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Subject: STP 06 01

The New York State Department of Environmental Conservation has reviewed the Draft Proposed Rule: 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, and 150 "Expanded Definition of Byproduct Material" (STP-06-001). We offer the following comment for the NRC's consideration.

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to include certain accelerator-produced radioactive materials. The New York State Department of Environmental Conservation has many years of experience in regulating the emission of accelerator-produced radioactive materials from medical radionuclide production cyclotrons; i.e., those involved in the production of low-atomic-weight, short-lived positron emitters. Medical production cyclotrons emit significant activities to air on a yearly basis. As a class, medical cyclotrons are the largest emitters of radionuclides to air in New York State.

As part of the expansion of the definition of byproduct material, the NRC should amend Appendix B of 10 CFR Part 20 (i.e., the Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; and Concentrations for Release to Sewerage). Most accelerator-produced isotopes currently encountered are already listed in the Appendix, as they are also fuel-cycle or reactor generated. However, two nuclides commonly produced in cyclotrons do not appear in Column 1 of Table 2 and are therefore considered to be unlisted. These unlisted nuclides are nitrogen-13 and oxygen-15. N-13 is a common byproduct of medical cyclotron operation, through activation of residual O-16 to O-17 in O-18 enriched water in target solutions, with subsequent alpha decay to N-13. (Oxygen-18 enriched water is used to manufacture F-18 via O-18(p,n)->F-18.) It is also produced via inadvertent activation of O-16 in residual wash water used to flush radionuclide transfer lines. Additionally, N-13 is widely used for myocardial perfusion investigations. Oxygen-15 is frequently manufactured via N-15(p,n) -> O-15 for research purposes; these purposes include neurology, cardiology, neuropsychiatry, and angiology and circulation studies.

In New York State, cyclotron operators are required to demonstrate compliance with the public dose limits, similar to the requirements in 10 CFR 20.1302. As NRC knows, emissions can be compared to the values in Column 1, Table 2, in Appendix B to help make that demonstration.

Currently, any single radionuclide not listed in Table 2, with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours, must use the overly conservative default values provided: a Table 1, Column 1 inhalation ALI of 2E2 microcurie/ml, and a Table 2 Column 1 effluent concentration of 1E-9 microcurie/ml. These default values are unnecessarily restrictive, given the dose conversion factors for these nuclides. Those factors have been readily available for many years in such publications as NCRP Report No. 123 I, Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground (National Council on Radiation Protection and Measurements, 1996).

We recommend that the NRC update Appendix B to include specific values for all cyclotron-produced radioactive materials in current production and use. Dose assessments are commonly required for regulatory approvals for emissions from medical cyclotrons, and inclusion of these common nuclides in the tables will facilitate such evaluations for both applicants and regulators.

Thank you for the opportunity to review this draft. If you have any questions, please contact me.

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