APPENDIX F: ISSUE CLOSURE FORM

Title: Reporting of Medical Treatment of a Contaminated Individual

I. Problem Statement

(Provide a summary of the problem statement drawn from the Regulatory Evaluation Summary and the Issue Resolution Project Plan. This section is provided for completeness to ensure the issue is understood.)

As stated by the Nuclear Energy Institute (NEI) in its Regulatory Evaluation Summary:

> Industry is seeking clarification on the definitions of "medical facility (onsite vs. offsite)" and "with spreadable contamination" under Title 10 of the *Code of Federal Regulations*, (10 CFR) Parts 40.60(b)(3) and 70.50(b)(3). We seek an interpretation that aligns "medical facility" to be consistent with 10 CFR 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.

II. Closure Statement

(For rejected issues, summarize the reason(s) for issue rejection and forward to the identifying organization. For resolved issues, summarize the resolution and any action items required by NRC and/or industry to be tracked in order to bring final resolution to the issue. List any remaining tracking items and the responsible party in Section V and VI below.)

The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the last 5 years of data in the Nuclear Materials Events Database and the Fuel Cycle Operating Experience Database to determine whether the issue raised was generic for the fuel cycle industry. The search revealed that only one fuel cycle facility licensee, Honeywell Metropolis Works, made a significant number of medical treatment reports (41 event reports) under the 10 CFR 40.60(b)(3) requirement, and that only two other fuel cycle facility licensees, Nuclear Fuel Services and the Westinghouse Columbia Fuel Fabrication Facility, reported (a combined 4 event reports) under the 10 CFR 70.50(b)(3) requirement. The data reviewed indicates that these reporting issues are not generic in nature. However, in several public meetings, the licensees and NEI requested further clarification regarding these requirements. In these meetings, a position was presented that the lack of reporting was due to a different interpretation of the 10 CFR 40.60(b)(3) and 70.50(b)(3) requirements.

The statement of considerations (SOC) for the 1991 rulemaking establishing the 10 CFR 40.60(b)(3) and 70.50(b)(3) provisions [56 *Federal Register* 40757 *et seq*. (August 16, 1991)] explained the need for 24-hour reporting. In responding to comments on the proposed rule, the Commission made clear that contaminated patients treated at onsite medical facilities – even such facilities that only administer first aid – are included in the reporting requirements, and emphasized the importance of reporting onsite medical treatment events in order to minimize the spread of radiological contamination [56 *Federal Register* 40757, at 40762-63].

Based on the information discussed above and on the points raised during the public meetings, the NRC staff concluded that the 10 CFR 40.60(b)(3) and 70.50(b)(3) issues first discussed in

NEI's July 27, 2015, letter, could be resolved via an alternate approach that is within the NRC's existing regulatory framework. This approach is outlined in the section below.

Alternative Path for Resolution

In accordance with the exemption provisions contained in 10 CFR 40.14 and 70.17, the NRC staff would consider, on a case-by-case basis, requests seeking relief from the reporting requirements of 10 CFR 40.60(b)(3) and 70.50(b)(3) in situations involving the treatment of contaminated workers at onsite medical facilities. The NRC staff would review such requests using the following guidance:

1. The onsite medical facility is in a restricted area and not accessible to members of the public;

2. An injured worker can reach the onsite medical facility without traversing any areas accessible to the public;

3. Radiation safety personnel, who have been trained and qualified in contamination control, are readily available;

4. Equipment and facilities that may be needed for contamination control are readily available; and

5. The licensee commits to establish and maintain a log of contaminated workers treated at the onsite medical facility, and provides this information for NRC inspection upon request.

III. Summary of Teams' Actions

(Provide a brief chronology of actions taken to bring the issue to resolution.)

Consistent with the NEI 14-14 process, multiple public meetings were held among NRC, NEI and fuel cycle industry representatives to gain insights on this issue and to ensure that all parties had an opportunity to present their positions. These meetings were held on October 15, 2015 (Agencywide Documents Access and Management System [ADAMS] Accession Number ML15296A421), December 1, 2015 (ADAMS Accession Number ML15351A339), March 23, 2016 (ADAMS Accession Number ML16112A146), May 25, 2016 (ADAMS Accession Number ML16158A330), August 30, 2016 (ADAMS Accession Number ML16260A351), and October 12, 2016 (ADAMS Accession Number ML16306A050).

During the May 25, 2016, public meeting, industry representatives stated their positions that 10 CFR 40.60(b)(3) and 70.50(b)(3) should be interpreted as excluding medical treatment of contaminated individuals at an on-site medical facility (ADAMS Accession Number ML16144A384). The NRC position is that the SOC for the August 1991 rulemaking establishing these 24-hour reporting requirements made clear that events involving contaminated patients treated at onsite medical facilities – even such facilities that only administer first aid – are subject to the reporting requirements [56 *Federal Register* 40757, at 40762-63].

There were also discussions concerning potential approaches to addressing these reporting issues. To the extent practical, these suggestions were incorporated into the "Alternative Path for Resolution" discussion presented in Section II above. Additionally, NRC staff does agree

with the industry position that determinations regarding the presence of the radiological contamination on an individual receiving medical treatments, and whether such contamination is spreadable, should be determined by standard methods of detection and be based on accepted health physics practices and protocols.

The staff position is that the 10 CFR 40.60(b)(3) and 70.50(b)(3) reporting issues can be addressed through the existing NRC regulatory framework.

IV. Satisfaction of Success Criteria

(Discuss how the success criteria were satisfied.)

N/A

V. Tracking of Durable Guidance

(Identify the specific documents that were created, revised or endorsed.)

N/A

VI. Responsibility

(Each organization is responsible for maintaining records of issues addressed under this protocol including durable guidance.)

N/A

Date: January 27, 2017