U.S. NUCLEAR REGULATORY COMMISSION

PDR-016

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) REQUEST

NRC FOIA REQUEST NUMBER(S)		
FOIA-87-47		
RESPONSE TYPE		
	FINAL	X PARTIAL
DATE	MAR 4 1987	
DOCKET NUMBER(S) (*If applicable*)		

REQUESTER
Robert M. Rader, Esquire

PART I. – RECORDS RELEASED OR NOT LOCATED (*See checked boxes*)

	No agency records subject to the request have been located.
	No additional agency records subject to the request have been located.
	Agency records subject to the request that are identified in Appendix _____ are already available for public inspection and copying in the NRC Public Document Room, 1717 H Street, N.W., Washington, DC.
X	Agency records subject to the request that are identified in Appendix D are being made available for public inspection and copying in the NRC Public Document Room, 1717 H Street, N.W., Washington, DC, in a folder under this FOIA number and requester name.
	The nonproprietary version of the proposal(s) that you agreed to accept in a telephone conversation with a member of my staff is now being made available for public inspection and coying at the NRC Public Document Room, 1717 H Street, N.W., Washington, DC, in a folder under this FOIA number and requester name.
	Enclosed is information on how you may obtain access to and the charges for copying records placed in the NRC Public Document Room, 1717 H Street, N.W., Washington, DC.
	Agency records subject to the request are enclosed. Any applicable charge for copies of the records provided and payment procedures are noted in the comments section.
	Records subject to the request have been referred to another Federal agency(ies) for review and direct response to you.
	In view of NRC's response to this request, no further action is being taken on appeal letter dated _____.

PART II.A – INFORMATION WITHHELD FROM PUBLIC DISCLOSURE

	Certain information in the requested records is being withheld from public disclosure pursuant to the FOIA exemptions described in and for the reasons stated in Part II, sections B, C, and D. Any released portions of the documents for which only part of the record is being withheld are being made available for public inspection and copying in the NRC Public Document Room, 1717 H Street, N.W., Washington, DC, in a folder under this FOIA number and requester name.

Comments

SIGNATURE, DIRECTOR, DIVISION OF RULES AND RECORDS
Brian K. Grimes

APPENDIX D

1.	4/23/86	Ltr from D.A. Nussbaumer to B. Salus re: changes to radiation protection rules w/various draft ltrs dated April 8 and April 9, 1986 (89 pages)
2.	8/6/86	Ltr from P.D. Eastvold to J. Lubenau re: training needs (2 pages)
3.	8/9/86	Ltr from D. Nussbaumer to T.R. Lash re: draft radiation protection rules (2 pages)
4.	8/19/86	Ltr from B. Salus to J. Lubenau re: Senate Bill 2117 (6 pages)
5.	8/29/86	Ltr from D.A. Nussbaumer to T. Lash re: draft radiation protection rules (12 pages)
6.	9/8/86	Memo from G.W. Kerr to J.G. Davis re: Licensing of Kress Creek Radioactive Material (3 pages)
7.	10/3/86	Memo from G.W. Kerr to H.R. Denton re: Illinois Request for 274b Agreement w/enclosures (64 pages)
8.	10/21/86	Memo from G.W. Kerr to T.A. Rehm re: Speech - Illinois Department of Nuclear Safety Conference on Future Radioactive Material Licensing in Illinois w/enclosure (18 pages)

(STP) IL-ASC

Ref: SA/JOL

APR 23 1986

Ms. Betsy Salus
Staff Legal Counsel
Department of Nuclear Safety
1035 Outer Park Drive
Springfield, Illinois 62704

Dear Ms. Salus:

Thank you for your letter of April 10, 1986 to Joel Lubenau concerning the planned changes to the Department's radiation protection rules. We also appreciated the opportunity to meet you on April 14, 1986 to discuss our comments on the planned changes.

We believe that the changes proposed in response to our Category I comments contained in my March 5, 1986 letter to Mr. Seiple satisfactorily address those concerns.

We also reviewed with you the changes proposed in response to our other comments and to those submitted by other commentors. We found these to be acceptable with the following exceptions:

- The proposed change to Section 330.400(b)(4) should not include the NRC as a possible transferee of radioactive material. We consider the need to delete NRC to be Category I comment.

- In Section 330.40(c)(4) and, we understand, elsewhere in the regulations, the phrase "these regulations" is to be replaced by "this Part." To ensure that no misunderstanding occurs, when "this Part" is used in lieu of "these regulations" in the context of exemptions from the regulation, it should be accompanied by an explanation that it means codes 310, 320, 330, 340, 350, 351, 370, 400 and 601 or equivalent language. Since this can affect the interstate distribution of certain radioactive materials to persons exempt from regulation, we must identify this as a Category I comment.

- You may wish to modify your response to the Amersham comment concerning A_1 and A_2 values for certain sources of Am and Pu. A limited exemption for these sources exists in Illinois' present proposed regulations at 341.40c(2) which corresponds to the NRC exemption provided in 10 CFR 71.10(b)(2).

APR 28 1986

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OFFICE ▶
SURNAME ▶
DATE ▶

OFFICIAL RECORD COPY

IDNS seems to have made excellent progress in their drafting the revision to the regulations and the staff should be commended. We will look forward to continuing to working with the State on the proposed Section 274b agreement.

Sincerely,

Original signed by:
D. Nussbaumer
Donald A. Nussbaumer
Assistant Director for
State Agreements Program
Office of State Programs

Distribution:
SA R/F
Dir R/F
JMapes
RLickus, w/incoming
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OFFICE	SA	DirSA	ELD				
SURNAME	JQLubenau/bh	DANussbaumer	JMapes				
DATE	4/15/86	4/15/86	4/17/86				

NRC FORM 318 (10-80) NRCM 0240 OFFICIAL RECORD COPY

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE
SPRINGFIELD 62704
(217) 546-8100

TERRY R. LASH
DIRECTOR

April 10, 1986

Joel O. Lubenau
Senior Project Manager
State Agreements Program
Office of State Programs
4550 Montgomery Avenue, Rm. 5523
Bethesda, MD 20814

Dear Mr. Lubenau:

Thank you for speaking with me today. I found it quite helpful to discuss with you the changes we are planning to make to the Department's proposed Agreement State rules.

As promised in our conversation, enclosed please find copies of our Draft Second Notice. I look forward to going over these with you on Monday. Since the Department's ability to change the proposed rules after the filing of Second Notice is very limited, we need to resolve any problems which may still remain.

Sincerely,

Betsy Salus
Staff Legal Counsel

BS:sp
Enc.

8701150139

DRAFT

ao 4/8/86

April 8, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 330

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Amendment pertaining to Licensing of Radioactive Material.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Amendment is Licensing of Radioactive Material, 32 Ill. Adm. Code 330.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1511.

4) Changes in the rule made during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Amendment is enclosed.

7) The Proposed Amendment does not include an incorporation by reference pursuant to Section 6.02(b) of the Illinois Administrative Procedure Act.

The incorporations by reference are made pursuant to Section 6.02(a) of the Illinois Administrative Procedure Act. The Department has:

a) fully identified by location and date in the rule the incorporated material;

b) included a statement that the incorporated material does not include any subsequent amendments or editions; and

c) made a copy of the incorporated material available for public inspection.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit. In accordance with these recommendations, the Department intends to recodify this Part and will adopt this Part in the recodified format.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Amendment on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Joseph M. Zlotnicki, Radiation Safety Officer, Amersham Corporation; A.D. Riley, Plant Manager, Allied Corporation; and Joel O. Lubenau, U.S. Nuclear Regulatory Commission (NRC), Office of State Programs.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM AMERSHAM CORPORATION

COMMENT

Section 330.40 - License Exemption - Radioactive Materials Other Than Source Material

"There is no exemption from licensing for carriers of radioactive material in Part 330. Section 330.110 requires that no person shall receive, possess, use, or transfer (etc.) material except as authorized in a specific or general license issued pursuant to Part 330 or as otherwise provided in that Part. It is assumed that the Department intended to exempt carriers from licensing as Part 341.40 includes provisions for exempting them from the requirements for a license to transport material."

DEPARTMENT RESPONSE:

The licensing provisions of 32 Ill. Adm. Code 330 do not apply to carriers of radioactive material. In order to clarify this, the Department has added an exemption for carriers which has been incorporated into Section 330.10(b). Subsection (b) now states:

> In addition to the requirements of Section 330.10(a), all licensees are subject to the requirements of 32 Ill. Adm. Code 310, 320, 331, 340, 341, and 400. Licensees engaged in industrial radiographic operations are subject to the requirements of 32 Ill. Adm. Code 350. Licensees using sealed sources in the healing arts are subject to the requirements of 32 Ill. Adm. Code 370 and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 32 Ill. Adm. Code 351. The requirements of 32 Ill. Adm. Code 330 do not apply to carriers. Carriers are subject to the requirements of 32 Ill. Adm. Code 341.

COMMENT

"It is recommended that provisions for exempting carriers be included in Part 330. This would also make the IDNS regulations consistent with the NRC's provisions (See 10 CFR 30.13, 40.12, and 70.12)."

DEPARTMENT RESPONSE:

As stated above, the Department has added an exemption for carriers in subsection 330.10(b) as modified.

COMMENT

"An exemption is also required for persons using byproduct, source or special nuclear material under certain Department of Energy and Nuclear Regulatory Commission contracts. (See 10 CFR 30.12, 40.11, and 70.11.) 10 CFR 70.13 and 70.14 also include other exemptions for the Department of Defense and the Department of Energy. Unless Illinois' provisions are made consistent with the NRC, numerous license verification problems will occur for suppliers in Illinois."

DEPARTMENT RESPONSE:

The specific exemption for contractors and subcontractors of the United States Department of Energy and of the United States Nuclear Regulatory Commission who receive, possess, use, transfer, or acquire

sources of radiation under their contracts is contained in the Department's rule 32 Ill. Adm. Code 310.30(b). This subsection was not included in the Proposed Amendments as published in the Illinois Register as there were no changes to that subsection of the Part.

COMMENT

Amersham sent a copy of the Atomic Industrial Forum's comments on the NRC proposed rulemaking concerning financial surety arrangements.

"Additionally, Amersham requests the inclusion of an option for demonstrating financial surety. A provision to allow a Parent Company Guarantee as an acceptable arrangement should be added to the proposed section."

DEPARTMENT RESPONSE:

The Department has received and reviewed the Atomic Industrial Forum's comments on the NRC proposed rulemaking concerning financial surety arrangements. At present, the Department chooses to allow only the more conservative forms of financial surety listed.

COMMENT

Section 330.270 - Special Requirements for Specific Licenses of Broad Scope

"Section 330.270(e)(1)(C) requires that persons licensed pursuant to 330.270 shall not conduct activities for which a specific license issued by the Department under Sections 330.260, 330.280, or 330.290 is required. We did not find a Section 330.290 in the proposed regulations. Clarification is needed on what provisions were meant to apply here."

DEPARTMENT RESPONSE:

The references to Section 330.290 was a typographical error. Section 330.290 is not contained in the Proposed Amendments and therefore this reference has been deleted.

COMMENT

Section 330.280 - Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material

"Section 330.280(f) describes the requirements which must be met in order to have a license approved for the distribution of americium-241, plutonium, or radium-226 calibration or reference sources to

general licensees. It is assumed that a prospective supplier must apply to the department for such authorization but this section is somewhat confusing because only the NRC regulations are referenced."

DEPARTMENT RESPONSE:

Under this subsection, the Department is the entity to which an application for a specific license should be submitted. The NRC regulations referred to in subsection 330.280(f)(2) are incorporated by reference into the rule. It is also noted that NRC regulations are not the only regulations referenced in this subsection. Section 330.280(f)(1) clearly refers to Section 330.250 of the Department's rule.

COMMENT

"Section 330.280(1) lists the requirements for the distribution of sources or devices containing radioactive material for medical use. Paragraph 330.280(1)(3) requires that the label affixed to the source or device (or to its storage container) contain a statement that the item is authorized to be distributed to Group VI licensees. This statement is misleading for calibration and reference sources since these types of sources may be transferred in quantities not to exceed 3 mCi per source to any medical group licensee. (See 330.260(c)(4)(D) not just those in Group VI.)

We recommend a modification of the wording to reflect this. If the change is made, time must be allowed to make the change (which has already been recommended by NRC Region III) to current literature."

DEPARTMENT RESPONSE:

A close reading of Section 330.280(1)(3) reflects that it does not contain the limitation which Amersham suggests. The subsection requires that the label state "that the source or device is licensed by the Department for distribution to persons licensed pursuant to Section 330.260(c) and/or Appendix C, Group VI of this Part or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State." Medical licensees are authorized to receive calibration and reference sources pursuant to 330.260(c). Therefore, the label proposed is appropriate.

COMMENT

"Section 330.280(n) introduces a requirement which is not present in the NRC regulations or in the Suggested State Regulations. It contains special requirements for the manufacture or importation of devices for transfer to persons having a specific license.

It is not clear why such a provision has been included in the

regulations. In practice, a specific licensee cannot receive an amendment to his license to add a new device unless the device has been evaluated. This evaluation (which covers all of the items in 330.280(n)(2)(A)-(H)) is often requested by the manufacturer/importer of a device to enable him to distribute his device to the widest possible market. However, if a custom device is being manufactured for one customer, it is often the customer who requests and pays for the evaluation to be done (not the manufacturer). Therefore, it seems inappropriate to require that the manufacturer/importer be held responsible for submitting and paying the fee for the evaluation of any device that could be sold to a specific licensee."

DEPARTMENT RESPONSE:

This requirement is not new for manufacturers in Illinois. The evaluation requirement in Section 330.280(n) was in place prior to the proposing of these amendments. While it is true that neither the Suggested State Regulation nor the NRC regulations require such an evaluation to be performed by the manufacturer, neither of these regulations precludes it. Thus, the Department's requirement raises no compatability question. It is the belief of the Department that by requiring the manufacturer/importer to conduct the evaluation in all cases, the rule will be more efficiently administered. Furthermore, in those cases where the manufacturer/importer is working with a custom device, the cost of the evaluation can be passed on to the customer by the manufacturer/importer.

COMMENT

"Item (3) under 330.280(n) seems to be redundant as the transfer of material is addressed much more completely in 330.400.

It is also unclear what constitutes a 'device'. There does not seem to be a definition for this in the proposed rules.

It is also unclear whether the requirements of this section constitute a specific distribution license for a manufacturer/distributor (as do much of the other sections in 330.280(n)). If so, the licensee would seem to be subject to two fees for the device approval - Section 331 Appendix A - Item 3P and Item 9A (or 9B).

We feel that this section of the proposed rule should be deleted since its provisions seem to be unnecessary in the practical sense and may cause duplicate regulation of manufacturers/importers."

DEPARTMENT RESPONSE:

The Department agrees that subsection 330.280(n)(3) as proposed in the First Notice was redundant. Therefore, subsection 330.280(n)(3) has been modified to refer to Section 330.400 rather than reiterate the requirements therein. Subsection 330.280(n)(3) has been modified to state as follows:

> The licensee under this paragraph shall not transfer a device to any person ~~until he has ascertained that such person has a license which authorizes him to possess such radioactive material as may be contained in the device~~ except in accordance with the requirements of Section 330.400.

Furthermore, a specific licensee under Section 330.280(n) who wishes to distribute goods is required to pay two fees. One fee relates to the thing to be distributed, the other fee relates to the distributor. Items 9A and 9B of Appendix A, 32 Ill. Adm. Code 331, set out the fee which must be paid for the required safety evaluation of devices or products for commercial distribution. The fee for a license to distribute approved devices is assessed against the distributor pursuant to 32 Ill. Adm. Code 331, Appendix A, Item 3P.

COMMENT

Section 330.360 - Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical mass on Effective Date of These Regulations

"Licensees need assurance that their current NRC licenses will not expire until an equivalent license or licenses are issued by IDNS. Section 330.360 indicates that NRC licensees will be deemed to possess a like license issued by the Department but that the license may be terminated by the Department 90 days after a notice of expiration is issued. No provisions are included which assure a licensee that a new IDNS license will be issued prior to the expiration date set by the Department.

It is also unclear whether the Department will issue 'new' licenses or simply expand the scope of existing licenses to include the provisions of current NRC licenses. This could be a concern if licensees were subject to the fees for a new license when IDNS issues licenses for activities previously licensed by the NRC."

DEPARTMENT RESPONSE:

Amersham's concern, that a current NRC license could expire by order of the Department before an equivalent license has been issued by the Department, has merit. Therefore, Section 330.360 has been modified as follows:

> Any person, who, on the effective date of these regulations possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like

license issued under this Part and the Act (Ill. Rev. Stat. 1983, ch. 111 1/2, par. 211 et seq.), ~~such~~. Such license shall expire ~~either 90 days after receipt from the Department of a notice of expiration of such license, or~~ on the date or of expiration specified in the U.S. Nuclear Regulatory Commission license, ~~whichever is earlier~~.

It should be noted however, that this provision does not prevent revocation of licenses.

The Department will not issue "new" licenses, but will expand the scope of existing licenses to include the provisions of current NRC licenses.

COMMENT

Section 330.320 - Expiration and Termination of Licenses

"Section 330.320 requires that an operator of a radiation installation must notify the Department within 30 days of the discontinuance of operations at the installation. Section 340.4070 also requires licensees to notify the department not less than 30 days before vacating or relinquishing possession of the premises. Clarification is needed as to whether these notifications are intended to be separate requirements or whether the intention of these provisions will be fulfilled if users of radioactive material comply with the termination requirements of Section 330.320."

DEPARTMENT RESPONSE:

The notification requirements of Section 330.300 and 32 Ill. Adm. Code 340.4070 are separate requirements. The requirements of Part 330 are intended to assist the Department in keeping current records of possession of radioactive materials. The requirements in 32 Ill. Adm. Code 340 are intended to assure adequate decontamination.

COMMENT

Section 330.400 - Transfer of Material

"It is unclear if the provisions in Section 330.400 are intended to allow persons regulated by IDNS to transfer radioactive material to the U.S. Nuclear Regulatory Commission or to the agencies in Agreement or Licensing States which regulate the use of radioactive material. It could be interpreted that the provisions apply only to persons authorized by those agencies and not to the agencies themselves.

Please clarify the scope of this provision."

DEPARTMENT RESPONSE:

The Department did not intend Section 330.400 to prohibit the transfer of radioactive material by Department licensees to the U.S. Nuclear Regulatory Commission or other agencies which regulate the use of radioactive material. To clarify the Department's intent, subsection 330.400(b)(4) has been modified to provide:

b) Except as otherwise provided in his license and subject to the provisions of Section 330.400(c) and (d), any licensee may transfer radioactive material:

4) to the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, an Agreement State, or a Licensing State; or

COMMENT

"The provisions of Section 330, Appendix C Group III(f) are not consistent with the other medical groups involving radiopharmaceuticals. No provisions have been included for the use of Group III materials under a 'New Drug Application' (NDA) which has been approved by the FDA."

DEPARTMENT RESPONSE:

The Department agrees with Amersham that a provision for the use of Group III materials under a "New Drug Application" approved by the FDA should have been included. Such a provision has been added by modifying Group III (f) which now provides:

f) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which ~~generator or reagent kit~~ a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA) or a "New Drug Application" (NDA) has been approved by the Food and Drug Administration (FDA).

COMMENTS FROM U.S. NUCLEAR REGULATORY COMMISSION

Joel O. Lubenau, Senior Project Manager, State Agreements Program, of the Office of State Programs, submitted the following comments on the proposed Amendment.

COMMENT

The following corrections should be made:

In 330.40(c)(3)(A), add "initially" after "or" in the 9th line.

In 330.200(a) and 330.200(b), "General licenses" should be singular not plural.

In 330.220(i)(4)(A), "selenium" in the 9th line should be "selenium-75".

In 330.280(b)(2)(D)(ii), the word "Human" in the first line should be followed by "Use-".

In 330.280(b)(3)(A), "of" in the second line should be replaced with a comma.

In 330.280(b)(3)(B), "isotope" in the second line should be "radioisotope".

In 330.280(j), "radiopharmceuticals" should be "radiopharmaceuticals".

In 330.320(d)(2), insert an "n" in "departmet".

In 330.360, change the "or" at the end of the tenth line to "of".

In 330.500, "of Licenses" should be retained in title.

DEPARTMENT RESPONSE:

The Department has incorporated all of these suggested corrections into the rules.

COMMENT

Section 330.250 - General Requirements for the Issuance of Specific License

The language of 330.250(b)(1), (c)(1) and (d)(1) is "garbled" and should be changed to be understandable.

DEPARTMENT RESPONSE:

The Department disagrees that subsection 330.250(d)(1) is "garbled" and therefore has not modified this subsection. However, the language in subsections 330.250(b)(1) and (c)(1) have been modified as stated below. In addition, subsection 330.250(f) has been modified to clarify the reference as 330.250(c)

b) Environmental Report, Commencement of Construction

1) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the Department determines will significantly affect the quality of the environment, a license application ~~will~~ must be reviewed and approved ~~if~~ by the Department ~~determine~~, before commencement of construction of the plant or facility in which the activity will be conducted. ~~has concluded, after weighing~~ Issuance of the license shall be based upon a consideration by the Department of the environmental, economic, technical and other benefits ~~against~~ in comparison with the environmental costs and ~~considering~~ available alternatives, and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values;

c) Financial Surety Arrangements for Site Reclamation

1) ~~A license application will be approved if~~ Issuance of a license shall be dependent upon satisfactory evidence of financial surety to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the Act and this Part. ~~pursuant~~ Pursuant to the Radiation Protection Act (Ill. Rev. Stat. 1984 Supp., ch. 111 1/2, par. 216(a)(5)), and as otherwise provided, financial surety arrangements for site reclamation ~~which~~ may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in Section 330.250(~~f~~c)(4) ~~has been established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to met the requirements of the Act and these regulations~~. Determination of satisfactory surety arrangements shall be subject to the following conditions:

COMMENTS FROM ALLIED CORPORATION:

A.D. Riley, Plant Manager of Allied-Signal's Metropolis Plant made the following comments:

COMMENT

"The IDNS should correct references to sections which were not included in the published rules, or provide the sections which are referenced. For example:

a. Section 330.250(a)(4), Page 1550, refers to special requirements in Sections 330.260, 330.270, 330.280 or Section 330.290; however, Section 330.290 is not provided in the "as published" rules.

b. Section 330.250(c)(1) refers to Section 330.250(f)(4) which is not provided in the "as published" document. Likewise, four (4) additional references are made to 330.250(f) in Section 330.250(c)(1), none of which are provided in the proposed rules."

DEPARTMENT RESPONSE:

The reference to Section 330.290 is a typographical error and has been deleted.

Although the Sections were renumbered, the references in the text to subsection 330.250(f) were inadvertently left unchanged in the "as published" rule.

The references in the text to subsection 330.250(f) should have been to subsection 330.250(c). Therefore, the Department has modified subsection 330.250(f) to read subsection 330.250(c).

COMMENT

"Each section of the proposed rules should support and agree with the intent of other pertinent sections. For example: Section 330.30 exempts licensing requirements for source material concentrations of less than 0.05%; however, Section 330.320(d)(2) and (3) both state that no detectable or residual contamination is allowed, or the license continues, even though Section 330.30 says a license is not required if source material concentrations are less than 0.05%.

Section 330.320 should be appropriately modified to agree with Section 330.30."

DEPARTMENT RESPONSE:

The two provisions contained in Section 330.320 and 330.30 are not inconsistent. Allied-Signal is correct in suggesting that under 330.320 a license can continue beyond its expiration date if detectable levels or residual radioactive contamination attributable to the licensee's activities are found. This requirement, that licensees decontaminate their facilities to the level that existed prior to commencement of their activities, demands nothing more than that licensees assume responsibility for their activities.

On the other hand, it would be administratively impracticable to license every possessor, user, owner or transferor of source material no matter how small the quantity. Thus, the Department, under Section 330.30 has set a threshold level (0.05% by weight source material). If this quantity is never exceeded, no license is required.

COMMENT

"In view of the rather substantial changes we propose, a 90-day extension should be granted to allow IDNS an opportunity to delete amended or obsolete regulations from the "as published" rules. The IDNS should redraft the proposed rules into an organized, numerical sequence of sections in a single document. This will provide for improved reading and understanding by members within the nuclear industry and the public."

DEPARTMENT RESPONSE:

As the Department has resolved the issues raised by Allied-Signal without substantially changing the rules as proposed, no extension of the comment period is necessary.

The following provisions have been modified to properly incorporate by reference material published in the Code of Federal Regulations.

Section 330.40(c)(4):

> Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from ~~these regulations~~ this Part to the extent that such person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to

those in Sections 32.16 and 32.17 of 10 CFR Part 32, revised as of January 1, 1985, of the regulations of the U.S. Nuclear Regulatory Commission.* This exemption does not authorize the manufacture of any resins containing scandium-46.

*AGENCY NOTE: Licensing requirements contained in subsequent amendments or editions of 10 CFR 32 are not incorporated into this rule. A copy of 10 CFR 32 is available for public inspection at the Department of Nuclear Safety.

Section 330.220(e)(1)(B):

each device has been manufactured, assembled, or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32, revised as of January 1, 1985, exclusive of any subsequent amendments or editions. A copy of 10 CFR 32 is available for public inspection at the Department of Nuclear Safety.

Section 330.220(g)(4):

The general licenses in Section 330.220(g)(1), (2) and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70, revised as of January 1, 1985 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Department, any Agreement State, or Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 20 CFR Parts 32 or Section 70.39 of 10 CFR Part 70, revised as of January 1, 1985. Licensing requirements contained in subsequent amendments or editions of 10 CFR 32 or 10 CFR 70 are not incorporated into this rule. Copies of 10 CFR 32 and 10 CFR 70 are available for public inspection at the Department of Nuclear Safety.

Section 330.260(c)(2)(A):

For Groups I, II, IV, and V, no licensee or registrant shall receive, possess, or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with a specific license issued by the Department pursuant to Section 330.280(j), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations equivalent to those contained in Section 32.72 of 10 CFR 32, revised as of January 1, 1985, exclusive of any subsequent amendments or editions. A copy of 10 CFR 32 is available for public inspection at the Department of Nuclear Safety.

Section 330.260(c)(2)(B)(ii):

Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Department pursuant to Section 330.280(k), a special license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.73 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations equivalent to those contained in Section 32.73 of 10 CFR 32, revised as of January 1, 1985, exclusive of any subsequent amendments or editions. A copy of 10 CFR 32 is available for public inspection at the Department of Nuclear Safety.

Section 260(c)(2)(C):

For Group VI, no licensee or registrant shall receive, possess, or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Department pursuant to Section 330.280(l), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an Agreement State or a Licensing State pursuant to equivalent regulations equivalent to those contained in Section 32.74 of 10 CFR 32, revised as of January 1, 1985, exclusive of any subsequent amendments or editions. A copy of 10 CFR 32 is available for public inspection at the Department of Nuclear Safety.

Section 330.260(c)(4)(D):

Any radioactive material, in amounts not to exceed 3 millicuries (111 MBq) per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific licensed issued by the Department pursuant to Section 330.280(1), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an Agreement State or a Licensing State pursuant to ~~equivalent~~ regulations equivalent to those contained in Section 32.74 of 10 CFR 32, revised as of January 1, 1985, exclusive of any subsequent amendments or editions. A copy of 10 CFR 32 is available for public inspection at the Department of Nuclear Safety.

Section 280 (c):

Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Section 330.40(c)(3) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32, revised as of January 1, 1985*. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

*AGENCY NOTE: Licensing requirements contained in subsequent amendments or editions of 10 CFR 32 are not incorporated into this rule. A copy of 10 CFR 32 is available for public inspection at the Department of Nuclear Safety.

Section 330.280(e)(2):

The applicant satisfied the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32, revised as of January 1, 1985, exclusive of subsequent amendments or editions, or their equivalent. A copy of 10 CFR 32 is available for public inspection at the Department of Nuclear Safety.

Section 330.280(f)(2):

> The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70, revised as of January 1, 1985, exclusive of subsequent amendments or editions, or their equivalent. Copies of 10 CFR 32 and 10 CFR 70 are available for public inspection at the Department of Nuclear Safety.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these amendments as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

April 8, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 331

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Propcsed Rule pertaining to Fees for Radioactive Material Licenses.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Rule is Fees for Radioactive Material Licenses, 32 Ill. Adm. Code 331.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1438.

4) Changes in the rule made during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Rule is enclosed.

7) The Proposed Rule does not include any incorporations by reference.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Rule on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Joseph M. Zlotnicki, Radiation Safety Officer, Amersham Corporation; Kenneth V. Schreiner, Vice President, St. Francis Hospital; and Richard V. Cushman, Administrative Assistant, Thorek Hospital and Medical Center.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM AMERSHAM CORPORATION

Joseph M. Zlotnicki, Radiation Safety Officer for Amersham made the following comments regarding the Department's proposed Fee Schedule and Collection Procedures.

COMMENT

"Amersham Corporation has a number of concerns with the proposed fee schedule. Large increases are proposed for many of the operations for which Amersham is licensed. Overall, the renewal fees for licensed activities are expected to cost more than four times as much with Illinois than the same renewals would have cost with the NRC. The renewal of the major license could be almost ten times as costly. In dollars, the increase in renewal fees for licensed activities is expected to be almost $12,000. These increases seem high, especially in light of the fact that NRC fees were only recently increased."

DEPARTMENT RESPONSE

The Department's eventual objective is to make the licensing program proposed in 32 Ill. Adm. Code 330 self-supporting. This could not be accomplished if the Department were to retain the current U.S. Nuclear Regulatory Commission (NRC) license fee schedule. After

reviewing the experiences of other Agreement States, the Department has determined if current NRC license fees were increased 20% across the board, the Department would recover about 40% of the costs associated with the licensing program. The fee schedule in the Appendix provides such an increase.

Through public comments, it came to the Department's attention that the proposed increase of 20% would result in actual increases of a much greater magnitude for holders of multiple licenses. (See comments of St. Francis Hospital and Thorek Hospital below). The Department learned from the NRC that the NRC charges such licensees for only one inspection. The disproportionate impact of the proposed fee scheme on holders of multiple licenses was due to the fact that the Department's proposed rule had no analogous provision.

In most cases, the Department does not break its fees into license fees and inspection fees. Therefore, to avoid the disproportionate impact that the proposed fee increases would have on holders of multiple licenses, the language of Agency Note (1) (a) and (c) in Appendix 331 has been modified. This Section now provides that holders of multiple licenses must submit the entire fee for the most expensive license and 30% of the fee for other licenses which it may hold. Agency Note (1) (a) and (c) now states:

> (1) Types of fees - Separate charges as shown in the schedule will be assessed for applications for new licenses and approvals, issuance of new licenses and approvals, and amendments and renewals to existing licenses and approvals. The following guidelines apply to these charges:
>
> (a) Application fees - Applications for materials licenses and approvals must be accompanied by the prescribed application fee. ~~for each category, except that applications for~~ For licenses covering ~~more than~~ only one ~~fee~~ category and for approvals, the prescribed fee shall be the fee for the appropriate category or approval identified in Appendix A. ~~of special nuclear material or source material to be used at the same location must be accompanied by the prescribed application fee for the highest fee category. When a license or approval has expired, the application fee for each category shall be due, except for licenses covering more than one fee category of special nuclear material or source material for use at the same location, in which case the application fee for the highest category applies~~ For licenses covering more than one fee category, the fee shall be 100% of the fee listed for the highest fee category for which a license is sought, plus 30% of the fee listed for each

other category for which a license is sought.

For licenses covering more than one fee category of special nuclear material or source material, the prescribed application fee is the fee for the highest fee category for which a license is sought.

The application fees listed in Appendix A are based on a 5 year license term. In those situations where a license is issued for less than 5 years, a prorated portion of the application fee will be refunded by the Department to the licensee.

(c) Renewal fees - Applications for renewal of materials licenses and approvals must be accompanied by the prescribed renewal fee, except that applications for renewals of licenses covering more than one fee category must be accompanied by the prescribed renewal fee for the highest fee category for which a license renewal is sought, and 30% of the renewal fee for each of the other fee categories for which license renewal is sought. ~~for each category, except that applications~~ Applications for renewal of licenses and approvals in fee categories 2C through 2E, 4A, 5B, and 12 must be accompanied by an application fee of $150 for each fee category, and the additional renewal fee for each category shall be due upon notification by the Department in accordance with the procedures specified in Section 331.120(d).

The renewal fees listed in Appendix A are based on a 5 year renewal term. In those situations where a license is renewed for less than 5 years, a prorated portion of the renewal fee will be refunded by the Department to the licensee.

COMMENT

"It is our understanding that the fees listed are the maximum fees that would have to be paid in each category. It is not clear, however, if the licensee will be reimbursed for funds submitted in excess of the required fee for the review and what the timescale for reimbursement would be."

DEPARTMENT RESPONSE

The fees listed in Appendix A are actual, not maximum fees. Therefore, if a licensee pays the amount listed in the Appendix, no reimbursement would be made. Those fees which are determined on a "full cost" basis will be assessed in accordance with Section 331.120(b) and should not result in overpayment by a licensee.

COMMENT

"It is also not clear what 'payable upon notification' means. Does this mean within 30 days of the receipt of the bill? This would seem in most cases to be reasonable."

DEPARTMENT RESPONSE

The Department agrees with Amersham that some time frame for payment should be included in the rules. Section 331.120(b) has been changed to reflect that payment is due within 30 days of receipt of the bill.

COMMENT

"It also should be defined what one 'full inspection' will entail. Will an annual inspection cover all licensed activities? Will inspections be performed on each licensed activity every year? This is probably excessive for some activities as the NRC conducted inspections of certain licensed activities (such as distribution of exempt quantities) only once in three years."

DEPARTMENT RESPONSE

The "full inspection" language used in footnote 4 of Appendix A applies only to category 2E licenses (Applications to terminate category 2C and 2D licenses and to authorize decommissioning, decontamination, reclamation or site restoration activities or the possession and maintenance of a facility in a standby mode). It does not reach the type of activities about which Amersham seems concerned.

In order to clarify that footnotes 3 and 4 apply only to specific categories of licenses, the notes have been amended to reflect the categories to which they refer. Additionally, footnote 4 has been modified to clarify that the full cost of inspection will be based on a) professional staff time required multiplied by the rate shown in 331.200, and b) any appropriate contractual support services costs.

COMMENTS FROM ST. FRANCIS HOSPITAL

Kenneth V. Shreiner, Vice President, St. Francis Hospital submitted

the following comments:

COMMENT

"Our hospital currently holds four radioactive material licenses for human use:

1) USNRC for sealed sources in a teletherapy unit

2) USNRC for sources not in a teletherapy unit

3) USNRC for plutonium pacemakers

4 IDNS for sources not in a teletherapy unit

Our current five year cost for renewal and inspection is $2,330. The proposed IDNS agreement state fees would cost us $5,046, more than a twofold increase. Most of the additional cost is due to separate rather than multiple license inspections at a rate of $72/hour rather than the $60/hour as stated in the Illinois Register at page 1444.

The current cost to have an IDNS radioactive material license is $250 per five year period which includes all amendments and inspections. If the IDNS can currently manage its licenses at $50 per annum as a non-agreement state, why does the department need to raise its fees 600% to 800% for medical licenses for agreement state status?

If the USNRC can operate on their current fee schedule (revised May, 1984), Illinois as an agreement state should be able to do the same. If the State of Illinois cannot deliver the same quality of service at the same or lower cost than the federal government, then the State of Illinois should not impose additional economic burdens upon its subjects just so one of its departments can expand. If Illinois being an agreement state is going to cost us more than twice as much as being governed by the USNRC, then Illinois should not be an agreement state."

DEPARTMENT RESPONSE

See response to Amersham Corporation's first Comment, above.

COMMENT

"The main purpose of Illinois becoming an agreement state should be to provide better and more cost-effective service to its citizens. By keeping the current USNRC fee and inspection schedule, the IDNS will increase its revenues substantially and the licensees can reduce their costs by license consolidation.

We are very proud of our record at this hospital of keeping expenses as low as possible without compromising care. We are doing our part

in containing health care costs."

DEPARTMENT RESPONSE

Because the Department has revised the license fee scheme to account for the disproportionate impact on holders of multiple licenses, the effect of the license fees on health care providers should be minimal.

COMMENTS FROM THOREK HOSPITAL & MEDICAL CENTER

COMMENT

"Our hospital currently holds three radioactive material licenses for human use:

1) USNRC for sealed sources in a teletherapy unit

2) USNRC for sources not in a teletherapy unit

3) IDNS for sources not in a teletherapy unit

Our current five year cost for renewal and inspection is $1,980. The proposed IDNS agreement state fees would cost us $3,675, more than a twofold increase. Most of the additional cost is due to separate rather than multiple license inspections at a rate of $72/hour rather than the $60/hour as stated in the Illinois Register at page 1444.

The current cost to have an IDNS radioactive material license is $250 per five year period which includes all amendments and inspections. If the IDNS can currently manage its licenses at $50 per annum as a non-agreement state, why does the department need to raise its fees 600% to 800% for medical licenses for agreement state status?

If the USNRC can operate on their current fee schedule (revised May, 1984), Illinois as an agreement state should be able to do the same. If the State of Illinois cannot deliver the same quality of service at the same or lower cost than the federal government, then the State of Illinois should not impose additional economic burdens upon its subjects just so one of its departments can expand. If Illinois being an agreement state is going to cost us more than twice as much as being governed by the USNRC, then Illinois should not be an agreement state."

"The main purpose of Illinois becoming an agreement state should be to provide better and more cost-effective service to its citizens. By keeping the current USNRC fee and inspection schedule, the IDNS will increase its revenues substantially and the licensees can reduce their costs by license consolidation.

We are very proud of our record at this hospital of keeping expenses

as low as possible without compromising care. We are doing our part in containing health care costs."

DEPARTMENT RESPONSE

See response to Comments from St. Francis Hospital, above.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these rules as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

April 8, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 340

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Amendment pertaining to Standards for Protection Against Radiation.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Amendment is Standards for Protection Against Radiation, 32 Ill. Adm. Code 340.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1722.

4) Changes in the rule during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Amendment is enclosed.

7) The Proposed Amendment does not include an incorporation by reference pursuant to Section 6.02(b) of the Illinois Administrative Procedure Act.

The incorporations by reference are made pursuant to Section 6.02(a) of the Illinois Administrative Procedure Act. The Department has:

a) fully identified by location and date in the rule the incorporated material;

b) included a statement that the incorporated material does not include any subsequent amendments or editions; and

c) made a copy of the incorporated material available for public inspection.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit. In accordance with these recommendations, the Department intends to recodify this Part and will adopt this Part in the recodified format.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Amendment on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Joseph M. Zlotnicki, Radiation Safety Officer, Amersham Corporation, and Donald A. Nussbaumer and Joel O. Lubenau, U.S. Nuclear Regulatory Commission Office of State Programs.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM AMERSHAM CORPORATION

Joseph M. Zlotnicki, Radiation Safety Officer, Amersham Corporation, commented on the Department's proposed amendment concerning dose subtraction from personnel monitoring records (340.4010) and notification and reporting lost or stolen source material (340.4020). His specific comments and the Department's responses thereto are as follows:

COMMENT

"Amersham Corporation foresees some potential administrative difficulties with the provisions of Section 340.4010(a)(2). Amersham has encountered numerous problems with film badge suppliers

concerning the reporting of exposures. Most of the time, artificially high exposures are reported on the films because of problems such as processing errors, exposure of the badge to light, or damage to the original control badge sent with a set of badges. In these cases the faulty exposure is recognized as a mishandling of the film, not an exposure to the wearer. In other cases, when an exposure could have been received by a wearer, subtraction of an exposure can be done only when it is clearly justified.

If IDNS approval is required for the subtraction of any exposure from the records, it is assumed that a comprehensive explanation for the action would have to be submitted in either of the cases noted above. This explanation would presumably have to be retrieved and approved by IDNS in writing. This could cause delays in the compilation of other reports (e.g. RMA 1/2), possibly the submission of unnecessary reports, and could occupy time that could more effectively be spent on other health physics matters.

It seems more appropriate that licensees continue to be allowed to make appropriate alterations to exposure records as long as they supply written justification within the records. The changes should be carefully reviewed by the Department's inspector during the annual inspection. Corroborating situations could more easily be demonstrated to the inspector while he is on site than in written form to the Department."

DEPARTMENT RESPONSE:

The Department firmly believes that any inconvenience which is created by this "prior approval" requirement is far outweighed by the benefits of accurate personnel monitoring. The Department has the responsibility to assure that accurate records are maintained. This requirement, that subtractions of exposures are only performed where appropriate, is consistent with carrying out the Department's responsibility.

The language of subsection 340.4010(a)(2) has been modified to clearly state this requirement. The subsection now states:

2) ~~Each~~ No licensee or registrant shall ~~not have~~ subtract radiation exposures ~~subtracted~~ from official personnel monitoring records ~~unless~~ without the prior approval ~~is obtained from~~ of the Department.

COMMENT

"Amersham concurs with the Department concerning the need to report the loss or theft of radioactive materials that could cause a substantial safety hazard immediately after such an occurrence becomes known.

However, we have some concerns about the provisions of Section 340.4020. The apparent loss or theft of material most commonly occurs during transportation. It often can take days or even weeks to trace a shipment of material after a customer complains that it has not been received.

'Immediate' notification of the loss or theft cannot be given until it can be confirmed that the material is truly missing and not simply in the transit system. Amersham also questions the need for reporting that any quantity of radioactive material has been lost or stolen. It is clear that the Department must be informed of the loss or theft of materials that could give rise to high internal or external exposures. It is not clear why small quantities (even those exempt from licensing) must be reported. Amersham recommends that the provisions of this section be modified to avoid the additional administrative burden."

DEPARTMENT RESPONSE:

Given the health risks involved, the Department feels that all material should be accounted for at all times. When a licensee or registrant is aware that the material cannot be located, the Department is to be notified. This is the case even if the material is later found to have been detained in the "transit system". Additionally, because the Department must be able to account for the cumulative effects of lost or stolen material, incidents involving even small quantities of material must be reported to the Department.

In order to remove any ambiguity concerning the requirement of filing a written report, subsection 340.4030(c) has been modified. This subsection now states:

> ~~Any report filed with the Department pursuant to Section 340.4020 shall be prepared in such a manner that names of individuals who have received excessive doses will be stated in a separate part of the report~~ In addition to the Immediate Notification and Twenty-Four Hour Notification required by subsections (a) and (b), each licensee or registrant shall file a written report with the Department in accordance with the provisions of Section 340.4050.

COMMENTS FROM U.S. NUCLEAR REGULATORY COMMISSION

Donald A. Nussbaumer, Assistant Director for State Agreements Program, Office of State Programs, and Joel O. Lubenau, Senior Project Manager, Office of State Programs, had the following comments on Part 340:

COMMENT

In Part 340.3070(d), fourth line, "However" should be "However".

In Part 340.3080(a)(9), second line, add "to" after "reduce".

"In Section 340.3110, Transfer for Disposal and Manifests, subparagraph a) states that "Each shipment of radioactive waste to a licensed land disposal facility shall be accompanied by a shipment manifest that contains the name, address, and telephone number of the person transporting the waste to the land disposal facility" (underlining added). The person identified on the manifest must be the person generating the waste. The generator will be the person who will be knowledgeable about the contents of the waste shipment (as described in the manifest). The change is also necessary to assure nationally uniform requirements for manifests, regardless of origin or destination of the licensed waste shipment. We apologize for not having brought this to your attention earlier."

DEPARTMENT RESPONSE:

The Department has modified Sections 340.3070(d) and 340.3080 to incorporate these changes. The Department has also substituted the word "generating" for the word "transporting" in Section 340.3110. Additionally, the Department has modified the fourth sentence of subsection 340.3110(a) to clarify that the weight percentage of the chelating agent must be estimated if a waste contains more than 0.1% chelating agents. This sentence now states:

a) Each shipment of radioactive waste to a licensed land disposal facility shall be accompanied by a shipment manifest that contains the name, address, and telephone number of the person ~~transporting~~ generating the waste to the land disposal facility. The manifest shall also indicate as completely as practicable: a physical description of the waste; the waste volume; radionuclide identity and quantity; the total radioactivity; and the principal chemical form. The solidification agent shall be specified. Wastes containing more than 0.1% chelating agents by weight shall be identified and the weight percentage of the chelating agent shall be estimated. Wastes classified as Class A, Class B, or Class C in Section 340.3070 shall be clearly identified as such in the manifest. The total quantity of the radionuclides H-3, C-14, Tc-99 and I-129 shall be shown.

COMMENT

The Department has received comments regarding confusing references to Section 330.290, formerly Section 330.29. (See comments from Amersham to Section 330.290)

DEPARTMENT RESPONSE:

Section 330.29 was deleted from 32 Ill. Adm. Code 330 in a previous rulemaking. Therefore, to avoid confusion, Section 340.1060(g) which would have been applicable only to persons licensed pursuant to Section 330.29 has been deleted.

The following Sections have been modified to properly incorporate into the rule the material being referenced.

Section 340.1030(c):

When respiratory protective equipment is used to limit the inhalation of airborne radioactive material pursuant to Section 340.1030 (c)(2), the licensee or registrant may make allowance for such use in estimating exposures of individuals to such material provided that such equipment is used as stipulated in Section 20.103(c) of 10 CFR 20, revised as of January 1, 1985, exclusive of subsequent amendments or editions. A copy of 10 CFR 20 is available for public inspection at the Department of Nuclear Safety.

Section 340.1030(d):

Unless otherwise authorized by the Department, the licensee or registrant shall not assign protection factors in excess of those specified in Appendix A of Section 20.103(d) of 10 CFR 20 in selecting and using respiratory protective equipment.* The Department may authorize a licensee to use higher protection factors on receipt of an application providing that the applicant:

1) describes the situation for which a need exists for higher protection factors; and

2) demonstrates that the respirator protective equipment will provide these higher protection factors under the proposed conditions of use.

*AGENCY NOTE: The reference to 10 CFR 20 is to the version revised as of January 1, 1985, exclusive of subsequent amendments or editions. A copy of 10 CFR 20 is available for public inspection at the Department of Nuclear Safety.

Section 340.2020(e):

All personnel dosimeters, except extremity dosimeters and pocket ionization chambers, that require processing to yield a dose equivalent and

that are supplied by licensees to comply with paragraph (a) of this section:

1) shall be processed by a processor holding a current personnel dosimetry accreditation certificate from the National Voluntary Laboratory Accreditation Program of the National Bureau of Standards in accordance with accreditation criteria established in 15 CFR 7b, revised as of January 1, 1985 in conformity with National Standard for dosimetry testing ANSI N13.11-1983, 1983 edition*, and

2) shall be approved in this ~~accreditation~~ accreditation process for the type of radiation or radiations from Table 1 of ANSI N13.11-1983, 1983 edition* that most closely approximate the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

*AGENCY NOTE: This Section incorporates the criteria in the January 1, 1985 revision of 15 CFR 7b, and in ANSI N13.11-1983, 1983 edition, exclusive of subsequent amendments or editions. Copies of both 15 CFR 7b and ANSI N13.11-1983 are available for public inspection at the Department of Nuclear Safety. Copies of ANSI N13.11-1983 can be obtained directly from the American National Standards Institute, 1430 Broadway, New York, New York 10018..

Section 340.2030(c)(6):

Each area in which there may exist radiation levels in excess of 500 rems (5.0 Sv) in 1 hour at 1 meter from a sealed radioactive source that is used to irradiate materials shall have entry control devices and alarms meeting the criteria specified in Section 20.203(c)(6) of 10 CFR 20, revised as of January 1, 1985, exclusive of subsequent amendments or editions. A copy of 10 CFR 20 is available for public inspection at the Department of Nuclear Safety.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these amendments as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT
as ? 4/F/F6

April 8, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 351

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Rule pertaining to Radiation Safety Requirements for Wireline Service Operations & Subsurface Tracer Studies.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Rule is Radiation Safety Requirements for Wireline Service Operations & Subsurface Tracer Studies, 32 Ill. Adm. Code 351.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1696.

4) No comments were received by the Department during the First Notice Period.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Rule is enclosed.

7) The Proposed Rule does not include an incorporation by reference pursuant to Section 6.02(b) of the Illinois Administrative Procedure Act.

The incorporation by reference is made pursuant to Section 6.02(a) of the Illinois Administrative Procedure Act. The Department has:

a) fully identified by location and date in the rule the incorporated material;

b) included a statement that the incorporated material does not include any subsequent amendments or editions; and

c) made a copy of the incorporated material available for public inspection.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Rule on February 24, 1986. No comments were received from this Public Hearing.

2) No written comments were received.

3&4) Not applicable.

Section 351.1080(c) has been modified to prcperly incorporate by reference American National Standard N542, "Sealed Radioactive Sources, Classification". This Section now states that:

> Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations two (2) years after the effective date of this Part shall be certified by the manufacturer or other testing organization acceptable to the Department as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N542, "Sealed Radioactive Sources, Classification" ~~in effect on the effective date of this Part~~ 1978 edition. Subsequent amendments or editions of American National Standard N542 are not incorporated in this rule. A copy of American National Standard N542 is available for public inspection at the Department of Nuclear Safety. Copies of the Standard can be obtained directly from the American National Standards Institute, 1430 Broadway, New York, New York 10018.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these rules as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

as y 4/8/86

April 8, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 370

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Amendment pertaining to Use of Sealed Radioactive Sources in the Healing Arts.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Amendment is Use of Sealed Radioactive Sources in the Healing Arts, 32 Ill. Adm. Code 370.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1845.

4) No comments received by the Department during the First Notice Period.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Amendment is enclosed.

7) The Proposed Amendment does not include any incorporations by reference.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Amendment on February 24, 1986. No comments were received at this Public Hearing.

2) No written comments were received.

3&4) Not applicable.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these amendments as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

ao g 4/8/86

April 8, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 400

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Rule pertaining to Notices, Instructions and Reports to Workers and Inspections.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Rule is Notices, Instructions & Reports to Workers; Inspections, 32 Ill. Adm. Code 400.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1687.

4) Changes in the rule made during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Rule is enclosed.

7) The Proposed Rule does not include any incorporations by reference.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Rule on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Joseph M. Zlotnicki, Radiation Safety Officer, Amersham Corporation.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM AMERSHAM CORPORATION

Joseph M. Zlotnicki, Radiation Safety Officer, Amersham Corporation, submitted the following comments:

COMMENT

Section 400.130 - Monitoring and Reporting Exposure of Workers

"Amersham Corporation requests clarification of the provisions of Section 400.130(b). This section requires that the licensee shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained pursuant to Section 340.4010(a) and (c). Since Section 340.4010(a) and (c) require that records be maintained only for persons who are required to be monitored, Amersham is assuming that annual reporting is only required for workers who are required to be monitored (not all employees irrespective of their exposure to radiation).

Please confirm that this interpretation is correct.

The same question also applies to Section 400.130(c). It is assumed that this requirement was meant only to apply to persons who are required to be monitored.

Amersham Corporation does not believe that reports of exposure upon termination should automatically be supplied to a terminating employee. Many employees, when terminating employment at Amersham, go on to positions which do not involve exposure to radiation. The employee's records are maintained and can be obtained by an employee

upon request, but we have found that only a small percentage of employees have requested their records.

It is recommended that the IDNS regulations be modified to be consistent with the U.S. Nuclear Regulatory Commission, i.e., that the records of a worker's exposure be generated at the request of the worker and not automatically at his termination."

DEPARTMENT RESPONSE

Amersham's assumptions are correct. Annual reporting is only required for workers whose exposure levels are required to be monitored. Similarly, the licensee or registrant need only furnish reports upon termination of employment to those employees who are required to be monitored.

Amersham's point, that because few employees actually wish to obtain their exposure records, the employer should not be required automatically to provide such records, is well taken. The Department has, therefore, modified subsection (c) to reflect that exposure records must be furnished only upon request. Subsection 400.130(c) now states:

> ~~Each~~ At the request of a worker, each licensee or registrant shall furnish to ~~each~~ the worker a report of the worker's exposure to radiation or radioactive material upon termination of employment. Such report shall be furnished within 30 days from the time ~~of termination of employment~~ the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar quarter in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these rules as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory

authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

April 9, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 200

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Amendment pertaining to Administrative Hearings.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Amendment is Administrative Hearings, 32 Ill. Adm. Code 200.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1405.

4) Changes in the rule made during the First Notice Period are discussed below, and a copy of the amended version for publication as adopted is attached.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Amendment is enclosed.

7) The Proposed Amendment does not include an incorporation by reference pursuant to Sections 6.02(a) or (b) of the Illinois Administrative Procedure Act.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit. (i.e., the section source notes have been corrected to reflect the action taken by the Department; the shortened form of the Department's name has been set out in parentheses and thereafter the shortened form has been used and the term "these regulations" or "these rules" has been changed to "this Part" wherever it appears.)

9) Joint Committee questions may be directed to Kathleen Knepper at 546-8100, Ext. 218.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Amendment on February 24, 1986. No comments were received during this Public Hearing.

2, 3, &4) Written comments were received from Commonwealth Edison. These comments and the Department's response thereto are set forth below.

COMMENT

Section 200.30(c) - Misnomer of Party

"This subsection authorizes the Department to correct the name of a party at any time. It is not clear whether such corrections will be limited to clerical errors or will include changing parties to proceed against the real party in interest. If the latter is intended, how would such a change in party affect an ongoing proceeding? These matters need to be clarified."

DEPARTMENT RESPONSE:

The Department believes that the rule is clearly limited in scope to provide that the name of an individual who has already been made a party to the proceeding may be corrected at any time. Therefore, we have not modified the rule.

COMMENT

Section 200.40 - Joinder and Intervention

"The rules would no longer provide for joinder by persons necessary for a complete determination of a controversy or whose interest may be affected by an order. The rules would also no longer provide for intervention by persons whose interests would be affected by a final order. The deletion of opportunities for joinder and intervention prevents the possibility that IDNS orders could unfairly affect licenses not permitted to participate in IDNS proceedings. Such exclusion from proceedings also presents the possibility of denial of due process rights. Accordingly, joinder of and intervention by licensees should be provided for under standards which establish the showing necessary to establish that a licensee's interest would be affected by a proceeding."

DEPARTMENT RESPONSE:

In the Proposed Amendments, Section 200.40 has been retitled "Form of Papers" and Section 200.140, has been retitled "Amendments". Section 200.140 covers joinder and intervention of parties as well as amendments to the pleadings. Therefore, it is not necessary nor would it be appropriate to retain joinder and intervention in Section 200.40. Nonsubstantive modifications have been incorporated in Section 200.40 and the subsequent Section for clarity. In Section 200.40 subsections (c) and (d), the word "notices" has been changed to "documents". This is intended to make clear that any documents submitted by Respondent must conform to these requirements. In Section 200.50 subsection (a) the word "papers" has been changed to "pleadings, motions"; in subsection (b) the Order and Notice are made more generic to conform to other changes in the rules; and in subsection (c) the word "papers" has been changed to "other documents".

COMMENT

Section 200.70 - Right to a Hearing

"The rules do not address whether a request for a hearing stays the Department's taking of a proposed action until the hearing is completed. Because a hearing is designed to determine whether allegations are correct, it would violate elementary notions of justice not to stay proposed Department actions until the conclusion of a hearing. The only situation justifying a deviation from such a rule would be an instance involving significant, imminent irreversible harm to the public health and safety. This section should be amended by adding provisions implementing these comments."

DEPARTMENT RESPONSE:

The Department agrees that this Section, as written in the Proposed Amendments, was unclear and imprecise. The Department intends that a request for a hearing by a Respondent will stay any action by the Department unless there is an immediate threat to public health or safety in which case the Department may act immediately pending a hearing. This is now detailed in subsection (d). At the same time, the Initial Order sent out by the Department is intended to take effect in the event that the Respondent does not request a hearing. We have modified Section 200.70 to establish that the initial documents sent out pursuant to Section 200.60 will notify Respondent of the nature of the allegations and the Respondent's right to request that a hearing be held before any action is taken by the Department. The documents are renamed Preliminary Order and Notice of Opportunity for Hearing to provide greater clarity regarding their impact on the Department's procedures. Sections 200.30, 200.60, 200.100, 200.180 and 200.200 have been corrected to provide consistency with the changes in Section 200.70 and, as appropriate, to further clarify these procedures. The Department has also corrected an internal inconsistency which was noted between Sections 200.60 and 200.70 regarding the time frame within which a Respondent must request a hearing.

COMMENT

Section 200.80 - Motions

"This section would delete all provisions for discovery. Discovery is essential to preparation for a formal hearing. It should be included subject to limitations to prevent its abuse."

DEPARTMENT RESPONSE:

We believe that sufficient opportunity for pre-hearing discovery is assured by the rights afforded by the State Freedom of Information Act coupled with the Respondent's right to receive information in a pre-hearing conference in accordance with Section 200.120. However, Section 200.120 has been modified to clarify that "exchange of witness lists" is one of the procedures which may occur in a pre-hearing conference. Nonsubstantive clarifications have been incorporated in Section 200.80 by adding the words "by the hearing officer" and "for a decision". These modifications do not alter the Department's initial intent, but simply clarify it.

COMMENT

Section 200.100 - Hearing Officer

"Subsection 200.100(b) would not disqualify a person from being a Hearing Officer even if that person was involved in preliminary procedures or was familiar with the facts of a case from sources other than for testimony. Does involvement in preliminary procedures

include investigation and/or preparation of a Notice of Violation? If so, the appointment of a person so involved might seem afoul of the due process requirement of a hearing by a unprejudiced examiner. Problems of inherent bias are also raised by permitting a Hearing Examiner to be a person familiar with the facts from sources extrinsic to a hearing. These problems should be avoided by amending the proposed rules to limit Hearing Officers to persons having no previous involvement in a particular case."

DEPARTMENT RESPONSE:

The Department agrees in part with the thrust of this comment and has modified subsection (b) of this rule by deleting the words "involvement in preliminary procedures or" from this rule.

COMMENT

Section 200.110 - Ex Parte Consultation

"The bar on ex parte communications would be extended to preclude communications between parties. Such a restriction is not required for a fair proceeding. In fact, such an unusual restriction could preclude negotiations leading to the settlement of contested issues. Accordingly, this restriction should be deleted."

DEPARTMENT RESPONSE:

The Department agrees and has concluded that the rule should simply state that we will follow the express provisions of the Administrative Procedure Act on this matter.

COMMENT

Section 200.130 - Conduct of Hearing

"The Hearing Officer's authority under this section suggests that hearings are to be more in the inquisitorial style of continental jurisprudence than in the adversarial style of the Common Law. It is not clear that such a radical departure from customary practice would comport with the requirements of Due Process. For example, subsection (c) gives the Hearing Officer sweeping powers to shape a proceeding without providing the parties with sufficient advance notice to prepare themselves properly to participate in such a hearing. Accordingly, this section should be amended to establish in advance an order of hearing."

DEPARTMENT RESPONSE:

We agree and have modified the rule in accordance with this comment to set forth the usual order of these hearings. In order to provide consistency between these changes and other Sections, we have modified Section 200.100(d) by adding the words "oral testimony and other" to subsection (d)(3) and by adding the words "in accordance with Section 200.80" to subsection (d)(5).

COMMENT

Section 200.140 - Amendments

"This provision, by failing to set either time limits on the late addition or modification of allegations or even reasonable criteria for such late developments creates the likelihood of lengthy, uncontrollable proceedings. Accordingly, this provision should be amended to provide deadlines for establishing the issues in a hearing and criteria for substantial changes to those issues beyond those deadlines."

DEPARTMENT RESPONSE:

While the Department does not wish to place a time limit on the introduction of these matters, we have narrowed the standard for permitting such introduction by changing the standard to "for good cause shown". We have also added a provision which gives the hearing officer the authority to suspend the proceedings if such modifications are permitted during the hearing and have amended Section 200.170(a) to similarly clarify that the hearing officer may suspend the hearing if new matters are introduced in accordance with that subsection.

COMMENT

Section 200.160 - Witnesses at Hearings

"Subsection (c) permits the direct and cross-examination of witnesses to the extent 'shown to be necessary to a full and fair disclosure of facts'. This standard could embroil a hearing in lengthy, tangential arguments over what is 'necessary'. Accordingly, this section should be amended to delete any such standard and to simply authorize the Hearing Officer to exercise his/her authority to conduct a hearing in accordance with the commonly accepted procedures at common law."

DEPARTMENT RESPONSE:

We disagree and believe that the standard is appropriate.

COMMENT

Section 200.170 - Evidence at Hearings

"This provision is somewhat schizophrenic. On the one hand it applies the rules of evidence applied in the Circuit Courts instead of the more relaxed rules usually associated with administrative proceedings. But on the other hand, the provision also provides for the discretionary admission of evidence 'of the type commonly relied upon by reasonably prudent persons in the conduct of their affairs'. This vague standard will not only generate substantial, tangential agreements over issues of what is commonly relied on and who is reasonably prudent, but also, when coupled with the provision's predisposal to admit evidence of arguable admissibility, will result in the admission of material not usually admissible even under the more relaxed standards of most administrative proceedings. Accordingly, this provision should be amended to provide a clear, workable rule for the admissibility of evidence."

DEPARTMENT RESPONSE:

We agree that the rule was unclear as written and have modified subsections (a) and (b) of this subsection. We have deleted the words "of the type commonly relied upon by reasonably prudent persons in the conduct of their affairs" and replaced this phrase with "necessary to a full and fair disclosure of facts bearing upon matters at issue" in subsection (b), a standard which appears elsewhere in this Part, and therefore affords more consistency.

COMMENT

Section 200.210 - Hearing Record

"Moreover, no provision is made for curing the effects of an ex parte communication. The inclusion of such communications in the record, Section 200.210(b)(6), will not give the parties an opportunity to respond meaningfully to such communications. Accordingly, provisions should be made for the prompt disclosure of such communications and for opportunities by the parties to respond to them."

DEPARTMENT RESPONSE:

The Department has modified the rule to provide that any ex parte communications should be disclosed in the record.

b) These amendments will not necessitate any changes in the programs or structure of the Department.

c) Not applicable.

d) The Department by adopting these Amendments will provide a consistent, workable framework for conducting administrative hearings and for affording other due process protections to licensees and other affected persons.

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

April 9, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 310

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Amendment pertaining to General Provisions for Radiation Protection.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Amendment is General Provisions for Radiation Protection, 32 Ill. Adm. Code 310.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1459.

4) Changes in the rule made during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Amendment is enclosed.

7) The Proposed Amendment does not include an incorporation by reference pursuant to Section 6.02(b) of the Illinois Administrative Procedure Act.

The incorporations by reference are made pursuant to Section 6.02(a) of the Illinois Administrative Procedure Act. The Department has:

a) fully identified by location and date in the rule the incorporated material;

b) included a statement that the incorporated material does not include any subsequent amendments or editions; and

c) made a copy of the incorporated material available for public inspection.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Amendment on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Donald A. Nussbaumer and Joel O. Lubenau of the U.S. Nuclear Regulatory Commission (NRC) Office of State Programs, and from Joseph M. Zlotnicki, Radiation Safety Officer, Amersham Corporation.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM U.S. NUCLEAR REGULATORY COMMISSION:

Donald A. Nussbaumer, Assistant Director for State Agreements Program, Office of State Programs, and Joel O. Lubenau, Senior Project Manager, State Agreements Program, commented on Section 310.10. Their comments are as follows:

COMMENT

Sec. 310.10 - Scope

"In our opinion, the language used by Illinois to revise the Scope limits the applicability of the Illinois regulations with respect to those matters 'for which Federal law gives exclusive regulatory jurisdiction to the U.S. Nuclear Regulatory Commission.' (Emphasis supplied.) Although it can be argued that the language used by

Illinois accurately reflects the fact that under the provisions of the 1959 Federal-State Amendment to the Atomic Energy Act, regulatory authority over Atomic Energy Act materials was either to be exercised by the Commission or by the State but not by both, the criterion of 'exclusive jurisdiction' if applied literally would permit the State to claim that Illinois regulations remain applicable in those cases in which regulatory authority over atomic energy materials is exercised by NRC and by any other Federal or State authority. EPA's authority to regulate radioactive pollutants under the Clean Air Act Amendments of 1977, and EPA's Atomic Energy Act authority to establish generally applicable environmental standards for the protection of the general environment from radioactive material are cases in point. The preferred language is that used in the SSR. However, the problem could also be remedied by striking the word 'exclusive' from the text of Section 310.10." Also, in Section 310.10 - Agency Note, "The first 'and' in the next to the last line of the note should be 'an'."

DEPARTMENT RESPONSE:

The Department, in response to NRC's comments, has modified this Section to incorporate the language of the Suggested State Regulations (SSR). Section 310.10 now provides:

Section 310.10

Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation within the State of Illinois ~~where the Department maintains jurisdiction for regulating such sources of radiation~~; provided, however, that nothing in these regulations shall apply to ~~those matters for which federal law gives exclusive regulatory jurisdiction to~~ any person to the extent, such person is subject to regulation by the U.S. Nuclear Regulatory Commission.*

*AGENCY NOTE: Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of and an agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

COMMENTS FROM AMERSHAM CORPORATION:

COMMENT

Sec. 310.20 - Definitions

"The definition of 'Licensing State' needs further clarification. It is not clear who assesses if a state's regulations are equivalent to the Suggested State Regulations and if the state has an effective program for the regulatory control of NARM (therefore meeting the current definitions in 310.20). This is of practical importance to licensees since some products cannot be received by certain licensees unless the products have been manufactured in accordance with the regulations of a Licensing State."

DEPARTMENT RESPONSE:

It was the intent of the Department that the assessment of other States' regulations for equivalency with the Suggested State Regulations is to be made by the Conference of Radiation Control Program Directors. This group will designate a State as a "Licensing State" if the State's regulations are equivalent to those of the Suggested State Regulations for Control of Radiation and if the State has an effective program for the regulatory control of naturally occurring and accelerator-produced radioactive material (NARM). The Department has modified the definition of the term "Licensing State" to clarify this intent. The definition now reads:

Section 310.20

"Licensing State" means any State ~~with regulations equivalent to these regulations for the control of accelerator-produced and naturally occurring radioactive material~~ which has been provisionally or finally designated as such by the Conference of Radiation Control Program Directors, which reviews state regulations to establish equivalency with the Suggested State Regulation's and ascertains whether a State has an effective program for control of NARM. The Conference will designate as Licensing States those States with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of naturally occurring radioactive material (NARM)."

COMMENT

Sec. 310.40 - Records

"Clarification is needed as to the scope of the requirement for maintaining records of storage of sources of radiation. It is felt that special records for 'storage' need not be generated if records such as inventory and/or transfer records can account for materials

awaiting sale or further action. Amersham acknowledges that records of the storage of waste must be generated in order to complete IDNS's waste survey forms."

DEPARTMENT RESPONSE:

Section 310.40 states in part that "...each licensee and registrant shall maintain records showing the receipt, transfer, use, storage and disposal of all sources of radiation." To the extent that inventory and/or transfer records document storage, no other storage records need be maintained to satisfy this requirement. If existing records do not document storage, additional "storage records" would have to be generated.

COMMENT

Sec. 310.130 - The International System of Units (SI)

"Amersham Corporation congratulates the Department on its acknowledgment of the need to include S.I. Units in the proposed regulations. It is not clear, however, if S.I. Units alone are acceptable for use by licensees. This is especially important to Amersham Corporation as Amersham's parent company in England must comply with international rules on the use of S.I. Units. To avoid relabeling, etc., in the United States, it will be important that the use of S.I. Units alone is seen to be acceptable."

DEPARTMENT RESPONSE:

The use of S.I. units alone will not be acceptable. Because radioactive material may be used by persons not familiar with the International System of Units, it is imperative that where labeling is required, measurements be given, at least parenthetically, in English units.

The Department received the following general comments from Pei-Jan Paul Lin, Ph.D., President, American Association of Physicists in Medicine, Midwest Chapter:

COMMENT

"In the past the MCAAPM has supported agreement state status with qualifications. Those qualifications have expressed two major concerns. The first of these is for the background and training of the State of Illinois personnel which has traditionally been far behind that of the staff of the US Nuclear Regulatory Commission (NRC). The second has been a question as to whether the IDNS rules and procedures will be more or less rational than those of the USNRC which have often been less than optimal. Associated with this latter question is whether the users of radioactive materials will have a reasonable input into the regulatory process under an agreement

state. The MCAAPM had hoped that there would be major movement on these two items before the final decision came. Unfortunately, about the only positive indication that we have seen recently is the apparently more frequent use of the Radiation Protection Advisory Council.

Because the two principal conditions considered necessary by the MCAAPM have not been adequately met, the MCAAPM is against the State of Illinois becoming an agreement state at this time. We would like to emphasize that this position is not a shift in our historical stance but indicates our concern with the conditions which we feel are necessary for an improvement in the present regulatory situation."

DEPARTMENT RESPONSE:

The Department of Nuclear Safety takes exception to the suggestion that its staff is "far behind that of the staff of the USNRC". In fact, an examination of the staff's qualifications would reveal that the Department's employees are well credentialed, and that they actively engage in continuing education and professional development.

The Department also takes exception to the Association's suggestion that users of radioactive materials do not have reasonable opportunities to participate in the regulatory process. When Illinois becomes an Agreement State, the regulatory framework provided in the Administrative Procedure Act will be applicable to the Department's rulemaking activities. This framework provides opportunities for the public to participate.

The Department is pursuing Agreement State status pursuant to the decision of the Governor and the General Assembly. Furthermore, the Department objects to Dr. Lin's assertion that "the two principal conditions considered necessary by the MCAAPM (for endorsement of the decision to pursue Agreement State status) have not been met". The Department of Nuclear Safety has both the competence and the desire to implement a regulatory program which is responsive to the needs of users of radioactive materials as well as protective of the health and safety of the citizens of Illinois.

The Department also notes that it is not alone in taking exception to the suggestions made by Dr. Lin, on behalf of the MCAAPM. Dr. Jacques Ovadia, past president of the MCAAPM, and past president of the American Association of Physicists in Medicine (AAPM), addressed a letter to Director Lash in which he expressed disagreement with the substance of Dr. Lin's assertions. Dr. Ovadia stated the following:

> "I am distressed that some members who are presently in the leadership of the Midwest Chapter of the AAPM have expressed their opposition to the efforts directed at attaining agreement State Status for Illinois. For example, I consider some of the comments made in Mr. Lin's letter to Mr. Sieple

(sic) to show a lack of mature judgment, particularly in assessing the relative 'rationality' of IDNS rules and procedures as compared to those of the NRC. I am not aware that a vote was taken with suitable notice that this subject would be discussed at the February meeting of the Midwest AAPM at Evanston Hospital. This meeting was the first opportunity to see the letters and I am personally offended by letters written on the letterhead of my professional society which have gross errors in spelling, grammar, or syntax. I have expressed verbally my objections to this entire action to Mr. Paul Lin.

I have great confidence in your leadership of the IDNS, having followed tne development of the Central Midwest Compact, and in the considered and thoughtful advice you will receive from the Advisory under the chairmanship of Larry Lanzl."

The following definitions have been modified to properly incorporate by reference material published in the Code of Federal Regulations:

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Section 71.4 of 10 CFR 71, revised as of January 1, 1985, exclusive of any subsequent amendments or editions. A copy of 10 CFR 71 is available for public inspection at the Department of Nuclear Safety.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR 100-189, revised as of November 1, 1984, exclusive of any subsequent amendments or editions. A copy of 49 CFR 100-189 is available for public inspection at the Department of Nuclear Safety.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these amendments as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985 ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

April 9, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 320

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Amendment pertaining to Registration of Radioactive Material or Radiation Machine.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Amendment is Registration of Radioactive Material or Radiation Machine, 32 Ill. Adm. Code 320.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1715.

4) Changes in the rule made during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Amendment is enclosed.

7) The Proposed Amendment does not include any incorporations by reference.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit.

9) Joint Committee questions may be directed to Bets Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Amendment on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Donald A. Nussbaumer and Joel O. Lubenau of the U.S. Nuclear Regulatory Commission (NRC) Office of State Programs and Norman Wandke, Assistant Vice President, Nuclear Services of Commonwealth Edison.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM U.S. NUCLEAR REGULATORY COMMISSION

Donald A. Nussbaumer and Joel O. Lubenau of the U.S. Nuclear Regulatory Commission, Office of State Programs, made the following comment regarding Section 320.10:

COMMENT

Section 320.10 - Registration

"The proposed revision of Section 320.10, Registration, presents a similar problem. (See NRC comments to Section 310.10) In this case, it is our view that the words 'unless Federal law gives exclusive regulatory jurisdiction over such operation, any operator of a facility where radiation machines are used or where radioactive material is produced, transported, stored, used, or disposed of any purpose, shall register such radiation installation with the Department...' Either of tne remedies suggested earlier would be acceptable here as well."

DEPARTMENT RESPONSE:

The Department, in response to NRC's comments, has modified this Section to incorporate the language of the Suggested State Regulations (SSR). Section 320.10 now provides:

Section 320.10

Any operator of a facility where radiation machines are used or where radioactive material is produced, transported, stored, used, or disposed for any purpose, ~~unless federal law gives exclusive regulatory jurisdiction over such operation to~~ which is not subject to regulation by the U.S. Nuclear Regulatory Commission, shall register such radiation installation with the Department. Registration shall be before the installation is placed in operation and shall be on a form prescribed by the Department which shall include:

a) the operator's name,

b) the location and confines of the radiation installation,

c) the type, strength, and number of sources of radiation expected to be produced, used, operated, stored, or disposed.

COMMENTS FROM COMMONWEALTH EDISON:

Norman Wandke, Assistant Vice President, Nuclear Services of Commonwealth Edison, commented on Sections 320.10, 320.20 and 320.40. His comments are as follows:

COMMENT

Section 320.10 - Registration

"Section 320.10, the principal registration requirement is vague. This section requires the registration of 'radiation installations.' This term is not defined. From the structure of the section, the term appears to mean a 'facility where radiation machines are used or where radioactive material is produced, transported, stored, used or disposed of for any purpose.' If the foregoing is intended to constitute the definition of radiation installation, that intention should be made explicit. Moreover, the term 'radiation machine' should be defined."

DEPARTMENT RESPONSE:

The terms "radiation installation" and "radiation machine" are defined in 32 Ill. Adm. Code 310.10. The definitions contained in Part 310 also apply to the following Parts: 32 Ill. Adm. Code 320, 330, 331, 340, 341, 350, 351, 370, 400 and 601 unless specifically indicated therein.

COMMENT

"Section 320.10 exempts from registration any radiation installation the operation of which, under federal law, is subject to the exclusive regulatory jurisdiction of the U.S. Nuclear Regulatory Commission ('NRC'). By tying this exemption to exclusive federal regulation of operation the scope of this exemption is unclear. Edison understands this provision to mean that any facility which requires any license from the NRC is not subject to any registration requirement for any activity conducted within that facility. If this is the Department's intent, it should be stated explicitly. If this is not the Department's intent, revised proposed rules clarifying the Department's intent should be republished for notice and comment."

DEPARTMENT RESPONSE:

The exemption in the registration requirement is intended to cover only those activities for which the federal government has preempted all regulatory authority. Thus, an NRC licensee would be subject to the registration requirement to the extent that activities conducted at the licensee's facility are subject to state regulation.

COMMENT

Section 320.20 - Amendments

"Section 320.20 requires the registration of any changes in the 'number or strength of sources or of the output of radiation produced in or by the installation.' Natural radioactive decay will cause changes in the strength of sources and their outputs of radiation. Thus, this provision will require all operators of sources continually to obtain amendments. This section should be amended to exclude changes due to the natural decay process and to limit amendments to substantial changes."

DEPARTMENT RESPONSE:

The Department does not intend to require registration of changes in strength of sources due to natural radioactive decay. To clarify the Department's intent, the exclusion of such changes from the registration requirement has been incorporated into the requirement. Section 320.20 now states that:

Section 320.20

> "Registration shall be required only at the time the radiation installation is placed in operation unless there is a change in the number or strength of sources or of the output of energy of radiation produced in or by the

installation so registered. If there is any change~~(s)~~, other than change due to natural radioactive decay, the operator shall register such change~~(s)~~ with the Department. Registration shall be on a form prescribed by the Department and shall be submitted in accordance with the following schedule:

COMMENT

Section 320.40 - Exemptions

"Section 320.40(a) exempts from registration 'natural radioactive materials of an equivalent specific radioactivity not exceeding that of natural potassium.' Is this criterion intended to refer to the level of naturally radioactive potassium in the human body? If so, that intent should be clarified: If not, the reference level should be specified."

DEPARTMENT RESPONSE:

The reference level here is the specific radioactivity of naturally occurring potassium, and not the level of natural radioactive potassium in the human body.

COMMENT

"Section 320.40(b) exempts from registration 'radioactive material in such quantity that if the entire amount were taken internally, continuously or at one time by a person, no harmful effect would be likely to result.' This criterion implicitly sets a de minimis level. This is because under the linear hypothesis, any exposure to radiation results in a commensurate increase in the probability of radiation-induced cancer. Therefore, this provision establishes a level of likelihood of harm below which no registration is required. That de minimis level of probability of harm should be made explicit and be applied consistently to all potential exposures."

DEPARTMENT RESPONSE:

Section 320.40(b) is intended to exempt from registration "radioactive material in such quantity that if the entire amount were taken internally, continuously, or at one time by a person, no harmful effect would be likely to result." The subsection then lists maximum quantities, in microcuries, for which registration is not required. While it is true that, theoretically, the criterion sets a de minimis level of harm determined linearly, such a regulatory standard would not be practical. Therefore, the Department has set maximum quantities for which registration is not required.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these amendments as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement Stat status in accordance with the legislative directives contained in t Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985 ch 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

April 9, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 341

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Rule pertaining to Transportation of Radioactive Material.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Rule is Transportation of Radioactive Material, 32 Ill. Adm. Code 341.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1800.

4) Changes in the rule made during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Rule is enclosed.

7) The Proposed Rule does not include an incorporation by reference pursuant to Section 6.02(b) of the Illinois Administrative Procedure Act.

The incorporations by reference are made pursuant to Section 6.02(a) of the Illinois Administrative Procedure Act. The Department has:

a) fully identified by location and date in the rule the incorporated material;

b) included a statement that the incorporated material does not include any subsequent amendments or editions; and

c) made a copy of the incorporated material available for public inspection.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Rule on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Joseph M. Zlotnicki, Radiation Safety Officer, Amersham Corporation, and Norman Wandke, Assistant Vice President, Nuclear Services, Commonwealth Edison.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM AMERSHAM CORPORATION

Joseph M. Zlotnicki, Radiation Safety Officer for Amersham Corporation, submitted comments in response to Sections 341.40, 341.200, and Appendix A of the Department's proposed transportation rules. The comments, and the Department's responses, are as follows:

COMMENT

"Clarification is required on several points in Section 341.40.

We believe that 341.40(b) and (c) intends to exempt any licensee, that is, any person who might otherwise be subject to these regulations because he is licensed to possess or own (etc.) material pursuant to Section 330, from the requirements of Part 340. We do

not believe that "licensee" in this sense refers to person (sic) being licensed to Part 340.

Please confirm that this interpretation is correct.

We also believe that there is a typographical error in 341.40(c). To make the requirements of 341.40(c) consistent with the USNRC regulations (which we believe was intended) the reference to 341.140 should be changed to read '341.160'."

DEPARTMENT RESPONSE:

Amersham Corporation's interpretation is correct. Subsections 341.40 (b) and (c) exempt, under specific conditions, persons licensed pursuant to 32 Ill. Adm. Code 330. Amersham is also correct that the reference in 341.40(c) should be to Section 341.160, not 341.140. This error has been corrected.

COMMENT

"Amersham Corporation has several questions concerning the Quality Assurance Program required in Section 341.200.

In this section, the Department is requiring each 'licensee' to establish, maintain, and execute a quality assurance program. It is not clear who the 'licensee' is intended to be in this case: someone licensed pursuant to Part 330 or someone licensed pursuant to Part 341.

We believe the Department intended that this requirement apply to those persons licensed pursuant to Part 341 to make its rules consistent with those of the USNRC.

If this is not the case, Amersham takes strong objection to the requirement. It would be practically impossible to document the comprehensive Q.A. program that would apply to all radioactive material packages (from exempt through Type B) between the implementation date of the regulations and the first shipment of a package.

Even if this requirement applies only to licensees of Part 341, it is not clear whether a separate Q.A. program must be submitted and approved by IDNS before a licensee's first shipment (again, a practical impossibility) or if the licensee's present NRC-approved Q.A. programs will be deemed to be acceptable.

There are presently no provisions for continuing operations under NRC-approved Q.A. programs as there are for NRC-issued licenses. (Refer to Section 330.360). Amersham feels that such provisions are essential.

It is also felt that IDNS did not intend this requirement to apply to

carriers. However, if the definition of 'licensee' as someone being licensed pursuant to Part 341 is applied, generally licensed carriers (341.60) would seem to be included.

We note that the requirements in 10 CFR 71 for obtaining the approval for a Type B package are apparently being retained by the NRC. Please clarify whether the NRC will retain its authority to regulate the Q.A. programs developed for these packages and approved by the NRC or if IDNS is assuming the responsibility for approving Q.A. programs in place of the NRC."

DEPARTMENT RESPONSE:

The Department intends the Quality Assurance requirements of Section 341.200 to apply only to persons licensed pursuant to Part 341. The Department is sympathetic to Amersham's concern that operations remain uninterrupted during the transition of regulatory authority from the U.S. Nuclear Regulatory Commission (NRC) to the State. The requirements of Section 341.200 apply only to the shipper, not the transporter of radioactive material. This is the only reasonable reading of the provision. Furthermore, subsection 341.200(a) clearly states that the Department is responsible for the approval of quality assurance programs.

The Department has modified this section to clarify the Department's intent, and has further modified subsection 341.200(a) to permit the continuance of operations with quality assurance programs which have been approved by the NRC prior to the execution of an agreement by the NRC and the State. Of course, failure to maintain a quality assurance program which meets the Department's standards for approval would result in a withdrawal of approval by the Department. Section 341.200, as modified, now states:

a) Each ~~licensee~~ person licensed pursuant to this Part shall establish, maintain, and execute a quality assurance program to verify, by procedures such as checking, auditing, and inspection, that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive materials are promptly identified and corrected. Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain Department approval of its quality assurance program; provided, however, that quality assurance programs approved by the U.S. Nuclear Regulatory Commission prior to the State's attainment of Agreement State status will be deemed to have been approved by the Department.

b) Each ~~licensee~~ person licensed pursuant to this

Part shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program.

c) ~~The licensee~~ A person licensed pursuant to this Part shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records pertaining to the use of a package for shipment of radioactive material must be retained for a period of two (2) years after shipment.

COMMENT

"We have noted a significant omission from Section 341, Appendix A. A special note is included next to americium-241 and plutonium in the table of A_1 and A_2 values in the Department of Transportation regulations in 49 CFR 173.435. This note indicates that for shipments solely within the United States, the A_1 value is 20 curies for americium and plutonium contained in Am-Be or Pu-Be neutron sources or in nuclear-powered pacemakers.

We trust that this notation will be included in the final version of the IDNS regulations."

DEPARTMENT RESPONSE:

Table A-1 of Appendix A does not contain an omission. The table came from the regulations of the U.S. Nuclear Regulatory Commission, 10 CFR 71.137, not the U.S. Department of Transportation. The table, as published in the NRC regulations, does not have a note concerning americium and plutonium contained in Am-Be or Pu-Be neutron sources or in nuclear-powered pacemakers. Therefore, no such note has been included in the Department's regulations.

COMMENTS FROM COMMONWEALTH EDISON

Norman Wandke, Vice President, Nuclear Services for Commonwealth Edison, made the following comment:

COMMENT

"Edison recognizes that these proposed rules are similar to those promulgated by the NRC for the same purposes. 10 CFR Part 71. However, the Department's proposed rules are not identical to the NRC's rules and one of those differences is significant. The

Department's proposed rules do not include an exemption similar to the NRC's exemption from certain requirements on the use of type B packages for low specific activity material. See 10 CFR 71.52. Clearly, in the NRC's view, such an exemption is consistent with protection of the public health and safety. Therefore, the Department's failure to provide such an exemption could result in a shortage of type B casks and unnecessarily higher costs for transporting and disposing of such waste without a commensurate increase to public health and safety. Accordingly, these proposed rules should be amended to include an exemption similar to the NRC's exemption in 10 CFR 71.52."

DEPARTMENT RESPONSE:

10 CFR 71.52 provides only that low specific activity material need not be packaged in Type B packages. If such material is not packaged in a Type B package, it must be packaged in a package which meets the standards for all packages (10 CFR 71.43 - 71.47). Since the Department's regulations do not generally require that radioactive material be packaged in Type B packages, exemption of low specific activity material from such a requirement is unnecessary.

The following provisions have been modified to properly incorporate by reference material published in the Code of Federal Regulations:

Section 341.20:

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189, revised as of November 1, 1984, exclusive of subsequent amendments or editions. A copy of 49 CFR 100-189 is available for public inspection at the Department of Nuclear Safety.

"Type B packaging" means a packaging designed to retain the integrity of containment and shielding required by U.S. NRC regulations when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71, revised as of November 1, 1984, exclusive of subsequent amendments or editions. A copy of 10 CFR 71 is available for public inspection at the Department of Nuclear Safety.

Section 341.80(b):

The package may not be used for a shipment to a location outside the United States after August 31, 1986, except under special arrangement approved by the U.S. Department of Transportation in accordance with 49 CFR 173.417, revised as of November 1, 1984, exclusive of subsequent amendments or editions. A

copy of 49 CFR 173 is available for public inspection at the Department of Nuclear Safety.

Section 341.90(a):

A general license is issued to any licensee of the Department to transport or to deliver to a carrier for transport licensed material in a specification container for a Type B quantity of radioactive material as specified in the regulations of the U.S. DOT in 49 CFR Parts 173 and 178, revised as of November 1, 1984, exclusive of subsequent amendments or editions. Copies of 49 CFR 173 and 178 are available for public inspection at the Department of Nuclear Safety.

Section 341.90(d):

The general license in ~~Subparagraph~~ subsection (a) is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States after August 31, 1986, except under special arrangements approved by U.S. DOT in accordance with 49 CFR 173.472, revised as of November 1, 1984, exclusive of subsequent amendments or editions. A copy of 49 CFR 173 is available for public inspection at the Department of Nuclear Safety.

Section 341.190(c)(2):

A description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation, 49 CFR 172.202 and 172.203(d), revised as of November 1, 1984*;

*AGENCY NOTE: Requirements contained in subsequent amendments or editions of 49 CFR 172 are not incorporated into this rule. A copy of 49 CFR 172 is available for public inspection at the Department of Nuclear Safety.

b) This rulemaking will result in no direct changes in the Department's program. No additional people will be hired to implement and enforce this program. The Department, under its existing rules and in cooperation with Illinois Department of Transportation, is currently involved with the enforcement of packaging and transportation requirements. The degree of involvement should not increase significantly as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these rules as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

ao 8 4/8/86

April 8, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 350

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Amendment pertaining to Industrial Radiography.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Amendment is Industrial Radiography, 32 Ill. Adm. Code 350.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1486.

4) Changes in the rule made during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Amendment is enclosed.

7) The Proposed Amendment does not include an incorporation by reference pursuant to Section 6.02(b) of the Illinois Administrative Procedure Act.

The incorporation by reference is made pursuant to Section 6.02(a) of the Illinois Administrative Procedure Act. The Department has:

a) fully identified by location and date in the rule the incorporated material;

b) included a statement that the incorporated material does not include any subsequent amendments or editions; and

c) made a copy of the incorporated material available for public inspection.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit. In accordance with these recommendations, the Department intends to recodify this Part and will adopt this Part in the recodified format.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Amendment on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Joel O. Lubenau, U.S. Nuclear Regulatory Commission, Office of State Programs.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM U.S. NUCLEAR REGULATORY COMMISSION

Joel O. Lubenau, Senior Project Manager, State Agreements Program, Office of State Programs, made the following comment regarding this Amendment.

COMMENT

In Section 350.30, "requirement" in the fifth line should be "requirements".

DEPARTMENT RESPONSE

The Department has corrected Section 350.30 by changing "requirement" to "requirements".

The following Sections have been modified to properly incorporate reference material published in the Code of Federal Regulations.

Section 350.3060(a)(4):

> Comply with all applicable requirements of 32 Ill. Adm. Code 340. If such a system is a certified cabinet x-ray system, it shall also comply with all applicable requirements listed in 21 CFR 1020.40, revised as of April 1, 1985, exclusive of subsequent amendments or editions. A copy of 21 CFR 1020 is available for public inspection at the Department of Nuclear Safety.

Section 350.3070(c):

> Each cabinet x-ray system shall be in conformance with the applicable regulations in 21 CFR 1020.40, revised as of April 1, 1985, exclusive of subsequent amendments or editions, unless approval has been granted by the Department pursuant to 32 Ill. Adm. Code 310. A copy of 21 CFR 1020 is available for public inspection at the Department of Nuclear Safety.

b) Direct changes in the agency's programs include the increase of computer use and the hiring of eight additional inspectors and necessary support staff for the implementation of this program. There will be no change to the structure of the Department as a result of this rulemaking.

c) Not applicable.

d) The Department proposed these amendments as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the

Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

DRAFT

April 9, 1986

Mr. Bruce A. Johnson
Executive Director
Joint Committee on Administrative Rules
509 South Sixth Street
Room 500
Springfield, Illinois 62701

Re: 32 Ill. Adm. Code 601

Dear Mr. Johnson:

This SECOND NOTICE is for the Department of Nuclear Safety's Proposed Rule pertaining to Licensing Requirements for Land Disposal of Radioactive Waste.

In compliance with Section 220.500 of the Operational Rules of the Joint Committee on Administrative Rules, the Department of Nuclear Safety states as follows:

1) The name of the agency is the Department of Nuclear Safety.

2) The title of the Proposed Rule is Licensing Requirements for Land Disposal of Radioactive Waste, 32 Ill. Adm. Code 601.

3) The First Notice Period began on January 24, 1986, with the publication of Vol. 10, Issue 4 of the Illinois Register, beginning at p. 1659.

4) Changes in the rule made during the First Notice Period are discussed below.

5) Not applicable.

6) An analysis of the economic and budgetary effects of the Proposed Rule is enclosed.

7) The Proposed Rule does not include any incorporations by reference.

8) The Department has incorporated the recommended changes received from the Office of the Secretary of State, Administrative Code Unit.

9) Joint Committee questions may be directed to Betsy Salus, Staff Counsel with the Department of Nuclear Safety at 546-8100, Ext. 216.

In compliance with Section 220.600, the Department of Nuclear Safety states as follows:

a) 1) The Department of Nuclear Safety held a Public Hearing on the Proposed Rule on February 24, 1986. No comments were received at this Public Hearing.

2) Written comments were received from Norman Wandke, Assistant Vice President, Nuclear Services, Commonwealth Edison, and Donald A. Nussbaumer and Joel O. Lubenau of the U.S. Nuclear Regulatory Commission, Office of State Programs.

3&4) The specific comments and suggestions made by these individuals and entities and the Department's responses thereto are set forth below.

COMMENTS FROM COMMONWEALTH EDISON

Norman Wandke, Assistant Vice President, Nuclear Services of Commonwealth Edison, had the following comments pertaining to Sections 601.120, 601.140, 601.150, 601.160, 601.200, 601.260 and 601.300 of the Department's proposed rules:

COMMENT

Section 601.120 - Conditions of Licenses

"Section 601.120(b) does not establish any conditions on the Department's authority to suspend or revoke a license. Although the Department has substantial discretion to regulate within its jurisdiction, licensees are entitled to notice of how such discretion will be exercised. For example, the NRC in 10 CFR 61.24(e) enumerates the conditions which could lead to the revocation or suspension of a NRC license for the land disposal of radioactive waste. Therefore, Section 601.120(b) should be amended to incorporate a similar enumeration of the conditions which could lead the Department either to suspend or to revoke a license."

DEPARTMENT RESPONSE:

As was stated in the First Notice, 32 Ill. Adm. Code 601 is a modified version of the U.S. Nuclear Regulatory Commission (NRC)

regulations regarding the licensing of land disposal of radioactive waste (10 CFR 61). The Department has proposed this Part to achieve compatibility with NRC regulations, a prerequisite to becoming an Agreement State. The Department recognizes that there must be additional rulemaking to implement the provisions of the Illinois Low-Level Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, pars. 241, et seq.). Such rulemaking will include standards for licensing a low-level waste disposal facility. Until those standards are developed fully, it is impossible to enumerate all the conditions which could result in suspension or revocation of a license. Once licensing standards are developed, the Department anticipates that this rule will be expanded. In the meantime, it must be adopted in its present form to ensure compatibility with NRC requirements.

COMMENT

Section 601.140 - Contents of Application for Closure

"Section 601.140(b) does not acknowledge any findings and requirements on closure which would have been made during the initial licensing proceeding. To the extent that any new information developed from operational data obtained after that proceeding supports those initial findings and requirements, no additional requirements should be imposed as a condition of closure."

DEPARTMENT RESPONSE:

It is unnecessary for Section 601.140(b) to provide for the acknowledgment of findings and requirements on closure made during the initial licensing proceeding. This is because section 601.130(b) does so. Section 601.130(b) states that "information contained in previous applications, statements or reports filed with the Department under the license may be incorporated by reference if the references are clear and specific". If the information has not been included in any of these documents, it may be included in the application pursuant to Section 601.140(a)(1).

COMMENT

Section 601.150 - Post-Closure Observation
Section 601.160 - Post-Closure Procedures
Section 601.310 - Funding for Disposal Site Closure and Stabilization

"Sections 601.150 and 601.160 do not establish time limits in which the Department would have to act on a licensee's application for the State to accept custody of a low-level radioactive waste disposal facility. The addition of such time limits would reduce the regulatory uncertainties which could be expected to deter potential applicants for a license to operate such a facility.

Sections 601.160(c) and 601.310(a)(2) do not establish any limit on the time for which funds should be available for the long term care of a decommissioned low-level waste facility. Such a facility will not require indefinite care because radioactive decay of its radioactive contents will reduce those contents to insignificant levels in time periods which can be determined from the initial radioactive contents of the waste. Therefore, to ensure that potential applicants for a facility license are not discouraged by unnecessarily high facility decommissioning costs, the rules should include a provision for determining the period for which long-term care would be required."

DEPARTMENT RESPONSE:

See the Department's response to the comment on Section 601.120. Until a particular facility design has been chosen, the Department is not in a position to propose an appropriate time span for agency action on a licensee's application for transfer of custody. Once facility licensing standards have been adopted, this Section can be expanded to include a specific time.

COMMENT

Section 601.200 - Performance Objectives - Protection of Individuals from Inadvertent Intrusion

"Section 601.200 would require a licensee to design, operate and close a land disposal facility in a manner which ensures the protection of any individual who enters the disposal site after the removal of active institutional controls. Such an absolute requirement cannot be implemented nor can such implementation be demonstrated. Accordingly, this provision should be amended to incorporate the standard of reasonable assurance as applied to all other nuclear activities."

DEPARTMENT RESPONSE:

The requirements of Section 601.200 are identical to those contained in the U.S. Nuclear Regulatory Commissions regulations, 10 CFR 61.42. In order to achieve compatibility with the regulations of the NRC and to become an Agreement State, the Department's regulations must not be less stringent than the language proposed in Section 601.200.

COMMENT

Section 601.260 - Technical Requirements - Environmental Monitoring

"Section 601.260(b) requires a monitoring system capable of detecting releases to the environment prior to the escape of those release over the site boundary. Such a system may not be implementable for releases to ground water. Accordingly, this provision should be modified to provide for such a circumstance."

DEPARTMENT RESPONSE:

The Department disagrees with Commonwealth Edison on this point. Of all releases to the environment, releases to groundwater are the easiest to detect prior to escape over site boundaries, since groundwater is easily monitored and travels slowly.

COMMENT

Section 601.330 - Maintenance of Records, Reports, and Transfers

"Section 601.330(b) would require all records to be retained indefinitely unless retention periods are explicitly established. This will result in the indefinite retention of too many unnecessary records. To prevent such an unwarranted burden, this provision should be amended to establish a reasonable retention period for all records except for those which should be retained indefinitely."

DEPARTMENT RESPONSE:

Since custody of the facility is transferable to the State, it is not unreasonable that all records necessary for safe post-closure management be maintained by the licensee for ultimate transfer to the State. The intent of this requirement is to ensure that the State will have all information necessary to assume custody of the facility.

COMMENT

"Section 601.330(h)(2)(F) would authorize the Department to obtain any information it desired from a licensee. Such broad authority could result in unwarranted burdensome requests for information unrelated to the operation of a disposal facility. To prevent the unwarranted imposition of such requests, this provision should be amended to limit information requests to information relevant to regulating a land disposal facility."

DEPARTMENT RESPONSE:

This provision has been modified to incorporate the change suggested by Commonwealth Edison. This was the intent of the Section as proposed originally. Section 601.330(h)(2)(F) will now read as follows:

2) The report shall include:

F) any other information, relevant to regulation of the land disposal facility, that the Department may require.

COMMENTS FROM U.S. NUCLEAR REGULATORY COMMISSION

Donald A. Nussbaumer, Assistant Director for State Agreements Program, Office of State Programs, and Joel O. Lubenau, Senior Project Manager, State Agreements Program, made the following comments:

COMMENT

Section 601.20 -Definitions

"Section 601.20, Definitions, provides a definition for (low-level radioactive) waste and states that the term "waste" "has the same meaning as in the Low Level Radioactive (Waste) Policy Act, P.L. 96-573." That act was amended in 1985 and the definition of waste should track the recent amendments. The following would be acceptable:

> '...has the same meaning as in the Low Level Radioactive (Waste) Policy Act, P.L. 96-573, as amended, i.e., radioactive material that (A) is not high-level radioactive waste, spent nuclear fuel, or byproduct material (as defined in section 11e.(2) of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2))); and (B) the Nuclear Regulatory Commission, consistent with existing law and in accordance with paragraph (A), classifies as low-level radioactive waste.'"

DEPARTMENT RESPONSE:

The Department has modified the definition of "waste" (low-level radioactive waste) to conform with the definition of low-level radioactive waste found in the 1985 amendments to the Low-Level Radioactive Waste Policy Act. The definition has been modified to read as follows:

> "Waste" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended, i.e., radioactive waste material that (A) is not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct

material (as defined in Section 11 e.(2) of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)); and (B) the Nuclear Regulatory Commission, consistent with existing law and in accordance with paragraph (A), classifies as low-level radioactive waste ~~(uranium or thorium tailings and waste)~~.

COMMENT

In Section 601.20, Chelating Agent, second line, the word "glucinic" is misspelled.

In Section 601.80(d), second line, close up lines 2 and 3 on page containing 601.90.

In Section 601.140(a)(2), second line, shouldn't "or" be "of"?

In Section 601.250(b), second line, add "top of the" before "waste".

In Section 601.250(b), third line, add "below the top surface of the cover" after "meters".

DEPARTMENT RESPONSE:

The Department has incorporated the suggested changes in Sections 601.20 and 601.80(d). In Section 601.140(a)(2) "or" is the correct word. The suggested changes for 601.250(b) were not made because the Department believes that all surfaces, not just top surfaces, should be protected by a 5 meter barrier.

b) This rulemaking, by itself, will result in no direct changes in the Department's programs. The Waste and Transportation Division of the Department's Office of Environmental Safety is in the process of expanding, but the expansion is primarily due to the increased responsibilities imposed on the Department by the Illinois Low-Level Radioactive Waste Management Act, Ill. Rev. Stat. 1985, ch. 111 1/2, pars. 241-1, et seq.

c) Not applicable.

d) The Department proposed these rules as a preliminary step towards achieving Agreement State status. Adoption of a comprehensive State regulatory program with respect to byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass is a prerequisite for execution by the U.S. Nuclear Regulatory Commission of an agreement transferring regulatory authority and responsibility for these materials to the State. The Department of Nuclear Safety is pursuing Agreement State status in accordance with the legislative directives contained in the Low-Level

Radioactive Waste Management Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 241-2 (b) and the Radiation Protection Act (Ill. Rev. Stat. 1985, ch. 111 1/2, par. 216(b)).

Sincerely,

Terry R. Lash
Director

TRL:rm
Enclosure

(STP) [handwritten routing notes: Kennedy, Ashley, Schmotter, Bollinger, Deda, Woodruff, Lieberman]

STATE OF ILLINOIS

DEPARTMENT OF NUCLEAR SAFETY

1035 OUTER PARK DRIVE
SPRINGFIELD 62704
(217) 546-8100

TERRY R. LASH
DIRECTOR

August 6, 1986

Mr. Joel Lubeneau
Office of State Programs
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Joel:

Enclosed is the chart outlining the training needs for the Agreement State staff which you wanted. Sorry it took so long to get this to you.

If you have any questions, please let me know.

Sincerely,

Paul

Paul D. Eastvold, Manager
Office of Radiation Safety

PDE:lhs

Enclosure

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Staff Training Needs
July 30, 1980

X = Completed Training
O = Anticipated Training
* = Could Train Other Staff

Name	Position	Location	Licensing	Inspection Procedures	Medical Use of Radio Nuclides	Industrial Radiography	Well Logging	Five Week Course	Teletherapy	Engineering/ Ventilation	Transportation	Radiochemistry	Internal Dosimetry	Biological Effects	Management	Data Processing	Technical Writing	Emergency Response (RERO)
Gulczynski*	Inspection & Enf.	Chicago	O	X	X	O	O	X	O	O	X	O	X	X	X		X	X
Papendorf	Inspection & Enf.	Chicago	O	X	O	X	O	O	O	O	X	O	O	O			O	X
Bauer*	Inspection & Enf.	Chicago	O	O	O	O	O	X	O	O	O	O	O	X		O	X	O
Kark*	Inspection & Enf.	Chicago	O	O	O	O	O	O	O	O	O	O	O	X			X	O