Roland G. Fletcher, Manager Radiological Health Program Air and Radiation Management Administration Maryland Department of the Environment 1800 Washington Boulevard, Suite 750 Baltimore, MD 21230-1724

## Dear Mr. Fletcher:

We have reviewed your letter dated November 16, 2005, regarding your request for changing the Integrated Materials Performance Evaluation Program (IMPEP) criteria to allow initial inspections of new Maryland licensees to be conducted at an eighteen-month frequency instead of the currently mandated one-year frequency. The IMPEP criteria for the twelve-month inspection requirement is based on the U.S. Nuclear Regulatory Commission (NRC) Inspection Manual Chapter (MC) 2800, *Materials Inspection Program*, (September 28, 2005). The Office of State and Tribal Programs worked with the Office of Nuclear Material Safety and Safeguards, to evaluate the ability to relax the 12-month initial inspection requirement in MC 2800. Based in part on the items listed below, we cannot grant your request.

As we indicated in the May 2, 2006, teleconference with you and members of your staff, we understand the reasons for your request and appreciate the time spent in putting together a sound approach based upon a radiation risk-benefit analysis. As you know, there has been increased interest in security and control of radioactive material. While your proposed approach to performing initial inspections is risk-informed and performance-based, to an outside individual, the approach may appear to be less stringent than current NRC-required practices.

We commend Maryland's performance of pre-licencing visits for new licensees. Although we consider this a good practice, the NRC does not consider these visits as actual inspections. The applicant is not a licensee at the point of the pre-licensing visit, nor could it be said that at the time of a pre-licensing visit, a facility would be in the operational status that a licensed facility would be in during an initial inspection. Therefore, the data gathered during a pre-licensing visit may or may not be an accurate reflection of the potential licensee's future performance. However, the NRC is aware that many State programs, such as yours, continue to institute the practice of pre-licensing visits. We believe that these pre-licensing visits further enhance the safety and security of the use of radioactive materials. Recently, the NRC has recognized the advantages of pre-licensing visits and has developed guidance to incorporate this practice into the licensing of risk-significant sources. This initiative began an initial implementation phase on May 1, 2006. State feedback and questions on the guidance will be evaluated monthly by NRC staff during the six-month preliminary period.

The Maryland request makes reference to the fact that inspections prior to the one-year mark usually do not provide a full year of licensed activities to be reviewed (e.g., dosimetry, bioassay etc.) and it might be a long period until the next scheduled inspection, depending on the

category of licensee and its corresponding priority. NRC inspection priorities in MC 2800 are based on the risk significance of the licensee and the radioactive materials being used. Licensees of higher risk would be inspected at a one or two year interval following the initial inspection. From a risk informed, performance-based inspection perspective, we do not believe that it is inappropriate to re-inspect these licensees at a one or two year frequency following the initial inspection, even if the initial inspection was performed within the first year of becoming a licensee.

NRC periodically revises MC 2800. Comments from the Agreement States are welcome and taken into consideration during the revisions. We encourage you, independently of or in conjunction with the Organization of Agreement States, to submit your views regarding prelicensing visits and initial inspection intervals during the next revision of MC 2800. Due to the requirements included in the Energy Policy Act of 2005 and other upgraded security measures, the revisions to the Manual Chapter are expected to be made in the near future. If you have any questions regarding this issue or any other IMPEP criteria, please contact Mr. Aaron T. McCraw of my staff at 301-415-1277 or e-mail: <a href="mailto:ATM@NRC.GOV">ATM@NRC.GOV</a>.

Sincerely,

/RA/

Janet R. Schlueter, Director Office of State and Tribal Programs **Distribution**:

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