Appendix B: Acceptable Training and Experience Guidelines For Medical Uses of Radioactive Material

Section 30195 (a) of the California Radiation Control Regulations provides that the Department will approve a license application by an institution for medical use of radioactive material if it determines, among other things, that the physicians designated as authorized users are adequately trained and experienced in (1) basic radionuclide handling techniques and (2) the clinical uses of radioactive material proposed in the application. Similar criteria are established in Section 30195 (b) for approval of licenses for medical use of radioactive material by individual physicians. Outlined below are training and experience criteria that the Department has found acceptable for physicians who use radioactive material. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radioactive material but does not have the training or experience described, he may submit an application listing his specific qualifications and these will be reviewed by the Department with the assistance of the Medical Advisory Committee.

1. **Group 1 - Training Requirements for Uptake, Dilution, or Excretion Studies, But Not Involving Imaging.**

   To qualify as adequately trained to use or directly supervise the use of radioactive material listed in group a of the Well-Established Medical Uses List (RH 2010R), a physician should have:

   a. Training in basic radionuclide handling techniques (40 hours) consisting of lectures, laboratory sessions, discussion groups, and supervised experience in a nuclear medicine laboratory in the following areas:

      (1) Radiation physics and instrumentation.

      (2) Radiation protection.

      (3) Mathematics, statistics, and computer sciences pertaining to the use and measurement of radioactivity.

      (4) Radiation biology.

      (5) Radiopharmaceutical chemistry.

   b. Supervised clinical training and experience under the supervision of an authorized user (20 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:

(1) Supervised examination of patients to determine the suitability for radionuclide diagnosis and recommendation on dosage to be prescribed.

(2) Collaboration in calibration of the dose and actual administration of the dose to the patient, including calculation of the radiation dose, related measurement and plotting data.

(3) Supervised interpretation of results of radionuclide diagnostic procedures and follow-up of patients when required.

(4) Study and discussion with the preceptor of case histories to establish most appropriate diagnostic procedures, limitations, contraindications, etc.

Note A

For each physician named in item 4 of form RH 2000, complete form RH 2000A (Preceptor statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained and the dates, total number of hours, and type of training (e.g., lectures, laboratory sessions).

Alternatives

Certification by the American Board of Nuclear Medicine or by the American Board of Radiology in Diagnostic Radiology (Diagnostic Radiology with Special Competence in Nuclear Radiology if prior to July 1984), or by the American Osteopathic Board of Radiology in Diagnostic Radiology or Radiology, or completion of a residency program in Nuclear Medicine that is approved by the Accreditation Council on Graduate Medical Education will be accepted as meeting the training and experience requirements for use of Group 1. Copies of certificates may be submitted in lieu of form RH 2000A. (See Section 8 for recentness of training.)

2. **Groups 1, 2, and/or 3 - Training Requirements for Imaging and Localization Studies and/or the Use of Generators and Reagent Kits for Preparation of Radiopharmaceuticals.**

To qualify as adequately trained in use or directly supervise the use of radioactive material listed in Groups 1,2, and/or 3 of the Well-Established Medical Uses List (RH 2010R), a physician should have:

a. Training in basic radionuclide handling techniques (200 hours) consisting of lectures, laboratory sessions, discussion groups, and supervised experience in a nuclear medicine laboratory in the following areas:

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

(The hours listed for each of the subjects above are suggested values and should not be interpreted as specific requirements.)

b. Supervised clinical training and experience under the supervision of an authorized user (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:

(1) Supervised examination of patients to determine the suitability for radionuclide diagnosis and recommendation on dosage to be prescribed.

(2) Collaboration in the calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data.

(3) Supervised interpretation of results of radionuclide diagnostic procedures and follow-up of patients when required.

(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindications, etc.

c. Supervised work experience under the supervision of an authorized user (500 hours). The experience should include:

(1) Ordering, receiving, and performing precautionary checks and measurements on radioactive packages.

(2) Quality assurance tests on dose calibrators, diagnostic instruments, and survey instruments.

(3) Elution of Technetium 99m from generators, testing for molybdenum and alumina contamination, and preparing radiopharmaceuticals with reagent kits.

(4) Radioactive spillage containment and decontamination procedures.

(5) Administration procedures to prevent misadministration of radiopharmaceuticals.

Note A

It is expected that the requirements specified in Sections 2.a, b, and c could be satisfied in less than a six-month training program.

Note B

For each physician named in item 4 of form RH 2000, complete from RH 2000A (Preceptor statement and the statement of training in basic radioisotope handling techniques). For each subject covered in basic training, state where the training was obtained and the date, the number of hours, and type of training (e.g., lectures, laboratory sessions).

Alternatives

Certification by the American Board of Nuclear Medicine or by the American Board of Radiology in Diagnostic Radiology (Diagnostic Radiology with Special Competence in Nuclear Radiology if prior to July 1984), or by the American Osteopathic Board of Radiology in Diagnostic Radiology or Radiology, or completion of a residency program in Nuclear Medicine that is approved by the Accreditation Council on Graduate Medical Education will be accepted as meeting the training and experience requirements for use of Groups 1 through 3. Copies of certificates may be submitted in lieu of form RH 2000A. (See Section 8 for recentness of training.

3. **Groups 4 and 5 - Training Requirements for Therapy Procedures involving Radiopharmaceuticals**

A Physician who is qualified to use radioactive material listed in Groups 1 through or 6, RH 2010R, may also qualify to use or directly supervise the use of radioactive material listed in Groups 4 and/or 5 by submitting evidence of clinical training and experience in specific therapy procedures. (Physicians certified by the American Board of Nuclear Medicine need not submit this information.)

a. **For Group 4**

(1) Iodine 131 for treatment of hyperthyroidism:

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

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

Treatment of three patients with any combination of the above three conditions.

(3) Colloidal Phosphorus 32 intracavity treatment:

Active participation in the treatment of three or more patients.

b. **For Group 5**

(1) Iodine 131 for treatment of thyroid carcinoma:

Clinical experience in diagnosis of thyroid function and treatment of hyperthyroidism and active participation in the treatment of three or more patients with thyroid carcinoma.

4. **Training Requirements for Use of Iodine 131 for treatment of Hyperthyroidism/ Thyroid Carcinoma Only**

To qualify as adequately trained to use or directly supervise only the use of Iodine 131 for the treatment of hyperthyroidism/thyroid carcinoma in Groups 4 and/or 5, the physician should have special experience in thyroid diseases and should have:

a. Training in basic radionuclide handling techniques (80 hours) consisting of lectures, laboratory sessions, discussion groups, and supervised clinical experience in the following areas:

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

(The hours listed for each of the subjects above are suggested values and should not be interpreted as specific requirements.)

b. Clinical training and experience in the diagnosis of thyroid function, and active participation in the treatment of ten or more patients with hyperthyroidism and three or more patients with thyroid carcinoma.

5. **Groups 6 and 8 - Training Requirements for Therapy Procedures involving Sealed Sources.**

To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group 6, RH 2010R, a physician must be in active practice of therapeutic radiology and should have:

a. Training in basic radionuclide handling techniques (200 hours) consisting of lectures, laboratory sessions, discussion groups and supervised experience in the following areas:

(1)	Radiation physics and instrumentation	100 hours
(2)	Radiation Protection	40 hours
(3)	Mathematics, statistics, and computer sciences pertaining to the use and measurement of radioactivity	40 hours
(4)	Radiation biology	20 hours

(The hours listed for each of the subjects above are suggested values and should not interpreted as specific requirements.)

b. Three years of supervise clinical experience that includes one year in a formal residency training program that is either approved for therapeutic radiology by the Accreditation Council on Graduate Medical Education or for radiation oncology by the American Osteopathic Association. The remaining two years should be spent under supervision of an authorized user in an institutional radiation therapy program, and the experience should include:

(1) Supervised examination of patient and their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindication.

(2) Collaboration with the preceptor in selecting proper brachytherapy sources and doses, dose calculations, and method of administration.

(3) Collaboration with the preceptor in postadministration follow-ups

c. Supervised work experience in an institutional radiation therapy program (500 hours). The experience should include:

(1) Ordering receiving, and performing precautionary checks and measurements on radioactive packages.

(2) Checking survey meters for proper operation.

(3) Preparing, implanting, and removing sealed sources from the patient.

(4) Using administrative controls to maintain inventory of sealed sources, and to prevent misadministrations.

(5) Reviewing full calibration measurements and periodic spot checks if request is for teletherapy.

(6) Preparing treatment plans and calculating treatment times.

(7) Familiarity with emergency procedures for controlling radiation exposures during radionuclide incidents.

Alternatives

For use of radioactive material listed in Groups 6 and 8, evidence of certification by the American Board of Radiology in Therapeutic Radiology or Radiation Oncology, or certification by the American Osteopathic Board of Radiology in Radiation Oncology, or certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR), or a Canadian certification in Therapeutic Radiology by the Canadian Royal College of Physicians and Surgeons (RCPS), or completion of a residency program in therapeutic radiology that is accredited by the Accreditation Council on Graduate Medical Education or Committee on Postdoctoral Training of the American Osteopathic Association may be submitted in lieu of form RH 2000A.

British certificates in Radiology must be accompanied by evidence of specialization in radiotherapy. (See Section 8 for recentness of training.)

6. **Training Requirements for Therapy Procedures involving Sr-90 Ophthalmic Eye Applicators Only**

To qualify as adequately trained to use or directly supervise the use of Sr-90 eye Applicators, a physician must be in active practice of therapeutic radiology or ophthalmology and should have:

a. Training in basic radionuclide handling techniques (24 hours minimum) consisting of lectures, laboratory sessions, discussion groups, and supervised experience in the following areas:

(1) Radiation physics and instrumentation 6 hours

(2) Radiation Protection 6 hours

(3) Mathematics pertaining to the use and measurement of radioactivity — 4 hours

(4) Radiation biology — 8 hours

(The hours listed for each of the subjects above are suggested values and should not be interpreted as specific requirements.)

b. Supervised clinical training and experience in an institutional ophthalmic radiotherapy program. The clinical training should include active participation in the treatment of five or more individuals which includes:

(1) Examination of each individual to be treated

(2) Calculation of the dose to be administered

(3) Administration of the dose

(4) Follow-up and review of each individual's case history

Alternatives

Certification by the American Board of Radiology in Therapeutic Radiology or Radiation Oncology may be submitted in lieu of form RH 2000A.

7. **Group 7 - Training Requirements for Use of Sealed Sources for Diagnosis**

To qualify as adequately trained to use or directly supervise the use of sealed sources in devices listed in Group 7, a physician, dentist, or podiatrist should have:

Eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device to include:

(1) Radiation physics, mathematics relative to the use and measurement of radiation, and instrumentation

(2) Radiation protection

(3) Radiation biology

(4) Training in the use of the device for the users requested

Alternatives

Certification by the American Board of Radiology in Diagnostic Radiology or Therapeutic Radiology or Radiation Oncology, or by the American Osteopathic Board of Radiology in Diagnostic Radiology or Radiology, or by the American Board of Nuclear Medicine. A physician who is specifically named as an authorized user for one or more of Groups 1 through 6 may also be accepted as meeting the training requirements for Group 7.

8. **Recentness of training**

The training and experience specified in this appendix must have been obtained within the five years preceding the date of application. Failing to meet this requirement, the individual must provide evidence of continuing education and experience since training and experience were completed.