



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 12, 2006

ALL AGREEMENT STATES, PENNSYLVANIA, VIRGINIA

**GUIDANCE FOR THE INCREASED CONTROLS PRIORITIZATION METHODOLOGY
(STP-06-033)**

By letter dated November 4, 2005 (STP-05-079), we provided each of the Agreement States with the final prioritization methodology for use in determining which increased controls licensees will need to be inspected within the first year of implementation. That letter indicated that we would provide guidance on using the methodology. Enclosed please find guidance in the format of questions and answers that can be used to assist each of the regulatory agencies in prioritizing inspections for the first year of the implementation of the increased controls.

If you have any questions regarding this correspondence, please contact Mr. Andrew Mauer or Mr. Joshua Palotay of my staff.

STP CONTACT:	Andrew Mauer	Joshua Palotay
TELEPHONE:	301-415-3962	301-415-6231
INTERNET:	anm@nrc.gov	jxp5@nrc.gov
FAX:	301-415-3502	301-415-3502

/RA/
Janet R. Schlueter, Director
Office of State and Tribal Programs

Enclosure:
As stated

STP-06-033

April 12, 2006

Distribution:
DIR RF

SISP Review Complete

- : Publicly Available Non-Publicly Available
: Non-Sensitive Sensitive

DOCUMENT NAME:ML061020481.wpd

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	STP	STP	STP:DD	STP:D	
NAME	JXPalotay	ANMauer:kk	DKRathbun	JRSchlueter	
DATE	4/12/06	4/12/06	4/12/06	4/12/06	

OFFICIAL RECORD COPY

Questions and Answers for the Inspection Prioritization Methodology

- Q1. Will this new methodology replace the inspection priorities established in Inspection Manual Chapter (IMC) 2800 for licensees receiving the increased controls?
- A1. This methodology was developed to ensure that "higher risk" licensees are inspected within the first year of the implementation of the Increased Controls. After the initial three year inspection period, licensee inspections will be conducted according to the priorities established in IMC 2800 or the Agreement State equivalent. Guidance for inspections to assess licensees' continued compliance with the Increased Controls after the initial three year inspection period will be integrated into IMC 2800. When this is accomplished, inspection priorities for some licensee categories may need to change to reflect the relative risk when the increased controls are also considered.
- Q2. Is this methodology intended to apply to all inspections conducted over the three years after implementation, or only for inspection of higher risk licensees in the first year?
- A2. T This methodology is primarily intended to identify higher risk licensees that will be inspected in the first year after implementation, but also includes guidance for deviations from Inspection Manual Chapter 2800 (or Agreement State equivalent) that may need to be made to conduct all inspections within three years after implementation. It is expected that the methodology will need to be applied to all licensees to ensure that all higher risk licensees are identified, and can also be used as a tool for prioritizing inspections in the second and third years after implementation.
- Q3. What documentation are the Agreement States and Regional Offices expected to keep concerning the final prioritization of inspections for the first year after implementation?
- A3. For inspection of higher risk licensees in the first year, each program is expected to have a documented basis for how it established its prioritization of inspections and identified the higher risk licensees, in a form that can be audited during the program's next Integrated Materials Performance Evaluation Program (IMPEP) review. The program will need to maintain documentation of how it applied this inspection prioritization methodology, and the basis for any deviations from this methodology (see the answer to Q4 below for additional guidance on deviations from this prioritization methodology).
- Q4. Can a program establish its own, or deviate from this inspection prioritization methodology?
- A4. The Agreement States and Regional Offices are expected to use this inspection prioritization methodology for identifying higher risk licensees that must be inspected during the first year after implementation. However, it is recognized that there may be specific conditions at an individual licensee that warrants increasing or decreasing the licensee's inspection priority. In such cases, the program will need to document its basis for determining that the specific conditions warrant changing the inspection priority for the individual licensee. This inspection prioritization methodology also provides a sound basis for establishing the prioritization of inspections during the second and third years after implementation, and Agreement States and Regional Offices should consider its use to establish inspection priorities for all three years.

- Q5. Are the seven factors listed in order of highest to lowest importance for identifying higher risk licensees and inspection priorities?
- A5. As indicated in Section B of the methodology, no single factor will definitively determine the specific priority for inspection of a licensee, and all factors should be considered to establish a final prioritization. When applying factor 1, higher priority should be given to a licensee identified as a higher priority in IMC 2800. When applying factor 2, higher priority should be given to licensees possessing larger quantities of material, licensees possessing individual sources in quantities at or greater than 100 times a Table 1 quantity of concern, and situations where a licensee may possess larger quantities or where control over the material could be more difficult (e.g., source exchanges). In addition, for events that significantly increase the risk for an individual licensee (such as source exchanges), inspections should coincide with the event whenever possible.
- Q6. The guidance references Groups 1-4. Haven't these groups been replaced by "licensees in possession of radionuclides in quantities of concern" as referenced in the order?
- A6. The "Groups 1-4" terminology should be replaced with risk significant radionuclides (Category 1 and 2 quantities), which have previously been referred to as radionuclides in quantities of concern. Given the existing references to the STP letter (STP-05-079) transmitting the prioritization methodology, we are not changing the methodology itself, and are addressing this question in this guidance.
- Q7. The guidance indicates the basis for establishing prioritization includes IMC 2800 or the Agreement State Equivalent. Some States have established inspection frequencies at intervals that are more restrictive than IMC 2800. Does the State have the option of using either basis (as long as the choice is documented and auditable) when establishing its prioritization method?
- A7. In cases where the Agreement State equivalent of IMC 2800 is more restrictive than IMC 2800, States can use either basis when establishing the prioritization as long as the choice is documented and auditable.
- Q8. Can you provide some examples of application of the methodology consistent with the instruction found in section "B" of the methodology? (i.e. a facility with a blood irradiator [less than 2700 Ci of Cs-137] and a good inspection history, a similar facility with a poor inspection history, a hospital with a new gamma knife with no established 'track record' with large quantity sources, etc.).
- A8. The initial prioritization should be based primarily on factors 1 and 2. If the licensee demonstrates previous violations or points of concern as outlined in factors 3-7, the prioritization ranking would increase. For example, if the licensee demonstrates a history of control violations, the prioritization would be increased (with a graded approach) depending on the number and severity of the violations. Alternatively, if a licensee has a good inspection and compliance history, this information should be considered in determining whether the licensee presents a reduced risk, and these decisions will be part of the documented methodology. A licensee without an "inspection track record" may need to be inspected earlier, in similar manner to the need

to perform an initial inspection after the issuance of a materials license.

- Q9. What type of guidance will be given to IMPEP team members who are evaluating the second bullet in the section regarding extended inspection intervals for licensees who are not subject to the increased controls (as a deviation from IMC 2800)? Is there some formula being developed to indicate how much variation is allowed or what is considered reasonable?
- A9. When reviewing the indicator, Status of Materials Inspection Program, IMPEP team members are requested to record the reasoning or justification for overdue inspections based on State or Regional input. Those routine inspections that were extended in order to ensure that higher risk licensees implementing increased controls could be inspected in the first year should be identified and subtracted from the calculation of percentage of inspections completed overdue. IMPEP team members will be instructed to determine the State's or Region's action plan to make up the extended routine inspections.
- Q10. Is it necessary to further prioritize high risk licensees into 'even higher risk' licensees for cases where a licensee may be encompassed by more than one of the methodology criteria such that rankings within rankings are created (i.e. radiography licensee with adequate management controls vs. radiography licensee with poor inspection history)?
- A10. Yes. Each program will need to perform a prioritization that takes into account each of the factors contained within the methodology. Forming a prioritization based on several factors could mean that based on a combination of reasons, a particular licensee presents a "higher risk" than another licensee. The "cutoff" for determining which licensees present the "highest risk" will need to be determined and documented by the regulatory agency.
- Q11. Was it the intent of the prioritization methodology that 90-100% of the increased controls licensees be inspected within the first year of implementation?
- A11. No. The intent of the prioritization methodology was to provide flexibility to each of the regulatory agencies in deciding which increased controls licensees present the "highest risk." The methodology includes several factors that should be considered in combination with each other.