INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
QUESTIONNAIRE RESPONSES

Reporting Period: July 17, 2021 to August 25, 2022

A. GENERAL

1. Please prepare a summary of the status of the State's or Region's actions taken in response to each of the open recommendations from previous IMPEP reviews.

   Recommendation 1: Maryland will review the qualification of all Radiation Safety officers, Authorized Users, and Authorized Medical Physicists listed on their medical licenses to ensure that they meet the qualifications in accordance with Maryland's regulations for medical use of byproduct material.

   Status: The Radiological Health Program (RHP) staff is in the process of evaluating all Radiation Safety Officers (RSOs), Authorized Users (AUs), and Authorized Medical Physicists (AMPs) listed on medical licenses. To allow for staff to continue to process incoming licensing actions and advance in training, we are currently evaluating the qualifications for the licensees as amendments or renewals are submitted.

   An exhaustive review of the regulations and NUREG guidance was conducted to ensure proper understanding of the qualification requirements. These requirements have also been reviewed with new staff. Additionally, RHP maintains communication with NRC as needed for guidance, clarification, and input on specific situations.

   This qualifications check is very extensive and can take anywhere from one hour to several days of work to search through old license files for historical documents. Currently, two of the four licensing staff members are able to independently complete a qualifications review and are in the process of training the newer staff members. Licensees have also had to wait several months to obtain copies of original board certificates for RHP review. We have found that the most common issues result from incorrectly filled out attestation forms or missing historical documents within files.

   In circumstances where it has been determined that the RHP does not have sufficient documentation for an individual, the licensee is contacted and required to submit updated or missing information. The licensee is provided with a detailed description of the deficiency and what is required to resolve the issue. If the licensee is unable to provide such documentation for a specified individual, they are removed from the license and/or their approved uses are adjusted to accurately reflect their approved qualifications. On several occasions, the licensees have chosen to remove an individual from a license rather than search for previously provided attestations that were not on file with the RHP, go through the lengthy process of requesting an official board certificate (as a Maintenance of Certification certificate is not acceptable for these purposes), or re-do an incorrectly filled out attestation form.

At this time, approximately 40% of the more than 250 medical licensees have had all listed individuals evaluated and determined to be sufficiently qualified. Another 10% have been partially evaluated and/or are awaiting submission of documentation from licensees. Since the beginning of the review period, only a handful of individuals have been found to lack the necessary qualifications and have been removed from a license. Of those affected licenses, there have been no incidents, such as misadministrations, and the licensees are in good standing. If we continue at this review pace, we anticipate completion of *all* medical licenses in about 2 years. We note that this qualification review, due to it being raised as an issue needing attention only during the most recent IMPEP, involves correcting a deficiency that has existed for decades. As such, it will take some time to fully correct. The approach and time frame laid out above seem reasonable in our eyes considering the circumstances.

Recommendation 2: Maryland will develop and implement a procedure to ensure protection of sensitive information as it applies to written correspondence with licensees.

Status: RHP has developed "Sensitive/Confidential Document Handling Procedures" (Attachment A), which were effective as of October 18, 2021. Additionally, staff has been provided with stamps so that incoming documents can be appropriately marked.

B. COMMON PERFORMANCE INDICATORS

I. Technical Quality of Licensing Actions

1. How many specific radioactive material licenses does your program regulate at this time?

As of July 21, 2022, there are 505 active licenses.

2. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification, or renewed in this period.

- **MD-15-007-02 Terumo submitted an amendment to request 5-year extension of source use as the end useful life is approaching. Amendment request was approved.**
- **MD-07-232-01 Maryland Proton Treatment Center (complex license with financial assurance) renewal issued 9/7/2021.**
- **MD-0600-D-101-B Shimadzu SS&D amendment required secondary review from another Agreement State.**
- **MD-1362-D-101-S Xcision GammaPod amendment required secondary review from another Agreement State.**

- **MD 31-025-04 and 31-025-05 Neutron Products Inc. renewal applications are currently being evaluated. The complexity of these renewal applications requires extensive evaluation.**

3. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

- **Variance in licensing policy for Terumo license number 15-007-02. Licensee requested a 5-year extension of source use beyond approximate useful life as indicated in the SS&D registration. The licensee performed a radiation safety evaluation of the irradiator system to demonstrate that extended use would not have any negative effect on radiation safety. The report was reviewed and approved by the Department. Note: the useful life of the source ends in 2023, and the licensee plans to exchange the source at that time. This extension request was out of an abundance of caution.**

- **Exemption from regulation/variance in policy for University of Maryland College Park (reactor license) license number 33-004-02: This licensee currently has a decommission funding plan/financial assurance (DFP/FA), however, during the current renewal application, the licensee questioned the necessity of the DFP and FA. Reason: sealed source vs. special nuclear material.**

- **Variance in policy/exemption from license condition for University of Maryland College Park (irradiator license) license number 33-004-03: Licensee has requested an amendment to repair the cable used to raise the irradiator sources. This amendment would require dry cask storage which is currently not allowed per their license conditions. RHP has met with the licensee and has received a copy of the proposed procedures for dry cask storage. A final decision is pending Department management review/approval.**

- **Exemption from financial assurance for RLS Radiopharmacy license number 31-222-01 for possession of multiple Ge/Ga generators: This request is currently under review and discussion with management. The Department has consulted with the NRC for guidance on this action and is currently reviewing the submitted decommission funding plan proposal.**

4. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

- **"Sensitive/Confidential Document Handling Procedures" (Attachment A), were effective as of October 18, 2021.**

- **Supplement 31 of COMAR 26.12.01.01 effective December 27, 2021.**

5. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

Attachment B includes a list of renewal applications that will have been pending for one year or more if not completed by August 25, 2022 (the end of the reporting period). A detailed status description is included for each licensee. All renewal applications on this list have undergone at least an initial review by the Department, and many are awaiting additional information from the licensee after the issuance of a request for additional information. The Department continues to maintain communication with each licensee on this list.

There have been many contributing factors for the delay of the review and/or processing of these renewal applications. Specifically:

- **Financial Assurance requires review by our Attorney General's (AG) office for legal sufficiency. Staff changes in the AG's office has led to delays in these reviews. During the review period, one license reviewer left RHP, and one license reviewer was re-assigned. All assignments were re-distributed to other license reviewers, adding to their workload. Note that two license reviewers started in February of 2022.**

- **All license reviewers are still in the process of becoming fully qualified. Currently, only the supervisor is capable of independently reviewing complex licensing actions. In order to properly train the license reviewers, many assignments require peer review and guidance to ensure that all licensing actions are reviewed/approved in accordance with the regulations. This necessary training leads to a slower review.**

- **As a result of the last IMPEP, all medical licenses require an in-depth review of qualifications for all users listed on the license. This review is extensive and time consuming, leading to a slower review process. The newer license reviewers require additional guidance through this process until they are familiar enough with the requirements to perform these evaluations independently.**

In order to reduce the backlog, RHP staff is prioritizing applications that are in RHP the longest (we are reviewing applications in the order that they were received). The simpler renewal applications such as XRF devices and portable gauges are being assigned to the newer, less experienced, RHP staff. As the new staff members are trained, additional types of renewals will be assigned to them for review.

Additionally, the RHP continues to issue renewal reminders in advance of license expiration so that future renewal applications are received with sufficient time for review. Licensees that submit complete renewal applications are issued letters of Timely Renewal so that they may continue operations under their existing license if their license expires while still under review by RHP. RHP will review and issue amendments, as needed, while the licensee is on Timely Renewal.

Radiological Health Program Procedure for Sensitive/Confidential Document Handling

Effective Date: October 18, 2021
References: NRC Regulatory Issue Summary 2005-31, Rev. 1 (RIS 2005-31)

Criteria for determining if a document is Sensitive/Confidential

According to the NRC: "Sensitive (but unclassified, non-safeguards) information covers a range of information for which the loss, misuse, modification or unauthorized access can reasonably be foreseen to harm the public interest, commercial or financial interests of an entity, the conduct of NRC and Federal Programs, or the personal privacy of individuals." This includes documents in four categories: proprietary, medical records (including dose records), personally identifiable information and security-related.

Proprietary Information: RHP will consider any information that the licensee requests to remain confidential because it is proprietary as sensitive/confidential information.

Medical Records: RHP will consider any information relating to an individual's health as sensitive/confidential information. This includes records of radiation exposure.

Personally Identifiable Information (PII): PII is defined as information that (a) can be used to identify or contact a person uniquely and reliably or (b) can be traced back to a specific individual. RHP will consider the following personal information as sensitive/confidential:

- Social Security number (or some other national identification number)
- Vehicle registration plate number
- Driver's license (or license number)
- Facial photograph
- Fingerprints
- Credit card numbers
- Birthday
- Birthplace
- Personal phone number
- Personal email

Security-Related Information: This criteria applies only to licensees who possess Category 1, 2, or 3* quantities of radioactive materials. RHP will consider the following information pertaining to these licensees as sensitive/confidential information:

- Building numbers and room numbers (other than mailing addresses) or similar information which identifies locations of material
- Manufacturers and model numbers of sealed sources and devices
- Possession limits
- Actual inventories of radionuclides
- Information on security programs/plans, guards, access controls, key cards, alarms, barriers, chains, locks, etc.
- Drawings and designs of buildings/rooms/devices where radioactive material is located
- Information on routes to and from locations of radioactive material
- Information related to responses to security events and malevolent events
- Information on responses of offsite law enforcement officials
- Site-specific emergency planning information and response capabilities
- Detailed descriptions of key personnel, roles, duties (Category 1 & 2 only)

**Licensees with quantities of radioactive materials below Category 3 levels are not subject to the above-listed security-related criteria with the following exception: Any documents that identify the exact location of radioactive materials (i.e. specific room or diagram showing the exact storage location) should be marked as defined in the next section.*

Marking Sensitive/Confidential Documents

RHP staff will review all licensee submissions (electronic or hardcopy) and RHP-generated documents. These documents will be marked according to the following criteria:

- Incoming documents containing proprietary information as indicated by the licensee, medical records, and/or PII will be marked with the word "Confidential" on the bottom center of the page.
- Incoming documents that are from Category 1, 2, or 3 licensees that contain Security-Related Information will be marked with the words "Security-Related Information" on the top center of the page and "Confidential" on the bottom center of the page.
- Incoming documents that are from licensees with below Category 3 quantities that contain exact location of radioactive materials shall be marked at the bottom center of the page as "Confidential."
- Incoming electronic media, including flash drives, DVDs, CDs, etc. that contain PII or Security-related information will be labeled with a "Confidential" or "Security Information" sticker.
- RHP-generated documents will be marked as follows:
  - Cover letters accompanied by documents containing security-related information will include the following statement: "Documents transmitted herewith contain sensitive

information. When separated from the sensitive information, this document is decontrolled." This statement will appear at the bottom center of the cover letter.

- Licenses, Inspection Reports, Notices of Violation, and other documents:
  - Category 1, 2, or 3 documents will be marked with "Security-Related Information *** Withhold Under 10 CFR 2.390" at the center top of the page and "Proprietary and Confidential" at the center bottom of the page. These markings will only be on pages that contain Security-Related Information.
  - Documents for licensees with below Category 3 quantities that contain exact location of radioactive materials shall be marked at the bottom center of the page as "Confidential." These markings will only be on pages that contain exact location information.
  - Documents for licensees containing PII will be marked at the bottom center of the page as "Confidential." These marking will only be on pages that contain PII.

- Licensees will be provided with the above criteria for sensitive/confidential information and will be instructed to mark documents that are sent to us and contain sensitive/confidential information as "Sensitive", "Proprietary", and/or "Confidential"

Filing Sensitive/Confidential Documents

- All category 1, 2, & 3 files will have a "Security Information" sticker on the front of the binder.
- IC (Category 1 and 2) licenses and licenses with sources listed in the National Source Tracking System (NSTS) will be filed in a separate locked cabinet in the file room.
- Incident/Allegation files will be filed in a locked cabinet in the file room.
  - Incident files will be filed in a red folder and have the Licensee Name (if applicable), the MD License No. (if applicable), and the date RHP was made aware of the incident on the file label. These files will be stored in chronological order.
  - Allegation files will be filed in a green folder and will have the Licensee Name, MD License No., and date RHP was made aware of the allegation on the file label. These files will be stored in chronological order.

Controlling Access to Security-Related Sensitive/Confidential Documents

Access to security-related sensitive/confidential information will be controlled by requiring documentation to be locked up when not being used.

- Category 1, 2 and NSTS license files will be stored in a locked cabinet in the file room. Only persons with a need-to-know will have keys to the locked cabinet.
- Category 3 files will be maintained in the locked high-density files. Only RAM staff will have access to keys for the high-density files.
- At the end of the day, all of the above-listed files and/or documents must be locked up either in their respective filing cabinets, or at a staff member's desk.

Electronic storage of Sensitive/Confidential Documents
Sensitive/Confidential Documents can be stored electronically on either:

- Individual staff member's computer (if staff member has a need-to-know) and the computer is password controlled.
- Access to the M-Drive, where electronic files are stored, will be restricted to staff members who have a need-to-know.

Public release of Sensitive/Confidential Documents
Sensitive/Confidential documents will not be released to the public. When the Division receives a request from the public to view a Radioactive Materials License file that is not a Category 1, 2, 3 or NSTS licensee, any document not marked as sensitive information may be released without consent of the OAG. When RHP receives a request from the public to view the file for a category 1, 2, 3 or NSTS licensee, records center staff will notify a technical staff member of the Radioactive Materials Division. The technical staff member will work with the Attorney General's office (if needed) to review the file and release the appropriate documents. These requirements are in addition to any existing Public Information Act (PIA) request procedures or Department policies.

Authorizing Signatures:

Eva Klain RHP Manager

List of renewal applications pending for 1 year or more (if still pending as of 8/25/2022)

Lic No	Name	Doc Dt	Stmp Dt	Log In Dt	current status
41-002-01	Eurofins/EAG	3/4/2020	3/5/2020	3/12/2020	Waiting for AGs office to review FA (Sent in January 2022 with follow up on 7/11/2022).
33-021-02	RSO, Inc	6/22/2020	6/22/2020	7/25/2020	Additional information requested for DFP/Trust in October of 2021 with follow up in January 2022.
03-005-03	Northrup Grumman	7/28/2020	8/5/2020	8/28/2020	Waiting for AGs office to review FA (Sent in. January 2020 with follow up on 9/3/2021).
33-029-01	Doctor's Community Hospital	3/30/2021	4/14/2021	4/15/2021	Note: this was initially assigned to a reveiwer that has left the Department; RAI was issued via email on 5/11/2021 and the licensee submitted an entirely new applicaion in December of 2021. Matt revewiewed and determied it to be insufficient. He contacted the licensee and they did not respond. Talya requested additional information on 7/21/2022; further contact with the licesee on 7/22/2022 revealed staffing changes that lead to this oversight. The licensee is aware of the issue and is working to resolve.
33-029-02	Doctor's Community Hospital	4/28/2021	5/4/2021	5/6/2021	Note: this was initially assigned to a reveiwer that has left the Department; Review is completed and license has been prepared, however, this licensee has tax liability and cannot be released: Verified tax liability status on 7/19/2022.
31-222-01	RLS Radiopharmacy	4/30/2021	6/1/2021	6/3/2021	RAI response was received on 7/13/2022 and is under review; Additionally, this requires further discussion with supervisors to determine if DFP exemption request can be granted.
07-231-01	GAF	4/29/2021	6/2/2021	10/14/2021	Note: this was initially assigned to a reveiwer that has left the Department; Cheryl is reviewing 3rd RAI response received on 7/13/2022.
33-058-01	Riverside Medical	3/10/2021	6/3/2021	6/3/2021	RAI was issued on 2/4/2022 and we are awaiting response, the licensee was emailed on 5/17/22 for a follow up.
31-025-04	Neutron Products Inc	6/15/2021	6/16/2021	8/12/2021	First RAI was issued but a response is not yet submitted, pending the outcome of their -05 license. They were instructed to hold off on a response so that any defficiencies noted in the -05 license can be sufficiently addressed on this license.
31-025-05	Neutron Products Inc	6/15/2021	6/16/2021	8/12/2021	2nd RAI mailed 7/20/2022.
33-004-02	U of MD College Park	6/16/2021	6/16/2021	10/14/2021	RAI was issued on 4/26/2022, Response to RAI received on 7/7/2022 is under review.
05-247-01	One Source Environment, LLC	6/5/2021	6/22/2021	7/12/2021	Note: this was initially assigned to a reveiwer that has left the Department; Review is completed and license has been prepared, however this licensee has tax liability and cannot be released; Verified tax liability status on 7/19/2022.
03-011-01	Hardin-Knight Associates	6/3/2021	6/22/2021	6/29/2021	License complete and sent foward, pending management review
17-021-01	Geo-Technology Associates Inc	6/11/2021	6/22/2021	6/29/2021	License complete and sent foward, pending management review
01-002-04	Western Maryland Regional Medical Center	5/28/2021	6/22/2021	6/29/2021	RAI issued on 3/31/2022 . Additional information received on 7/19/2022 is under review. Note: the response delay was due to the licensee waiting for updated qualification documentation as requested by the Department due to defficiencies discovered during the qualifications check.
31-386-01	Holy Cross Germantown	6/7/2021	6/22/2021	6/29/2021	Note: this was initially assigned to a reveiwer that has left the Department; Review of renewal and responses to RAI is complete, however, at this time we are waiting on qualifications for individuals listed on the license as the attestation forms previously submitted were incorrectly completed; Additional information received on 7/19/2022 is pending review.
31-183-01	Fisher BioServices	6/29/2021	7/1/2021	7/20/2021	RAI drafted, requires discussion with supervisor; Additionally, FA was sent to AGs office for review in January of 2020.
31-185-01	Montgomery County Materials Testing Lab	6/21/2021	7/2/2021	7/22/2021	Note: this was initially assigned to a reveiwer that has left the Department; RAI mailed 5/27/2022; A follow up with the licensee on 7/15/2022 noted that they received the RAI on 6/13/2022 and are experiencing extreme understaffing. They hope to have the response to the Department by 7/22/2022.
31-386-02	Holy Cross Germantown Hospital	7/6/2021	7/21/2021	7/26/2021	License complete and sent foward, pending management review.

33-200-01	Nader A. Dakak MD	7/21/2021	7/21/2021	7/26/2021	Note: this was initially assigned to a reveiwer that has left the Department; Response to RAI received on 6/21/2022 pending review.
31-120-01	AMG Cardiovascular Specialists	7/19/2021	7/26/2021	7/28/2021	RAI mailed 6/23/2022 awaiting response.
13-010-01	Advanced Radiology - Fisher Building	7/27/2021	7/27/2021	7/28/2021	Note: this was initially assigned to a reveiwer that has left the Department; RAI mailed 6/8/2022, awaiting response.
31-258-01	CardioCare	7/27/2021	7/27/2021	8/2/2021	Note: this was initially assigned to a reveiwer that has left the Department; RAI sent for signature 6/24/2022.
07-199-01	Arc Environmenttal	7/28/2021	8/4/2021	8/9/2021	License complete and sent foward, pending management review.
21-037-01	ECS Mid-Atlantic	8/1/2021	8/17/2021	8/23/2021	Note: this was initially assigned to a reveiwer that has left the Department; RAI mailed 5/27/2022 and waiting for response. Follow up email 7/15/2022.
31-370-01	Olney Medical Group	8/8/2021	8/18/2021	8/23/2021	RAI mailed 7/12/2022
07-014-07	U of MD Gamma pod	2/19/2021	2/24/2021	2/25/2021	Under review by Atna.