

Appendix

NOTICE OF VIOLATION

Gladstone Laboratories, Inc.

License No. 34-01764-02

As a result of the inspection conducted on July 14, 1983, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. 10 CFR 34.11(d) requires that the licensee have an internal inspection system adequate to assure that Commission regulations, Commission license provisions, and the licensee's operating and emergency procedures are followed by radiographers and radiographers' assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections.

Contrary to the above requirement, the licensee failed to perform any internal inspections to be assured that their radiographers and radiographers' assistants are complying with Commission requirements and their operating and emergency procedures since the previous inspection.

This is a Severity Level IV violation (Supplement VI).

2. 10 CFR 34.33(c) requires that pocket dosimeters be checked at periods not to exceed one year for correct response to radiation.

Contrary to the above requirement, as of July 14, 1983, the licensee's pocket dosimeters No. 1040952 and No. 1040968, which were in use recently, have not been checked for correct response to radiation since they were procured in January 1982.

This is a Severity Level IV violation (Supplement VI).

3. 10 CFR 34.26 requires that each licensee conduct a quarterly physical inventory to account for all sealed sources received and possessed and that records of the inventories be maintained for inspection by the Commission.

Contrary to the above requirement, the licensee failed to conduct a physical inventory to account for all sealed sources received and possessed from July 15, 1982 to January 22, 1983, a period exceeding a calendar quarter.

This is a Severity Level V violation (Supplement VI).

4. 10 CFR 20.407(b) requires that the licensee submit to the Commission within the first quarter of each calendar year, a report of personnel monitoring information for individuals under this licensed program for the preceding calendar year.

Contrary to the above requirement, as of July 14, 1983, the licensee failed to submit a report of personnel monitoring information for the years 1981 and 1982.

This is a Severity Level V violation (Supplement IV).

This is a repeat item of noncompliance.

5. 10 CFR 34.25(c) requires that records of leak test results be maintained for inspection by the Commission for six months after the next required leak test is performed or until the sealed source is transferred or disposed of.

Contrary to the above requirement, as of July 14, 1983, a record of a leak test conducted sometime in October 1982 on the licensee's iridium-192, Serial No. 28.042, sealed source was unavailable for inspection; this source was last used on January 24, 1983.

This is a Severity Level V violation (Supplement VI).

6. 10 CFR 20.401(b) requires that each licensee shall maintain records showing the results of surveys required by 10 CFR 20.205(c).

Contrary to the above requirement, the licensee failed to maintain a record showing the results of a survey of a package containing more than 20 curies of iridium-192 which they received on January 21, 1983.

This is a Severity Level V violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

AUG 09 1983

Dated _____

J. R. Miller, Chief
Materials and Safeguards Branch