

SAFETY INSPECTION

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97 MAY 19 PM 12:27
U.S. NUCLEAR REGULATORY COMMISSION

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1. LICENSEE

Gen-Probe, Inc.
9880 Campus Point Drive
San Diego, CA 92121

2. REGIONAL OFFICE

REGION V
U S NUCLEAR REGULATORY COMMISSION
1450 MARIA LANE SUITE 210
WALNUT CREEK CA 94596-5368

3. DOCKET NUMBER(S)

030-22269

4. LICENSE NUMBER(S)

04-23500-01E

5. DATE OF INSPECTION

April 21 and 29, 1997

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

- ☐ 1. Within the scope of this inspection, no violations were observed.
- ☐ 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.
- ☒ 3. During this inspection certain of your activities, as described below or attached, were in violation of NRC requirements. This form is a **NOTICE OF VIOLATION**, which is required to be posted in accordance with 10 CFR 19.11.

☐ A. _____ was not properly posted to indicate the presence of a _____ 10 CFR 20.203(b),(c),(d),(e) or 34.42.

☐ B. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ or License Condition Number _____

☐ C. Records of _____ were not properly maintained. 10 CFR _____ or License Condition Number _____

☐ D. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

☐ E. Reports or notification of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____

☒ F. Failure to enclose a notice in or on excepted packages containing tritium standards shipped since 1992 which states: "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package - limited quantity of material, UN 2910." 10 CFR 71.5(a) and 49 CFR 173.422(a)(1).

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

SIGNATURE -- LICENSEE

Edward J. Scott

DATE

5/14/97

SIGNATURE -- NRC INSPECTOR

James A. Ross

DATE

5/6/97

TE07

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X 3. (Continued)

X

G.

Failure to measure or otherwise assure by examination or appropriate tests that the external contamination levels of packages containing tritium distributed since 1992, were within the allowable limits specified by the U.S. Department of Transportation. 10 CFR 71.5(a) and 49 CFR 173.475(i), and letter dated 10/13/94, (Item 10) incorporated into the license.

H.

X

I.

Packages containing tritium standards distributed to persons exempt from licensing did not have labels or brochures which specified certain radiation safety precautions and the wording required by 10 CFR 32.19(d).

4.

The violations listed below are not being cited because they were self-identified, and corrective action was or is being taken, and the remaining criteria in 10 CFR 2, App. C, to exercise discretion were satisfied.

A.

B.

C.

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