APPENDIX A

ACCEPTABLE TRAINING AND EXPERIENCE FOR

MEDICAL USES OF BYPRODUCT MATERIAL

Section 35.11 (d) of 10 CFR 35 provides that the Commission will approve a license application by an institution for medical use of byproduct material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in (a) basic radioisotope handling techniques and (b) the clinical use of byproduct material proposed in the application. Similar criteria are established in Section 35.12 (c) of 10 CFR 35 for approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria that the Commission, with the assistance of its Advisory Committee on the Medical Uses of Isotopes, has found acceptable for physicians who use radiopharmaceuticals. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radiopharmaceuticals but does not have the training and experience described, he may submit an application listing his specific qualifications and this will be reviewed by the Commission with the assistance of the Medical Advisory Committee.

I. GENERAL TRAINING

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups I, II and/or III, Section 35.100 of 10 CFR Part 35, a physician should have:

A. Training in basic radioisotope handling techniques (200 hours) including:

1. Radiation physics and instrumentation (100 hours)
2. Radiation protection (30 hours)
3. Mathematics pertaining to the use and measurement of radioactivity (20 hours)
4. Radiation biology (20 hours)
5. Radiopharmaceutical chemistry (30 hours)

B. Experience with the types and quantities of byproduct material for which the application is being made, or equivalent (500 hours).

C. Clinical training in a supervised institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and include:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.
2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements and plotting data.
3. Follow-up of patients when required.
4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitations, contraindication, etc.

ITE: THE REQUIREMENTS SPECIFIED IN SECTIONS A, B, AND C MAY BE SATISFIED CONCURRENTLY IF ALL THREE ARE INCLUDED IN THE TRAINING PROGRAM. FOR EACH PHYSICIAN NAMED IN ITEM 4 OF FORM NRC-313 COMPLETE A SEPARATE PAGE 3 OF THE FORM NRC-313a (PRECEPTOR STATEMENT) AND APPEND THE STATEMENT OF TRAINING IN BASIC RADIOISOTOPE HANDLING TECHNIQUES. FOR EACH SUBJECT COVERED IN BASIC TRAINING, STATE WHERE THE TRAINING WAS OBTAINED, THE DATES, TOTAL NUMBER OF HOURS, AND TYPE OF TRAINING (E.G., LECTURES, LABORATORY).

II. TRAINING REQUIREMENTS FOR SPECIFIC DIAGNOSTIC PROCEDURES

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of byproduct material being requested. Such requests will be examined on a case-by-case basis by the Commission with the assistance of the Advisory Committee on the Medical Uses of Isotopes.

III. TRAINING REQUIREMENTS FOR THERAPY PROCEDURES INVOLVING RADIOPHARMACEUTICALS

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups IV and/or V, Section 35.100 of 10 CFR Part 35, a physician should have:

A. Training in basic radioisotope handling techniques (80 hours) including:

1. Radiation physics and instrumentation (25 hours)
2. Radiation protection (25 hours)
3. Mathematics pertaining to the use and measurement of radioactivity (10 hours)
4. Radiation biology (20 hours)

B. Clinical training in specific therapy procedures:

For Group IV

(i) Iodine-131 for treatment of hyperthyroidism and/or cardiac conditions:

- Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

(ii) Phosphorus-32 for treatment of polycythemia vera, leukemia and/or bone metastases:

- Treatment of three patients with one of these conditions.

(iii) Collodial phosphorus-32 for intracavitary treatment:

- Active participation in the treatment of three patients.

For Group V

(i) Iodine-131 for treatment of thyroid carcinoma:

- Clinical experience in diagnosis of thyroid function and treatment of hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of three patients with thyroid carcinoma.

(ii) Colloidal gold-198 for intracavitary treatment:

- Active participation in the treatment of three patients.

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IV. TRAINING REQUIREMENTS FOR THERAPY PROCEDURES INVOLVING SEALED SOURCES

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Group VI, Section 35.100 of 10 CFR Part 35, a physician should have:

A. Training in basic radioisotope handling techniques (200 hours) as described in Section I.A. of this Appendix.

B. Clinical training in specific therapy procedures:

(i) Radiation sources for interstitial, intracavitary, or surface treatment of cancer:

- Active practice in therapeutic radiology with a minimum of three years experience.

(ii) Beta ray applicators for the treatment of superficial eye disease:

- Active practice in therapeutic radiology or ophthalmology and experience in the therapeutic use of beta rays or soft X-rays.