NRC Requests Comments on Draft Guidance

Jeffry A. Siegel, PhD, Nuclear Physics Enterprises, Marlton, NJ; Michael G. Stabin, PhD, Vanderbilt University, Nashville, TN; and Carol S. Marcus, MD, PhD, David Geffen School of Medicine at UCLA, Los Angeles, CA

The United States Nuclear Regulatory Commission (NRC) recently published a draft revised NUREG-1556, Vol. 9, and on December 6 issued a request for public comments in the *Federal Register* (https://www.federalregister.gov/documents/2016/12/06/2016-29214/program-specific-guidance-about-medical-use-licenses). The 405-page guidance document contains a number of appendices. Of particular concern is Appendix U, dealing with the release of patients administered radioactive materials. We have published more than 20 articles and commented directly to the NRC on numerous occasions about the deficiencies of the previous version of this appendix and are dismayed that our work and that of other experts has been either ignored or dismissed.

The purpose of the revised Appendix U is to provide "acceptable procedures for the release of patients. . . ." However, this entire appendix sets back the practice of radiation protection science at least 15 years, with material that is scientifically baseless and disregards the large body of published literature demonstrating the proper methodology. The entire first part of the appendix bases patient release on the discredited "point source in air physical decay only" algorithm, which uses parameter values that have been scientifically demonstrated to be incorrect. The result essentially retains the "30 mCi" rule for $Na^{131}I$ patient release as an acceptable methodology. The assumed "calculated" dose is fictional, making it impossible to properly instruct patients. This is certainly not a risk-informed, performance-based approach and should be eliminated.

Radiation protection science and the evidence-based literature demand that patient release be determined at the very least with patient-specific dose calculations. These calculations are both feasible and easily derived. If licensees are unable to perform these simple calculations, this would suggest that the mandated training and experience to attain Authorized User or Radiation Safety Officer status are inadequate and should be strengthened. It is no surprise, however, that based on the draft guidance many licensees might be unable to perform patient-specific calculations, because the appendix deals almost exclusively with $Na^{131}I$—and does so incorrectly.

The revised Appendix U unfortunately retains essentially all of the discredited science from the previous version, and the proposed methodologies remain terribly flawed. The regulated community should no longer allow the NRC to simply ignore or dismiss the consensus of the peer-reviewed literature. In addition, regulatory burden is added, something outside the usual content of a guidance document. Blind adoption of the recommendations in this flawed appendix will result in significant negative impacts in daily practice for medical licensees administering radionuclide therapy treatments.

We are providing a lengthy critique to the NRC and strongly encourage all affected licensees to carefully read the proposed NUREG, particularly Appendix U, and provide comments to the NRC by the February 6 deadline.