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DEPARTMENT OF RADIATION ONCOLOGY
Jack D. Schocker, M.D., *Chairman*
Daniel C. Han, M.D.
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Michael A. Vince, Ph.D.
Gregory M. Price, M.S..

September 14, 2000

Environmental Quality Board
Rachel Carson State Office Building
15th Floor
400 Market Street
Harrisburg, PA 17101-2301

Original: 2138

Subject: Pennsylvania Bulletin, Vol. 30, No. 35: Proposed rulemaking on Radiological Health

Subchapter A. General, 224.10 (a) of the subject bulletin states that the requirements of 10 CFR Part 35 (relating to the medical use of byproduct material) are to be incorporated by reference. This presumes that the NRC documentation is right. Categorically it is not, and presuming so will lead to misinterpretations and confusion. One does not have to search deeply to find inconsistencies and contradictions in the NRC regulations. Compare the training requirements for a Radiation Safety Officer (RSO) given in 10 CFR 35.900 with that required for a *teletherapy* physicist given in 10 CFR 35.961. Obviously the training for a *teletherapy* physicist is considerably more stringent. Yet, in Policy and Guidance Directive FC 86-4; Revision 1: *Information Required for Licensing Remote Afterloading Devices*, Section VIII. (i), it is stated, "During all patient treatments using a medium or high dose rate afterloading device, both the authorized user and either the *medical* physicist or radiation safety officer must be physically present. Physical presence . . . is defined as within audible range of normal human speech." Incidentally, the term '*medical* physicist' does not appear in 10 CFR 35 in reference to HDR brachytherapy. 'Teletherapy physicist' is used instead, which is clearly an incorrect application of the term. According to the NRC, a licensee's Radiation Safety Committee (RSC) may approve *medical* physicists for their HDR brachytherapy program. Authorizations are limited to physicists who meet the requirements of 10 CFR 35.961 (a), (b) or (c), or those named on a current NRC or Agreement State license. Another physicist or radiation therapist, who may not rigorously meet the requirements of 10 CFR 35.961, but who may have more genuine experience with HDR brachytherapy emergency procedures, may not be appointed by the RSC to perform this task. Yet a RSO, who may not meet the requirements of 35.961 and, also, may be unfamiliar with HDR emergency procedures, may do so without approval by the RSC. This is inconsistency in spades. Florida, for example, which is an agreement state, has no such requirement for the physical presence of a medical physicist. The console operator who has been trained in HDR emergency procedures must be present. An authorized user who can be contacted if necessary must also be available. The development of independent Pennsylvania regulations, based on NRC regulations to be sure but clearer and devoid of ambiguities, should be a relatively uncomplicated project for a task group consisting of 'expert' physicists, legal counsel and clerical personnel appointed by the State for a reasonable length of time.

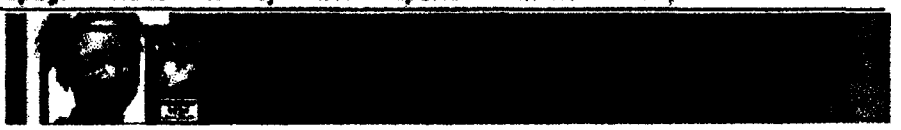
Sincerely,

Michael A. Vince, Ph.D.
Chief Medical Physicist & RSO

IRRC

From: Barton, Marylou [Barton.Marylou@dep.state.pa.us]
Sent: Monday, October 23, 2000 2:11 PM
To: 'irrc@irrc.state.pa.us'
Subject: reg package 7-350

Original: 2138
http://www.usatoday.com/news/poison/cover.htm



USA TODAY Nation

10/06/00- Updated 12:46 AM ET

Poisoned Workers & Poisoned Places

GRAPHIC: Nuclear contracting sites across the USA

COVER PAGE | TIMELINE | PHOTOS | VIDEO | DOCUMENTS | DISCUSS | ABOUT
Overview of this series | Key dates in U.S. nuclear program | People and places | Reports from the field | Key records, study from secret program | Live chats, message board | Series, author

Secret project carried hidden dangers

In the 1940s and '50s, the U.S. government secretly hired scores of private companies to process huge volumes of nuclear weapons material. But the companies were not prepared for the hazards of handling nuclear material. Workers were not informed of the risks. Thousands were exposed to dangerous levels of radiation. Government reports were classified and buried. The result is a legacy of poisoned workers and communities that lingers to this day. The full story of the secret nuclear contracting has never been told, until now.

- Compromise reached on compensation plan
- Compensation for sick workers a potent political issue
- Senator fumes at delays on worker-aid plan
- Nuclear sites list made public
- Sick workers want Congress to act quickly

September 6

Toxic legacy
During the Cold War, the U.S. government secretly hired hundreds of private companies to work on America's nuclear weapons program — and never told the workers or communities of the dangers they might face from radiation and other hazards.

- Full story
- 'Devil is in the dose'

September 7

The workers
Many of the surviving workers now have higher risks for cancer and other ailments, but there has been almost no effort to learn whether such problems have occurred. That oversight might cost those who have gotten sick a chance for compensation.

- Full story
- Beryllium workers

September 8

The environment
Radioactive and toxic contamination at many of the contracting sites lingered for years, sometimes with serious health risks. Some still are not cleaned up, ignored by federal programs meant to address pollution from nuclear weapons production.

- Full story
- Food, equipment

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- 'Devil is in the dose'
- Richardson: U.S. committed to cleanup
- Beryllium workers to get compensation
- Research ignores private contractors
- Hearings sought on toxic exposure
- Food, equipment contaminated, too
- Congress mulls compensation

- Go to Nationline
- Go to News front page

Trostle, Sharon F.

From: Rosen_Jerry [rosen@radsafe.pitt.edu]
Sent: Monday, September 25, 2000 3:42 PM
To: 'RegComments@dep.state.pa.us'

Environmental Quality Board
Harrisburg, PA 17105-8477

Original: 2138

The following are comments on the proposed amendments to 25 PA. CODE Radiological Health as published in the Pennsylvania Bulletin on August 26, 2000. As a member of the State Radiation Protection Advisory Committee, I believe that many of my comments reflect the current thinking of the committee.

1. While many definitions and other items have been eliminated because of reference to 10CFR, a clear and bolded statement regarding incorporation by reference should be included at the start of each chapter as appropriate.

2) At a minimum a copy of the definitions contained in 10CFR should be made available by the State to licensees and registrants who do not also hold NRC licenses. This might be accomplished by inclusion on the States Web site.

3) Under definitions: Misadministration

Replace the word "Misadministration" with "Medical Event"

Either strike Item (i) "An administration of a dose to the wrong individual" or change it to "An administration of a therapeutic dose to the wrong individual".

Strike Item (ii) - the statement is so subjective as to make it unlikely that any event would ever be reported.

Item (iii) - the term "wrong site" needs to be defined. Wrong site may be taken to include both a site that is separate from the intended treatment site or involve a misalignment which includes both a portion of the intended site as well as tissue that is marginally outside of the treatment site. The latter is a common occurrence and is not justified in being included in the definition of a "medical event". Item (iii)(B) appears to try to address this issue but is to confusing.

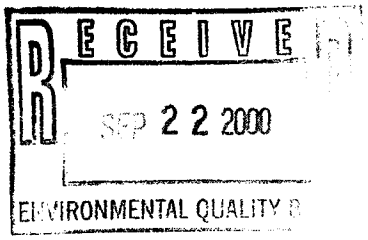
If the "wrong site" is taken to include a partial misalignment then better wording for (iii)(B) is, "The result is an increase in the total expected dose that exceeds the larger of 20 % of the expected dose or 2.5 Gy (250 rad) or is expected to cause functional damage."

Trostle, Sharon F.

From: Sheetz_Michael [sheetz@radsafe.pitt.edu]
Sent: Friday, September 22, 2000 1:14 PM
To: 'RegComments@dep.state.pa.us'
Subject: Comments on Proposed Rulemaking

Radiation Safety Office
G-7 Parran Hall
Pittsburgh, PA 15261
412-624-2728

Original: 2138



September 22, 2000

Environmental Quality Board
Rachael Carson State Office Building, 15th Floor
400 Market Street
Harrisburg, PA 17101-2301

Re: Comments on Proposed Rulemaking: 25 PA Code Ch. 215

Dear Sir or Madam:

The definition for Medical Event from X-ray in Ch. 215.2 should be revised to read as follows:

Medical Event from X-ray - The administration to a human being, except for administrations resulting from the direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a dose for diagnosis or therapy to the wrong individual that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

(ii) An administration of a dose for diagnosis that results in or is likely to result in acute functional damage to tissue, unless the damage is an expected outcome of the prescribed procedure or the damage can not be avoided without compromising the efficacy of the procedure.

(iii) An administration of a dose for therapy when one of the following applies:

(1) The total dose delivered to the intended treatment site identified in a written directive differs from the prescribed dose by more than 20%.
(2) The total weekly fractionated dose delivered to the intended treatment site identified in a written directive differs from the prescribed dose, for the number of fractions to be delivered in a week, by more than 50%.
(3) A dose is delivered to the wrong anatomical site from that which was specified in the written directive (this does not include positional errors of the treatment field targeting the intended treatment site).

(iv) An administration of a dose for therapy by the wrong treatment mode (photon versus electron), wrong effective energy, wrong applicator or wrong treatment geometry which results in a dose to the skin or an organ or tissue outside of the intended treatment site and causes clinically significant functional damage to the tissue.

The purpose of number (1) is to include diagnostic errors which exceed a certain dose limit to the patient - consistent with NRC definition. Number (2) limits the type of damage which can occur from excessive interventional procedures only to acute effects to the skin, and does not include stochastic effects. For X-ray therapy, a tolerance level of 50% for one fraction is too restrictive. It is more appropriate, from a clinical standpoint, to control the total amount of radiation delivered over a week. The 50% tolerance level on a single fraction of dose incorporated in the new 10 CFR 35 regulations is intended for HDR brachytherapy and Gamma Knife radiosurgery where the doses per fraction are in excess of 500 rads. Typical doses for external beam therapy are 150 to 250 rads per fraction. The definition of wrong treatment site needs to be defined to address both anatomical errors (right lung versus left lung) and positional or setup errors (deviation of the treatment field orientation from that intended, but still targeting the treatment site). The former clearly qualifies as a medical event from one fraction. However, with the later, is very difficult to set a rational threshold for these types of deviations due to the subjective nature of defining appropriate treatment fields. Therefore, such errors should only be considered a medical event if it results in clinically significant damage.

Sincerely,

Michael Sheetz, M.S., CHP
Senior Health Physicist
Sheetz@radsafe.pitt.edu

II-VI INCORPORATED, 375 Saxonburg Boulevard, Saxonburg, PA 16056
eV Products, 373 Saxonburg Boulevard, Saxonburg, PA 16056
General Offices: 724-352-4455 FAX:724-352-5284

September 14, 2000

Original: 2138

Environmental Quality Board
P.O. Box 8477
Harrisburg, PA 17105-8477

RE: Notice of Proposed Rulemaking – Radiological Health
25 PA. CODE CHS. 215, 217, 219, 220, 224, 225, 226, 230 AND 232

Dear Sirs:

II-VI Incorporated wanted to take this opportunity to express our support for the Commonwealth of Pennsylvania assuming authority from the United States Nuclear Regulatory Commission (NRC) for radioactive material licensees in this Commonwealth as an agreement state.

II-VI Incorporated presently has been granted licenses by both the NRC and the Pennsylvania Department of Environmental Protection (PADEP) to receive, acquire, possess, and transfer regulated materials. Maintaining these dual licenses mechanism has resulted in increased compliance costs for fees and management of our radiation protection program. II-VI Incorporated supports the centralizing of these licenses.

We look forward to continuing the partnership developed between II-VI Incorporated and the PADEP in providing a safe and healthy workplace, and protection of the community. If you have any questions, please do not hesitate to contact anyone on the Radiation Safety Staff of II-VI Incorporated.

Best regards,

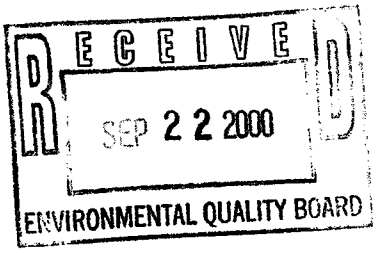
John A. Labrecque
Radiation Safety Director

Michael J. Nanney
Assistant Radiation Safety Director

Cc: Carl J. Johnson
J. Bruce Glick

Trostle, Sharon F.

From: Eric Boeldt [ejb6@psu.edu]
Sent: Friday, September 22, 2000 8:32 AM
To: RegComments@dep.state.pa.us
Subject: Proposed Rulemaking of Title 25, Comments

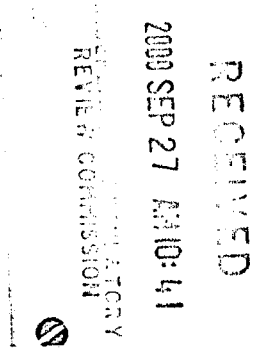


Good morning,

I am writing to comment on the proposed revisions to Title 25. There are two sections that I believe should be changed prior to finalizing these rules.

Original: 2138

The first is paragraph §217.191(c)(4).
"Subchapter I. TRANSFER OF RADIOACTIVE MATERIAL.
§217.191 Transfer of material.
(c) methods of verification
(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the NRC . . . .
."



Paragraph (4) should be deleted. I have on two occasions prevented shipments of radioactive material to Penn State University because the transferor contacted me to ask for license verification. In both cases the amount of material being transferred was less than our license limit, however upon receipt Penn State would have exceeded its license limit. I strongly feel that license verification should ONLY come from the recipient's radiation safety office. Paragraph §217.191(b) of this section states ". . . the licensee transferring the material shall verify that the transferee's license authorizes receipt of the type, form, and quantity of radioactive material to be received " A provision of licenses is not exceeding procession limits. If the shipper does not know how much I currently possess, how is he able to know how much I am allowed to receive? Thus I do not feel that method described in paragraph (c)(4) would satisfy the requirements of paragraph (b).

Please delete paragraph §217.191(c)(4).

The second section to be changed is §220.2 (a) (3)
"§220.2 Posting of notices to workers.
(a) A licensee or registrant shall post current copies of the following documents
(3) The operating procedures applicable to activities under the license or registration."

Although this is not a change from the current regulations, posting comprehensive operating procedures for a research and development organization does not seem possible. Posting operating procedures for radioactive devices or X-ray machines (check meter, turn on voltage, warm up, stand back, etc) is a reasonable and useful requirement. Trying to post procedures for wet chemistry work would just be confusing. Quite often dozens of different procedures may be performed in the same room by many people. In addition, these procedures are frequently revised as researchers try different methods of obtaining worthwhile results.

Please revise §220.2(a)(3) to "The operating procedures applicable to activities under the registration"

Thank you for this opportunity to comment on these Proposed Regulations.

Eric Boeldt
Radiation Safety Officer
Penn State University 814-865-6391
6 Eisenhower Parking Deck FAX-865-7225
University Park, PA 16802