



## Department of Health Radiation Protection Audit

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**Audit Period: January through June 2017**

### Results Summary:

Objective	Conclusion
Agreement State Program Licensing	Improvement Needed
X-ray Program Radiologic Licensing and Inspection	Improvement Needed

Refer to Appendix A for classification of audit objective conclusions.



## **Executive Summary**

### **Background**

Within the Ohio Department of Health's (ODH) Office of Health Assurance and Licensing is the Bureau of Environmental Health and Radiation Protection. The Bureau of Environmental Health and Radiation Protection regulates the possession, use, handling, storage and disposal of radiation sources in order to maintain the radiation dose as low as reasonably achievable to the general population. Radiation Protection programs are comprised of three program areas, Agreement State, X-ray and Radiological Health and Safety.

The Agreement State Program licenses all handlers of radioactive materials not under the jurisdiction of the federal government and provides regulatory oversight throughout operation and license termination for radioactive materials users, facilities and organizations in Ohio other than nuclear power plants and certain government facilities, which are under federal jurisdiction. During the period January through June 2017, the program processed 225 applications to amend, renew, and terminate licenses.

ODH issues radiologic licenses for the following: Radiographer, Nuclear Medicine Technologist, Radiation Therapist and General X-ray Machine Operator. The Radiologic Licensure program ensures standards of knowledge and skill for operators who apply radiation to humans for diagnostic and therapeutic purposes. The program is funded by initial license application fees, renewal fees and educational provider fees. The X-ray Program is responsible for inspecting facilities that use x-ray equipment and businesses that install x-ray equipment in Ohio. Health physic inspectors travel throughout Ohio performing inspections on approximately 7,300 x-ray machines at 3,300 facilities annually. During the period January through June 2017, the program processed 3,181 applications for initial and renewal licenses and performed 1,337 inspections.

During the audit, OIA identified opportunities for ODH to strengthen internal controls and improve business operations. OIA conforms with the *International Standards for the Professional Practice of Internal Auditing*. OIA would like to thank ODH staff and management for their cooperation and time in support of this audit.

This report is solely intended for the information and use of agency management and the State Audit Committee. It is not intended for anyone other than these specified parties.



## **Scope and Objectives**

OIA staff was engaged to perform an assurance audit related to the controls over the agency's radiation protection licensing and inspection processes. This work was completed July through September 2017. The audit period was January through June 2017. The scope of this audit included the following Radiation Protection Programs:

- Agreement State Program
- X-ray Program

The following summarizes the objectives of the review:

- Evaluate the design and effectiveness of controls for the Agreement State Program licensing processes.
- Evaluate the design and effectiveness of controls for the X-ray Program radiologic licensing and inspection processes.

## **Detailed Observations and Recommendations**

The Observations and Recommendations include only those risks which were deemed high or moderate. There were no low risk observations.



## Observation 1 – Agreement State License Application Reviews

An effective system of internal controls includes clear documentation of work to be performed and supervisory review of work performed to ensure processes are accomplished completely, accurately, timely, and consistently. The reviews and results should be documented and any issues should be communicated to staff to provide assurance that procedures are followed and to ensure issues are addressed.

Per the Ohio Administrative Code § 3701:1-38-02(D)(5), ODH shall grant a new license, license amendment, or license renewal to any applicant who has submitted a complete application and is in compliance with Chapter 3748 of the Revised Code and the rules adopted thereunder. Per Ohio Revised Code (ORC) § 3748.01(K), "Inspection" means an official review, examination, or observation, including, without limitation, tests, surveys, and monitoring, that is used to determine compliance with rules, orders, requirements, and conditions of the department of health.

The Agreement State program documents results of the license applications reviews as part of the Quality Assurance/Quality Control (QA/QC) Checklist within the RADMAT licensing database. However, there is no clear documentation in the QA/QC Checklist to indicate a review of inspection files was performed as part of the license application review process. Per ODH management, reviews of inspection files are performed as part of inspection processes.

After completion of the review of the license application by the License Reviewer, the license application is assigned in RADMAT to the Supervisor for review. The Supervisor completes a review of the license application and work performed by the License Reviewer, completing the Supervisor portion of the QA/QC Checklist to evidence their review. However, for 21 of 23 (91%) licenses tested that were issued during the period January through June 2017, the Supervisor did not complete the QA/QC Checklist to document their reviews of the license applications.

Supervisor reviews that are not documented do not provide management with assurance that staff work is complete and accurate. The lack of a documented review control activity can also increase the likelihood of a license issuance without a review of the license documents and inspection records to ensure compliance with regulations.

### Recommendation

Update the QA/QC Checklist to specifically document inspection reviews for timeliness of completion and to identify outstanding inspection issues as part of the application review process. Ensure supervisory reviews and all the steps of the QA/QC Checklist are completed and documentation is maintained within RADMAT. Implement a quality assurance process to perform a review of a sample of license applications to ensure License Reviewers and Supervisors complete and document all work performed.



**Management Response**

The Quality Assurance/Quality Control process for license review has been completely revised, and includes the use of two new forms to replace the old QA/QC Checklist.

A new “*Radioactive Material License QA CHECKLIST*” has been developed as a single-page form. This document includes the recommendation adding specific language regarding license reviewer evaluation of the licensee’s inspection history during license reviews.

The second form addresses those parts of the license review process related to enhanced security of radioactive materials as applicable. This “*Checklist to Ensure That Radioactive Materials Will Be Used as Intended*” incorporates those portions from the previous QA/QC Checklist with changes mandated by the US Nuclear Regulatory Commission for these types of license reviews. Completion will be as a one-page OHIO SHORT FORM or five-page OHIO LONG FORM, dependent on the licensee’s application.

These two new forms are in a pdf-fillable format, which will make it easier for completion and attachment within RADMAT. This format also permits digital signatures and allows the Supervisor to “lock” the documents upon completion and final signatures.

Staff and Supervisors have been instructed to complete and sign a *QA CHECKLIST* **and** either a *SHORT FORM* or *LONG FORM* (as applicable) for every licensing action. This will be verified as part of the Agreement State Program Administrator’s final review prior to submission of licenses for signature.

Risk*	Remediation Owner	Estimated Completion Date
Moderate	Agreement State Program Administrator	December 2017

**Observation 2 – X-ray License Applications**

In accordance with ORC Chapter 4773, the Bureau of Environmental Health and Radiation Protection (the Bureau) issues licenses to individuals seeking to practice as a general x-ray machine operator, radiographer, radiation therapy technologist and nuclear medicine technologist. Initial applicants are required to submit proof of education and proof of passing the appropriate exam or an active ARRT (American Registry of Radiologic Technologists), along with a \$65 application fee. Renewal applicants are required to submit proof of twelve hours of continuing education or an active ARRT membership, along with a \$45 application fee. The Bureau typically receives license applications and the fees online via the X-ray Licensure system. The licensure reviewer evaluates and approves applications within the X-ray Licensure system.



Preventive and detective controls, including a system designed to restrict approvals without input of all required information and documented secondary supervisory review processes, help to ensure appropriate license approval and fee collection. During the period January through June 2017, the Bureau approved 3,181 license applications. The licensure supervisor indicated “spot checks” are sporadically performed over approved license applications; however, there is no set criteria or quantity of applications to spot check, nor is any documentation maintained. In addition, the X-ray Licensure system may allow approval of a license without payment and/or completion of all sections of the application. One of 25 (4%) approved applications tested had the ARRT membership information noted in the ‘Requirements’ tab; however, ARRT membership information was not noted in the ‘Credentials’ tab in the X-ray Licensure system. The membership information is required to be noted in both tabs in the system. Upon viewing the ARRT website, OIA verified the applicant’s membership is active; therefore, while this should have been documented in the ‘Credentials’ tab in the X-ray Licensure system, the renewal of the license was valid.

Failure to perform secondary reviews increases the likelihood for inappropriately issued licenses. Lack of documented secondary reviews increases the likelihood that reviews are not performed and does not provide management assurance of the accuracy of staff application reviews. Lack of system controls increases the likelihood that license applications are approved without accurate payment and/or with missing required information, which is particularly elevated due to the lack of documented secondary reviews.

### Recommendation

Develop and implement periodic supervisory review procedures for supervisors to perform over a sample of approved license applications. Ensure supervisory reviews are completed from a sample of every employee’s approved applications. Document the results of the supervisory review and any subsequent error resolution or necessary staff corrective action. Use results of supervisory reviews to identify training needs.

Develop and implement formal policies and procedures to outline the periodic supervisory review process, including roles and responsibilities, application selection methodology, documentation standards and corrective action criteria.

Enhance the X-ray Licensure system functionality to prevent approval of license applications if the correct payment has not been received and/or if key required information is missing.

### Management Response

To improve the design and controls of the X-ray Program – Radiologic Licensing and Inspection Processes, ODH will do the following:



Supervisor Review: The supervisor shall review five license application records from each day and record the results of the reviews in Microsoft Excel, on a weekly basis. This review will result in the evaluation of 25 records weekly. The documented review will record the license approval date, name of approver, license number, license type, required fields check, any errors and documented corrective actions. Collecting information from each day ensures that every person approving licenses are evaluated to identify and correct individual errors. Also, this data will be used to identify training needs for the group. Sampling method – a stratified sampling of the approved licenses will be used to ensure samples are pulled from mutually exclusive groups, so data are collected from Radiographers, Nuclear Medicine Technologists, Radiation Therapists and General X-ray Machine Operators. A random sample will then be drawn from the exclusive groups.

Fee and Other Required Fields: The supervisor documented review will increase the confidence of accurate payment information. ODH will also explore (pending other department priorities including funding, etc.) conducting an IT project to make changes to certain fields and eliminate duplicate data entry for credentials within the system used for approving licenses, the Radiologic Licensing Software System. ODH will also explore (pending other department priorities including funding, etc.) conducting an IT project to enhance the automation between ODH’s Accounts Receivable system and the Radiologic Licensing Software System.

Risk*	Remediation Owner	Estimated Completion Date
<b>Moderate</b>	Chief of Office of Environmental Health and Radiation Protection	December 2017

\*Refer to Appendix A for audit observation classification ratings.

Due to the limited nature of our audit, we have not fully assessed the cost-benefit relationship of implementing the observations and recommendations suggested above. However, these observations reflect our continuing desire to assist your department in achieving improvements in internal controls, compliance, and operational efficiencies.



Appendix A – Classification of Conclusions and Observations

**Classification of Audit Objective Conclusions**

Conclusion	Description of Factors
<b>Well-Controlled</b>	The processes are appropriately designed and/or are operating effectively to manage risks. Control issues may exist, but are minor.
<b>Well-Controlled with Improvement Needed</b>	The processes have design or operating effectiveness deficiencies but do not compromise achievement of important control objectives.
<b>Improvement Needed</b>	Weaknesses are present that compromise achievement of one or more control objectives but do not prevent the process from achieving its overall purpose. While important weaknesses exist, their impact is not widespread.
<b>Major Improvement Needed</b>	Weaknesses are present that could potentially compromise achievement of its overall purpose. The impact of weaknesses on management of risks is widespread due to the number or nature of the weaknesses.

**Classification of Audit Observations**

Rating	Description of Factors	Reporting Level
<b>Low</b>	Observation poses relatively minor exposure to an agency under review. Represents a process improvement opportunity.	Agency Management; State Audit Committee (Not reported)
<b>Moderate</b>	Observation has moderate impact to the agency. Exposure may be significant to unit within an agency, but not to the agency. Compensating controls may exist but are not operating as designed. Requires near-term agency attention.	Agency Management and State Audit Committee
<b>High</b>	Observation has broad (state or agency wide) impact and possible or existing material exposure requiring immediate agency attention and remediation.	Agency Management and State Audit Committee