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

HEALTH PHYSICS ASSOCIATES, INC.
RADIATION PROTECTION CONSULTANTS
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(215) 756-4153

Secretary
US NUclear Regulatory Commission
Washington, DC 20555

Attn: Docketing and Service Branch

re: Proposed Revision of Fees, 10 CFR Parts 170 and 171
June 27, 1988 Federal Register
Vol 53, No. 123, Pages 24077 through 24093

Dear Gentlemen:

Health Physics Associates would like to register its opposition to the proposed elimination of the maximum inspection frequency in Part 170.32. The NRC has not offered any real justification for eliminating this protection to the licensee and we are concerned with the potential for abuse.

As presently written, Part 170.32 lists a maximum inspection frequency for routine inspections for each license category. Non-routine inspections have no maximum. This arrangement satisfies the needs of both the Commission which can inspect any number of times as a result of a complaint, and the licensee who knows that if he provides a good radiation control program, he will be inspected a minimum number of times. In a discussion on a recent listing of records retention periods, the Commission answered commentors that were asking for permanent records retention by stating that the periodic inspections, averaging about once every five years, for most licensees was sufficient to determine if records were being properly maintained. We assumed from this that the Commission was not anticipating increasing its inspection frequency. While the proposed change to Part 170.32 does not indicate an actual increase in inspection frequency, we are concerned that this may become a defacto situation for certain licensees.

Should a licensee have a good radiation protection program, the licensee represents a relatively easy inspection, both technically and psychologically for an inspector who knows that the inspection will probably be a non-confrontational one. There could easily be a tendency to inspect such licensees more frequently. Since we are a small business, grossing less than $100,000 per year, such a practice would have a severe financial impact on us due to both the actual inspection fees and the lost productivity of our primary employee who would have to accompany the inspector.

Mr. LaMastra performs management audits, akin to your inspections, at various facilities around the country for several clients. He too must efficiently arrange travel. We are, therefore, sure that with some ingenuity, the NRC can efficiently work out inspection schedules

so that maximum inspection frequencies and travel optimization are combined.

Since the Commission has not provided any real justification for this change, and the potential for abuse would have an impact on licensees, potentially penalizing those with good programs, we strongly request that the NRC retain the maximum inspection frequencies in 170.32.

We also would like to take this opportunity to object to a fee for a specific license category (3N). It appears that the justification used by the NRC in regard to specific fees is that those licenses requiring more review time should be assessed larger fees.

We are a licensee that uses our own byproduct material to test detection systems, calibrate survey meters for ourselves and clients, and install devices containing byproduct material. For this we are required to pay $930 for the initial license, $930 for the renewal and $120 for an amendment. A manufacturer who distributes several specific devices to Part 30 licensees (3B), has a $460 initial and renewal license fee which covers both the manufacture and distribution. A manufacturer who distributes byproduct material that requires device review, to persons exempt from specific Part 30 licenses (3H) has a $580 initial and a $230 renewal fee. We cannot imagine that it takes twice as much time to review our application as opposed to a 3B or 3H application.

Or compare the 3N fees with a license authorizing industrial radiography at field sites (30), carrying a $700 initial and renewal fee. Having prepared both types of applications, there certainly is no difference in preparation time.

If we were installing our own devices at our own facilities, testing our own detection systems in several states and calibrating our own survey instruments, our license fee would be $230 for the initial application and $120 for a renewal. For a large gauge user, the program and resulting application is at least as extensive as our 3N program, and we assume, would take the same amount of time to review. However, there is a substantial disparity in fees.

We would appreciate it if the Commission would review this apparent disparity and provide some equity to the fee schedule.

Thank you for your consideration of these comments.

Sincerely,

A. LaMastra

A. LaMastra
President