NEW MEXICO
ENVIRONMENT DEPARTMENT

SUSANA MARTINEZ
Governor
JOHN A. SANCHEZ
Lieutenant Governor

1100 St. Francis Drive Suite 1211
Post Office Box 5469
Santa Fe, NM 87502-5469
Phone (505) 476-8600 Fax (505) 476-8654
www.nmenv.state.nm.us

RYAN FLYNN
Cabinet Secretary
BUTCH TONGATE
Deputy Secretary

Monday, November 17, 2014

US Nuclear Regulatory Commission
Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)

Re: Part 35 proposed rule revision comments

The New Mexico Environment Department, Radiation Control Bureau has reviewed the July 21, 2014 Federal Register notice (NRC-2008-0175) which contained the proposed revision to 10 CFR Part 35. The Bureau offers the following comments for review by the NRC.

1. 10 CFR 30.34 “Terms and conditions of licenses.” The revision includes a reference to 10 CFR 35.204(a) and 35.3204. The Bureau questions whether 30.34(g) is necessary as it describes the testing of molybdenum-99 and strontium-82 generators which is described in 35.204. This regulatory issue should be included in 10 CFR 32.72. The Bureau recommends moving the regulation from 30.34(g) to 32.72.

2. 35.24 “Authority and responsibilities for the radiation protection program.” In the revision to 35.24(b), the last sentence states “These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer has radiation safety training.” The Bureau recommends this be changed to read: “These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on the license as an authorized user, authorized medical physicist or authorized nuclear pharmacist, or has training in the radiation safety, regulatory issues and emergency procedures.” This revision would align it with 30.50(d).

3. 35.50 “Training for Radiation Safety Officer and Associate Radiation Safety Officer”. The revision states in (b)(2) that the written attestation may be signed by either an RSO or ARSO. The Bureau does not agree that an ARSO should preceptor an RSO as the ARSO’s roles and responsibilities are limited to sections of a license while the RSO is responsible for the entire radiation safety program. The Bureau recommends that the regulation be revised to state an ARSO can preceptor another ARSO only.

4. 35.65 “Authorization for calibration, transmission and reference sources”. The revision in (b)(1) states: “Used for medical use as defined in 35.2 except in accordance with the requirements in 35.500”. The Bureau does not understand the inclusion of 35.500 in this section. The sources in this section are to be used for calibration, transmission or reference while 35.500 are for sources to be used for diagnosis. Also paragraph (c) states the sources used in this section do not need to be listed on a license whereas sources and users must be listed on a license for 35.500. The Bureau recommends that “except in accordance with the requirements in 35.500” be removed from (b)(1).

5. 35.390 “Training for use of unsealed byproduct material for which a written directive is required”. A new paragraph (c) was included which states: “Is an authorized user for any of the parenteral administrations specified in 35.390(b)(1)(ii)(G) or equivalent Agreement State regulations.” The Bureau does not understand how an individual who is only authorized for parenteral administrations should be listed as an authorized user for 35.300 without completing the I-131 treatments listed in 35.390(b)(1)(ii)(G). There was no verbiage included in the discussion section of 35.390 for this paragraph. The Bureau questions if this is correct in being included in section 35.390 or whether it should be moved to 35.396.

6. 35.500 “Use of sealed sources and medical devices for diagnosis”. This revision amends the sentence in paragraph (a) and (b) to state “A licensee must only use sealed sources or diagnostic devices that are approved in the Sealed Source and Device Registry …” and also states “may be used for…”. These statements seem to cause contradictions as it states the licensee “must” but then uses “may” for other uses. The Bureau feels this puts the burden on the SSD reviewing agency to ensure that proper conditions are included in the SSD allowing for other uses. The Bureau does not recommend allowing this and instead recommends that any other uses of these sealed sources should be approved by the licensing regulatory agency.

7. 35.600 “Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit”. This revision splits the section into two paragraphs where (a) is used for sources and (b) is used for units. The Bureau recommends either changing the name of the section or adding a new section for the units. The Bureau also recommends the paragraph for the units be revised to read

a. “A licensee must use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic units: i. That are approved in the Sealed Source and Device Registry; or
ii. In research ….

This would remove the “must” and “may” words from the regulation which seem to contradict each other.

We thank you for the opportunity to comment on part 35.

Sincerely,

Michael Ortiz, Bureau Chief
Radiation Control Bureau
New Mexico Environment Department

From:	Ortiz, Michael, NMENV
To:	RulemakingComments Resource
Subject:	Part 35 Comments New Mexico
Date:	Tuesday, November 18, 2014 11:00:26 AM
Attachments:	part 35 comments NM RCB MO 11-17-14.doc

From: Ortiz, Michael, NMENV
Sent: 11/18/2014 8:57 AM
To: Rulemaking comments, NRC

The attached are New Mexico Radiation Control Bureau comments to Part 35.

Sincerely,

Michael Ortiz, Bureau Chief
Radiation Control Bureau
NMED/ EPD/ Montoya Bldg
1100 St. Francis Dr.
P.O. Box 5469
Santa Fe, NM 87502-5469
michael.ortiz1@state.nm.us
505-476-8605 Office
505-699-0060 Cell
505-476-8654 Fax
OUR Core Values INTEGRITY EXCELLENCE RESPECT STEWARDSHIP COLLABORATION

Please visit the NM Environment Department Radiation Control Bureau website at http://www.nmenv.state.nm.us/nmrcb/home.html for the latest information concerning the Department's radiation programs.