REGULATORY ANALYSIS

REVISION 2 OF REGULATORY GUIDE 8.20, "APPLICATIONS OF BIOASSAY FOR RADIOIODINE"

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The purpose of a Regulatory Analysis for a revision to an existing regulatory guide is: (1) to clearly state the need for and consequence of the proposed revision; (2) to identify and evaluate alternate approaches; (3) to clearly describe how the proposed revision will improve nuclear safety or security.

1. Statement of the Problem

The U.S. Nuclear Regulatory Commission (NRC) is considering revising Regulatory Guide 8.20 to update reference to the appropriate regulations and to incorporate the NRC's implementation of a risk-informed, performance-based approach to licensing.

The NRC published Revision 1 of Regulatory Guide 8.20, "Application of bioassay for radioiodine," in September 1979 to provide licensees and applicants with agency-approved guidance for complying with the then-current version of Title 10, of the Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation " (10 CFR 20.1204). The current version of Regulatory Guide 8.20 is outdated because it does not reference the correct sections of the regulations and does not reflect the NRC's implementation of a risk-informed, performance-based approach to licensing.

2. Objective

The objective of this regulatory action is to update NRC guidance and provide applicants with a method to demonstrate compliance with the current 10 CFR Part 20 regulations, applying advanced technology and updated recommendations for protection, and harmonizing with International Safety Standards.

Revising this regulatory guide to endorse portions of a consensus standard is consistent with the NRC policy of evaluating the latest versions of national consensus standards to determine their suitability for endorsement by regulatory guides. This approach will also comply with the NRC's directive that standards developed by consensus bodies must be used in accordance with Public Law 104-113, "National Technology Transfer and Advancement Act of 1995."

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

1. Do not revise Regulatory Guide 8.20

2. Withdraw Regulatory Guide 8.20

3. Revise Regulatory Guide 8.20 to address the current methods and procedures.

Alternative 1: Do Not Revise Regulatory Guide 8.20

Under this alternative, the NRC would not revise guidance, and the current guidance would be retained. If NRC does not take action, there would not be any changes in costs or benefit to the public, licensees or NRC. However, the "no-action" alternative would not address identified concerns with the current version of the regulatory guide. The NRC would continue to review each application on a case-by-case basis. This alternative is considered the "no-action" alternative and provides a baseline condition from which any other alternatives will be assessed.

Alternative 2: Withdraw Regulatory Guide 8.20

Under this alternative the NRC would withdraw this regulatory guide. This would eliminate the current conflict that exists between the current regulatory guide and the newer regulations. It would also eliminate the only readily available description of the methods the NRC staff considers acceptable for demonstrating compliance with 10 CFR 20.1204. Although this alternative would be less costly than the proposed alternative, it would impede the public's safety and accessibility to the most current guidance information.

Alternative 3: Revise Regulatory Guide 8.20

Under this alternative, the NRC would revise Regulatory Guide 8.20. This revision would incorporate the latest technologies in the radiobioassay and associated radiochemistry, supporting new guidance, and review ALARA practices. By doing so, the NRC would ensure that the RG guidance available in this area is current, and accurately reflects the staff's regulatory position.

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide revision. The impact to the public would be the voluntary costs associated with reviewing and providing comments to NRC during the public comment period. The value to NRC staff and its applicants would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for license applications and other interactions between the NRC and its regulated entities.

Conclusion

The option (1) is unacceptable: the Guide is too old and inaccurate using outdated information. Alternative 1 is highly not recommended. Option (2) is impossible, because this is an important Guide for protecting nuclear workers (both reactor and medical) involving use and handling radioiodine. The alternative (3) is the only viable approach for this Guide, now and future.

Based on this regulatory analysis, the NRC staff recommends revision of Regulatory Guide 8.20. The staff concludes that the proposed action will enhance the health and safety on radioiodine users and handlers in nuclear medicine and for monitoring unwanted and unexpected intake of radioiodine in the reactor environments.