From:	Wainhouse, Leo (DOH)
To:	Henderson, Pamela; Schneider, Kathleen; Austin, Michelle (DOH)
Subject:	2009-1, Medical use of byproduct material - authorized user clarification
Date:	Wednesday, September 18, 2013 12:50:44 PM
Attachments:	OTS-5556 3Final.pdf 2009-1 NRC Comment WA 13-13.docx

Dear Ms. Henderson:

RE: RATS ID 2009-1, Medical use of byproduct material – authorized user clarification

This e-mail is in follow-up to your letter dated May 17, 2013. The Washington State Department of Health, Office of Radiation Protection submitted proposed changes to chapter 246-240 WAC , Radiation protection – medical use of radioactive material, for adopting RATS ID 2009-1, Medical use of byproduct material – authorized user clarification.

NRC had one comment on our proposed changes. We have made the appropriate changes to address NRC's comment. Language or punctuation we are deleting has a solid line through it, and new language or punctuation is underlined.

We believe these changes to our rule satisfy the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs Procedure SA-200.

If you have any questions, please contact Michelle Austin, Rules Coordinator, at (360) 236-3250 or by e-mail at michelle.austin@doh.wa.gov

Thank you

Leo Wainhouse
Deputy Director
Office of Radiation Protection
Division of Environmental Public Health
Department of Health
Phone: 360-236-3213
leo.wainhouse@doh.wa.gov
Always Working for a Safer and Healthier Washington

AMENDATORY SECTION (Amending WSR 13-11-021, filed 5/7/13, effective 6/7/13)

WAC 246-240-210 Training for use of unsealed radioactive material for which a written directive is required. Except as provided in WAC 246-240-078, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under WAC 246-240-201 to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, NRC or an agreement state. (Specialty boards whose certification process has been recognized by NRC or an agreement state will be posted on NRC's web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes seven hundred hours of training and experience as described in subsection (2) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postgraduate Training of the American Osteopathic Association; and

(b) 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 by-product material((~~; and~~

~~(c) Obtain written attestation that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under WAC 246-240-201. The written attestation must be signed by a preceptor authorized user who meets the requirements in WAC 246-240-078, 246-240-210, or equivalent NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in WAC 246-240-078 or 246-240-210 must have experience in administering dosages in the same dosage category or categories (i.e., this section) as the individual requesting authorized user status~~)); or

(2) Has completed seven hundred hours of training and experience, including a minimum of two hundred hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in WAC 246-240-078, or subsection (1) or (2) of this section, or equivalent NRC or agreement state requirements. A supervising authorized user, who meets the requirements in this subsection, must also have experience in administering dosages in the same dosage category or categories (i.e., this section) as the in-

dividual requesting authorized user status. 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 radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) ((~~Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and~~

~~(vii)~~)) 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:

(A) 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;

(B) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. Experience with at least three cases in this also satisfies the requirement in (b)((~~(vii)~~)) (vi)(A) of this subsection;

(C) 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; or

(D) Parenteral administration of any other radionuclide for which a written directive is required; and

(E) Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (1)(a) and (2)(b) ((~~(vii)~~)) (vi) of this section, ((~~WAC 246-240-078,~~)) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under WAC 246-240-201. The written attestation must be signed by a preceptor authorized user who meets the requirements in this section, WAC 246-240-078, or equivalent NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in this subsection ((~~(2)~~)), must also have experience in administering dosages in the same dosage category or categories (i.e., this section) as the individual requesting authorized user status.

COMPATIBILITY COMMENTS ON WASHINGTON FINAL REGULATIONS
Medical Use of Byproduct Material—Authorized User Clarification, Part 35 (74 FR 33901) RATS ID # 2009-1
Effective date 09/28/09 Date Due for State Adoption 09/28/12

STATE SECTION	NRC SECTION	CATEGORY	SUBJECT and COMMENTS	COMMENTS
WAC 246-240-210	35.390	B	**Training for use of unsealed byproduct material for which a written directive is required.** Washington needs to make the following changes: In WAC 246-240-210 (2)(b), Washington needs to include the reference to WAC 246-240-078 after the phrase, "Work experience, under the supervision of an authorized user who meets the requirements…" In WAC 246-240-210 (2)(b)(vii)(E), the first sentence, Washington needs to remove the reference to WAC 246-240-078 after the phrase, "has satisfactorily completed the requirements in subsection (1)(a) and (2)(b)(vii) of this section…" In WAC 246-240-210 (2)(b)(vii)(E), second sentence, Washington needs to include the reference to WAC 246-240-078 after the phrase, "The written attestation must be signed by a preceptor authorized user who meets the requirements in this section…" Washington needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 35.390.	**Washington is proposing to adopt these changes in WAC 246-240-210.**