



STATE OF NEW YORK DEPARTMENT OF HEALTH

Flanigan Square 547 River Street Troy, New York 12180-2216

#1

January 11, 2011

Rena Bryant
Secretary to the Board of Health
125 Worth Street CN-31
New York, NY 10013

RECEIVED
DOMHM/GENERAL
2011 JAN 18 PM 4:09

Dear Rena Bryant:

Please accept the following comments regarding the proposed amendments to Article 175 of The New York City Health Code as published in the December 17, 2010, edition of The City Record.

Proposed section 175.103(b)(5)(iii) states:

Personnel, other than physicians or registered professional nurses, at licensees involved in the performance of diagnostic procedures utilizing radioactive material which includes performing parenteral administration of radioactive material by intravenous, intramuscular or subcutaneous methods shall:

- (A) have satisfactorily completed an educational program in nuclear medicine technology accredited by the Committee on Allied Health Education and Accreditation or the accrediting agency of the state in which the program was completed, provided such state accreditation requires education and training in the above methods of parenteral administration; or
- (B) possess certification as a nuclear medicine technologist by the American Registry of Radiologic Technologists or certification by the Nuclear Medicine Technology Board; and
- (C) prior to permitting parenteral administration by a nuclear medicine technologist, the medical board of a hospital, a physician, or the radiation safety committee of an institution who have no medical board, shall adopt with governing authority approval:
 - (a) procedures to assure that the nuclear medicine technologist possesses the education and training or certification set forth in §175.103(b)(5)(iii)

of this Code and is proficient in the competent performance of parenteral administration; and

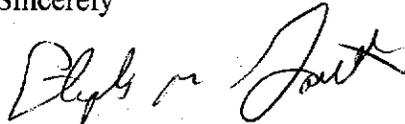
(b) requirements for authorized user physician which at a minimum shall require supervision by such a physician when parenteral administration of radioactive material for diagnostic testing is performed by a qualified nuclear medicine technologist.

(iv) A licensee that permits supervised activities under subparagraphs (i) and (ii) of this paragraph is responsible for the acts and omissions of the supervised individual.

Comment: This section is inconsistent with Public Health Law, Article 35- Practice of Radiologic Technology, in that it purports to empower any "personnel" to perform diagnostic procedures using radioactive materials, subject to limited conditions. Pursuant to Public Health Law § 3502, only physicians, registered professional nurses or individuals licensed under this Article to practice Nuclear Medicine Technology by the New York State Health Department may perform the functions described in proposed section 175.103(b)(5)(iii). To correct the inconsistency, the proposed section should either be repealed or amended to require that individuals be licensed by the New York State Department of Health to practice Nuclear Medicine Technology prior to performing any functions described in PHL Article 3501(7).

Please contact me at: 518-402-7550 if you have any questions.

Sincerely



Stephen M. Gavitt, CHP, Director
Bureau of Environmental Radiation Protection

RECEIVED
DOMINION/OFFICE OF THE COMPTROLLER
RECORDS MANAGEMENT

2011 JAN 21 PM 4:57



January 20, 2011

Rena Bryant
Secretary to the Board of Health
125 Worth Street CN-31
New York, New York 10013

RE: Comments on the Recently Proposed Amendment of Article 175 of the New York City Health Code.

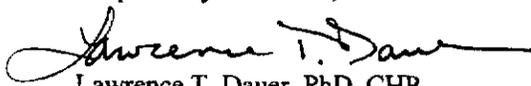
Ms. Bryant,

We hereby submit the following general and specific comments on the recently proposed amendment of Article 175 of the New York City Health Code:

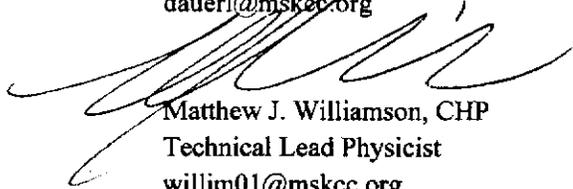
1. General Comment - The term "byproduct material" appears throughout the revised text in place of "radioactive material." As of 25 October 2010, the on-line text of Article 175 provided by the City of New York contains a limited definition of byproduct material. Please ensure the definition of "byproduct material" contained within 175.02(29) is consistent with current definition of 10 CFR 20.1003 or at a minimum includes some reference to accelerator produced radioactive material.
2. General Comment - Throughout the revised text there are references to various sections of the NRC code. Have each of these references been checked to ensure that the revised NYCDOHMH code references mean to have licensees utilize the referenced NRC code (e.g. Part 35 references) and not related sections of NYCDOHMH code? The mixture of the two codes is confusing and it seems that in many cases the NRC code references should indeed rather refer to internal NYCDOHMH code sections. Perhaps these are typos from the integration of the NRC revisions? Or is it the NYCDOHMH expectation that licensees do indeed follow the NRC code for these specific referenced items.
3. The revised code includes the following new definition, "(141) Medical event means an event that meets the criteria in §175.03(1)(8)(a) or (b) of this Code." However, this definition refers to an incorrect designation in the subsequent revised Code. The section referenced does not exist in that manner and this reference should be corrected.
4. 175.103(a) (2) (iii) Notes that "If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its NRC medical use license..." Does the NYCDOHMH expect an NRC medical use license or is this reference an oversight that should refer to a NYCDOHMH medical use license?
5. Revised 175.103(a)(4)(v) is added to include the following "when a requirement in this Code differs from the requirement in an existing license condition, the requirement of this Code shall govern." It would suggest that a stricter license condition added for increased safety or security is then rendered in valid by this requirement. Is this the intent of this added requirement?

6. Revised 175.103(c)(1)(ii)(A) incorrectly requires the use of a dedicated check source in performing a dose calibrator constancy test with a sealed source of not less than 370 kBq (10 mCi) of radium-226 or 1.85 MBq (50 mCi) of any other photon-emitting radionuclide with a half-life greater than 90 days. The parenthetical milli-Curie amounts should be assigned as micro-Curies.
7. Revised 175.103(c)(1)(ii)(B) incorrectly requires the use of at least two sources in performing accuracy tests with a sealed source of not less than 370 kBq (10 mCi) of radium-226 or 1.85 MBq (50 mCi) of any other photon-emitting radionuclide with a half-life greater than 90 days. The parenthetical milli-Curie amounts should be assigned as micro-Curies.
8. Revised 175.103(c)(1)(ii)(C) incorrectly lists the activity of 370 kBq as (10 mCi). The parenthetical activity should be represented as 10 micro-Curies.
9. Revised 175.103(c)(1)(iv) incorrectly lists the activity of 370 kBq as (10 mCi). The parenthetical activity should be represented as 10 micro-Curies.
10. Revised 175.103(e)(3)(i)(F) requires that a patient's room not be reassigned "until removable contamination is less than 5 Bq (1200 disintegrations per minute) per 100 square centimeters." Two errors appear. First, there is a typographical error as the parenthetical statement should read 200 disintegrations per minute not 1200. Second, 5 Bq equals 300 disintegrations per minute, and 200 disintegrations per minute equals 3.3 Bq. It is unclear which value meets the applicable requirement. This section needs clarification and correction.

Respectfully submitted,



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#3

Resolution Comments

From: Joe Giardina [jgiardina@petroneassoc.com] **Sent:** Fri 1/21/2011 11:44 AM
To: Resolution Comments
Cc: tpetrone@petroneassoc.com
Subject: Article 175 Notice of Intent Hearing Comment- Activity Measurement
Attachments:

My comment is regarding the use of direct activity measurement (ie with Dose Calibrator) of radioactive materials prior to administration to humans. It seems that in the new revision a direct measurement will not be required for unit doses prepared by commercial vendors. I believe this is not a desirable practice, as we are depending on radio pharmacies who are producing hundreds of unit doses at a given time for certain delivery deadlines. Those who work in Nuclear Medicine, can attest that these doses may be within 10% of prescribed dose, but are certainly not as precise as may be desired. In these days where radiation dose to the patient is in the news weekly, direct measurement should be required to continue, not increase the chance of errors occurring. I would also note that our neighbor New Jersey which became an Agreement State in 2009, did not follow the NRC and still requires direct measurement of radioactive materials prior to human use.

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(718) 815-6807

4

Resolution Comments

From: Jussi Sillanpaa [JSillanp@chpnet.org]
To: Resolution Comments
Cc:
Subject: Comments on proposed article 175
Attachments:

Sent: Fri 1/21/2011 2:10 PM

Dear Sirs,

I read the proposed article 175 with great interest. Over all, I found the article well written, but there are a few parts which I feel would benefit from a change or clarification.

P. 6: In the definition of a medical misadministration, it should be clarified if an incorrect radiation energy is a misadministration (e.g., the patient was meant to be treated with 6 MV X-rays but was actually treated with 10 MV - the definition says "radiation from a source other than the one ordered", but it is not clear to me if this covers treating with the same accelerator but with a wrong energy)

P. 23:

(c): Occasionally, a treatment unit will malfunction in the middle of a fraction, resulting only some of the fields being treated on that day. This can lead to an underdose of more than 50%, but since it can easily be made up by lengthening the treatment course by one day and giving the missing fields then, it should be explicitly stated that this circumstance does not constitute a misadministration.

(C): Unless a CT scan is performed immediately after a prostate implant, it is impossible to say whether permanent implant seeds were implanted in the wrong place or migrated there afterwards (e.g., most institutions perform post-implant scans for prostate implant patients 30 days after the implant)

P. 55:

(iv): 1 mSv/h is 100 mREM/h, I assume the article should read "as low as 1 uSv (0.1 mrem) per hour"?

P. 73:

(A) Our institution's radioactive materials license currently says the activity of the source should be determined within +/- 3%, I feel this stricter threshold is better.

I also feel that (D), (F) and (G) do not need to be checked every time the source is changed - the properties of the applicators and transfer tubes do not depend on the source. Also, they are numerous (we have 50+ transfer tubes and 20+ applicators) and often stored in sterile containers, they would need to be resterilized after every test. An annual test would be sufficient. Also, single use, sterile applicators should be excepted from tests.

P. 79:

(ii): We have an afterloader unit that is used in two different rooms at the same address. Should this unit be checked every time it is moved between rooms (the current wording does not require this, since the rooms are at the same address; I feel checks should still be required)

P. 80:

(A) Probably a typo, should read 100 uSv (10 mREM) and 20 uSv (2 mREM) per hour?

I would also like to commend the authors for requiring full board certification for authorized medical physicists. I

feel this is important for ensuring patient safety.

Best Regards

Jussi Sillanpaa, PhD DABR

Lead Physicist, Dept. of Radiation Oncology, Beth Israel Medical Center

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#5

From: ArunKumar Saxena
<ArunKumar.Saxena@nychhc.org>
To: tlickerm@health.nyc.gov
CC:
Subject: Re: Amendment of Article 175 per 10 CFR
Part 35
Attachments:

Thanks for the email.

On page 49 and 50, please look into the following, it needs correction.

370 kBq (10 mCi) and 1.85 MBq (50 mCi) should be 370 kBq (10 μ Ci) and 1.85 MBq (50 μ Ci).

It may appear in few other pages.

-Saxena.

Visit www.nyc.gov/hhc

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From: Kamen, Jacob [mailto:jacob.kamen@mssm.edu]
Sent: Friday, January 21, 2011 9:33 AM
To: Tobias Lickerman
Subject: Article 175 changes

#6

Hi Tobias,

We reviewed the proposed Amendment of the Article 175 and noticed a few minor typo that should be corrected in the final version. They are summarized in below table. I hope this helps.

Thank you.

Reference Code (Proposed)	Existing code	Proposed Changes
§175.103(c)(1)(ii)(A)	Dose calibrator constancy checks should be performed with sealed source of not less than 370 kBq (10 uCi) of Ra-226 or 1.85 MBq (50 uCi) of any other photon emitting radionuclides with half life greater than 90 days	<p>Dose calibrator constancy checks should be performed with sealed source of not less than 370 kBq (10 mCi) of Ra-226 or 1.85 MBq (50 mCi) of any other photon emitting radionuclides with half life greater than 90 days</p> <p>This is clearly a mistake and all units under this code should be corrected to uCi instead of mCi. The kBq and MBq values are correct.</p>
§175.103(e)(3)(F)	The room must not be reassigned until removable contamination is less than 5 Bq (~ 200 DPM)	The room must not be reassigned until removable contamination is less than 5 Bq (1200 DPM). It is a mistake.

J. Kamen, Ph.D., CMLSO, CHP
 Radiation Safety Officer
 Associate Professor of Radiology
 Mount Sinai Medical Center
 212-241-2269

#7

From: Dennis Mah <DMAH@montefiore.org> **Sent:** Mon 12/20/2010 12:47 PM
To: tlickerm@health.nyc.gov
CC:
Subject: Comments on the amendments to Article 175
Attachments: Dennis Mah.vcf

Dear Mr. Lickerman,

Man Yu Chen, our RSO, forwarded the proposal to me. I have a couple of comments:

1. It says that survey meters should be calibrated at approximately 1/3 and 2/3 of full scale. The ADCL calibrates at 20% and 80%. Is that close enough?
2. It says that external audits must be done annually. We use ACR which is valid for 5 years. There are proposed new regulations from NYS that were discussed at the local physics meeting (RAMPS) a few months ago. They indicated that all licensees must be either ACRO, ACR or equivalent certified.

Does that mean the ACR must visit all NYC sites annually or that we must have an additional external audit annually even if we are ACR accredited? Can the regulations be modified to accept ACR accreditation as a valid external audit for the period of the certification reflecting the current practice?

Thank you for the opportunity to provide feedback.

Happy Holidays,

Dennis

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