



STATE OF WASHINGTON

DEPARTMENT OF HEALTH
DIVISION OF RADIATION PROTECTION

7171 Cleanwater Lane, Bldg. 5 • P.O. Box 47827 • Olympia, Washington 98504-7827

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September 26, 2000

TO: All Radioactive Materials Licensees & Interested Parties
FROM: Terry C. Frazee, Supervisor, Radioactive Materials Section
SUBJECT: PROPOSED REGULATION CHANGES; PUBLIC HEARING

The department is proposing to amend its regulations for radiation protection in order to maintain compatibility with the U. S. Nuclear Regulatory Commission (NRC). The proposed rule covers two issues: 1) clarification that any individual engaged in deliberate misconduct may be subject to enforcement action (WAC 246-220-060) and 2) an exemption permitting distribution of a radioactive drug containing one microcurie of carbon-14 urea to any person for "in vivo" diagnostic use (WAC 246-232-014). In addition, a long section (WAC 246-232-010) is broken up into nine smaller sections and cross-references are corrected.

PROPOSED REGULATION CHANGES: Here is a brief overview:

- WAC 246-220-060 is amended to define categories of persons that may be subject to department enforcement action if engaged in deliberate misconduct (see reverse);
- WAC 246-232-006 "Exemption of certain source material" is established based on a previous subsection of WAC 246-232-010, as are WAC 246-232-007 "Exemption of certain depleted uranium items", WAC 246-232-008 "Exemption of certain timepieces, hands or dials", WAC 246-232-009 "Exemption of certain items containing radioactive material", WAC 246-232-011 "Exemption of certain self-luminous products containing radioactive materials", WAC 246-232-012 "Exemption of certain gas and aerosol detectors containing radioactive material", and WAC 246-232-013 "Exemption of certain resins containing scandium-46 and designed for sand consolidation in oil wells".
- WAC 246-232-010 is amended to delete moved subsections and renamed "Exempt concentrations and exempt quantities" to reflect its new emphasis;
- WAC 246-232-014 "Exemption of C-14 urea diagnostic capsules for human use" is established (see reverse).

The complete text of these rules will appear as Washington State Register # 00-19-080 (available October 4); at our WEB site (<http://www.doh.wa.gov/ehp/rp/rp-regs.htm>) or obtained by calling (360) 236-3220.

The **PUBLIC HEARING** on these rule changes is scheduled for Wednesday, October 25, 2000 at 10:00 AM in the conference room of Building 5, 7171 Cleanwater Lane, Tumwater, Washington. Written comments should be submitted by October 25, 2000 to Terry C. Frazee at P.O. Box 47827, Olympia, Washington 98504-7827 or via fax at 360-236-2255 or by e-mail at terry.frazee@doh.wa.gov. Assistance for persons with disabilities is also available by contacting Terry C. Frazee at (360) 236-3221 or via e-mail. The TDD number for the hearing impaired is (800) 833-6388.

DSP-006 Template
RIDS Distribution: SP08



AMENDING WAC 246-220-060 Violations.

(1) An injunction or other court order may be obtained prohibiting any violation of any provision of the act or any regulation or order issued thereunder.

(2) Any person who violates any provision of the act or any regulation or order issued thereunder may be guilty of a gross misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(3) A person who knowingly provides to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to these regulations, may be individually subject to department enforcement action for deliberate misconduct.

(a) For the purposes of this subsection, "person" means:

(i) a radioactive materials licensee,

(ii) an applicant for a radioactive materials license,

(iii) an employee of a radioactive materials licensee or applicant; or

(d) any contractor (including a supplier or consultant), subcontractor, or employee of a contractor or subcontractor of any radioactive materials licensee or applicant for a radioactive materials license.

(b) Persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to these regulations may not:

(i) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the department; or

(ii) Deliberately submit to the department, a licensee, an applicant, or a licensee's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the department.

(c) For the purposes of this section, deliberate misconduct by a person means an intentional act or omission that the person knows would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the department.

NEW SECTION WAC 246-232-014 Exemption of C-14 urea diagnostic capsules for human use.

(1) Except as provided in subsections (2) and (3) of this section, a person is exempt from the requirements for a license set forth in chapters 246-233 and 246-235 WAC if the person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kilobecquerels (1 microcurie) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(2) A person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license under WAC 246-235-080.

(3) A person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution these capsules shall apply for and receive a specific license from the United States Nuclear Regulatory Commission under Sec. 32.21 of 10 CFR Part 32.

(4) Nothing in this section relieves persons from complying with applicable United States Food and Drug Administration, other Federal, and State requirements governing receipt, administration, and use of drugs.