U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-30284/90-001

Docket No. 030-30284

License No. 20-28122-01 Priority 5 Category E Program Code 03620

Licensee: Vitek Systems, Inc.
1022 Hingham Street
Rockland, Massachusetts 02370

Facility Name: Vitek Systems, Inc.

Inspection At: 273 and 333 Weymouth Street
Rockland, Massachusetts 02370

Inspection Conducted: August 29, 1990

Inspectors: C. T. Oberg 11/13/90
C. T. Oberg, Health Physicist date

for J. D. Kinneman 11/13/90
C. D. Eckert, Health Physicist date

Approved by: J. D. Kinneman 11/13/90
John D. Kinneman, Chief date
Nuclear Materials Safety Section B

Inspection Summary: Closeout inspection on August 29, 1990, (Inspection No. 030-30284/90-001).

Areas Inspected: Unannounced closeout safety inspection limited to a survey of the facilities for residual contamination prior to release of the facilities for unrestricted use. The facilities were surveyed to identify any fixed or removable radioactive contamination and material remaining after clean-up and decontamination. The surveys included all of the first and second floor areas of the leased facilities at 273 and 333 Weymouth Street, Rockland, Massachusetts, in which licensed material was used or stored.

Results: No violations were identified. No residual levels of radioactivity, significantly different from background levels, were identified. No remaining radioactive material was found. The results of the survey performed by the licensee's consultants, Bolton and Galanek, Inc., enclosed with their letter dated December 5, 1989, accurately reflect the condition of the facilities.

DETAILS

1. Persons Contacted

*John P. Gojcz, Manager of Quality Assurance, Safety and Regulatory Affairs
Kenneth Hoffman, Director of Reagent Development
Daniel Boudria, Production Manager
Representatives of the Buildings' Owners

*Attended Exit Interview

2. Background

The two facilities vacated and cleaned up by the licensee were each one half of a two story building and were located at 273 and 333 Weymouth Street, Rockland, Massachusetts.

Iodine-125 was the only radionuclide used in these facilities by the licensee. The radioiodine was used in the production and distribution of in-vitro diagnostic kits for medical use.

During 1987, the production areas at 273 Weymouth Street (the 273 address) were relocated to 333 Weymouth Street (the 333 address). The 273 address then became a storage facility for products and waste, a staging areas for distribution, and office space for personnel.

Until October 1989, the 333 address facility was used for production, processing, packaging, product and waste storage, and shipping of products. Between October 20 and November 21, 1989, the entire operation of the two facilities was relocated to a new, single building, about a mile away. License No. 20-28122-01 had been amended to include the new address at 1022 Hingham Street, Rockland, Massachusetts. All radioactive materials were transferred to the new location in accordance with the NRC Form 314 submitted with the licensee's closeout survey results.

The licensee cleaned and decontaminated the facilities at the 273 and 333 addresses. The furnishings and equipment were removed from the 273 and 333 addresses and moved to the new location or disposed of. The licensee retained the services of a consultant to perform their closeout survey. This survey was performed by Bolton and Galanek, Inc., on November 21, 1989, and the results were received at the NRC Region I Offices during April 1990.

3. Instruments Used In Survey

Direct reading survey measurements were made by the NRC Inspectors at the vacated facilities of the 273 and 333 addresses using Ludlum Models 16 and 14C radiation survey instruments.

The Ludlum Model 16 instrument incorporated a thin, NaI (Tl) crystal, scintillation detector (NRC Unit No. 19621). This unit is specifically used for the detection of low energy gamma and x-ray photons and has a relatively high sensitivity for iodine-125. The instrument was used to detect any possible iodine-125 contamination. The meter readings from this instrument are in counts per minute (cpm).

The Ludlum Model 14C instrument was equipped with a thin, end window GM detector. The unit (NRC Unit No. 09663) was calibrated on June 4, 1990, over a range of from 0 to 200 millirem per hour (mr/hr) with the external, thin end window probe, and up to 2,000 mr/hr with the internal detector.

4. Survey for Contamination

In areas where the licensee used, packaged, or stored licensed material at the two addresses, radiation surveys were conducted by the inspectors using both survey instruments identified in Section 3.

The floors and all horizontal surfaces were surveyed, including electrical switches, switch and junction boxes, piping, and any other protrusions encountered.

Because, for the two survey instruments used, no meter readings indicated significantly greater activity levels than those of background, and since no radioactive material had been used in the facility for nearly a year no wipe surveys for removable radioactive contamination were conducted.

The background levels measured with the two survey instruments were 0.02 to 0.04 mr/hr for the Ludlum 14C and 200 to 300 cpm for the Ludlum 16 instruments.

No violations were identified.

5. Remaining Material and Equipment

As stated in Section 1 of this report, all radioactive materials and equipment, contaminated and clean, were transferred to the new location during October and November 1989. No remaining radioactive material, residual radioactive contamination, or equipment was identified by the inspectors.

The areas previously used by the licensee at the 273 and 333 Weymouth Street, Rockland, Massachusetts, addresses were free of radioactive contamination and clear of any obstructions.

No violations were identified.

6. Exit Interview

The results of the follow-up closeout safety inspection and survey, were discussed with those individuals indicated in Section 1 of this report.

The inspectors stated that the licensee would receive a report of the results of this inspection. Further, that an amended license reflecting these results and the status of the facilities at 273 and 333 Weymouth Street, Rockland, Massachusetts, would be issued.