



MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard • Baltimore MD 21230

410-537-3000 • 1-800-633-6101

STP Rev'd 11/25/2005

Robert L. Ehrlich, Jr.  
Governor

NOV 16 2005

1:26 p.m. Kendl P. Philbrick  
Secretary

Michael S. Steele  
Lt. Governor

Jonas A. Jacobson  
Deputy Secretary

Janet R. Schlueter, Director  
Office State and Tribal Programs  
U. S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Dear Ms. Schlueter:

Please find attached a Maryland Department of the Environment's (MDE) Radiological Health Program (RHP) request for consideration by the IMPEP's Management Review Board (MRB). The subject of the request is specific to the changing of RHP's IMPEP criteria to allow initial inspections of new licensees to be conducted at an eighteen-month frequency instead of the currently mandated one-year frequency. This request was first brought to the Commission's attention during Maryland's informal IMPEP review meeting held on August 31, 2005. The request was further discussed during the October 17, 2005 MRB teleconference review of Maryland's informal IMPEP review.

Maryland again wishes to thank the NRC for the professionalism and high level of preparedness demonstrated by NRC personnel during our informal IMPEP review and the follow up MRB meeting. We are looking forward to the NRC's response to this request. Should you have any questions regarding this letter, please contact Ray Manley or me at 410-537-3301. You may also reach our office toll-free by dialing 1-800-633-6101 and requesting extension 3301.

Sincerely,

Roland G. Fletcher, Manager III  
Radiological Health Program

RM  
RGF/REM/blr

cc: Thomas C. Snyder, Director ARMA  
Sheri Minnick, Region I NRC

# ATTACHMENT

## MARYLAND DEPARTMENT OF THE ENVIRONMENT RADIOLOGICAL HEALTH PROGRAM

**Stated Request:** Maryland's Radiological Health Program requests that the State's IMPEP criteria for inspection frequency of initial inspections as found in NRC's Management Directive 5.6 "Integrated Materials Performance Program (IMPEP) and SA-101 "Reviewing the Common Performance Indicator Status of Materials Inspection Program" (referencing IMC 2800 11/25/05) be changed from the current one-year frequency to an eighteen-month frequency.

**Reason for Request:** This request is made in an effort to maximize the most efficient use of Program resources. The RHP has no outstanding backlogs in our category 1-3 inspections. However, the Program wishes to employ its inspectors in a way that emphasizes best judgment in radiation risk assessment and safety through the inspection and compliance process.

**Radiation Risk Benefit Assessment:** RHP has conducted a risk benefit analysis of potentially conducting initial inspections at eighteen months as opposed to the current one-year frequency. Taken into consideration in this analysis is the potential risk for occurrence of significant violations (NRC's severity levels 1-III) during the additional 6-month period of time requested; changes in the efficacy (efficiency and quality) of inspection; and current Maryland licensing practices that differ from the NRC.

### Current Maryland Licensing Practices That Differ From NRC:

- A. Maryland conducts a pre-licensing on-site visit for all applicants of a radioactive material license prior to the issuance of the license. These pre-licensing visits were initiated to provide better initial assurance that license applicants understand the responsibilities of radioactive material licensure in Maryland. The audit procedure was also implemented to decrease the number of violations identified during initial inspections. Maryland license reviewers have been conducting these audits since the late 1990s. The general purpose and scope of RHP's pre-licensing inspection is as follows:

INSPECTION EVALUATION IN THE FOLLOWING AREAS (discussed with licensee): Are all the below items understood by the company and facility to safely establish the use of radioactive material in place or immediately available upon receipt of the license?

1. What radioactive materials are authorized under the license?
2. What activities are authorized under the license?

2. What activities are authorized under the license?
3. Who is authorized to use radioactive material under the license?
4. Company management oversight of licensed activities.
5. How the radioactive material will be received.
6. How the radioactive material will be secured.
7. How radioactive material will be transferred and/or disposed of under the license.
8. License amendment process.
9. Emergency response and reporting requirements.
10. Documentation requirements under the license.
11. Radioactive material posting and signage requirements.
12. What specific radiation regulations must be understood and followed.
13. What are the specific condition requirements for this license?
14. Discussion of licensee type (code) and annual fees.

B. Under Maryland's COMAR 26.12.01.01 Sec.G "Use of Radionuclides in the Healing Arts" RHP Licensing Section will continue to pre-approve diagnostic procedures in the licensing process. We feel this proactive practice assists to identify potential weaknesses in medical licensee's radiation safety program's that would not be identified under the NRC compliance process until the initial performance based inspection. This continued RHP licensing practice is another reason why RHP' initial performance based inspections of these types of licenses could be conducted at eighteen months instead of twelve months.

Changes in the Efficacy (efficiency and quality) of Inspection:

- A. With no 25% leeway (backlog) for the one-year initial inspections, scheduling of such audits must be conducted at periods of time prior to the one-year deadline. A RHP initial inspection of licensees prior to one year usually does not provide a full year of licensed activities to be reviewed by the inspector. For example, an inspector is often required to evaluate an initial licensee without that licensee having conducted a full year evaluation of their radiation safety program procedures and implementation under COMAR 26.12.01.01D.101 (CFR 20.1101). Examples of these program elements include dosimetry, bioassay, leak test of sources, quality management review, maintenance of critical equipment, and evaluation of training program

Depending on the category of inspection it may be a long time after the initial inspection that RHP gets to re-visit the licensee. This type of inspection frequency can result in an extended period of time where all aspects of the licensee's radiation safety program have not been completely reviewed.

- B. The inspection frequency change from twelve months to eighteen months will allow the inspection staff to spend additional resources on the inspection and compliance of Category 1-3 licensees as well as additional staff resources on certain Maryland Companies with complex and long standing compliance concerns.

Potential Risk for Occurrence of Significant Violations (NRC's severity levels 1-III) During the Additional Six-Month Period of Time Requested:

RHP has reviewed its history of initial inspections that have occurred since July of 2003. Given understandings, post the 2003 IMPEP that the initial inspection frequency was six-months, RHP was able to evaluate results of initial inspections that vary from three months to one year. This review did not indicate any increase of significant (I-III) violations from the six-month frequency to the one-year frequency. RHP does not anticipate an increase of these types of violations if the frequency is extended from one year to eighteen months. Should RHP be allowed to extend the initial inspection frequency from one-year to eighteen months we will carefully evaluate (two years) results of initial inspections for any results or trends that reflect an increase in radiological incidents, decrease in safety or compliance, and all other evaluation variables as defined above.

<b>NRC FORM 253</b> <small>(9-96)</small>		<b>U.S. NUCLEAR REGULATORY COMMISSION</b>		<b>DATE OF REQUEST</b> <i>11/23/05</i>	<b>CONTROL NUMBER</b>
<b>MESSENGER/COURIER RECEIPT</b>					
<b>TO:</b> <i>TANET SCHLUETER</i>		<b>OFFICE</b> <i>OSTP</i>	<b>BUILDING</b> <i>OWFN</i>	<b>ROOM NUMBER</b> <i>3C10</i>	
<b>FROM:</b> <i>MOE</i>		<b>OFFICE</b> <i>Adm</i>	<b>BUILDING</b> <i>OWFN</i>	<b>ROOM NUMBER</b> <i>P1-37</i>	
<b>DESCRIPTION</b>  <i>7002 0860 0006 7898 4832</i>		<b>MESSENGER/COURIER SIGNATURE</b>			
		<b>MESSENGER/COURIER</b> <i>[Signature]</i>		<b>DATE RECEIVED</b> <i>11/23/05</i>	
				<b>TIME RECEIVED</b>	
		<b>MESSENGER/COURIER</b>		<b>DATE RECEIVED</b>	
				<b>TIME RECEIVED</b>	
		<b>RECIPIENT'S SIGNATURE</b>			
		<b>RECIPIENT</b> <i>[Signature]</i>		<b>DATE RECEIVED</b> <i>11/25/05</i>	
				<b>TIME RECEIVED</b> <i>1:26 pm</i>	
<b>SENDER:</b> 1. Complete "DATE OF REQUEST," "TO:," "FROM:," and unclassified "DESCRIPTION" blocks. 2. Obtain MESSENGER/COURIER signature, date received, and time received in first blocks provided. 3. Retain "SENDER'S SUSPENSE COPY."		<b>MESSENGER/COURIER:</b> 1. Deliver package to recipient or next messenger/courier enroute to addressee. 2. Obtain MESSENGER/COURIER or RECIPIENT signature, date received, and time received in the appropriate blocks provided.		<b>RECIPIENT:</b> 1. Provide signature, date received, and time received in the appropriate blocks. 2. Retain RECIPIENT'S COPY. 3. Return original to mesenger/courier immediately, who will return it to the sender.	