



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

February 27, 1997

U.S. Nuclear Regulatory Commission
Attn: Regional Administrator, Region I
476 Allendale Road
King of Prussia, PA 19406-1415

SUBJECT: Reply to a Notice of Violation

To whom it may concern:

The enclosed Reply to a Notice of Violation is in response to the violations cited during a safety inspection; at 5516 Nicholson Lane, Kensington, Maryland; conducted by Pamela J. Henderson of the NRC Region I office on January 22, 1997.

If there are any questions regarding this response please contact me at (301) 827-5246.

Sincerely yours,

Michael A. Ussery, Ph.D.
Laboratory Director
Radiation Safety Officer
Antiviral Research Laboratory
HFD-535, 5600 Fishers Lane
Rockville, MD 20857

License No. 19-07538-06
Docket No. 030-32506

Enclosures:
Reply to Notice of Violation

cc w/enclosures:
Document Control Desk, Washington D.C.

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Reply to a Notice of Violation

February 26, 1997

Antiviral Research Laboratory-FDA
Rockville, Maryland

Docket No. 030-32506
License No. 19-0753806

During the NRC inspection conducted on January 22, 1997, violations of the NRC requirements were identified. The Notice of Violation that we received cited the following violations:

1. As of January 8, 1997, licensed material was used in rooms 2339 and 2341 which were not included in the floor plan of the facility in Tab B of the license application.
2. As of January 21, 1997, whole body exposures were not evaluated on a monthly exchange basis as specified in Item 5.1, on page 9, of the license application. Specifically, monitoring was conducted for TEDE and extremity dose using TLD badges that were exchanged on a quarterly basis.

The reasons for the above violations are listed below:

1. As both the extension of the license expiration date and the preparation of rooms occurred at roughly the same time I did not remember to amend the license for use in the new rooms.
2. The personnel monitoring for this facility is handled through a larger contract through one of our centers at FDA, CDRH. CDRH made a decision to change to quarterly exchanges which was at first not recognized by the radiation safety officer. Once it was recognized, I did not realize this specific change was needed in the materials license.

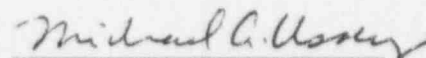
Corrective Steps Taken

A response letter, was sent to the NRC dated January 22, 1997 (see enclosed copy), which requested the needed license amendment items. Additionally, this letter was followed up by a phone conversation on January 28, 1997 between Dr. Carl Nielsen of our staff and Dr. Sattar of the NRC Region I office. This letter and conversation addressed the two areas in which we were in violation. Attached to our letter on January 22, 1997, we included an updated floor plan of suite 300. Note that room numbers such as 302 are now listed as 2302. As stated in our

letter, room 2339 is now used for radiation storage (and has improved characteristics over our old storage room, e.g. solely dedicated to radiation safety and storage uses, sealed floor, etc.), and rooms 2343 (dark room), 2341 (instrument lab) and 2345 (microbiology lab) are designated use areas for radioactive materials. Rooms 2302, 2303, 2307, (listed on floor plans in August 9, 1991 application as "BACTEC/Radiation Waste Storage Room") and 2309 are not currently being used for radioisotope work and complete close-out surveys documenting no contamination above background are on file at our facilities. As stated in our letter of 22 Jan 1997, we have amended our exchange of TLD badges and rings to a quarterly frequency, as we generally work with microcurie quantities and all exposures over the past three years have been a minimal. Our badges are TLD and not "film" as misstated in my letter of 22 Jan 1997. We continue to have ring TLDs available on the premises for any user of P32 who might handle more than 10 millicuries in one month.

In order to prevent these violations from occurring in the future our office has proposed instituting a few changes in our policies. The first change will be to evaluate our internal audit program and expand it to include these and other areas that may be compliance issues in the future. Additionally, a complete review of all the license criteria will be made prior to any changes in facility design or operation to insure compliance with the license conditions and NRC regulations.

According to the letter that was sent by John Kinneman of the Region I office dated February 1, 1997; our license has been amended to correct the two areas of noncompliance. Full compliance has therefore been achieved.



Michael A. Ussery, PH.D.
Radiation Safety Officer

22 January 1997

U.S. Nuclear Regulatory Commission
Attn: Betsy Ullrich
475 Allendale Road
King of Prussia, PA 19406-1415

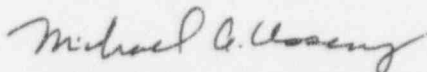
To whom it may concern:

I would like to request that we add new areas of radioisotope use to our license 19-07538-06. These are laboratories within Suite 300 at 5516 Nicholson Lane, Kensington, MD (the area currently covered under our license) that have been remodeled to provide more suitable storage and use areas for radioactive materials. We propose adding Room 2339 for radiation storage, and dark room 2343, instrument lab 2341, and microbiology lab 2345 for radioisotope use as shown on the accompanying plans. We propose moving our scintillation and gamma counters into room 2341. Once these areas are approved for addition to the license we proposing decommissioning of rooms (2)302, (2)303, (2)307 and (2) 309 and will send in surveys to close out these use areas.

Additionally, we would propose amending our license to a quarterly frequency for exchange of film badges. Our experiments generally involve working with quantities in the microcurie range. Our history over the past three years indicates that all exposures have been minimal.

Please let me know if additional information is needed.

Sincerely yours,



Michael A. Ussery, Ph.D.
Laboratory Director
Radiation Safety Officer
Antiviral Research Laboratory
HFD-535, 5600 Fishers Lane
Rockville, MD 20857

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