APPALACHIAN GEOPHYSICAL SURVEYS

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Apollo, Pennsylvania 15613
Telephone (724) 327-8119
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Division of Radiation Control
Bureau of Radiation Protection
13th Floor, Rachel Carson State Office Building
P.O. Box 8469
Harrisburg, PA 17105-8469

March 19, 1998

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Attn: Stuart R. Levin
Chief, Division of Radiation Control,
Bureau of Radiation Protection

re: Comment on Proposed Rulemaking, as per
PENNSYLVANIA BULLETIN , Volume 28 Number 7, February 14, 1998.

Dear Dr. Levin:

We would like to make the following comments on Proposed Rulemaking found in the PENNSYLVANIA BULLETIN , Volume 28 Number 7, February 14, 1998:

1) CHAPTER 226. RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING.
Section 226.17 Design and performance criteria for sealed sources.

> "A licensee may not use a sealed source, except those containing radioactive material in gaseous form, in well logging unless the sealed source meets the following minimum criteria....."

We presume that the requirements of this proposed rule (226.17) recognizes the "temporary generic exemption published in the Federal Register on July 25, 1989 (54 FR 30683). The generic exemption exempted well logging licensees from the requirement specified in 10 CFR 39.41 (a)(3). The exemption applied to (and allowed the continued use of) well logging sources that meet certain alternate prototype testing criteria." These sources were identified by manufacturer and model number in an attachment titled "WELL LOGGING SOURCES APPROVED UNDER PART 39 REQUIREMENTS" in a USNRC memorandum dated November 1, 1991, to "All Well Logging Licensees" on the subject "STATUS OF WELL LOGGING SOURCES".

If proposed rule (226.17) does not permit recognition of this generic exemption we would like to suggest that language be added to make such an allowance possible. An intolerable financial burden would befall small businesses who currently possess sources of these types, such as ours, if the NRC generic exemption is not allowed.

2) We did not see any discussion of fees of any type in the captioned Bulletin. We presume fee structure, including annual fees and reciprocity fees will be the subject of future Bulletins upon which comments can be made.

Respectfully Submitted,

Craig B. Clemmens
Managing Partner
Radiation Safety Officer

ALLEGHENY
UNIVERSITY OF
THE HEALTH SCIENCES

Broad & Vine
Philadelphia, PA 19102-1192
215-762-7000

2900 Queen Lane
Philadelphia, PA 19129
215-991-8100

4/6/98

Environmental Quality Board
PO 8477
Harrisburg, PA 17105-8477

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Dear Environmental Quality Board:

I would like to comment on the proposed rulemaking concerning 25 PA code chs. 225, 217, 219, 220, 224-226, 230 and 232.

219.51 Dose limits for individual members of the public.

- I believe the reduction from 5 mSv to 1 mSv is in general wise since it is consistent with other regulatory and advisory organizations. However, there should be a "grandfather clause" for existing facilities shielded to the current 5 mSv limit. I have heard rumors that this has not been included since shielding calculations are already "done overly conservatively." I believe this argument is invalid for the following reasons:

1. While most shielding calculations have been performed using the method outlined in NCRP 49, most physicists use various modifications on this method as more current/accurate data have become available. Actually this is consistent with the spirit of NCRP 49 since its introduction says, "While specific recommendations are given, alternate methods may prove equally satisfactory in providing radiation protection." Therefore, there is not necessarily the conservatism built into all calculations as might be presumed.
   - The method used to calculate shielding for a recent facility may be the exact same method used to calculate shielding for a facility after the new proposed rules go into effect. It is not consistent for the state to say the method is overly conservative before its rule goes into effect but not overly conservative afterwards.
2. The state regulates the dose limit to an individual. It does not regulate how shielding calculations are performed (nor should it). The state therefore should not make presumptions regarding the amount of conservatism involved in the calculations.
3. Shielding for CT equipment is not directly addressed in NCRP 49. The shielding method used most often for CT equipment is based on isodose lines supplied by the manufacturer. To the best of my knowledge, this method has not changed much since initial use and does not contain many of the conservative assumptions used in "conventional" x-ray shielding calculations. Most existing CT facilities would therefore have to be rebuilt in order to provide extra shielding if the regulations do not grandfather them.
4. The financial and time costs associated with recalculating and possibly re-shielding, every x-ray facility in the state would be astronomical. This is needless since the benefits of doing this are unproved and extremely minimal if any.

NCRP 49 supersedes NCRP 34. It is interesting to note that NCRP 49 says, "installations designed before the publication of this report and meeting the requirements of ... NCRP Report No. 34 need not be re-evaluated." In other words, they grandfathered existing facilities. The state should do likewise.

Sincerely,

Dan Beideck

Dan Beideck, M.S., DABMP
Radiation Physics and Safety, MS 106
Allegheny University of the Health Sciences
Broad and Vine
Philadelphia, PA 19102

ST. FRANCIS HEALTH SYSTEM

ST. FRANCIS MEDICAL CENTER

400 - 45th Street
Pittsburgh, PA 15201-1198
412/622-4343

March 23, 1998

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

Gentlemen:

The following comments are in reference to published material in the Pennsylvania Bulletin Volume 28, #7, dated February 14, 1998, Part II. It is my understanding that Pennsylvania is in the process of becoming an agreement state and, therefore, has to be as stringent as the NRC in establishing the rules and regulations.

On Page 885, I noticed that the definition of misadministration, starting from the left column of the page until the end in the right column, starting with the words "misadministration that — administration to a human being of: ..... the total prescribed dose by more than 20% of the total prescribed dose" is to be deleted because it is within a third bracket. Without commenting whether this is a good idea to apply this strict definition to hospitals, I recommend that you not delete this paragraph until Pennsylvania becomes an agreement state and then discuss it with all the physicists and the administrations to see if it is applicable to hospitals.

I may send you some other comments prior to the April 15, 1998 deadline.

Very truly yours,

Krishnadas Banerjee

Krishnadas Banerjee, Ph.D.
Radiation Safety Officer

KB:cf

CC: Stuart Levin
James Yusko

PABulletincomments

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Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration (NUREG-1556, Vol. 3)

Publication Information

Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration

Draft Report for Comment

NRC Report Number: NUREG-1556, Vol. 3

Availability Notice

Manuscript Completed: September 1997

Date Published: September 1997

J. Lubinski, S. Baggett, D. Broaddus, M. Burgess, E. Compton, K. Randall, T. Rich, B. Smith

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Abstract

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the *NRC*'s Materials Licensing Process Redesign," and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance." Draft NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," dated September 1997, is designed to provide applicants for requests for a sealed source or device safety evaluations, and reviewers of such requests, with the information and materials necessary to make determinations that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

This document combines the guidance previously found in NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," Regulatory Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," and the Office of Nuclear Material Safety and Safeguards Policy and Guidance Directives 84-22, "What Source and Device Designs Require an Evaluation," and 84-5, "Source and Device Evaluation Technical Assistance Request."

Note that this document is strictly for public comment and NOT for use in preparation or review of applications for sealed source and device evaluations until it is published in final form.

Section Contents

- Appendix G: Industry and Concensus Standards
- Appendix H: Standard Registration Certificate Formats
- Appendix I: Assigning Registration Certificate Numbers
- **Appendix J: List of Approved Well Logging Sources**

4.7 Well-Logging Equipment

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of 10 CFR Part 39, Subpart C. One such requirement is that the licensed material be as insoluble and nondispersible as practicable. The vendor or custom user of the equipment may demonstrate that the equipment meets the requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of well-logging equipment, the items listed below must be addressed:

Area to be Addressed	Applicable 10 CFR Regulations
Labeling	39.31(a)
Leak Testing	39.35
Design	39.41(a)(1) & (2)
Prototype Testing	39.41(a)(3)

Figure 4.6 - Well-Logging Operations - Sealed sources used in well logging operations must meet the requirements of 10 CFR Part 39.

Appendix C: Application and Review Checklist

Well logging sources must be nondispersible and nonsoluble. (see Appendix J for a list of approved well logging sources as of November 1991)		

Appendix J: List of Approved Well Logging Sources

Title	From	Page	GIF (viewing)	TIFF (download for printing)
Status of Well Logging Sources Memorandum	John E. Glenn	1	srp00901.gif	srp00901.tif
		2	srp01001.gif	srp01001.tif

Well Logging Sealed Sources Approve Under Part 39 Requirements			
Sources From	Sources To	GIF (viewing)	TIFF (download for printing)
Amersham	Monsanto	srp01101.gif	srp01101.tif
P.A. Incorporated	US Department of Energy	srp01201.gif	srp01201.tif

Well Logging Sealed Sources Approved Under the Generic Exemption			
Sources From	Sources To	GIF (viewing)	TIFF (download for printing)
Comprobe, Inc.	Parkwell Laboratories, Inc.	srp01301.gif	srp01301.tif

Known Sealed Sources Not Approved for Use in Well Logging			
Sources From	Sources To	GIF (viewing)	TIFF (download for printing)
Amersham Corporation	ICN Pharmaceutical, Inc.	srp01401.gif	srp01401.tif
Isotopes Specialties	WSI	srp01501.gif	srp01501.tif

This document is available on the NRC Web Site at:
http://www.nrc.gov/NRC/NUREGS/SR1556/V3/index.html

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

NOV 9 · 1989

TO: All Well Logging Licensees

SUBJECT: STATUS OF WELL LOGGING SOURCES

In a memorandum dated August 10, 1989, we informed Nuclear Regulatory Commission (NRC) well logging licensees of a temporary generic exemption published in the Federal Register on July 25, 1989 (54 FR 30683). The generic exemption exempted well logging licensees from the requirement to use only sealed sources that meet the prototype testing requirement specified in 10 CFR 39.41(a)(3). The exemption applied to (and allowed the continued use of) well logging sources that meet certain alternate prototype testing criteria.

The notice indicated that the exemption would remain in effect until NRC published its final findings in the Federal Register. Thus far, NRC has been unable to initiate this action due to higher priority activities; however, NRC now anticipates commencing this task in the near future.

Included in the memorandum with the Federal Register notice were three enclosures that listed various sealed source models common to well logging and identified their suitability for continued use in well logging operations. There have been a few changes to the lists since first transmitted. There are a few sources which we have determined meet the criteria specified in 10 CFR Part 39, and have added the sources to the approved list.

Enclosed are the three enclosures which have been updated on a one-time-only basis to show the apparent current status of known well logging sources. Enclosure 1 lists those source models which appear to meet Section 39.41 requirements and are approved for continued use. Enclosure 2 lists those source models whose continued use is authorized under the temporary generic exemption. Enclosure 3 lists those source models that do not meet the requirements of Section 39.41 or the generic exemption. When a sealed source is contained (and normally stored) within a device (logging tool), the sealed source manufacturer and model number is shown below the entry. When NRC has been able to determine that a sealed source model was manufactured/distributed by another company, or more than one model designation may have been used, this information is shown in parentheses below the entry. Neutron generators are shown by the designation "NU GEN." An asterisk (*) indicates that the source is used within the logging tool's electronics package.

NOV 9 1 :98

We do not intend to update these lists in the future. Due to the time which has passed, we believe that all questions concerning sources identified on the unapproved list should have been answered. Any new well logging source introduced by source manufacturers must be designed to meet the criteria specified in 10 CFR 39.41. Therefore, it will not be necessary to update the list to incluoe a new source, as the NRC or Agreement State registration sheet for the source will indicate that use of the source in well logging operations is acceptable.

If you have any questions, please contact Torre Taylor at (301) 492-0611 or J. Bruce Carrico at (301) 492-0634.

John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures: As stated

WELL LOGGING SEALED SOURCES APPROVED UNDER PART 39 REQUIREMENTS

MANUFACTURER	MODEL
AMERSHAM CORPORATION	AMN.CYn (n = 1 to 14)
AMERSHAM CORPORATION	AMN.CY1
AMERSHAM CORPORATION	AMN.PEn (n = 1 to 4)
AMERSHAM CORPORATION	CDC.CYn (n = 2 to 12)
AMERSHAM CORPORATION	CKC.CDn (n = 2 to 12)
AMERSHAM CORPORATION	CKC.800 SERIES
AMERSHAM CORPORATION	CYN.CDn (n = 2 to 12)
AMERSHAM CORPORATION (GAMMA INDUSTRIES, GENERAL NUCLEAR)	VD(HP)
AMERSHAM CORPORATION	CYN.CY2
ANADRILL, INC.* ISOTOPE PRODUCTS MODEL 274 SEALED SOURCE	SGS-AA,SGS-BA, OR SGS-CA
COMPROBE, INC. GAMMA INDUSTRIES MODEL VD-HP SEALED SOURCE GULF NUCLEAR, INC. MODEL VL-1 SEALED SOURCE	1203 DENSITY PROBE
DRESSER INDUSTRIES INC. (Nu GEN)	C-58301, C-107298
E.I.DUPONT DE NUMOURS & CO. (NEW ENGLAND NUCLEAR)	NER-571
GEARHART INDUSTRIES, INC. (Nu GEN)	013-1004-000
GENERAL ELECTRIC. CO.	GE(N)-Cf-100 SERIES
GULF NUCLEAR, INC. (NEEI)	VL-1
GULF NUCLEAR, INC. (NEEI)	71-1 (NEEI-AMBE-71-1)
KAMAN SCIENCES CORPORATION (Nu GEN)	A-3061
KAMAN SCIENCES CORPORATION (Nu GEN)	A-320
KAMAN SCIENCES CORPORATION (Nu GEN)	A-520
KAMAR SCIENCES CORPORATION (Nu GEN)	E-3010 AND E-3020
MONSANTO CO., DAYTON LABORATORY	M-245258 (NSR-M)
MONSANTO CO., DAYTON LABORATORY	24113
MONSANTO CO., DAYTON LABORATORY	24154-C
MONSANTO CO., DAYTON LABORATORY	24174
MONSANTO CO., DAYTON LABORATORY	24181
MONSANTO CO., DAYTON LABORATORY	24183

Enclosure 1

WELL LOGGING SEALED SOURCES APPROVED UNDER PART 39 REQUIREMENTS (cont'd)

MANUFACTURER	MODEL
P.A. INCORPORATED (MONSANTO)	H-245258 (NSR-N)
P.A. INCORPORATED*	P-194693
SCHLUMBERGER (MONSANTO, NUMEC)	DWG H-115686
SCHLUMBERGER	DWG H-142108
SCHLUMBERGER	DWG H-239681
SCHLUMBERGER WELL SERVICES*	P-194693
SCHLUMBERGER WELL SERVICES	NSR-R
UNC NUCLEAR INDUSTRIES	PA2A, PA2B, PT2A, PT2B, PS2A, PS2B (OLD: SR-100)
E.I.DUPONT DE NUMOURS & CO. (NEN)	MODEL 478C SEALED SOURCE
US DEPARTMENT OF ENERGY	SR-CF-100 SERIES

WELL LOGGING SEALED SOURCES APPROVED UNDER THE GENERIC EXEMPTION

MANUFACTURER	MODEL
COMPROBE, INC. GULF NUCLEAR, INC. MODEL CSV SEALED SOURCE	1203 DENSITY PROBE
COMPROBE, INC. GAMMA INDUSTRIES (GAMMATRON) MODEL AN-HP SEALED SOURCE	2103 DENSITY PROBE
E.I.DUPONT DE NUMOURS & CO. (NEW ENGLAND NUCLEAR)	NER-572, NER-582
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	CS-1000 (HP)
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-NB (HP)
GAMMA INDUSTRIES	NB (HP)
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	NHP-A-#
GAMMA INDUSTRIES	WLG-I
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	AN-HP
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	AN-HPG, RN-HP
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	DA-20
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	DA-5
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	GT-GHP
GULF NUCLEAR, INC. (NEEI)	AMBE-71-2A
GULF NUCLEAR, INC. (NEEI)	C-73-2
GULF NUCLEAR, INC. (NEEI)	CS-2
GULF NUCLEAR, INC. (NEEI)	CSV
MONSANTO CO., DAYTON LABORATORY	24112
MONSANTO CO., DAYTON LABORATORY	24120
PARKWELL LABORATORIES, INC. (US NUCLEAR)	PL-104

Enclosure 2

KNOWN SEALED SOURCES NOT APPROVED FOR USE IN WELL LOGGING

MANUFACTURER	MODEL
AMERSHAM CORPORATION	CD CQ 5987
AMERSHAM CORPORATION	CDC.800 SERIES (.801 TO .811)
DRESSER ATLAS	B89596, B89597, B89598
FRONTIER TECHNOLOGY CORP.	100
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-DL-4
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-NB-S-5.0
GAMMA INDUSTRIES	NB-S-5, NB-S-20
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	PL-AMBE-2.7
GAMMA INDUSTRIES	RC-1 (HP)
GAMMA INDUSTRIES	S-14
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	GT-G
GENERAL NUCLEAR, INC.	GNI-C(G)M-5
GULF NUCLEAR, INC. (NEEI)	CO-50
GULF NUCLEAR, INC. (NEEI)	CS-50
GULF NUCLEAR, INC. (NEEI)	TG-1
GULF NUCLEAR, INC. (NEEI)	72-CO-200
HASTINGS RADIOCHEMICAL WORKS	CS-III-A-100
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	373
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	374
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	376
ICN PHARMACEUTICAL, INC.	3146

Enclosure 3

KNOWN SEALED SOURCES NOT APPROVED FOR USE IN WELL LOGGING (cont'd)

MANUFACTURER	MODEL
ISOTOPES SPECIALTIES	C-0037
LFE CORPORATION (TRACERLAB)	CS-15
MINNESOTA MINING AND MANUFACTURING	4F6B
MINNESOTA MINING AND MANUFACTURING	4F6H (REDESIGN OF MODEL 4F6B)
MINNESOTA MINING AND MANUFACTURING	4F6S
MINNESOTA MINING AND MANUFACTURING	4P6F
MINNESOTA MINING AND MANUFACTURING	4P6U
MINNESOTA MINING AND MANUFACTURING	4P6W
MONSANTO CO., DAYTON LABORATORY (SCHLUMBERGER WELL SERVICES)	H-142525
MONSANTO CO., DAYTON LABORATORY (SCHLUMBERGER WELL SERVICES)	H-207947
MONSANTO CO., DAYTON LABORATORY	MRC
MONSANTO CO., DAYTON LABORATORY	MRC-H-SS-W-AMBE(R)
MONSANTO CO., DAYTON LABORATORY	NS-WELEX
MONSANTO CO., DAYTON LABORATORY	2410
MONSANTO CO., DAYTON LABORATORY	24154-B
NUCLEAR MATERIALS AND EQUIPMENT CORP.	NUMEC-AM- 62, 63, 100, 123, 154
NUCLEAR MATERIALS AND EQUIPMENT CORP.	NUMEC DWG. 11-8-208
PARKWELL LABORATORIES, INC.	PL-AMBE
SCHLUMBERGER	DWG H-1061850
SCHLUMBERGER	DWG H-123615
SCHLUMBERGER	DWG H-123837
SCHLUMBERGER	DWG H-218733
SCHLUMBERGER	DWG X-113176
WELL RECONNAISANCE, INC. AMERSHAM/SEARLE MODEL X.154 SEALED SOURCE	10411
WSI	A4794

PENNSYLVANIA OIL & GAS ASSOCIATION
106 Locust Grove Road, P. O. Box 349, Bainbridge, PA 17502
Tel: 717-426-0067
Fax: 717-426-3010

May 1, 1998

Fax

To:	John Jewett	**From:**	Steve Rhoads
Fax:	717-783-2664	**Pages:**	[Click here and type # of pages]
Phone:		**Date:**	May 1, 1998
Re:	DEP Well Logging Regulations	**CC:**	

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply**

• **Comments:**

Attached are the documents we discussed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

NOV 9 · 1989

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TO: All Well Logging Licensees

SUBJECT: STATUS OF WELL LOGGING SOURCES

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We do not intend to update these lists in the future. Due to the time which has passed, we believe that all questions concerning sources identified on the unapproved list should have been answered. Any new well logging source introduced by source manufacturers must be designed to meet the criteria specified in 10 CFR 39.41. Therefore, it will not be necessary to update the list to include a new source, as the NRC or Agreement State registration sheet for the source will indicate that use of the source in well logging operations is acceptable.

If you have any questions, please contact Torre Taylor at (301) 492-0611 or J. Bruce Carrico at (301) 492-0634.

John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures: As stated

PENNSYLVANIA OIL & GAS ASSOCIATION
106 Locust Grove Road, P. O. Box 349, Bainbridge, PA 17502
Tel: 717-426-0067
Fax: 717-426-3010

April 30, 1998

Fax

To:	John Jewett	**From:**	Steve Rhoads
Fax:	7832664	**Pages:**	3
Phone:		**Date:**	April 30, 1998
Re:	Well Logging Regulation	**CC:**	

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply**

• **Comments:**

Here is the November 1, 1991 letter from the NRC that Mr. Clemmens refers to in his letter to Stu Levin.

I will be in touch when I find out from the NRC what the status of the temporary generic exemption is.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 15, 1998

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

Dear Board Members:

Pursuant to a request dated February 19, 1998, from Stuart R. Levin, Chief, Division of Radiation Control, Bureau of Radiation Protection, we have reviewed the proposed regulations that appeared in the Pennsylvania Bulletin, Volume 28, No. 7, February 14, 1998. These are contained in Chapter 215. General Provisions; Chapter 217. Licensing of Radioactive Material; Chapter 219. Standards for Protection Against Radiation; Chapter 220. Notices, Instruction and Reports to Workers; Inspections; Chapter 224. Medical Use of Radioactive Material; Chapter 225. Radiation Safety Requirements for Industrial Uses and Radiographic Operations; Chapter 226. Radiation Safety Requirements for Well Logging; Chapter 230. Packaging of and Transportation of Radioactive Material; and Chapter 232. Licenses and Radiation Safety Requirements for Irradiators. The proposed regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39 and 71. We also discussed our review of the regulations with Mr. Keith Kearns, Acting Director, Bureau of Radiation Protection, Mr. Stuart Levin, and Ms. Mary Lou Barton on March 10, 1998, and with Mr. Levin on other occasions.

As a result of our review, we have 30 comments that are identified in the enclosure. Please note that we have not limited our review to regulations required for compatibility and/or health and safety. All NRC regulations with a compatibility category "D" designation are not required for purposes of compatibility. All comments on regulations designated compatibility category "D" are for your consideration, only. We have enclosed an explanation of the compatibility and health and safety categories identified in our comments.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me or Dr. Stephen N. Salomon my staff at (301) 415-2368 or E-mail: SNS@NRC.GOV.

Sincerely,

Paul H. Lohaus, Deputy Director
Office of State Programs

Enclosures:
As stated

cc: Keith Kearns, BRP, PA

COMMENTS ON PROPOSED PENNSYLVANIA REGULATIONS
AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

Category	State Regulation	NRC Regulation	Subject and Comments
	CHAPTER 215		**GENERAL PROVISIONS**
A	215.2	20.1003	Definitions
			No comments
	215.12		Inspections
			Although no NRC regulations exist on inspection frequency, this paragraph indicates that major medical facilities, including hospitals, are to be inspected at least every 3 years. The inspection of major licensees at a 3 year interval seems to be a major deviation from the annual medical institution broad scope, annual brachytherapy remote afterloader, and annual nuclear pharmacy inspection frequencies stated in NRC Inspection Manual Chapter 2800.
	215.32		Exemption qualifications
			No comments
	CHAPTER 217		**LICENSING OF RADIOACTIVE MATERIAL**
D	217.42	31.5	Certain measuring, gauging or controlling devices.
			No comments.
	217.58	30.35	Financial assurance arrangements for reclaiming sites.
D	217.58(e)	30.35(3)	Decommissioning funding plan.
			The second sentence introduces a "commissioning" funding plan. However, this section deals only with decommissioning plans. The lack of a "de" before commissioning appears to be a typographical error that may cause confusion and should be corrected.

Category	State Regulation	NRC Regulation	Subject and Comments
D	217.58(f)(2)	30.35(f)(2)	A surety method. Appendix A to 10 CFR Part 30 gives the criteria relating to financial tests and parent company guarantees. Appendix C gives criteria relating to financial tests and company self-guarantees. Appendix F to Chapter 217 corresponds to Appendix C to Part 30 and was inappropriately used for Appendix A to Part 30, as well. The proper references to the Appendices should be made in paragraph 217.58(f)(2).
None	217.58(h)	None	Specific licensees that are required to make financial surety arrangements. There is no equivalent NRC regulation. It is not clear how this provision relates to the preceding ones. It appears to conflict with the earlier provisions specifying which licensees are required to provide financial assurance. For example, (3) refers to formerly United States Atomic Energy Commission (AEC) or NRC licensed facilities. Most NRC materials licensees become Pennsylvania licensees when Pennsylvania becomes an Agreement State so they would be subject to Pennsylvania regulations without this phrase. We do not know whether the former AEC licensees cited refer to the formerly licensed sites under study by the Oak Ridge National Laboratory that may be contaminated and require cleanup. The provision (h)(4)(I)(1) may conflict with paragraph 217.58(a) because different Appendices are used that list different radionuclides.
B	Appendix E	Appendix B	We found 12 discrepancies in the table that need to be corrected. American-241 should be Americium-241; Nickel-50 should be Nickel-59; Palladium-106 and 108 should be Palladium-103 and 109, respectively; Phosphorus-33 should be Phosphorus-32; Radium-236 should be Radium-

Category	State Regulation	NRC Regulation	Subject and Comments
			226; Rhenium-136 and 138 should be Rhenium-186 and 188, respectively; Rhodium-106 should be Rhodium-105; Rubidium-66 should be Rubidium-86; Rubidium-97 should be Ruthenium-97; Silver-106 should be Silver-105; The quantity for Silver-111 should be 100 microcuries instead of 111 microcuries; and the footnotes indicating that these quantities are based of [sic] alpha disintegration rates of thorium and uranium and their daughter products, should say "based on...". Given the number of discrepancies, a thorough review of the Tables by Pennsylvania staff should be conducted.
D	II.A.3 Appendix F 217.58	II.A.(3) Appendix C Part 30	Criteria Relating to Use of Financial Tests The nomenclature for Moody's bonds is Aaa, Aa, or A. Pennsylvania's provision uses all A's. This may be a typographical error but should be corrected to be consistent with Moody's to avoid confusion.
	CHAPTER 219	**Part 20**	**STANDARDS FOR PROTECTION AGAINST RADIATION** No comments.
	CHAPTER 220	**Part 19**	**NOTICES, INSTRUCTION AND REPORTS TO WORKERS; INSPECTIONS** No comments.
	CHAPTER 224	**Part 35**	**MEDICAL USE OF RADIOACTIVE MATERIAL**
D H&S (a), (b) & (c)	224.61	35.32	Quality management program The words, "human research subject" are omitted in many places. To satisfy the health and safety requirement, the underlined text should be added:

Category	State Regulation	NRC Regulation	Subject and Comments
			(a)(2) That, prior to each administration the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive. (b)(1)(I) A representative sample of patient and human research subject administrations.
D	224.253	35.315	Safety precautions The words, "human research subject" are omitted in many places. We recommend that the following underlined text be added: (a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized in compliance with 224.109 (relating to release of patients containing radiopharmaceuticals or permanent implants), a licensee shall: (a)(6), (a)(7) . . . patient or the human research subject.
D	224.462	35.961	Training for teletherapy physicist The word "physics" is omitted. We recommend that the following underlined text be added: (3) Is certified by the American Board of Medical Physics in radiation oncology physics.
D	224.466.	35.980	Training for an authorized nuclear pharmacist The word "radiation" is omitted. We recommend that the following underlined text be added to section (a)(2)(ii)(A) Shipping, receiving and performing related radiation surveys.

Category	State Regulation	NRC Regulation	Subject and Comments
	CHAPTER 225	**Part 34**	**RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL USES AND RADIOGRAPHIC OPERATIONS**
B	225.2	34.3	Definitions The following terms are omitted: Control tube, Field station, Hands-on experience, Lay-barge radiography, Offshore platform radiography, Practical Examination, Radiation Safety Officer for industrial radiography and Underwater radiography. The missing definitions should be adopted to meet the compatibility category for these definitions since radiographers may work in multiple jurisdictions (e.g., other Agreement States or where NRC has jurisdiction).
B	225.251	34.20	Performance requirements for radiography equipment. Paragraph 34.20 (a)(2) is omitted and should be added to meet the compatibility category.
B	225.261(a)	34.41	Radiographic operations, security and posting. Paragraphs 34.41 (b) and (c) are omitted and should be added to meet the compatibility category.
B	225.254	34.35 (c)	Storage precautions. Paragraph 34.35(c) omits the phrase: "The licensee shall store licensed material in a manner which will minimize danger from explosion or fire." The revised text should be added to meet the compatibility category.

Category	State Regulation	NRC Regulation	Subject and Comments
B D, para (a)(2) and (c)	225.72 and 225.73	34.43	Training and Testing The following phrases are omitted from 34.43: Paragraph 225.71(a)(1) omits 34.43(a)(1) "... in addition to a minimum of 2 months of on-the-job training..." This must be adopted to meet the compatibility category. Paragraph 225.72(a)(2) omits 34.43(a)(2) "... and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the Commission." Although not required to meet the compatibility category, we are pointing this phrase out for your consideration. Paragraph 225.73(b)(2) omits from 34.43(e)(2) "...a practical examination before these individuals can next participate in a radiographic operation." This phrase must be adopted to meet the compatibility category. Paragraph 225.73 (a) requires observation of the performance of each radiographer and radiographer's assistant at intervals not to exceed 1-calendar year. This is less stringent that the 6 month or less interval required by 33.43(e)(1). The period of 6 months or less must be adopted to meet the compatibility category.
C	225.153	34.47	Personnel monitoring control The statement in 225.153(a) "A licensee or registrant may not permit an individual to act as a radiographer or as a radiographer's assistant, unless, at all times during radiographic operations, each individual wears a combination of direct-reading pocket dosimeter, an operating alarm ratemeter and either a film badge or a thermoluminescent dosimeter (TLD)." This sentence conflicts with another statement in the

Category	State Regulation	NRC Regulation	Subject and Comments
			same paragraph "... Registrants are exempted from requiring the use of alarm rate meters." We recommend that you resolve the conflict. Paragraph 225.153 (c)(3) reads +/- 30 % instead of plus or minus 20 percent as required in 34.47(c) "... Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure." The tolerance of plus or minus 20 percent should be adopted to meet the compatibility category. Paragraph 34.47 (e) that starts, "If a film badge or TLD is lost or damaged,..." is omitted. The missing paragraph should be adopted to meet the compatibility category.
B	225.251(b)(2)	34.35(b)	This provision that deals with the transport of licensed material identified in the comparison table could not be found in the proposed regulation. It must be adopted to meet the compatibility category.
B	225.26	34.46	Supervision of radiographer's assistants. A paragraph equivalent to entire paragraph, 34.46, presented in the State supplied comparison list could not be found in the proposed regulations. This paragraph must be adopted to meet the compatibility category.
C	215.11	34.63	Records of receipt and transfer of sealed sources. Two paragraphs equivalent to 34.63 presented in the State supplied comparison list could not be found in the proposed regulations. These paragraphs must be adopted to meet the compatibility category.
C	227.72(c)	34.79(a)	Records of training and certification. A paragraph equivalent to 34.79(a) presented in the State supplied comparison list could not be

Category	State Regulation	NRC Regulation	Subject and Comments
			found in the proposed regulations. This paragraph must be adopted to meet the compatibility category.
C	None	34.81	Copies of operating and emergency procedures. A paragraph equivalent to 34.81 presented in the State supplied comparison list could not be found in the proposed regulations. This paragraph must be adopted to meet the compatibility category.
C	225.153(e)	34.83	Records of personnel monitoring procedures. A paragraph equivalent to 34.83 presented in the State supplied comparison list could not be found in the proposed regulations. This paragraph must be adopted to meet the compatibility category.
	CHAPTER 226	**Part 39**	**RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING**
B	226.2	39.2	Definitions Definitions of licensed material and sealed sources are omitted and should be adopted to meet the compatibility category.
C	226.19	39.43	Inspection, maintenance, and opening of a source or source holder. The provision in 39.43(a) "Each licensee shall visually check source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present" is omitted and should be adopted to meet the compatibility category.
C	225.21(e)	39.61	The statement in 39.61(d) regarding the record on each logging supervisor's and logging assistant's annual safety review is omitted and should be adopted to meet the compatibility category.

Category	State Regulation	NRC Regulation	Subject and Comments
	CHAPTER 230	**Part 71**	**PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL**
B	230.2	71.4	Low Specific Activity Material Subparagraph (ii)(C) for LSA-II should read that the average specific activity of the solid does not exceed $2x10^{-3}A_2/g$, not 2,000 A_2/g.
B	230.2	71.4	Surface contaminated object (SCO) The word "accessible" in sections (I)(c) and (ii)(c) is incorrect and appears to be a typographical error. The word should be changed to "inaccessible." The term "inaccessible" means surfaces that are not readily accessible to an individual, such as the inner surfaces of pipes, or the inner surfaces of glove boxes.
B	230.2	71.4	Natural uranium The term "uranium-238" is missing after the word "essentially" and appears to be a typographical error and should be added to meet the compatibility category.
B	Table A-1	Table A-1	Ba-133 is not listed.
	CHAPTER 232	**Part 36**	**LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS**
D	232.25(b)	36.25(b)	The value of 0.0002 Sv should be 0.00002 Sv. This is apparently a typographical error and should be corrected.

Compatibility Category and H&S Identification
for NRC Regulations

Key to categories:

A =	Basic radiation protection standard or related definitions, signs, labels or terms necessary for a common understanding of radiation protection principles. The State program element should be essentially identical to that of NRC.
B =	Program element with significant direct transboundary implications. The State program element should be essentially identical to that of NRC.
C =	Program element, the essential objectives of which should be adopted by the State to avoid conflicts, duplications or gaps. The manner in which the essential objectives are addressed need not be the same as NRC provided the essential objectives are met.
D =	Not required for purposes of compatibility.
NRC =	Not required for purposes of compatibility. These are NRC program element areas of regulation that cannot be relinquished to Agreement States pursuant to the AEA or provisions of Title 10 of the Code of Federal Regulations. The State should not adopt these program elements.
H&S =	Program elements identified as H&S are not required for purposes of compatibility; however, they do have particular health and safety significance. The State should adopt the essential objectives of such program elements in order to maintain an adequate program.

PROPOSED RULEMAKING 4/15/98

Environmental Quality Board

[25 PA. Code Chs. 215, 217, 219, 220, 224-226, 230 & 232]

RADIOLOGICAL HEALTH

ORIGINAL: 1922
COPIES: Smith, Jewett
Sandusky, Legal (2)

Comments:

215.2 Person -v- member of public -v- individual members of the public: definitions have conflicting meanings as well as unconstitutional inclusion of corporations, as a person.

— ± % of error in doses should not be greater than 10% for any over exposure, medical or occupational. Train people

— compatible regulations - regulations of state should remain if more stringent and other federal or states should adjust their regulations accordingly.

— consistency - use of Rems or Sievets should be uniform throughout DEP. Best if both would be utilized at all times w/ one being in parentheses.

— Beta doses - should be more specific. Some betas are more than a quality factor of 1 (one).

— theft, sabbotage - unfortunately a current problem that I didn't see mentioned. How many insufficient amounts would be required to form a critical mass?

Continued...See over →

theft, sabbotage: how long could it be estimated it would take to collect this "critical mass" amount? What are the positions/jobs held that would enable one to "collect" a "critical mass" amount? How easy or difficult would this be? What, if any, background or screening searches are done prior to employment? It only takes less than "1/3 coke can" of radioactive substance to create critical mass. What about other ~~[illegible]~~ terrorist ic uses?

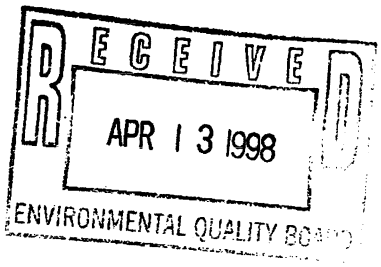
Mary Stamos Osborn
(717) 939-2890 4951 Highland St
Harrisburg, Pa. 1711
4/15/98

I inquired as to extension of time to reply - but NO ONE at 787-3720 or 787-7060 could answer my request or find someone there who could.

Much, if not all, of this is unconstitutionally unsound - U.S. Constitution, Declaration of Independence & the Constitution of the Commonwealth of Pennsylvania. D.E.R./D.E.P. has failed repeatedly to protect the air, water and earth, as well as the humans, flora and fauna. Shame on you all.

MO

April 9, 1998



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

ORIGINAL: 1922
COPIES: Smith
Jewett
Sandusky
Legal (2)

ATTN: Stuart Levin

RE: Proposed Rulemaking
Medical Use of Radioactive Material-Chapter 224

Dear Mr. Levin:

Merck & Co. Inc. would like to provide the following comments concerning the Proposed Rulemaking addressing the Medical Use of Radioactive Materail

BACKGROUND

Merck & Co., Inc. is a large pharmaceutical company, developing pharmaceutical products in all major therapeutic categories. As part of the search for new drugs, the Company needs to add byproduct material to compounds under study so that absorption, distribution, metabolism, and excretion studies of these compounds may be performed in humans. Such studies are conducted under an IND accepted by the FDA by an investigator at a facility licensed by the NRC or Agreement State. These materials are not radiopharmaceuticals, but are used to gain information about the absorption, distribution, metabolism, and excretion of molecules in the drug research and development process. Merck & Co., Inc. is currently authorized by a 10 CFR Part 33 Broad Scope License to make compounds containing byproduct material for distribution to specific licensees. This distribution of radioactively-labeled compounds is not a commercial operation, but is intended to gain additional information concerning the pharmacokinetic performance of these compounds. Merck currently formulates the compounds containing byproduct materials and transfers the materials to specific licensees. The specific licensee then administers the compound to human research subjects in a manner consistent with an IND accepted by the FDA.

ANALYSIS

The Proposed Rulemaking for the Medical Use of Radioactive Material-Chapter 224 has expanded the definition of "medical use" to include the intentional administation of radioactive material to human research subjects. For years, pharmaceutical companies have been labeling compounds with byproduct material and transferring them to specific licensees for use in FDA-approved IND pharmacokinetic studies. The pharmacokinetic studies are critical to evaluating the efficacy of a compound and determining if the compound can be developed into a drug that would provide a medical benefit to society. The actual administration of the radiolabeled compound to humans is not performed by the pharmaceutical company, but rather by specific licensees authorized to perform such studies. The proposed rule appears to disregard this process.

Although pharmaceutical companies formulate compounds containing byproduct material intended for human research in pharmacokinetic studies and distribute these compounds to specific licensees, these activities clearly do not constitute commercial distribution and should not require a license to manufacture and distribute radiopharmaceuticals for medical use per section 217.90. Under the proposed rule, licensees

who administer byproduct material to a volunteer for a pharmacokinetic study would have to possess a medical use license and comply with Chapter 224. Unfortunately, the proposed revision to Chapter 224, specifically section 224.151 will require that the medical use licensee use byproduct material:

(1) obtained from a manufacturer or preparer licensed pursuant to section 217.90; or

(2) prepared by an authorized nuclear pharmacist who meets the training criteria specified under sections 224.466 or 224.467, a physician who is an authorized user and meets the training requirements specified in section 224.453, or an individual under their supervision of either per section 224.55.

Since pharmaceutical companies do not possess Chapter 224 Medical Use Licenses or maufacturing/distribution licenses per section 217.90, nor routinely employ radiopharmacists or physician-authorized users, this proposed rule will prove a unnecessary hardship to the pharmaceutical industry whose intent is not to manufacture and distribute radiopharmaceuticals.

The additional regulatory burden required by the proposed rule is not warranted in light of the following. Typically, the pharmacokinetic studies currently being performed under IND's approved by the FDA involve administering tens of microcuries of hydrogen-3 or carbon-14 to healthy volunteers. These compounds are formulated by radiochemists and pharmacists who work in the research and development programs at large pharmaceutical companies. Good Manufacturing Practice (GMP) required by the FDA assures that these compounds are formulated to exact dosages with appropriate quality control. At these levels of hydrogen-3 and carbon-14, the dosages present minimal radiological risk to the volunteers; therefore, to require pharmaceutical companies to hire radiopharmacists or obtain manufacturer and distribution licenses per section 217.90 would be excessive and unreasonable. Also, pharmaceutical companies cannot contract with a commercial radiopharmacy to label their compounds because of the proprietary nature of the compounds being labeled.

Merck & Co., Inc. agrees that including medical research involving human subjects under "medical use" will improve the radiological protection provided to the volunteers. We strongly disagree, however, with the requirement that the byproduct material for these studies must come from licensees with authorization per section 217.90 or Chapter 224. Many of the compounds currently used for pharmacokinetic studies in volunteers are formulated by 10 CFR Part 33 non-medical broad scope licensees, such as Merck, who have applied for and been granted exceptions to 10 CFR 33.17(a)(4).

We suggest that the following change be made to the proposed rule:

The addition of a new section to 224.151(3) that reads:

224.151(3) Obtained from an individual licensed pursuant to 10 CFR 33, Section 217.71, or equivalent Agreement State requirements, specifically authorized to add byproduct material to compounds for studies to be conducted under an IND accepted by the FDA.

I am sure that this comment will receive careful review and consideration before the final rulemaking is promulgated. I would also welcome an opportunity to discuss this matter with a member of the Environmental Quality Board. I can be reached at (215) 652-4890.

Sincerely,

Edwin A. Wurtz

Edwin A. Wurtz, Ph.D.
Director, Health Physics, Biosafety, and
Environmental Affairs