September 23, 2020

Lizette Roldan-Otero and Robert Johnson
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Ms. Roldan-Otero and Mr. Johnson:

The OAS Executive Board (Board) appreciates the opportunity to comment on the Nuclear Regulatory Commission’s (NRC) draft temporary instruction TI-003 entitled, “Evaluating the Impacts of the Coronavirus Disease 2019 Public Health Emergency as Part of the Integrated Materials Performance Evaluation Program (RCPD-20-008).”

The Board has reviewed the information provided in the draft temporary instruction TI-003. Based on our review of the information, the Board has the following question and comments:

1. Section I.A. (pg. 1) states "Due to the ever-changing nature of the COVID-19 PHE, the Office of Nuclear Material Safety and Safeguards (NMSS) will re-evaluate and as necessary, revise this Temporary Instruction (TI) every 24 months until such time as the COVID-19 PHE impacts on the National Materials Program are no longer seen during IMPEP reviews."

   Given that the COVID-19 PHE is ever-changing, does NMSS plan to re-evaluate/revise the TI more frequently than 24 months if warranted? If more frequent evaluation/revision is possible, consider adding the phrase “at least every” before “24 months”.

2. Section I.B. (pg. 1) states “In order to maintain consistency and bound the effects of the COVID-19 PHE, each Program will need to establish the dates in which impacts from the COVID-19 PHE applied within their jurisdiction.”

   The COVID-19 PHE will have both direct and indirect effects on programs; some indirect matters could last months or years beyond the perceived end date for the impacted period. The Board urges future Integrated Materials Performance Evaluation Program (IMPEP) teams to consider this fact while reviewing a program. The Board recommends that a statement be added to recognize this fact. Even if a state indicates one set of dates for an impacted period, the team should provide leniency and flexibility discussed by this TI in evaluating indirectly affected program areas beyond the bounded time period.
Example: A program may indicate the end of their impacted period to be when they resume normal inspection activities, and this would mark the end of the direct effect of the PHE. The indirect effect would be all the delayed or overdue inspections. The end of that indirect period would coincide with when the program is no longer backlogged on inspection activities. As long as the program has a plan and is carrying it out, then the IMPEP team should not penalize a program during this prolonged period of time.

3. Throughout the document the word "prompt" is used. Since it is not defined, it is important to acknowledge that "prompt" may mean something significantly different during the COVID-19 PHE situation than in a normal situation.

4. Under each section of “Indicator Specific Guidance”, performance indicator objectives that "should not be adversely affected" are identified. Two of the “should not be adversely affected” indicator objectives seem to have potential to be affected by obstacles caused by the COVID-19 PHE:

   a. Section V.D.2.f. (pg. 5) "Inspection findings lead to appropriate and prompt regulatory action". It should be made clear that regulatory relief is being provided for some items, and this may affect prompt regulatory action.

   b. Section V.F.2.e. (pg. 7) "Allegations are investigated in a prompt, appropriate manner." While this is the expectation and goal, it should also be made clear that if an investigation requires on-site activity, the promptness of this may be affected. Some hospitals or COVID-19 hotspots may not be accessible to inspectors in the same manner as in a non COVID-19 situation.

5. Section V.C.2.a. (pg. 4) states "Inspection findings are communicated to licensees in a timely manner." This could be affected if there are delays in sending results, i.e. office closures while having to send certified mail, or individuals with signature authority unavailable for extended times.

6. Section V.E.1.a. (pg. 6) states "Timeliness of renewal actions. Licensees, and in particular medical licensees may take longer to respond to deficiency letters due to having to respond to the COVID-19 PHE." A similar comment should be included in Technical Quality of Inspections for programs allowing additional time for licensees to respond to inspection deficiencies/violations.
The Board appreciates this opportunity to express our views and are available to answer any questions you may have.

Sincerely,

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