct material license is renewed in its entirety.

It was noted that in nearly all of the licensing actions reviewed, a pre-existing NRC license was available for use as the basis for the Department license. For those actions which did not involve a transferred NRC license, appropriate Bureau review procedures were followed and checklists were used, as appropriate.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were almost always clearly stated, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. Program staff followed appropriate licensing guides to ensure that licensees submitted information necessary to support their license requests. No potential health and safety issues were identified.

The team noted the desirability of retaining records of telephoned deficiencies or secondary deficiency letters in the license files. Also, in several casework reviews, the Bureau license reviewer was not documented or the supervisory sign off not documented. The review team discussed these two issues with the Bureau staff and they indicated that they would consider them.

In discussions with the Decommissioning Program Supervisor, it was noted that the decommissioning program is responsible for all license terminations, decommissioning including partial decommissioning, contaminated sites (such as the Site Decommissioning Management Plan (SDMP) sites that were transferred from NRC to the Bureau), and future licensing of decontamination service providers and waste processors. The Bureau issued each of the transferred SDMP sites a decommissioning license, except for the Horizons, Inc. site, which did not have an NRC license, and is being managed in a similar manner by the Bureau. The Chevron/Harshaw site was transferred to the Formerly Utilized Sites Remedial Action Program (FUSRAP) for remediation by the Army Corps of Engineers.

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 Response to Incidents and Allegations

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 eight incidents. A list of the incident casework with comments is included in Appendix E. The team reviewed the Bureau's response to the 18 allegations received during the review period involving radioactive materials including eight 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.

Responsibility for initial response and follow-up actions to material incidents and allegations rests with the Bureau staff. When the Bureau is notified of an incident during working hours, the assigned "Officer of the Week" takes the incoming notification and briefs the responsible Supervisor, Administrator, and/or the Bureau Chief to determine the approach to be taken regarding the incident. The Department provides a 24-hour emergency number for anyone to use to report emergencies involving hazardous materials. When a radiological incident is reported after work hours, Bureau staff are contacted at home.

The review team found good correlation of 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 ten reported incidents during this review period. The review team identified, through discussions with Bureau staff, an additional incident that was listed as an allegation which needed to be included in the NMED system.

The eight incidents selected for evaluation included one medical event with five misadministrations at a facility, three events involving lost/stolen gauges, one reported damaged portable gauge, one reported loss of control of radioactive material, one event involving contaminated scrap at a non-licensee facility, and one event involving exposure to a member of the public during a radiography incident.

The review of incident casework, licensing casework, and interviews with staff revealed that incidents are promptly evaluated for the need for on-site investigations. For those incidents not requiring on-site investigations, copies of letters to licensees were in the incident and licensing files indicating that the incident would be investigated during the next scheduled inspection. In response to incidents, the Bureau took prompt, appropriate action in all but one case. The evaluation of casework indicated that incident reports were thorough and well-documented. The incident reports were reviewed and signed by the appropriate level of management. The review team noted that one incident had been originally classified as an allegation and several deficiencies were identified by the review team with respect to this incident. These were discussed with the Bureau staff as is noted in Appendix E. The review team concluded that the root cause of these deficiencies was a lack of written procedures and guidance on handling of incidents at this facility. In their Program Description for the Agreement Application, the Bureau previously identified the need for such a procedure and had committed to develop it. The review team discussed the need for the Bureau to place a high priority on developing and implementing a written procedure on handling of incidents.

The evaluation of the 18 allegation cases indicated that the Bureau took prompt and appropriate action in response to the alлегers' concerns. Further review of the casework and a

staff interview determined that the Bureau did provide feedback to allegeders either verbally or in writing. The Bureau drafted an allegation procedure that was going through management examination at the time of the review. 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, Response to Incidents and Allegations, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Ohio's Agreement covers the SS&D evaluation, LLRW disposal, and uranium recovery programs. However, Ohio does not have any licenses or activity in the LLRW disposal or uranium recovery programs so only the first two non-common performance indicators were applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

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 legislation affecting the radiation control program was passed since being found adequate during the review to become an Agreement State. The Public Health Council approved modifications to rule 3701-38-02.1. This rule establishes fees for the radioactive materials program. As required by Ohio Law, the Joint Committee on Agency Rule Review (JCARR) reviewed the rules.

4.1.2 Program Elements Required for Compatibility

The Ohio Regulations for Control of Radiation, found in Section 3701-38 and 3701-39 of the Ohio Administrative Code apply to all ionizing radiation, whether emitted from radionuclides or devices. Ohio requires a license for possession, and use, of all radioactive material including Atomic Energy Act materials and NARM. Ohio also requires registration of all devices that emit radiation.

The review team examined the procedures used in the Department's regulatory process and found that regulations are developed by the staff with a committee of the Radiation Advisory Council and the regulated community. The regulations are posted on the Department web site with a 60-day comment period. The comments received are evaluated and the regulations revised and submitted to the Radiation Advisory Council for a recommendation to adopt. Following this recommendation, the formal rule adoption process begins with submittal to the Public Health Council (PHC) which will place it on their calendar, hold a hearing, and then

submit them to the JCARR. After JCARR completes its review of a proposed rule and takes no action against the rule, the PHC is able to take final action 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 responses to the questionnaire, 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) Regulation Assessment Tracking System. Since the Department incorporated NRC regulations by reference as of October 8, 1998, there were no regulations overdue at the time of the review. The Department is in the process of adopting specific Ohio regulations to replace the NRC regulations adopted by reference.

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

- "Transfer for Disposal and Manifest; Minor Technical Conforming Amendments," 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 1998.
- "Radiological Criteria for License Termination of Uranium Recovery Facilities," 10 CFR Part 40, Appendix A amendment (64 FR 17506) that became effective June 11, 1999.
- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543) that became effective February 2, 2000.
- "Energy Compensation Sources for Well Logging and Other Regulation Clarification," 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000.

Ohio has begun the process of adopting Ohio specific regulations to replace the referenced NRC regulations. They have submitted two regulation packages to NRC for review. The NRC comment letter for the first package was sent to the Bureau the week of the on-site review. The second letter was issued on June 11, 2001. The Bureau Chief anticipates that these regulations will be finalized by the end of July 2001. The Bureau plans to update the effective date of the incorporation by reference during the July 2001 rulemaking process; therefore, the rules listed above will be included in the Ohio Administrative Code by reference.

Based on the IMPEP evaluation criteria, the review team recommends that Ohio's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

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

In assessing the Bureau's SS&D evaluation program, the review team examined information provided by the Bureau in response to the IMPEP questionnaire on this indicator. A review of selected new, amended, and inactivated SS&D evaluations and supporting documents covering the review period was conducted. The team observed the staff's use of guidance documents and procedures, interviewed the staff involved in SS&D evaluations and the Technical Services Section Administrator who has supervisory responsibility for the SS&D program, and verified

the use of regulations and license conditions to enforce commitments made in the applications.

4.2.1 Technical Quality of the Product Evaluation Program

The review team reviewed all registration certificates issued for the review period. The six SS&D registration certificates issued by the Bureau and evaluated by the review team are listed with case-specific comments in Appendix F.

Analysis of the casework and interviews with staff confirmed that the Bureau follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, issued in September 1997. All pertinent American National Standards Institute standards, Regulatory Guides, and applicable references were confirmed to be available and were used when performing SS&D reviews.

The registration certificate background 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 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. Registration certificates summarize the product evaluation and provide license reviewers with adequate information to license the possession and use of the product.

Overall, the quality of the evaluations was good, but the review team identified and discussed with the staff several deficiencies in the files. For example, the section entitled "Safety Analysis Summary" in the Ohio registration certificates contained text that applied to both specifically and generally licensed devices regardless of the type of device. Certificates should contain only those requirements that are unique to the regulatory requirements for the type of device. The review team traced this deficiency to NUREG-1556, Vol. 3 which provides examples of safety analysis summary statements for registration certificates, but does not clearly distinguish between the statements for generally licensed devices versus specifically licensed devices. Ohio followed the guidance in NUREG-1556, Vol. 3 as they understood it and included the summary statements for both types of devices in each sheet. The review team believes that this guidance is potentially misleading. This issue was discussed during the MRB meeting on August 9, 2001. The MRB recommends that NRC staff revise NRC guidance so that the differences between safety analysis summary documentation for certificates for specifically licensed versus generally licensed devices is clarified.

The review team identified weaknesses in documentation in all six cases reviewed. The review team discussed the benefits of, and need for, the SS&D sheets being in a consistent format and that the Bureau may want to issue corrected sheets to address the weaknesses identified in Appendix F. During the exit meeting with the staff and management, the review team noted that the deficiencies were discussed with the Bureau's technical staff.

4.2.2 Technical Staffing and Training

Presently, there are five staff members involved in the SS&D evaluation program. The Technical Services Section Administrator has the program responsibility for the SS&D program. The technical reviewers are either in the Technical Services Section or the Non-medical

program in the Nuclear Materials Safety Section. Two staff members are fully qualified and have performed either the first reviews, or the concurrence reviews for the six SS&D actions completed by the Bureau. Two newly hired staff members are health physicists and one has a masters of science degree in nuclear engineering. They have recently attended the NRC's SS&D training workshop and a two-day, on-the-job training session at the State of Illinois to supplement their academic education.

The review team could not identify the qualification requirements for the new SS&D staff other than the general statements of meeting the reviewer requirements in MD 5.6. The minimum number and the types of case work should be formally established before a person is qualified to sign the registration certificates. Given the small number of SS&D reviews conducted by the Bureau, the review team discussed potential training in the form of actual reviews that could be obtained through working with other SS&D reviewers at the NRC or other Agreement States. The review team recommends that the Bureau develop formal training and qualification requirements for SS&D reviewers.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Two incidents or defects related to SS&D issues were reported to the Bureau during the review period concerning the devices registered by the Bureau and are noted in Appendix E. There were no generic design or performance issues identified from the review of SS&D incident files and documentation.

Based on the IMPEP evaluation criteria, the review team recommends that Ohio's performance with respect to the indicator, SS&D Device 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 that Ohio's performance to be satisfactory for all performance indicators reviewed. Accordingly, the review team recommended and the MRB concurred in finding the Ohio Agreement State program to be adequate and compatible with NRC's program. Based on the results of the current IMPEP review, the next full review will be in approximately four years.

Below is the single recommendation, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State. An additional recommendation was made for the NRC during the August 9, 2001 MRB meeting.

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)

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 is clarified. (Section 4.2.1)

LIST OF APPENDICES AND ATTACHMENTS

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 & Device Casework Reviews
Attachment	June 29, 2001 Letter from Dr. J. Nick Baird Ohio's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Dennis Sollenberger, STP, NRC	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility
Cynthia Sanders, Georgia	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Jacqueline Cook, Region IV, NRC	Technical Quality of Licensing Actions
Darrel Wiedeman, Region III, NRC	Response to Incidents and Allegations
Seung Lee, MSIB, NMSS, NRC	Sealed Source and Device Evaluation Program

APPENDIX B
OHIO
DEPARTMENT OF HEALTH
and
BUREAU OF RADIOLOGICAL PROTECTION

ORGANIZATION CHARTS
ML011630376

**Governor of Ohio
Robert Taft**



**Director of Health
J. Nick Baird, MD**



**Anne Harnish,
Assistant Director**

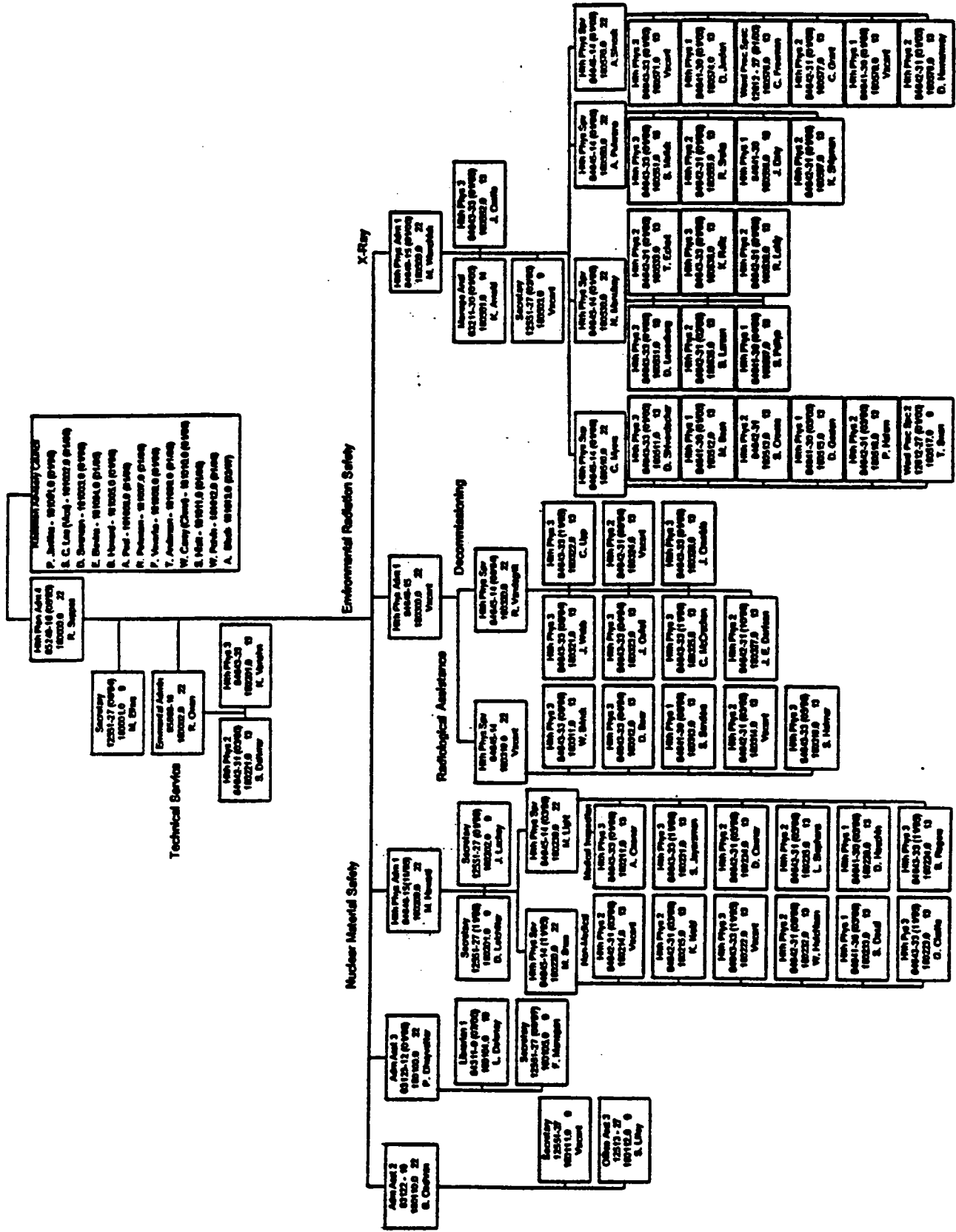


**Division of Prevention,
Deborah Arms, RN, PhD.**



**Bureau of Radiation Protection
Roger L. Suppes**

Prevention - Bureau of Radiation Protection



Attachment

June 29, 2001 Letter from Dr. J. Nick Baird
Ohio's Response to Draft IMPEP Report

ML011910388

OHIO DEPARTMENT OF HEALTH

246 North High Street
Post Office Box 118
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BOB TAFT
Governor
J NICK BAIRD, M.D.
Director of Health

01 JUL 10 AM 9:30

OSP

June 29, 2001

Paul Lohaus, Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Lohaus:

I am writing in response to your draft report concerning Ohio's Agreement State Program that is administered by the Bureau of Radiation Protection in the Division of Prevention. The department is very pleased with the draft report and your proposed recommendations that Ohio's Agreement State Program "be found adequate to protect public health and safety and compatible with NRC's program." The department is also pleased that the common and non-common performance indicators for Ohio's program have all been found as satisfactory.

There are some factual matters that I would like to point out for your consideration:

1. In paragraph 4.1.1 Legislation The last sentence of the paragraph indicates that the legislature approved a new fee schedule for the Bureau. The authorization for fee schedules for the radioactive materials program is the Public Health Council. It is recommended that the sentence is deleted and a new sentence is inserted that states: The Public Health Council approved modifications to rule 3701-38-02.1. This rule establishes fees for the radioactive materials program. As required by Ohio law, the Joint Committee on Agency Rule Review reviewed the rules.
2. In paragraph 4.1.2 the rule adoption process for Ohio is summarized. The name of the legislative body that reviews administrative rules is incorrect. The correct name is Joint Committee on Agency Rule Review (JCARR). In that same paragraph it is suggested that the last two sentences be deleted and the following sentences be inserted—After JCARR completes its review of a proposed rule and takes no action against the rule, the Public Health Council is able to take final action 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.

In regard to the SS&D activities specified in paragraph 4.2.1 of the report, the Bureau has reviewed the items identified in Appendix F of the draft report and plans to issue revised registration certificates to correct these items and/or make changes to file information as appropriate if revisions to certificates of registration are unnecessary. The Bureau also plans to revise the registration sheet so that sheets issued on and after August 31, 2001, are consistent with the NRC format. The Bureau plans to issue corrected registration sheets by August 31, 2001.

In paragraph 4.2.2, the draft report notes those qualification requirements for the new SS&D staff "other than the general statements of meeting the reviewer requirements in Management Directive 5.6 could not be identified." The Bureau plans to establish requirements regarding the specific minimum number and types of case work that are required before a person is determined qualified to sign registration certificates. The qualification requirements will include, to the extent necessary, training and working with SS&D reviewers at NRC and /or other agreement states. The Bureau plans to have these requirements in place by August 31, 2001.

The Bureau is revising its overall training program to provide sign-off sheets for each employee in the agreement state program. Each employee's supervisor will retain the sign off sheets. The sheet will indicate what areas the employee is deemed competent. The Bureau's Training Program will be revised to include these provisions by August 31, 2001.

Roger Suppes will represent the department at the Management Review Board meeting. Please contact him regarding any necessary travel arrangements. The department would also like for NRC to establish a video or teleconference for other Ohio program management staff to participate in the Management Review Board meeting if that is possible.

If you should have any questions regarding the responses in this letter, please contact Roger Suppes at 614-644-2727.

Sincerely,



J Nick Baird, MD
Director of Health

PC: Dennis Sollenberger, NRC
Carol O'Claire, State Liaison Officer
Roger Suppes

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