



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 11, 2003

Docket No. 03005222

License No. 29-00139-02

John Mamone  
Vice-President, Operations Support  
E. R. Squibb & Sons, Inc.  
311 Pennigton-Rocky Hill Road  
Mail Stop HW8T-1.12  
Pennington, New Jersey 08534-2130

SUBJECT: INSPECTION 03005222/2002002, E. R. SQUIBB & SONS, INC., ONE SQUIBB DRIVE, NEW BRUNSWICK, NEW JERSEY

Dear Mr. Mamone:

On September 5, 2002, through April 8, 2003, Betsy Ullrich, Jim Schmidt, and Donna Janda of this office conducted a safety inspection at of activities authorized by the above listed NRC license. The inspection was limited to a review of decommissioning of Building 124 and related areas. The findings of the inspection were discussed with Michael Vala, Beverly Good, and Paul Ely of your organization at the conclusion of the inspection by telephone.

Within the scope of this inspection, no violations were identified.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm.html>. No reply to this letter is required.

Your cooperation with us is appreciated.

Sincerely,

***Original signed by John D. Kinneman***

John D. Kinneman, Chief  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety

cc:  
Michael Vala, C.H.P., Radiation Safety Officer  
State of New Jersey

J. Mamone  
E. R. Squibb & Sons, Inc.

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NAME	D Janda/jdk for		J Schmidt/jdk for		E Ullrich/jdk for		J Kinneman/jdk	
DATE	04/08/2003		04/08/2003		04/08/2003		04/11/2003	

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U.S. NUCLEAR REGULATORY COMMISSION  
REGION I

INSPECTION REPORT

Inspection No. 03005222/2002002  
Docket No. 03005222  
License No. 29-00139-02  
Licensee: E. R. Squibb & Sons, Inc.  
Address: 311 Pennington-Rocky Hill Road  
Mail Stop HW8T-1.12  
Pennington, New Jersey 08534-2130  
Location(s) Inspected: One Squibb Drive  
New Brunswick, New Jersey  
Inspection Dates: September 5 and 26, 2002; October 3 and 30, 2002; January 23,  
2003, and April 8, 2003

Inspectors: **Original signed by J. W. Schmidt for: 4/10/03**  
\_\_\_\_\_  
Donna M. Janda  
Health Physicist  
date

**Original signed by: 4/10/03**  
\_\_\_\_\_  
James Schmidt  
Health Physicist  
date

**Original signed by: 4/8/03**  
\_\_\_\_\_  
Betsy Ullrich  
Senior Health Physicist  
date

**Original signed by  
John D. Kinneman April 11, 2003**  
\_\_\_\_\_  
John D. Kinneman, Chief  
Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety  
date

Approved By:

**EXECUTIVE SUMMARY**

E. R. Squibb  
NRC Inspection Report No. 03005222/2002002

The license currently authorizes the possession and use of various radionuclides in curie and millicurie quantities for research and development. Formerly authorized manufacturing, processing and distribution activities permanently ceased on June 29, 2001. As a result, the licensee is in the process of decommissioning Building 124, where manufacturing took place. Various radionuclides were used in Building 124, such as carbon-14, cobalt-60, selenium-75, strontium-89, strontium-90, molybdenum-99, cesium-137, mercury-197, thallium-201, and mercury-203. Tritium may have been used for research and development in laboratories in Building 124 in the 1960s. Although many of the radionuclides used in the building have half-lives of less than 65 days, it is likely that long-lived impurities were present in the bulk solutions, such as manganese-54, cobalt-57, cobalt-60, cesium-137, technetium-99, and iodine-129.

The licensee planned a three-phase decommissioning of the building and associated facilities. First, characterization surveys were performed. Second, based on the results of the characterization surveys, decontamination of areas would be performed during decommissioning of the facilities. Third, final status surveys will be performed. Inspection Report No. 03005222/2002001 discusses the review of E. R. Squibb & Sons, Inc.'s (Squibb) characterization phase of decommissioning of their former manufacturing and distribution facility in Building 124 and other nearby areas, including outdoor storage tanks, at the licensee's New Brunswick, New Jersey location of use.

This Inspection Report No. 03005222/2002002 covers the second phase of Squibb's decommissioning. The inspection was limited to a review of the decontamination and decommissioning activities in Building 124, the nearby areas and outdoor storage tanks. Based on the results of the characterization surveys and a review of the conditions of the license, a decommissioning plan was not required to be submitted to the NRC by Squibb. The licensee contracted with GTS Duratek, Inc. (Duratek) to perform decommissioning activities. Squibb also contracted with TLG Services (TLG) to provide independent oversight of the activities of Duratek. Region I inspectors visited the site periodically to observe the procedures, equipment, and methods used by the licensee. Region I inspectors also performed confirmatory and independent measurements to verify licensee and contractor measurements. Region I also plans to perform inspections during the final status survey phase of decommissioning to determine if a confirmatory survey by the NRC is required prior to release of Building 124 and associated facilities for unrestricted use.

Within the scope of this inspection, no violations were identified.

## REPORT DETAILS

### **I. Organization and Scope of the Decommissioning Program**

#### a. Inspection Scope

This inspection was limited to a review of the licensee's program for decontamination and decommissioning of Building 124 which was formerly used for manufacturing, packaging, and distribution of licensed products, and the decontamination and decommissioning of facilities related to activities performed in Building 124.

#### b. Observations and Findings

E. R. Squibb and Sons, Inc. (Squibb) is undergoing the second phase of a planned three-phase decommissioning of their former manufacturing and distribution facility in Building 124 and other nearby areas, including outdoor storage tanks, at the licensee's New Brunswick, New Jersey location of use. The first phase, performance of characterization surveys, is discussed in Inspection Report No. 03005222/2002001, issued March 15, 2002. Based on the results of the characterization surveys, the second phase involves decontamination of areas and decommissioning of the facilities. The licensee began mobilization for decontamination and decommissioning activities in late August 2002. Actual work began on August 27, 2002, and expected to finish in January 2003. Due to some unexpected areas of contamination, decommissioning activities continued through April, 2003. The third phase of the decommissioning program, final status surveys, will be performed in the spring of 2003. After the final status surveys are completed, Squibb plans to request that the former manufacturing facilities be released for unrestricted use. Following release, the licensee expects to renovate Building 124. The licensee is aware that they possess 37 generally-licensed EXIT signs containing tritium in Building 124, and plans to dispose of them prior to renovation and/or demolition. Because they are still required for safe egress, they cannot be removed earlier.

The inspection was limited to a review of the licensee's implementation of their "Radiological Decommissioning Plan for Radiodiagnostic Manufacturing Facility and Associated Equipment" dated December, 2001.

#### c. Conclusions

The licensee performed decontamination and decommissioning in accordance with license commitments. No safety concerns or violations were identified.

## II. Management Oversight of the Program

### a. Inspection Scope

The inspectors reviewed the licensee's management and oversight of the decommissioning program.

### b. Observations and Findings

Squibb maintains a staff of health physicists and support technicians to oversee the daily activities of research and development using licensed materials in North Brunswick, Lawrenceville, Hopewell and Ewing, New Jersey. In order to have as little impact on the required daily health physics activities, Squibb contracted with GTS Duratek, Inc. (Duratek) to perform decommissioning activities. Squibb also contracted with TLG Services (TLG) to provide independent oversight of the activities of Duratek. Duratek sub-contracts with other service providers when necessary. Health physics capability is required for the project, and representatives of Duratek and TLG include health physicists. In addition, the project requires knowledge of a various environmental and industrial hygiene areas, such as lead paint removal, asbestos abatement, noise and dust limitations, and confined space entry. Duratek and TLG staff have some experience in these areas, and coordinate with appropriate staff members at Squibb when hazardous materials or activities are of concern. The licensee also interacts with the State of New Jersey Department of Environmental Protection (NJDEP) on a regular basis to ensure compliance with NJDEP and Environmental Protection Agency (EPA) regulations and concerns.

Representatives of Squibb, Duratek, and TLG met weekly to discuss progress made on the planned schedule, and to outline specific tasks that were expected to be completed during the coming week. A summary of this meeting was provided each week to the NRC.

### c. Conclusions

The licensee provides adequate management and oversight of the decontamination and decommissioning activities. No safety concerns or violations were identified.

## III. Facilities and Equipment

### a. Inspection Scope

The inspectors reviewed the facilities and equipment used by personnel to support the decommissioning process.

b. Observations and Findings

Duratek was provided office and laboratory at the Squibb site in Building 115. There, Duratek maintained a Ludlum 2929 meter connected to a Model 43-10-1 detector for counting wipe samples. The system was in calibration during the inspections. Daily checks were made of background and with check sources to confirm proper operation. Records of calibration and daily checks were reviewed during the inspection.

Duratek primarily used a Ludlum 2350-1 Datalogger attached to a Ludlum Model 43-68 gas-flow proportional detector to perform surveys of building surfaces and equipment. Instruments encountered in the field were found to be functioning properly and personnel using the devices were found to be knowledgeable regarding their operation and limitations. Other instrument types used by the licensee were appropriate for the radiation types and conditions expected.

Soil and water samples were sent for analysis at a contract laboratory. In accordance with NJDEP requirements, the laboratories used were certified by the NJDEP.

c. Conclusions

Facilities and equipment used for decontamination and decommissioning activities were appropriate for the surveys and analyses performed, and were operable and in calibration. No safety concerns or violations were identified.

#### **IV. Security, Control and Radiation Protection**

a. Inspection Scope

The inspectors evaluated the process to control access to the facilities undergoing decommissioning, and to provide radiation protection to workers and the public.

b. Observations and Findings

Squibb's routine security procedures required all visitors to sign in at the main entrance and be escorted by an authorized individual while on site. Access to buildings at Squibb is controlled by a keycard system. During the decommissioning phase, the licensee established Building 124 and adjacent related facilities as a Radiation Control Area (RCA). All items considered to be potentially contaminated were maintained in the RCA. Outdoor areas were fenced off to keep unnecessary/unwanted personnel out of the areas. Inspectors observed that access to the RCA was limited to persons who had the required training or persons who were directly escorted by an individual with the required training. A sign-in/sign-out sheet was used to document entry into and out of the RCA.

Although no external radiation was expected based on characterization surveys, all persons in the RCA were issued thermoluminescent dosimeters (TLDs) that were

exchanged monthly. All persons were also required to meet the requirements of the Radiation Hazard Work Permit. Based on non-radiation hazards, persons in the RCA were required to wear hard hats, safety glasses, and safety shoes.

In addition to standard safety equipment, additional safety and security requirements were implemented depending on the conditions in which they were working. For example, workers entering the holding tank vault wore full body harnesses to support personnel extraction if necessary. Workers entering Tanks 3 and 4 to perform contamination surveys were observed to wear Tyvek coveralls and protective gloves and boots, also as required by on-site procedures.

c. Conclusions

Security and control of the facilities being decommissioned was adequate, and were consistent with the low levels of radiation and radioactivity involved. Adequate radiation protection was maintained. No safety concerns or violations were identified.

## V. Training of Workers

a. Inspection Scope

The inspectors observed the performance of supervisory, health physics and craft personnel supporting the decommissioning activities.

b. Observations and Findings

Duratek and subcontractor workers were provided radiation safety and on-site safety training by Duratek and Squibb representatives prior to beginning work on-site. Workers were required to pass a test given at the conclusion of the training, prior to working on-site.

Inspectors observed all workers in the RCA wearing the required dosimetry and required personal safety equipment. Workers performing surveys appeared to be familiar with the operation and use of radiation survey instruments, and to follow industry good practices for surveys and monitoring. Items from the decommissioning of facilities, including disassembled equipment, were appropriately segregated to assure that appropriate surveys were completed prior to disposition of the materials. Worker's equipment and other items to be removed from the RCA were controlled and surveyed by workers.

Licensee representatives were observed interacting with TLG and Duratek employees during decommissioning activities. TLG and Duratek representatives were knowledgeable of the activities to be performed, and familiar with the radiation safety and other hazards that could or did occur during decommissioning.

c. Conclusions

Individuals involved in performing, or supervising the performance of, decontamination and decommissioning activities were appropriately trained and knowledgeable about the activities they were assigned. No safety concerns or violations were identified.

## **VI. Equipment and Items Removed from the Facility**

### **a. Inspection Scope**

The inspectors observed the procedures used to allow materials to be removed from the facility. This included licensee items that were transferred to other licensees, disposed of as radioactive waste, or decontaminated and released for unrestricted use. It also included the procedures used to survey and release contractor equipment used in the decommissioning of the licensee's facilities.

### **b. Observations and Findings**

During decommissioning of the facilities, much of the laboratory and support equipment was dismantled and removed. Such equipment included building furniture, ventilation ducts, and formerly used pumps, tanks, processing valves and piping. The licensee implemented procedures to control and disposition the items. Some equipment was transferred to other licensees, some was disposed of as radioactive waste, and some equipment was released for unrestricted use.

Inspectors observed the arrangement and flow of equipment and dismantled items that were removed from the facilities undergoing decommissioning. The processes were established prior to decommissioning, and revised if necessary. The handling of disassembled equipment included surveys to determine if it could be released for unrestricted use, or otherwise classified as licensed material. The procedures included tracking of items for future reference, such as the process whereby each piece of duct was assigned and labeled with a number as it was disassembled; this number was used to relate it to specific unique surveys.

Much of the formerly-used equipment was transferred to other licensees, including manipulators and leaded glass windows from the hot cells, glove boxes, filter trains, packaging tables, pass-through cabinets and other such equipment used for manufacturing with radionuclides. Inspectors reviewed copies of the licenses of the purchasers, obtained by Squibb prior to shipment of the items. Records of the surveys performed of the items, and shipping records, were also reviewed.

Inspectors observed surveys performed to determine if items could be released for unrestricted use, and reviewed records of such surveys. Appropriate, calibrated instruments were used to perform the surveys. Items were released for unrestricted use only if they did not exceed the limits specified in the NRC "Policy and Guidance Directive FC 83-23, "Guidelines for the Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source, and Special Nuclear Material Licenses".

c. Conclusions

Equipment and other items removed from the facilities during decommissioning were adequately controlled and appropriately dispositioned. No safety concerns or violations were identified.

## VII. Radiation Surveys of the Building

a. Inspection Scope

The inspectors observed surveys performed by licensee representatives during decontamination and decommissioning of the building. Inspectors also conducted surveys in Building 124 to assure that the ambient dose rates were consistent with established postings.

b. Observations and Findings

Licensee representatives performed several types of surveys of the building. Ambient radiation levels were measured inside various areas of the building to ensure that no radiation levels existed that required posting. Surfaces such as floors, walls, ceilings, and laboratory furniture remaining in place were surveyed for total residual contamination using detectors for both alpha and beta/gamma radiation. Surfaces also were surveyed for removable contamination using swipes.

Surveys were also performed of trenches resulting from the removal of sub-floor piping. Scan surveys and static surveys were performed. Particular attention was given to trench surveys in two adjacent laboratories, where the licensee identified damaged sections of pipe. In these trenches, surveys identified contamination of the soil by cesium-137 from licensed activities. The licensee amended their decommissioning plan to include characterization and remediation of the contaminated trenches in these two laboratories.

c. Conclusions

Surveys of the building were adequate. No safety concerns or violations were identified.

## VIII. Surveys of Outdoor Areas

### a. Inspection Scope

The inspectors observed sample collection and other surveys performed by licensee representatives during decontamination and decommissioning of outdoor areas, including removal of underground storage tanks.

### b. Observations and Findings

Inspectors observed decontamination and decommissioning activities performed in outdoor areas. These included entry into the Building 124 vault and removal of the waste storage tanks, the Building 83 tank area, post-deconstruction surveys of the ventilation exhaust stack, and surveys of ground and paved areas immediately adjacent to the facilities being decommissioned.

Licensee representatives were observed performing surveys of a waste water tank removed from the waste vault. Contamination levels of slightly more than 1000 disintegrations per minute (dpm) per 100 square-centimeters area (100 cm<sup>2</sup>) were identified inside the tank; however, such low levels did not affect the ambient dose rates in the area where the tank was placed. Personnel were prepared to for the low levels of contamination on the tank, and planned to decontaminate any areas that were greater than criteria for release for unrestricted use. Similar surveys were observed performed for other equipment removed from the vault.

Licensee representatives were observed collecting samples of wastewater from the one tank in which waste water from decontamination activities continued to be collected. Samples were sent to an off-site laboratory for analysis. In addition, licensee representatives attempted to collect soil and/or water samples from beneath the vaults. Because of the high water table in the area, this was not successful. Collection procedures were in accordance with licensee commitments.

Inspectors measured dose rates outside Building 124, which were found to be at normal background levels of less than 10 microR/hour and consistent with licensee measurements. Radiation levels measured adjacent to Building 124 and the waste water storage tanks were also at background levels.

### c. Conclusions

Decontamination and decommissioning activities of outdoor areas were performed in accordance with licensee commitments. No safety concerns or violations were identified.

## **XVIII. Radioactive Waste Management**

### a. Inspection Scope

Inspectors reviewed the licensee's procedures for disposal of radioactive waste generated during the decontamination and decommissioning of Building 124 and adjacent areas.

### b. Observations and Findings

Liquid radioactive waste was generated during decontamination activities by washing of equipment. Waste water was initially collected in one of the waste water tanks in the Building 124 vault. Liquid from the tank was tested and disposed of to the sewer. Dry low-level radioactive waste included items removed from Building 124 that could not be decontaminated, cleaning materials, disposable protective items such as gloves, contaminated soil removed from a damaged pipeline area, and other similar items. Inspectors observed items segregated and tagged as contaminated waste for disposal, and Sealand containers of contaminated waste materials in use and in storage at the site.

### c. Conclusions

Radioactive waste was disposed of in accordance with licensee procedures and the regulatory requirements. No safety concerns or violations were identified.

## **IX. Posting and Labeling**

### a. Inspection Scope

Inspectors reviewed the existing radiological conditions facility postings to determine if the decommissioning activities were posted in accordance with regulatory requirements.

### b. Observations and Findings

Confirmatory radiation level measurements were made with a Ludlum 19 microR survey meter. The facility was found to be appropriately posted in accordance with existing ambient radiation levels. The NRC Form 3 and other required postings were observed.

Containers of radioactive waste were appropriately marked and labeled. Contaminated items for transfer were also marked and labeled. Inspectors noted that postings within Building 124 were consistent with the existing radiation levels. In general, dose rates in the Radiologically Controlled Area were less than 2 millirem per hour (<2mrem/hr). The highest radiation levels identified, which were at the remote handling hood, were dose rates ranging from 3-5 mrem/hr. All radiation and radioactive materials postings were in accordance with regulatory requirements.

c. Conclusions

Posting and labeling practices were found to be consistent with regulatory requirements. No safety concerns or violations were identified.

## **X. Transportation**

a. Inspection Scope

Inspectors reviewed transportation and shipping records for materials sold to other licensees.

b. Observations and Findings

Shipping paperwork associated with materials sold to other licensees was reviewed for adequacy. The licensee verified that customers possessed acceptable licenses for ownership of this material prior to shipment. Records of transfer reviewed included a licensee report of a deviation that was identified when a contaminated glove box, which was described as having fixed contamination only, was identified by the customer to have internal removable internal contamination. No hazard to the public was created by this event since the radioactive material involved remained in the package during shipment and was discovered by the purchaser at the time of package opening.

c. Conclusions

Shipment of radioactive material was found to be consistent with the licensee procedures and regulatory requirements. No safety concerns or violations were identified.

## **XI. Independent and Confirmatory Surveys**

a. Inspection Scope

Inspectors performed independent surveys and confirmatory measurements to assess radiological conditions at the facility, and to verify the licensee's survey results.

b. Observations and Findings

Confirmatory and independent surveys were routinely conducted during the inspection process. These included direct radiation surveys using a Ludlum 19 for verification of Radiologically Controlled Area postings and to identify areas of significant radioactive material presence not otherwise identified by the licensee. Direct frisk measurements using a Ludlum 12 were made in both affected and unaffected areas to confirm licensee surveys. Direct frisk measurements were also conducted in conjunction those of the licensee for materials being classified, and for materials removed from the RCA. This

included segments of ventilation ducts, pipes, valves and other similar pieces equipment being remove from the facility.

A split liquid sample of Building 124 waste water holding Tank #1 was collected and analyzed by both ORISE, the NRC contractor, and Duratek, the licensee contractor. Comparison of this data using the criteria stipulated in Inspection Procedure 84750 indicates acceptable agreement between the split sample results. Additionally, the reported results confirm that radioactivity contained in this water is several orders of magnitude lower than the sewer release limits listed in Appendix B of 10CFR20.

c. Conclusions

Inspector measurements were in agreement with licensee measurements. No safety concerns or violations were identified.

## **XII. Exit Meeting**

a. Inspection Scope

Inspectors reviewed the findings of the inspection with licensee staff.

b. Observations and Findings

Inspectors met with licensee and contractor staff at the end of each site visit to review any findings resulting from the visit. The lead inspector conducted an exit meeting for the decommissioning phase inspection by telephone with the Radiation Safety Office and contractor representatives to review the findings of the inspection. The inspector stated that the licensee implemented the decommissioning activities as planned, and appropriately determined actions to be taken when unexpected problems were identified.

c. Conclusions

No safety concerns or violations were identified.

## PARTIAL LIST OF PERSONS CONTACTED

### Licensee

\*Michael Vala, RSO, Bristol-Meyers Squibb (BMS)  
John Frankowski, BMS  
Craig Woodard, CIH, CSP, Director, EHS, BMS  
Larry Gaines, BMS, Health Physicist (HP)  
Debbie Silva, BMS, HP  
Dan Whalen, BMS, Engineering

### Duratek, Inc.

\*Paul Ely, Duratek, Inc., On-site Manager  
Doug Kjos, Duratek, Inc., HP Tech  
Betty Kjos, Duratek, Inc., HP tech  
Bill Hoey, Duratek, Inc.

### TLG Services

\*Beverly Good, TLG Services

### State of New Jersey

Ed Truskowski, NJDEP

\* present at exit meeting by telephone 4/8/03