Radiation Consultants of Mid-America, Inc.

X-RAY • NUCLEAR MEDICINE • THERAPY
5500 BUENA VISTA • SHAWNEE MISSION, KANSAS 66205
(913) 236-5126

October 25, 1984

Mr. William Miller
U.S. Nuclear Regulatory Commission
Licensing Fee Management Branch
Washington, D.C. 20555

Dear Mr. Miller:

I recently received a renewal application from the U.S. Nuclear Regulatory Commission. Radiation Consultants of Mid-America is involved in performing routine medical physics consulting for nuclear medicine facilities. Our consulting involves the use of equipment checks, record checks, and leak checks.

I was amazed at the licensing renewal fee required for our license. The fee is in excess of $1,000.00. A fee this high places an unnecessary burden on the small consultants who service a few small accounts. In addition, I do not believe that the NRC's costs for reviewing a license renewal for a consulting program is $1,000.

I discussed the licensing fee with Ms. B.J. Holt in the Regional Licensing Office in Chicago. She informed me that the licensing fees are being reviewed on an annual basis. I feel that the NRC should seriously consider reducing the fee structure for individuals doing routine medical physics consulting. The present fee structure will probably result in several people dropping their NRC license. This is the route that I plan to take. The fee is such that I do not feel that it is justified to maintain the NRC license.

If at some time in the future the fee structure is lowered to a point which makes the performance of services under an NRC license reasonable, I will reconsider applying for approval.

Sincerely,

Emory Larimore
Radiological Physicist

EL/bc

APR 10 1987

MEMORANDUM FOR: Ronald M. Smith, Attorney
Division of Rulemaking & Fuel Cycle
Office of the General Counsel

FROM: John J. Surmeier, Acting Director
Planning and Program Analysis Staff, NMSS

SUBJECT: COMMENTS ON PROPOSED REVISION OF PART 170

We appreciate the briefing you gave us on the proposed revision. In response to your March 10, 1987 memorandum and items discussed during the briefing, NMSS has the following comments:

1. Regional Involvement

We suggest that the Regions be given the opportunity to comment on the proposed rule. The Uranium Recovery Field Office of Region IV will have to be involved in the process of gathering/analyzing historical data on uranium recovery to support this new rule. All five regions issue materials licenses; NMSS will take the lead in gathering/analyzing historical data for this area.

2. Flat Fees for Materials Licensing

During the March 19, 1987 meeting, you mentioned $2,000 arbitrarily as the threshold. Such an approach for "full cost" vs. flat fees for materials licensees seems reasonable, provided that there are not too many material licensing cases in the "full cost" categories. The large number of material licensing actions (about 6,000 per year) would make it very difficult to keep accurate records of time spent on each individual licensing action. If $2,000 is the cutoff, it appears that "full cost" would apply principally to large irradiators (Category 3G). The number of licenses in this category is small enough that the licensing staff could be expected to keep accurate records. We hope that whatever the threshold is, it should be high enough that only a small percentage (e.g., 1-5 percent) of material licensing actions are subject to full cost.

Please note that the phrase describing Category 3G is broad enough to include not only the megacurie irradiators which might appropriately be charged "full cost," but also teletherapy units with 12,000 Curie cobalt-60 sources used to irradiate various items (e.g., animals, biological samples, etc.). Consideration may need to be given to revising the descriptive phrase for Category 3G to ensure that it covers only the "service" irradiators or adding a new category specifically for "service" irradiators.

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OFC	NMSS:PPAS	NMSS:PPAS	NMSS:PPAS				
NAME	CSeelig	DLoosley	JSurmeier				
DATE	4/ /87	4/ /87	4/ /87				

The following phrase should be added to section (2) of the "byproduct material" definition for consistency with Part 40.

> "including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute 'byproduct material' within this definition."

The definition of "materials license" should also be modified for the reason stated above.

> "'Materials license' means a byproduct material license issued pursuant to Part 30 of this chapter, or a source or byproduct material ..."

9. New Regulations

The text of the Federal Register notice needs to be revised to take into account recent revisions to the regulations and those that are anticipated; e.g, Part 39 should be published in effective form shortly; the revision of 10 CFR Part 35 that became effective April 1, 1987, deletes the in vivo general license authorized in 10 CFR 35.31.

10. Inspections

We recommend a review of the inspection frequencies listed in 10 CFR 170.32 to ensure that they correspond with those specified in the appropriate Manual Chapter.

11. Revisions to Fee Categories

This rulemaking provides an opportunity to clarify the descriptive phrases in several fee categories. We suggest the following:

- Add a statement to Category 1J that industrial measuring devices include x-ray fluorescence devices.
- Revise Categories 3C and 3D to include not only distribution, but also redistribution.
- Specifically exclude from Category 3L medical use (or human use).
- In 10 CFR 170.11(a), consider specifying that: (1) medical institutions that hold another NRC license are not subject to fees for a nuclear pacemaker license, and (2) individuals who hold an NRC license authorizing possession of an implanted nuclear pacemaker are also not subject to fees. This is the current practice and the proposed rule should document it.

OFC	NMSS:PPAS	NMSS:PPAS	NMSS:PPAS			
NAME	CSeelig	DLoosley	JSurmeier			
DATE	4/ /87	4/ /87	4/ /87			

- Consider establishing a separate fee category for organizations licensed to calibrate instruments. Alternatively, clarify that they are not covered by the phrasing in Category 3N and are included in the "all other" Category, 3P.

12. 10 CFR 170.2(b)

This should be changed as follows to include byproduct material.

"(b) An applicant for or holder of a specific source material or byproduct material license issued pursuant to Part 40 of this chapter,"

13. Enforcement

Paragraph 170.12(1) should be clarified to indicate NRC intends to bill for all NRC staff time associated with enforcement actions, not just time expended by OE and OGC.

NMSS has also marked minor corrections/typos on the enclosed draft. We recognize the sensitivity of the license fee issue and will work with you, given available resources, on formulating this proposed rule. If you have any comments, please contact Claudia Seelig on ext. 74072.

John J. Surmeier, Acting Director
Planning and Program Analysis Staff
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

DISTRIBUTION:
NMSS R/F
PPAS File 2.6.1
JRoe
CSeelig ✓
CJenkins, WITS 87203

OFC	NMSS:PPAS	NMSS:PPAS	NMSS:PPAS				
NAME	:CSeelig	:DLoesley	:JSurmeier				
DATE	:4/6/87	:4/6/87	:4/10/87				

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

SEP 15 1989

NOTE TO: Jim Holloway

FROM: Glenda Jackson

SUBJECT: FEES FOR CALIBRATION/LEAK TEST/OTHER SERVICES (CATEGORIES 3N AND 3P) AND HUMAN AND NON-HUMAN USE OF LIXI SCOPE DEVICES

On May 18, 1989, I discussed the subject fees with John Glenn, NMSS. The discussion for Categories 3N and 3P was based on Stan Huber Consultants' December 18, 1985 letter; Vandy Miller's March 19, 1985 memorandum to William O. Miller; John Surmeier's April 10, 1987 memorandum to Ron Smith; Health Physics Associates' July 22, 1988 comment on the June 27, 1988 proposed rule; and Vandy Miller's September 30, 1988 memorandum. Copies of these documents are attached. John confirmed that it is appropriate to treat calibration service the same as leak test service for fee purposes and recommended this change be included in revised Part 170.

The discussion on the medical versus non-medical use of the Lixiscope was based on a comment from Lixi, Inc. concerning the June 22, 1988 proposed rule and Vandy Miller's September 30, 1988 response. John Glenn stated that although the review effort may be the same for medical and industrial uses of the Lixiscope, the same could be said for all diagnostic sealed sources; however, it would not be reasonable to make a separate category for each manufactured item or for each individual use of an item. John believes that these licenses are currently grouped in the most logical manner. John recommended that the current fee categories be retained for the human and non-human use of diagnostic devices.

Sincerely,

Glenda Jackson

Glenda Jackson, Chief
Materials License Fee Section
License Fee and Debt
Collection Branch, OC/DAF

Attachments:
As Stated

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

SEP 3 0 1988

MEMORANDUM FOR: C. James Holloway, Jr., Chief
License Fee Management Branch
Division of Accounting and Finance
Office of Administration and
Resources Management

FROM: Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch, NMSS

SUBJECT: COMMENTS ON 10 CFR 170

This is in reference to your September 16, 1988 memorandum, requesting information on several issues. Our response follows in order your requested information.

A. Lixi, Inc.

1. In general, the staff effort required to review application for use of a Lixi device is the same for both human and industrial use.

2. In general, the staff effort required to inspect a licensed program for use of a Lixi device is the same for both human and industrial use.

3. In general, the staff effort required to review an application for human use of a Lixi device is about the same as other devices used for human use.

4. To our knowledge, Policy and Guidance Directive FC 85-1 did not result in a decrease in the staff effort required to review application for use of the Lixi devices. It was intended to ensure that all five Regions reviewed such request in a similar manner.

5. To our knowledge, Policy and Guidance Directive FC 85-1 did not result in a decreased effort required to inspect licensees.

B. Health Physics Association, Inc.

1. We basically agree with Health Physics Associates comments that the service category is to broad. Some types of service company, e.g., calibration company require far less review and inspection time, than other licensee such as manufacturing company's. The following are our answers for 1a. through 1d. of paragraph B.

a. Approximately 1/3 of the effort

b. About the same

c. Approximately 1/3 of the effort

d. About ⅓ of the effort

We hope this information will be helpful. If you require additional assistance, please contact Michael A. Lamastra of my staff on Ext. 23416.

Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch, NMSS

SEP 16 1988

MEMORANDUM FOR: Vandy Miller, Chief
Medical, Academic and Commercial
Use Safety Branch, NMSS

FROM: C. James Holloway, Jr., Chief
License Fee Management Branch, ARM

SUBJECT: COMMENTS ON 10 CFR 170

As you are aware, on June 27, 1988, proposed revisions to 10 CFR 170 and 171 were published in the Federal Register (53 FR24077). Most of the comments received from materials licensees related to the proposal to charge for each routine inspection rather than based on the current prescribed frequencies. Although we did not propose any changes to the license fees for small materials programs, Lixi, Inc. and Health Physics Associates commented on the current materials license fees. Copies of their comments, dated July 19, 1988 and July 22, 1988, respectively, are enclosed. In order to evaluate the issues raised by Lixi and Health Physics Associates, we would appreciate receiving information on the following:

A. Lixi, Inc.

1. Lixi has commented that they believe doctors should be charged the same as an industrial user for the review of an application for a new license to use a Lixi device. Is the staff effort required to review an application for use of the Lixi devices on humans the same as that required to review an application for the industrial use of the same device? If not, in what respects do the staff effort requirements differ? Currently, the fee for a doctor is $580 (Category 7C) while an industrial user is assessed a fee of $230 (Category 3P).

2. Is the staff effort required to inspect a licensed program the same for the human use of the Lixi devices as that for the industrial use of the same devices? If not, how do they differ? Currently, the routine inspection fee assessed for human use is $480 (Category 7C) while the inspection fee for industrial use is $530 (Category 3P).

3. Is the staff effort required to review an application for the human use of the Lixi devices less than the staff effort required to review an application for the human use of other devices? If so, is the difference significant enough to support a new category as Lixi suggests?

4. Did Policy and Guidance Directive FC 85-1 result in a decrease in the staff effort required to review applications for use of the Lixi devices? If so, to what extent was it lessened?

5. Did Policy and Guidance Directive FC 85-1 result in a decrease in the staff effort required to inspect licensed programs authorizing the use of the Lixi devices? If so, to what extent was it lessened?

B. Health Physics Associates, Inc.

1. Health Physics Associates objects to the fee of $930 (Category 3N) for a license that authorizes services for other licensees when compared to other types of licenses. How does the staff effort required to review an application for a license to provide services to other licensees (such as installation, calibration, and relocation) compare with the staff effort required to review applications for the following types of licenses:

   (a) Manufacturing of items containing byproduct material for commercial distribution to specific licensees?

   (b) Distribution of devices containing byproduct material which require a device evaluation to persons exempt from licensing? (Note: This refers to the "E" license only; separate fees are assessed for licenses to manufacture these products and for the safety evaluation of the products).

   (c) Industrial radiography at field sites?

   (d) "Large" gauge programs authorizing the licensee to install his own devices, to calibrate his own survey meters, and to test his detection system in several states?

We would appreciate receiving a response to this request by September 30, 1988 in order to address the comments in the final rule.

Signed by
C. James Holloway, Jr.

C. James Holloway, Jr., Chief
License Fee Management Branch
Division of Accounting and Finance
Office of Administration and
Resources Management

Enclosures:
1. 7/19/88 Ltr., Lixi
2. 7/22/88 Ltr., Health Physics Assc.

LIXI

'88 JUL 22 P12:21

DOCKET NUMBER
PROPOSED RULE PR 170-170
(53FR2707)

July 19, 1988

Secretary of the U.S.
Nuclear Regulatory Commission
Washington DC 20555

Attn: Docketing and Service Branch

Subject: Proposed revisions to 10CFR 170
and 171 on License and annual fees

Dear Sir:

We wish to point out an inequity in the current license fee schedule. Under category 7. "Human use of byproduct, source or special nuclear material", there is no distinction made between a user with one or two sealed sources for diagnostic use and a hospital that has many sources for teletherapy use.

In 1983, when the NRC began issuing licenses to doctors for I-125 Lixi Imaging Scopes, they were placed in Category 7(C) which was originally intended for hospitals with teletherapy devices. The Lixi Imaging Scope, like the Bone Mineral Analyzer, is a diagnostic instrument which uses a sealed I-125 source. It cannot be used as a teletherapy device. Its primary user is the individual doctor and not a hospital.

The NRC placed the Lixi Imaging Scope and the Bone Mineral Analyzer in category 7(C) because it had no other choice at that time. The NRC simplified the licensing procedure for this device in 1985, see attached "Policy and Guidance Directive FC 85-1". Recordkeeping by the doctors has been simplified and so has the NRC's inspection of these users.

We request that the NRC create a new category for diagnostic devices. Some Agreement States such as Texas have already done this. The license and inspection fees should also be reduced accordingly. Currently the NRC charges a doctor or clinic $580 for a license and $460 for an inspection which is the same as a hospital. At the same time, an industrial user is charged only $230 for a license and $210 for an inspection for use of a Lixi Imaging Scope, refer to category 3(E). We believe that doctors should be charged the same as an industrial user since there is no additional work required by the NRC to write or inspect the medical license over the industrial license.

JUL 26 1988

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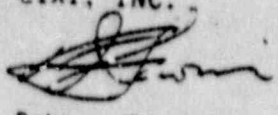
We were advised by various NRC personnel that this change was under consideration three years ago. We request that the NRC take this opportunity to correct this deficiency in its license categories.

Sincerely,

LIXI, INC.



Robert J. Savini
Executive Vice President

RJS/dh

Enclosure

FY 1990 Budget By Major Category
($ In Millions)

Salaries and Benefits	$196.40
Administrative Support	87.95
Travel	12.31
Total Nonprogram Support Obligations	$296.66
Program Support	178.34
Total Budget	$475.00

The Direct FTE Productive Hourly Rate ($95/hour rounded down) is calculated by dividing the annual nonprogram support costs ($296.66 million) less the amount applicable to exempted functions ($26.8 million) by the product of the direct FTE (1,618 FTE) and the number of productive hours in one year (1,744 hours) as indicated in OMB Circular A-76, "Performance of Commercial Activities."

Allocation of Direct FTEs by Office

Office	Number of Direct FTEs [1]
NRR/SP	982.2
RESEARCH	155.0
NMSS	307.5
AEOD	93.1
ASLAP/ASLBP	22.2
ACRS	25.0
OGC	33.0
Total Direct FTE	1,618.0

[1] Regional employees are counted in the office of the program each supports.

ESTIMATED COLLECTIONS
FY 1990
$ In Million

PART 171 Fees	$80
PART 170 Fees	50
DOE Waste Fund	27
Total Estimated Collection FY 1990	$157 million