STATE OF COLORADO

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Colorado Department
of Public Health
and Environment

March 31, 2010

Terrence Reis, Deputy Director
National Materials Program Directorate
Division of Materials Safety and State Agreements
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Mr. Reis:

Part 1, General Provisions, and Part 10, Notices, Instructions, and Reports to Workers; Inspections, of the State of Colorado *Rules and Regulations Pertaining to Radiation Control* will go before the Colorado State Board of Health on June 16, 2010. Today, March 31, 2010, the Colorado's Radiation Advisory Committee approved these minor revisions as final.

These changes incorporate, as required by Colorado's Radiation Control Act, available corresponding language from the Suggested State Regulations for the Control of Radiation. Basically, Part 1 corresponds to the definitions in 10 CFR 20 (SSRCR Part A). The Part 1 changes respond to your letter of December 29, 2009, add three radiation machines definitions and make minor revisions to several other definitions.

Part 10 corresponds to 10 CFR 19 (Part J of the SSRCR). The substantive change in section 10.4.2 is equivalent to 10 CFR 19.13 in accord with Regulatory Action Tracking System (RATS) 2008-1 (72 FR 68043). The other Part 10 changes are format improvements.

The proposed revised rules with statements of basis and purpose are at http://www.cdphe.state.co.us/hm/rad/regs/rules.htm. The text of these minor changes is attached for ease of comparison to existing Part 1 and Part 10.

Adoption of these revisions is consonant with the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs Procedure SA-200. Your confirmatory review at this time of these minor changes to Parts 1 and 10 would be appreciated. Review over the next two months would enable any necessary modification to be made at the mid-June rulemaking hearing before the Colorado Board of Health.

If you have any question, please feel free to contact Ken Weaver of my staff at 303-692-3431 or Kenneth.Weaver@state.co.us.

Steve Tarlton, Manager
Radiation Control Program
Hazardous Materials and Waste Management Division

ST:klkw

The following changes are made in Part 1, General Provisions, of the State of Colorado *Rules and Regulations Pertaining to Radiation Control,* 6-CCR-1007-1-1.

Section 1.1.4.2 and the accompanying footnote are modified.

1.1.4.2 Nothing in these regulations shall apply to any person to the extent such person is subject to regulation **NOT RELINQUISHED** by the U.S. Nuclear Regulatory Commission.[1]

[1] Regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 (January 1, 2010~~9~~) of the Commission's regulations.

Section 1.2.2 definitions are modified or added.

...

"Address of use" means the facility designated on the license or registration where radioactive material is permitted to be **RECEIVED,** produced, prepared, ~~received,~~ used, processed, or stored or where a radiation machine is permitted to be installed, operated, repaired or stored.

...

"Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

...

"AUTHORIZED NUCLEAR PHARMACIST" (ANP) MEANS A PHARMACIST WHO MEETS THE APPENDIX 7C REQUIREMENTS THAT ARE APPLICABLE TO A TYPE OF USE OF RADIOACTIVE MATERIAL LICENSED UNDER PART 7 AND HAS CURRENT DEPARTMENT APPROVAL TO PERFORM NUCLEAR PHARMACY ACTIVITIES.

"AUTHORIZED USER" (AU) MEANS AN INDIVIDUAL WHO MEETS STATE TRAINING AND EXPERIENCE REQUIREMENTS AND HAS DEPARTMENT APPROVAL FOR A USE OF RADIOACTIVE MATERIAL.

...

"Background radiation" means radiation from:

(1) Extraterrestrial sources;

(2) Naturally occurring radioactive material (which has not been technologically enhanced), including radon (except as a decay product of source or special nuclear material); and

(3) Global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that are not under the control of the licensee or registrant.

"BACKGROUND RADIATION" DOES NOT INCLUDE SOURCES OF RADIATION FROM RADIOACTIVE MATERIALS REGULATED BY THE DEPARTMENT.

...

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration per second **(dps)** or transformation per second (~~dps or~~ s^{-1}).

...

"Licensee" means any person who is:

...

(3) Responsible under 10 CFR 71 (January 1, 20~~09~~10) as certificate holder, or applicant for a certificate of compliance, or under Part 17, for demonstrating that package design, fabrication, assembly and testing requirements are met with respect to a package before the time a package approval is issued.

...

"Lost or missing licensed source of radiation" means **A** licensed or registered source~~(s)~~ of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

...

"Nationally tracked source" means a sealed source containing a quantity equal to or greater than a Category 2 level of any radioactive material listed in Appendix 4G. **CATEGORY 1 NATIONALLY TRACKED SOURCES ARE THOSE CONTAINING RADIOACTIVE MATERIAL AT A QUANTITY EQUAL TO OR GREATER THAN THE CATEGORY 1 THRESHOLD. CATEGORY 2 NATIONALLY TRACKED SOURCES ARE THOSE CONTAINING RADIOACTIVE MATERIAL AT A QUANTITY EQUAL TO OR GREATER THAN THE CATEGORY 2 THRESHOLD BUT LESS THAN THE CATEGORY 1 THRESHOLD.**

...

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation whether or not the sources of radiation are in the possession of the licensee, registrant or other person.

Occupational dose does not include doses received:

(1) ~~f~~**F**rom background radiation~~,~~;

(2) ~~f~~**F**rom any medical administration the individual has received~~,~~;

(3) ~~f~~**F**rom exposure to individuals administered radioactive material and released in accordance with ~~Section~~ 7.26 of these regulations~~,~~;

(4) ~~f~~**F**rom voluntary participation in medical research programs~~,~~; or

(5) ~~a~~**A**s a member of the public.

...

"Principal activity" means an activity authorized by the license which is essential to achieving the purpose(s) for which the license was issued or amended.

Not included as principal activities are:

(1) ~~r~~**R**adioactive material storage while no licensed material is accessed for use or disposal**;** and

(2) ~~a~~**A**ctivity incidental to decontamination or decommissioning.

...

"Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee.

Public dose does not include occupational dose or doses received from:

(1) ~~b~~**B**ackground radiation~~,~~;

(2) ~~from a~~**A**ny medical administration the individual has received~~,~~;

(3) ~~from e~~**E**xposure to individuals administered radioactive material and released in accordance with Section 7.26 of these regulations~~,~~; or

(4) ~~from v~~**V**oluntary participation in medical research programs.

...

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation. **RADIATION MACHINE INCLUDES ANY ACCELERATOR AND/OR X-RAY SYSTEM, SUBSYSTEM OR EQUIPMENT.**

...

"Regulations of the NRC" means the regulations in 10 CFR Parts 1-50 and Parts 51-199 (January 1, 201~~0~~**9**).

...

"Research and development" means:

(1) ~~t~~**T**heoretical analysis, exploration, or experimentation**;** or

(2) ~~t~~**T**he extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

...

"Residual radioactivity" means radioactivity in structures, materiel, soils, groundwater, and other media at a site resulting from activities under the licensee's control.

(1) This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation.

(2) It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Part 4.

...

"VOLUMETRIC DENTAL IMAGING SYSTEM" MEANS AN X-RAY MACHINE THAT PRODUCES, FOR ORAL AND MAXILLOFACIAL STRUCTURES, A THREE-DIMENSIONAL TOMOGRAPHIC DATA SET OR A TIME SEQUENCE OF THREE-DIMENSIONAL TOMOGRAPHIC DATA SETS. A DENTAL X-RAY MACHINE ONLY CAPABLE OF PRODUCING A TWO-DIMENSIONAL IMAGE IS NOT CONSIDERED TO BE A VOLUMETRIC DENTAL IMAGING SYSTEM.

...

"Waste handling licensees~~s~~" means **A** person~~s~~ licensed to receive and store radioactive waste~~s~~ prior to disposal and/or **A** person~~s~~ licensed to dispose of radioactive waste.

...

These changes are made in Part 10, "Notices, Instructions, and Reports to Workers; Inspections", 6-CCR-1007-1-10, of the State of Colorado *Rules and Regulations Pertaining to Radiation Control.*

In Section 10.1, Purpose and Scope, and 10.2.4, subsections are numbered.

10.1.1 Authority.

10.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of Sections 25-1-108, 25-1.5-101(1)(k) and (1)(l), and 25-11-104, and 24-60-2205, CRS.

10.1.2 Basis and Purpose.

10.1.2.1 A statement of basis and purpose of these regulations is incorporated as part of these regulations; a copy may be obtained from the Department.

10.1.3 Scope.

10.1.3.1 This part establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Department inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions.

10.1.4 Applicability

10.1.4.1 The regulations in this part apply to all persons who receive, possess, use, own, transfer or dispose sources of radiation registered with or licensed by the Department pursuant to Part 2 and/or Part 3 of these regulations.

...

10.2.4 Department documents posted pursuant to 10.2.1.4 shall be posted within 5 working days after receipt of the documents from the Department; the licensee's or registrant's response, if any, shall be posted within 5 working days after dispatch from the licensee or registrant.

10.2.4.1 Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

In Section 10.4, subsection 10.4.2 is revised in accord the change in the U.S. Nuclear Regulatory Commission's 10 CFR 19.13 (72 Federal Register 68043), consistent with NRC Regulatory Action Tracking System (RATS) 2008-01; several subsections are numbered or renumbered.

10.4 Notification and Reports to Individuals.

10.4.1 Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in 10.4.

10.4.1.1 The information reported shall include data and results obtained pursuant to these regulations, orders, or license or registration conditions, as shown in records maintained by the licensee or registrant pursuant to 4.46 of these regulations.

10.4.1.2 Each notification and report shall:

~~10.4.1.~~(1) Be in writing;

~~10.4.1.~~(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

~~10.4.1.~~(3) Include the individual's exposure information; and

~~10.4.1.~~(4) Contain the following statement:

"This report is furnished to you under the provisions of *Colorado Rules and Regulations Pertaining to Radiation Control*, Part 10. You should preserve this report for further reference."

10.4.2 Each licensee or registrant shall ~~advise~~ **MAKE DOSE INFORMATION AVAILABLE TO** each worker ~~annually of the worker's dose~~ as shown in records maintained by the licensee or registrant pursuant to 4.46 of these regulations.

10.4.2.1 THE LICENSEE OR REGISTRANT SHALL PROVIDE AN ANNUAL REPORT TO EACH INDIVIDUAL MONITORED UNDER 4.18 OF THE DOSE RECEIVED IN THAT MONITORING YEAR IF THAT INDIVIDUAL:

(1) RECEIVED AN OCCUPATIONAL DOSE GREATER THAN 1 MSV (100 MREM) TEDE OR 1 MSV (100 MREM) TO ANY INDIVIDUAL ORGAN OR TISSUE; OR

(2) REQUESTS AN ANNUAL DOSE REPORT.

10.4.3 Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant.

10.4.3.1 The report shall include the dose record for each year the worker was required to be monitored pursuant to 4.18 of these regulations.

10.4.3.2 Such report shall be furnished within 30 days from the date of the request or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later.

10.4.3.3 The report shall cover the period of time the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated.

10.4.4 When a licensee or registrant is required pursuant to 4.53 of these regulations to report to the Department any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a report on the exposure data included therein.

10.4.4.1 Such reports shall be transmitted at a time not later than the transmittal to the Department.

10.4.5 At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year.

10.4.5.1 If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

In Sections 10.5, 10.6, 10.7 and 10.8, subsections are numbered for clarity, ease of reference in licenses and inspection reports and to be more consistent with the Secretary of State's online XML rule format.

...

10.5.5 Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection.

10.5.5.1 However, only one workers' representative at a time may accompany the inspectors.

...

10.5.7 Notwithstanding the other provisions of 10.5, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection.

10.5.7.1 With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

...

10.6.2 During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or cause any violation of the Act, these regulations, or license or registration condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control.

10.6.2.1 Any such notice in writing shall comply with the requirements of 10.7.1.

...

10.7 Requests by Workers for Inspections.

10.7.1 Any worker or representative of workers believing that a violation of the Act, these regulations, or license or registration conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Department.

10.7.1.1 Any such complaint shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers.

10.7.1.2 A copy shall be provided to the licensee or registrant by the Department no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Department except for good cause shown.

10.7.2 If, upon receipt of such notice, the Department determines that the complaint meets the requirements set forth in 10.7.1, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred.

10.7.2.1 Inspection pursuant to 10.7 need not be limited to matters referred to in the complaint.

...

10.8 Inspections Not Warranted; Informal Review.

10.8.1 If the Department determines, with respect to a complaint under 10.7, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department shall notify the complainant in writing of such determination.

10.8.1.1 The complainant may obtain review of such determination by submitting a written statement of position with the Department.

10.8.1.2 The Department will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant and the name of individuals referred to therein.

10.8.1.3 The licensee or registrant may submit an opposing written statement of position with the Department.

10.8.1.4 The Department will provide the complainant with a copy of such statement by certified mail.

10.8.1.~~4~~**5** Upon the request of the complainant, the Department may hold an informal conference in which the complainant and the licensee or registrant may each orally present its views.

10.8.1.6 An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant or individuals referred to in the complaint will be made only following receipt of written authorization from the complainant.

10.8.1.~~2~~**7** After considering all written and oral views presented, the Department shall affirm, modify, or reverse the determination and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.