## REGULATORY ISSUE SCREENING FORM

**Title:** Reporting of Medical Treatment of a Contaminated Individual

**I. 1. Problem Statement** (Provide a clear, concise description of the issue.)

Industry is seeking clarification on the definitions of "medical facility (onsite vs. offsite)" and "with spreadable contamination" under 10CFR 40.60(b)(3) and 70.50(b)(3). We seek an interpretation that aligns "medical facility" to be consistent with Part 50 as being offsite and "spreadable contamination" to be consistent with standard health physics practices. These interpretations would reduce an unnecessary reporting burden with no benefit to the safety of the worker, public, or environment.

**2. Background Information** (Summarize industry events, licensing actions, inspection information, correspondence, and other documents germane to the issue. Attach documents as appropriate)

10 CFR 40.60(b)(3) and 70.50(b)(3) outline the reporting requirements for an event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination. Industry is seeking to obtain clarification on the interpretation of "medical facility" and "with spreadable contamination". Industry seeks to:

- Obtain consistency between 40.60(b)(3), 70.50(b)(3), and 50.72(b)(3)(xii) as it relates to a "medical facility". Part 50 requires reporting only if the facility is located offsite; and
- Align the interpretation of "with spreadable contamination" with standard health physics practices that measure spreadable contamination.

The requirements to provide 24 hour notification to the NRC based on current interpretation are an unnecessary burden with no benefit to the health and safety of workers, the public, or the environment. The tracking and reporting can cause a significant unnecessary administrative burden and could cause the distraction of resources from other higher safety priority work.

The Federal Register Notice publishing the notification of the final rule provides insight on the intent of the rule. The response to question B.31 states that "the NRC is concerned about the spread of contamination at the medical facility and the possible exposure of the general public to radiation and radioactive contamination." Licensees strongly recognize the importance of informing the NRC of any interaction of a contaminated individual with the general public, and when a worker requires offsite medical treatment industry has been appropriately following the reporting requirements. However, the fuel facility licensees that have onsite medical facility's that treat workers that have spreadable contamination do not pose any risk to the general public as these are facilities inside the owner controlled/protected area that are not accessible by members of the general public. Contaminated workers that received treatment onsite and return to work are monitored and do not leave the site with contamination. Reference 3 contains examples over the past several years of reports made to the NRC where a worker with spreadable contamination received onsite medical treatment, were released back to work or to an offsite medical facility, and subsequently left the licensee's facility uncontaminated. A majority of these events are superficial and none had the potential to expose members of the general public to radioactive contamination.

Fuel cycle facilities with medical treatment capabilities onsite have processes in place for managing potential contamination. The interpretation to report onsite medical treatment has led to the reporting of multiple low significance incidents. This interpretation is inconsistent with the reporting requirement for 10 CFR 50 licensees. 10 CFR 50.72(b)(3)(xii) applies to any event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment. Industry seeks consistency with this definition.

Regarding "with spreadable radioactive contamination", Federal Register Notice Response B.32, defines a radioactively contaminated individual as "a person who has removable surface contamination on their clothing or on accessible portions of their body that can be detected by standard methods and can be spread to other individuals." Recent NRC interpretation is contradictory to this definition in the rule. For example a Notice of

Violation (Inspection Report Number 70-143/2014-003) was issued based upon a regional interpretation that "the contamination on the skin of a person is not fixed, but spreadable due to the process during which the external layers of skin die and fall off." This interpretation is inconsistent with standard health physics professional practices which recognize that "spreadable/removable" contamination is characterized by the ability to physically transfer the material via contact with another medium.

The development of a notification report to the NRC involves a significant amount of licensee time and resources. The response to question A.16, in the Federal Register, noted the expected reporting burden to be a few days to complete and process a report. This burden did not consider all aspects associated with NRC reporting that licensees undertake. Nominally the costs associated with a generic 24 hour report have been up to 60 hours and $100,000. This is made up of line items including: the identification and assessment of an issue or event against the reporting criteria, the determination of reportability with oversight, the production of both the telephone notification as well as the follow up written report of 30 or 60 days, and the creation of the Corrective Action. This estimate does not include the cost of the follow up NRC inspection and NRC inspection report that will take place and be billed to the licensee. Furthermore, the response to question B.34 noted that "very few reports are expected, even if superficial injuries are included". Both estimates have been significantly inaccurate.

The references cited below provide additional details.

References:

1. July 27, 2015, Janet Schlueter (NEI) to Marissa Bailey (NRC); "Use of NEI 14-14, "Regulatory Issue Resolution Protocol" to clarify sections 10 CFR 40.60 and 70.50 Regarding Issues Associated with Contamination Events and Medical Treatment of Personnel at Fuel Cycle Facilities" (ML15217A487)

2. September 23, 2015, Marissa Bailey (NRC) to Janet Schlueter (NEI); "ACKNOWLEDGEMENT OF RECEIPT REGARDING NUCLEAR ENERGY INSTITUTE'S LETTER REQUESTING CLARIFICATION RELATED TO ISSUES ASSOCIATED WITH CONTAMINATION EVENTS AND MEDICAL TREATMENT OF PERSONNEL AT FUEL CYCLE FACILITIES" (ML15257A222)

3. NRC Event Numbers 50352, 50383, 47329, 49913, 50614, 50081, 50073, 50912, and 47620.

4. Federal Register, Volume 56, No. 159, August 16, 1991.

5. NRC Inspection Report 70-143/2014-003.

## II. Screening Criteria (Provide an explanation as to how the issue meets each of the screening criteria to be considered for generic issue resolution.)

**1. Does the proposed issue involve and affect multiple licensees** (provide basis)**?**

Yes. While the Event Numbers cited above only include two licensees, all fuel cycle facility licensees would benefit from a clarification and consistent interpretation of the definition of terms discussed above in 10 CFR 40.60(b)(3) and 70.50(b)(3). This clarification can prevent wasted efforts on issues that may be identified during inspections.

**2. Does the proposed issue warrant generic resolution with tangible benefits** (provide basis)**?**

Yes. A clear and consistently applied interpretation would reduce an unnecessary reporting burden on licensees that yields no benefit to the safety of workers, the public, or environment. Resolution would also reduce the burden on NRC to collect and follow-up on incidents that have no impact to health or safety.

**3. Does the issue warrant engagement between the industry and NRC** (provide basis)**?**

Yes. The industry believes engagement would provide clarification of the terms "medical facility" and "with spreadable contamination" and adopting the suggested industry interpretations will not negatively impact the health and safety of workers, the public, or the environment and is consistent with the focus of addressing the cumulative impact of regulatory requirements.

**4. Is there any alternate regulatory process for resolving the issue** (provide basis)**?**

No. An open dialogue can expeditiously resolve the clarification that industry seeks with the terms "medical

facility", and "with spreadable contamination" and determine the best path forward for reaching a resolution in timely manner outside of the rulemaking process.

**III. Are all screening criteria satisfied** ("Yes" responses to questions 1-3 and "No" to question 4)**?**
**Yes ___X____ No_____**

**IV. Are there extenuating circumstances indicating an alternate approach from the finding of the screening criteria and is there general agreement on a path forward (provide basis)**

**V. Should the issue be processed using the RIRP process**

NMSS Staff recommendation (yes/no) _____

Industry/NEI representative (yes/no) _____

**VI. Date:** 11/18/2015