June 3, 2005

The Royal College of Radiologists
ATTN: Ms. Cathryn J. Butler
Education Secretary
38 Portland Place
London, W1B 1JQ

Dear Ms. Butler,

I am responding to your letter of May 6, 2005, concerning recent correspondence from the United States Nuclear Regulatory Commission (NRC). You requested clarification on the questions listed below and any other information that could assist the College in determining its next step. I will answer the last question first because it may be the most important.

1. Is there additional information that would assist the Royal College of Radiology in determining its next step?

   I have enclosed the requirement sections that each specialty board has to meet for all the authorized user, authorized medical physicist, authorized nuclear pharmacist, and radiation safety officer sections of NRC's regulations. First and most importantly, the criteria require **all candidates for certification to meet** the requirements described in each section. Second, many sections require mandatory work experience under an appropriate NRC recognized authorized user, radiation safety officer, or authorized medical physicist. Third, some of the sections require residency training in programs approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association. You should carefully review the requirements for each section, especially the bolded text, to see if all your fellows meet the requirements.

2. How did the Royal College of Radiologists receive recognition under the NRC regulations in 10 CFR Part 35 Subpart J?

   Our records show that in 1982 when NRC published its "Notice of revised training and experience criteria for authorization to perform nuclear medicine procedures," in the Federal Register (47 FR 54376), the Royal College of Radiologists was listed on page 54380 in a table of acceptable medical specialty board certifications. Certification by these specialty boards was accepted evidence that a physician has had adequate training and experience for the procedures listed.

3. What are the privileges accorded to Fellows of the Royal College of Radiologists by being recognized by NRC?

   NRC and the Agreement States regulate the medical use of byproduct material in all 50 States, the District of Columbia, and territories. When a physician is certified by a specialty board included in 10 CFR Subpart J, the physician is by definition an "authorized user" for the particular medical use specified, provided the physician received his/her certification within the last 7 years.

   This automatic "authorized user" status via the "Board Certification Pathway" enables all medical facilities under NRC or Agreement State jurisdiction to permit your Fellows to work as an authorized user 30 days before the facility has to notify the regulatory authority. Physicians who were not board certified or have a board certification that is not included in 10 CFR Part 35 Subpart J must work under the supervision of an "authorized user" until his/her training and experience can be reviewed and approved by NRC, Agreement State, Master Materials Licensee, or broad scope medical use licensee. Further, these physicians would have to provide documentation that their training and experience met specific "Alternative Pathway" requirements in 10 CFR 35.940(b) or 35.960(b). This process can take time, especially if there are questions concerning training and experience received in a foreign country.

4. What are the implications of the lapse of Specialty Board Recognition by NRC and the Agreement States?

   If the Royal College of Radiologists does not receive recognition as a specialty board, then when 10 CFR Part 35 Subpart J expires on October 25, 2005, all your Fellows that want to become new "authorized users" at medical facilities under NRC and Agreement State jurisdiction will have to apply under the "Alternate Pathway" requirements. If the Royal College was seeking recognition for the same medical uses under 10 CFR Part 35, this would include the requirements in 10 CFR 35.490(b) and 35.690(b) and (c). The Royal College may find other medical uses for which its certification process is appropriate.

   It should be noted that the new training and experience requirements require board certified physicians to provide not only documentation of board certification, but also preceptor attestation statements and evidence of additional training for some of medical uses such use of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units. Therefore, if the Royal College of Radiologists were to apply and receive recognition, its Fellows would still need to obtain the required preceptor attestations and documentation of additional training before they were automatically recognized as "authorized users." With the additional required documentation, they could work as "authorized users" for 30 days before the regulatory authority needed to be notified.

5. Would recognition by NRC or the Agreement States assist only those Fellows of the College of Radiologists who practice as specialists in the US or United Kingdom trainees (residents) in clinical radiology who want a fellowship in the US?

The recognition would assist all board certified Fellows if they wanted to be authorized users in the US and they were practicing the specialty where the Royal College of Radiologists has been recognized. Since our discussion only refers to physicians that are certified by Royal College of Radiologists, I will assume you question concerning United Kingdom trainees (residents) in clinical radiology refers to physicians that already are certified. NRC continued recognition of the Royal College of Radiologists would not help either a Fellow that was practicing a specialty (for example, imaging and localization) for which the NRC had not recognized the Royal College of Radiology certification or that had a fellowship in a unrelated specialty.

I trust this information will be useful to you in deciding whether to pursue recognition by the NRC.

Enclosure:
Specialty Board Recognition by NRC

Sincerely,

/RA/

Thomas H. Essig, Acting Deputy Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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SPECIALTY BOARD RECOGNITION BY NRC

§ 35.50 Training for Radiation Safety Officer.
To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and
(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or
(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics–
(A) Under the **supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State**; or
(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the **direction of physicians who meet the requirements for authorized users** in §§ 35.290, 35.390, or, before October 24, 2005, §§ 35.920, or 35.930; and
(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety;

§ 35.51 Training for an authorized medical physicist.
To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
(2) Have 2 years of full-time practical training and/or supervised experience in medical physics –
(i) Under the supervision of a **medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State**; or
(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the **direction of physicians who meet the requirements for authorized users** in §§ 35.490 or 35.690, or, before October 24, 2005, authorized users who meet the requirements in §§ 35.940 or 35.960; and
(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery;

§ 35.55 Training for an authorized nuclear pharmacist.

To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Have graduated from a pharmacy program accredited by the **American Council on Pharmaceutical Education (ACPE)** or have passed the **Foreign Pharmacy Graduate Examination Committee (FPGEC)** examination;
(2) Hold a current, active license to practice pharmacy;
(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours 7 of the required training and experience; and
(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development.

§ 35.190 Training for uptake, dilution, and excretion studies.

To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and
(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control;
(c)(1) ...classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include–
(i) Classroom and laboratory training in the following areas–
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, involving–
(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(F) Administering dosages of radioactive drugs to patients or human research subjects;

§ 35.290 Training for imaging and localization studies.

To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and
(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
(c)(1) classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum,
(i) Classroom and laboratory training in the following areas–
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use;
(E) Radiation biology; and
(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, involving–
(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
(F) Administering dosages of radioactive drugs to patients or human research subjects; and
(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.

To be recognized, a specialty board shall require all candidates for certification to:
(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the **Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association**; and
(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required;

(b)(1) classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include–
(i) Classroom and laboratory training in the following areas–
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(ii) **Work experience, under the supervision of an authorized user** who meets the requirements in §§ 35§ 35.390(a), 35.390(b), or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2005, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve–
(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
(F) [Reserved]
(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status– Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).
(1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;
(2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;
(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or
(4) Parenteral administration of any other radionuclide, for which a written directive is required;

§ 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).
Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section
(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.
The training must include–
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Chemistry of byproduct material for medical use; and
(v) Radiation biology; and
(2) Has **work experience, under the supervision of an authorized user** who meets the

requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2). The work experience must involve–
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;
(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131

§ 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).
(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State
(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include–
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Chemistry of byproduct material for medical use; and
(v) Radiation biology; and
(2) Has **work experience, under the supervision of an authorized user** who meets the requirements in §§ 35.390(a), 35.390(b), 35.394, or, before October 24, 2005, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve–
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) Using administrative controls to prevent a medical event involving the use of byproduct material;
(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§ 35.490 or 35.690; and who meets the requirements in paragraph (d) of this section.
(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include–
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Chemistry of byproduct material for medical use; and
(v) Radiation biology; and
(2) Has **work experience, under the supervision of an authorized user** who meets the requirements in §§ 35.390 or 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in §§ 35.390 or 35.930 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve–
(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and
(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

§ 35.490 Training for use of manual brachytherapy sources.

To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program **approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association**; and
(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy;

§ 35.590 Training for use of sealed sources for diagnosis.

Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State.
(b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include–
(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity;
(4) Radiation biology; and
(c) Has completed training in the use of the device for the uses requested.

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program **approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association**; and
(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or