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Subject: SUPPLEMENT TO SUBMITAL FOR COLORADO PART 3 REGULATIONS
Date: Monday, February 10, 2014 2:05:54 PM
Attachments: [Part 3 Draft 4 - 2014 EXCERPT FOR NRC.pdf](#)

Ms. Schneider

On behalf of the Colorado Radiation Program, we wish to submit a slight modification of proposed regulatory changes for 6 CCR 1007-1, Part 3, "Licensing of Radioactive Materials" for NRC review. This is a supplement to the proposed changes submitted to NRC on January 16, 2014 and accepted by NRC on January 23, 2014.

Specifically, Colorado would like to submit revised changes for pages 3-19, and 3-48. The following summarizes the changes:

1. In Section 3.9.2, we are proposing to delete the (originally proposed) reference to later sections of the rule relating to reciprocity. As this section relates to applications for a new license, it was realized that entities using this section may or may not already have a license from another regulatory agency and therefore references to reciprocity may not be appropriate in all circumstances.
2. In Section 3.15.2.2, we are proposing additional items that our program requires as documentation pertaining to transfer of licenses. The additions go beyond those specified by NRC and are dictated by our internal processes and program needs.

Please refer to the attached, non-contiguous pages from the draft rule which shows the proposed changes. With the exception of the attached two pages, the remainder of the proposed rule changes are, at this time, unchanged from that previously submitted to NRC.

Please contact me should there be any questions.

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NOTE: As a public agency, the vast majority of CDPHE communications are public documents produced within the scope and course of our business and as such the Department does not want to create a false expectation of confidentiality in what are most likely public documents. To the extent that our statutes protect the information we are sending, we are not giving up any argument regarding confidentiality by omitting standard confidentiality language.

radionuclide production facility within its consortium from which it receives PET radionuclides.

3.8.10.2 Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 3.12.10.1(2).

Comment [JJ7]: The referenced section 3.12.10.2(2) is the reference equivalent to 10 CFR Part 32.72(a)(2).

3.8.10.3 Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 3.12.10.2(2).

Comment [JJ8]: The referenced section 3.12.10.2(2) is the reference equivalent to 10 CFR Part 32.72(b)(2).

3.8.10.4 Information identified in 3.12.10.1(3) on the PET drugs to be noncommercially transferred to members of its consortium.

Comment [JJ9]: The referenced section 3.12.10.1(3) is the reference equivalent to 10 CFR Part 32.72(a)(3).

3.9 General Requirements for the Issuance of Specific Licenses.

A license application will be approved if the Department determines that:

3.9.1 The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;

3.9.2 The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property **and the applicant's facilities are permanently located in Colorado;**

Comment [JJ10]: The Department has recently revised its policy regarding issuing a limited number of licenses located outside of but near Colorado's borders, to hold a Colorado specific radioactive materials license. The addition of this provision will clarify this requirement consistent with the policy/practice.

The prior policy of allowing licensees physically located outside, but near Colorado borders, presented jurisdictional and liability issues.

No similar language exists in NRC regulations as NRC regulates materials simultaneously in many geographical areas and non-Agreement states, whereas Agreement States such as Colorado, typically have jurisdiction only within state borders.

[The proposed language is based partially on language found in State of Utah radiation regulations at UT R313-22-33(c)]

3.9.3 The issuance of the license will not be inimical to the health and safety of the public;

3.9.4 The applicant satisfies any applicable special requirements in 3.10, 3.11, or 3.12; and

3.9.5 The applicant has established Department-approved financial assurance warranties in accordance with the following requirements.

3.9.5.1 A signed executed original copy of each warranty required by this part shall be furnished to and approved by the Department prior to the issuance of a new license, or any amendment or renewal of an existing license.

3.9.5.2 The Department may require any licensee to furnish a decommissioning warranty in a dollar amount determined by the agency as necessary to protect public health and safety, to ensure corrective action during operation, to ensure decontamination and decommissioning of a facility and disposal of radioactive materials in the event of abandonment, default or inability of the licensee to meet the requirements of the Act, these regulations, or the license.

3.9.5.3 The following specific licensees are required to furnish decommissioning warranties:

(1) Each licensee authorized to possess and use greater than 370 MBq (10 mCi) of source material in a readily dispersible form; and

(2) Each licensee authorized to possess and use radioactive material with a half-life greater than 120 days, in quantities:

(a) Greater than 10^3 times the applicable quantity of Schedule 3B in unsealed form. For a combination of isotopes if R divided by 10^3 is greater than 1

1901 3.15.1 Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or
1902 hereafter in effect, and to all rules, regulations, and orders of the Department.

1903 3.15.2 **Inalienability of Licenses.**

1904 **3.15.2.1** No license issued or granted under this part and no right to possess or utilize
1905 radioactive material granted by any license issued pursuant to this part shall be
1906 transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily,
1907 directly or indirectly, through transfer of control of any license to any person unless the
1908 Department shall, after securing full information, find that the transfer is in accordance
1909 with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations,
1910 and orders of the Department, and shall give its consent in writing.

1911 **3.15.2.2 An application for transfer of license must include:**

1912 **(1) The identity, technical and financial qualifications of the proposed transferee;**

1913 **(2) Financial assurance for decommissioning information required by 3.9.6;**

1914 **(3) A description of the acquisition or proposed transfer including dates;**

1915 **(4) An updated organizational chart including the proposed transferee's**
1916 **management structure for the licensed activities;**

1917 **(5) Documentation of registration with the Colorado Secretary of State for**
1918 **the proposed transferee;**

1919 **(6) A statement from the proposed transferee's management that they will conduct**
1920 **business in accord with all of the commitments previously submitted by the**
1921 **current licensee;**

1922 **(7) A statement from the proposed transferee's management accepting liability for**
1923 **all licensed materials that are and have been possessed under the license; and**

1924 **(8) A copy of the appropriate radioactive materials license application signed by**
1925 **the RSO and the proposed transferee's management.**

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1932 3.15.3 Each person licensed by the Department pursuant to this part shall confine use and possession of
1933 the material licensed to the locations and purposes authorized in the license.

1934 3.15.4 Notice and Disposition of Records Prior to License Termination.

1935 3.15.4.1 Each licensee shall notify the Department in writing when the licensee decides to
1936 permanently discontinue all activities involving materials authorized under the license.

1937 3.15.4.2 Prior to license termination, each licensee authorized to possess radioactive material
1938 with a half-life greater than 120 days, in an unsealed form, shall forward the following
1939 records to the Department.

1940 (1) Records of disposal required by 4.48; and

1941 (2) Records of surveys required by 4.42.

1942 3.15.4.3 If licensed activities are transferred or assigned in accordance with 3.15.2, each
1943 licensee authorized to possess radioactive material, with a half-life greater than 120 days,

Comment [JJ37]: The addition of this subsection title is necessary to maintain formatting compatible with NRC format of 10 CFR 30.34, 40.46 and 70.36 and due to the addition of provision in 3.15.2.2.

The addition of this subsection heading avoids renumbering of subsequent parts of 3.15, which are referenced elsewhere in Part 3.

Comment [JJ38]: This is a new provision that clarifies that certain additional information is required when a license is to be transferred from one entity to another. The provisions in 3.15.2.2(1), and 3.15.2.2(2) are added for compatibility with the requirements of 10 CFR 30.34(b), 40.46(b)(1), (2), and 70.36.

Provisions 3.15.2.2(3) through (8) are added based on current program needs and practices.

The intent of the provision is to ensure that the entity (transferee) receiving the license has the necessary qualifications, abilities, and finances to continue to safely operate and decommission the activities authorized under the license.

RATS 2011-1
NRC Compatibility = C
[Due date for state adoption = 12/17/2015]