

FIP

Fuji ImmunoPharmaceuticals Corp.

Feb 25, 1994

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Reply to a Notice of Violation

Dear Sir/Madame:

Thank you for the Notice of Violation, which we received earlier this month. It stated that (1) adequate radiation surveys were not performed by users after each experimental run or at the end of the day radioisotopes are used; and (2) the results of the radiation surveys performed by the licensee were in the units of counts per minute instead of disintegrations per minute as described in our Radiation Safety Manual.

I apologized for the oversight in the two violations above.

In the first violation, although we did perform radiation surveys using radiation survey meters (Geiger counters) after each experimental run involving ^{35}S , we did not maintain a record stating that the surveys were done. In experiments involving ^3H , wipe tests were not performed after each experimental run. Wipe tests were done on a monthly basis only.

The following corrective steps have already been put in place to address the first violation. After each experimental run involving ^{35}S , we perform radiation surveys using survey meters and we maintain a record of these surveys. After each experimental run involving ^3H , wipe tests are performed and the results recorded. Decontamination and re-surveys are performed of areas found to exceed 200 disintegrations per minute per 100 cm^2 .

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PDR ADOCK 03033051
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Hartwell Avenue • Lexington, MA 02173
phone: 617-861-5300 • fax: 617-861-5301

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We have also taken corrective steps to address the second violation. We had Packard service personnel come in to establish the counting efficiency of our Packard Topcount Microplate Scintillation Counter. Subsequently the counting program was converted to count in disintegrations per minute. Our wipe test results since December of last year have been in disintegrations per minute. Decontamination and re-surveys are performed of areas found to exceed 200 disintegrations per minute per 100 cm².

I believe the corrective steps we have taken are adequate. In addition, to prevent any further oversight on our part, we are going to have our Radiation Safety Consultant, Mr. Mitch Galenek, come to our facility in the coming weeks to reaudit our entire Radiation Safety Program. Meanwhile, if there is anything else we can do, please let us know.

Thank you very much for your attention to this matter.

Yours sincerely,



Kin-Ming Lo
Radiation Safety Officer
Fuji ImmunoPharmaceuticals

cc: U.S. NRC Regional Administrator, Region I.