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Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses

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Program-Specific Guidance About Medical Use Licenses; Request for Comments

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2

**General Comment**

With respect to Appendix U Model Procedures for the Release of Patients or Human Research Subjects Administered Radioactive Materials

This appendix explicitly references NCRP Report No. 37 Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides and suggests the use of equations contained within this report. The equations (U-1, U-2, U-3 and B-1) shown in Appendix U include the free in air gamma constant ( $\Gamma$ ) to calculate exposure rate at time  $t$  at a defined distance from the patient and the physical half-life.

These equations ignore the fact that much of the administered radioactive material is eliminated by biological processes with turnover rates that are considerable shorter than the physical half-life - in the case of I-131 administered for treatment of thyroid cancer, up to 95% of the activity is eliminated within 24 to 48 hrs. The implication of this additional pathway for elimination is that a multi-compartment equation should be considered. In addition, use of the gamma constant does not accurately represent the actual radiation levels surrounding the patient following administration as it does not take into account self-absorption.

NCRP Report No. 155 Management of Radionuclide Therapy Patients was published in 2007 and largely supersedes Report No. 37. This report acknowledges and incorporates biological turnover as a second pathway for elimination. In addition, the gamma constant is replaced with the air kerma rate ( $K$ ) at an index distance from the patient. Hence, the actual radiation levels emanating from the patient are used to estimate

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the dose to family and the public.

It is recommended that the processes outlined in NCRP Report No. 155 be used to provide guidance for release of these patients. This has become common practice in the medical health physics community.