SUMMARY OF COMMENTS FROM THE ORGANIZATION OF AGREEMENT STATES, WASHINGTON STATE DEPARTMENT OF HEALTH, AND COMMONWEALTH OF VIRGINIA DEPARTMENT OF HEALTH ON THE DRAFT REVISED ABNORMAL OCCURRENCE REPORTING CRITERIA AND STAFF RESPONSES

Criterion I.A: Human Exposure to Radiation from Licensed Material

Comment: Two commenters stated that § 35.3047 of title 10 of the *Code of Federal Regulations* (10 CFR), "Report and notification of a dose to an embryo/fetus or nursing child," and/or equivalent State regulations address reports of exposures to the embryo/fetus and therefore recommended removing that type of exposure from Criterion I.A.2 (Organization of Agreement States (OAS), Washington State Department of Health (WDH)).

Response: The U.S. Nuclear Regulatory Commission (NRC) staff made no changes in response to these comments. Section 208 of the Energy Reorganization Act of 1974, as amended, states, "For the purposes of this section an abnormal occurrence is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety." The Commission established thresholds in the abnormal occurrences (AO) criteria that the event needs to meet in order to reach the level of "public health or safety significance" and be reported to Congress. The NRC staff intends the AO criteria to identify those events that could signal a potential public health or safety issue. As such, 10 CFR 35.3047, which requires licensee reporting to the NRC or Agreement State, does not meet the requirement to evaluate the event for "public health or safety significance" because it only considers the single event in itself, while the AO criteria evaluate the event in a broader industrywide perspective.

Comment: One commenter stated that there should be a higher threshold for an AO than for typical reporting criteria, but noted that the AO threshold in Criterion I.A.2 for dose to an embryo/fetus is the same as the threshold for a medical event (50 millisieverts (mSv) (5 rem)). The commenter recommended having the AO threshold be "permanent functional damage to the fetal thyroid" because most events that meet this criterion are almost exclusively a result of exposure to iodine (I)131. The commenter stated that this change would eliminate reporting the medical events as AOs for those cases in which medical personnel administer I-131 very early in the pregnancy when the thyroid of the embryo/fetus does not yet concentrate I-131 (OAS).

Response: The NRC staff made no changes in response to these comments. The AO criteria and 10 CFR 35.3047 do not distinguish the fetal dose by gestational time periods. The AO threshold dose to an embryo/fetus, 50 mSv, is 50 times the public dose limit of 1 mSv. The NRC staff disagrees with having two different thresholds for reporting an AO involving exposure to an embryo/fetus; one for an embryo/fetus unintentionally exposed due to an administration to a pregnant individual and one for an embryo/fetus exposed from all other sources of licensed material. The threshold dose, 50 mSv, is large enough to capture all significant exposures to the embryo/fetus from the use of licensed material.

Comment: Three comments concerned the new provision in Criterion I.A.3 that an independent physician determine unintended permanent functional damage to an organ or a physiological system. One commenter recommended removing the provision because States do not typically seek out independent physicians to review cases of radiation exposure (OAS). Another commenter recommended changing the provision to include an authorized medical physicist (Commonwealth of Virginia Department of Health (VDH)), and another commenter

recommended modifying the description of an independent physician in Footnote 3 to confirm the physician to be a qualified specialist in the relevant field (WDH).

Response: The NRC staff made no changes in response to these comments. The NRC believes that an "authorized medical physicist" is neither qualified nor credentialed to make a medical determination that unintended permanent functional damage to an organ or a physiological system has occurred. The criterion provides that an independent physician "deemed qualified by the NRC or Agreement State" make the determination. The phrase "deemed qualified by the NRC or Agreement State" ensures that the NRC or Agreement State takes into account all pertinent credentialing aspects of the individual, including specialty in the relevant field.

Criterion I.C: Theft, Diversion, or Loss of Licensed Material; Sabotage; or Security Breach

Comment: One commenter recommended removing the requirement for "irretrievable well logging sources" from Criterion I.C.1 because it does not seem plausible that an irretrievable well logging source buried thousands of feet below the ground would cause exposures to exceed the limits in Criterion I.A.1 (VDH).

Response: The NRC staff made no changes in response to these comments. The regulations at 10 CFR 39.77(c) and (d) or compatible Agreement State regulations require the licensee to evaluate the potential threat to public health or safety from an abandoned irretrievable source. This evaluation and the subsequent action taken by the licensee would be dictated by the potential dose to the public. The dose assessment would be used as a basis to evaluate the event as a potential AO.

Comment: Two commenters questioned the applicability of the phrase "Any substantial breakdown of physical security, cyber security, or material control and accountability programs…" to material licenses and requested clarification (OAS, VDH).

Response: The NRC staff made no changes in response to these comments. Criterion 1.C.4 is principally for licensees that possess more than a critical mass of special nuclear material and whose activities are included in a security plan required by 10 CFR Part 73. AO Criterion 1.C.1 is triggered for any stolen, diverted, abandoned, or unrecovered lost radioactive material that meets or exceeds the thresholds listed in Appendix A of 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Radioactive Material." Criterion 1.C.1 is the principal criterion for security incidents involving materials subject to 10 CFR Part 37 for NRC or Agreement State radioactive materials licensee events to determine if an AO has occurred.

Criterion III.C: Medical Event Criteria

Comment: One commenter recommended that the NRC delete Section III.C from the AO reporting criteria because a medical event is a singular event to an individual patient and therefore has no impact on public health and safety. The commenter recommended that if the NRC did not delete Criterion III.C., the NRC should delete Criterion III.C.2 because this section duplicates the statement that defines a medical event in Criterion III.C.1 (VDH).

Response: The NRC staff made no changes in response to these comments. In response to Section 208 of the Energy Reorganization Act of 1974, the NRC developed and published the criteria in order to meet congressional tasking. The criteria reflect a range of health concerns and apply to unscheduled incidents that the Commission considers significant that involve a

single individual or the general public. As such, the Commission considered misadministrations to be a concern and thus, the NRC added Criterion III.C for medical AO. The AO criteria for misadministrations were not originally dose threshold based. Revisions since 1996 have been based on threshold doses, publications, such as National Council on Radiation Protection and Measurements Commentary 7, "Misadministration of Radioactive Material in Medicine-Scientific Background" (1991) and International Commission on Radiation Protection 41 "Nonstochastic Effects of Ionizing Radiation" (1984), and 10 CFR 35. The current criteria is based on doses that would likely have a significant potential for resulting in permanent deterministic effects. The two criteria, III.C.1 and III.C.2, are not duplicative because they describe two separate ideas; the first is associated with the dose imparted and the second relates to the dose imparted in view of the written prescription.

Comment: One commenter supported the revised language that states, "exceeds, by 10 Gy (1,000 rad), the expected dose to any other organ or tissue from the administration defined in the written directive" (OAS).

Response: No response needed.