NRC FORM 591 PART 1
(6-1997)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY AND COMPLIANCE INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
E.R. Squibb & Sons, Inc.	REGION 1 US NUCLEAR REGULATORY COMMISSION 475 ALLENDALE ROAD KING OF PRUSSIA PA 19406-1415

REPORT NUMBER(S) 03005222/01-001, 03010750/01-001, 03033066/01-001

3. DOCKET NUMBER(S) 03005222, 03010750, 03033066	4. LICENSE NUMBER(S) 29-00139-02, 29-00139-04MD, 29-00139-08	5. DATE(S) OF INSPECTION May 8 - 10, 2001

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 inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied. _____ non-cited violation(s) were discussed involving the following requirement(s): _____

☒ 3. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which is required to be posted in accordance with 10 CFR 19.11.

29-00139-02
License condition 25 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents listed below the condition which includes the application dated February 18, 1997. Page 22, paragraph 12 of the application dated February 18, 1997 states, "Operational contamination surveys in R&D areas will be performed daily, as practical, by researchers when unsealed sources of radioactive material are used." Contrary to the above, contamination surveys were not always performed following use of unsealed materials. Specifically, contamination wipes surveys following use of [redacted] unsealed H-3 and C-14 in several laboratories were not performed

STATEMENT OF CORRECTIVE ACTIONS

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE	Michael Vala	Michael Vala	5/10/01
NRC INSPECTOR	Pamela J. Henderson	Pamela J. Henderson	5/10/01

NRC FORM 591 PART 1 (6-1997)

NMSS/RGN-I-003 DESIGNATED ORIGINAL/IE:07

E/24

APPENDIX A MATERIALS PROCESSOR/MANUFACTURER INSPECTION RECORD (IP 87111)							
REGION I							
Insp.Report#	01-001 01-001 01-001	License #	29-00139-02 29-00139-04MD 29-00139-08	Docket #	03005222 03010750 03033066		
Licensee Name	E.R. Squibb & Sons, Inc.						
Street Address	One Squibb Drive						
City, State, Zip	New Brunswick, New Jersey 08903-0101						
Location (Authorized Site) Being Inspected	New Brunswick, Lawrenceville, Pennington, and Hamilton, New Jersey						
Licensee Contact Name	Michael Vala	Phone #	(732) 519-2987				
Priority	-02 : 1	Program Code	03211	Description	Manufacturing and Distribution Broad-Type A		
	-04MD:3		02511		Medical Distribution		
	-08: 5		03510		Self-Shielded Irradiator		
Date of Last Inspection:	-02: May 17-19, 1999, -04MD: August 26-18, 1997 -08: November 14-18, 1994						
Date of This Inspection:	May 8 - 10, 2001						
Type Insp.	Announced	X	Special		Initial		
	Unannounced		Routine	X			
Next Inspection Date	-02-5/03; 04MD-5/06; -08-5/08	Normal		Reduced		Extended	X
Justification for change in normal inspection frequency:	-02: 99-001 Clear, 01-001 One SL4 violation -04MD: 97-001 Clear, 01-001 Clear -08: 94-001 Clear, 01-001 Clear						
Summary of Findings and Actions							
No violations, Clear 591 or letter issued		Non-cited violations					
Violation(s), 591 issued	X	Violation(s), letter issued					
Follow up on previous violations:	NA - No previous violations						
Inspector/Printed Name	Mark A. Sitek, Health Physicist, NMSB2						
/Signature	/RA/	Date	05/14/2001				
Inspector/Printed Name	Pamela J. Henderson, Senior Health Physicist, NMSB2						
/Signature	/RA/	Date	05/14/01				

Insp.Report#	**01-001 01-001 01-001**	License #	**29-00139-02 29-00139-04MD 29-00139-08**	Docket #	**03005222 03010750 03033066**
Approved/Printed Name		**John D. Kinneman, Chief, NMSB2**			
/ Signature		***/RA BY JUDITH A JOUSTRA ACTING FOR/***		Date	05/15/01

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY		
1.	**AMENDMENTS AND PROGRAM CHANGES**	
License amendments issued since last inspection, or program changes noted in the license.		
Amendment No.	Date	Subject
For 29-00139-02:		
96	**6/7/99**	**Change of RSO.**
97	**2/8/01**	**Increase possession limits of C-14, H-3, Ca-45, and S-35 for Pennington, NJ site.**
97 Corrected Copy	**2/13/01**	**Correct condition 10.C. to authorize use of licensed material in 6.S. through 6.X. at Pennington, NJ Site.**
For 29-00139-04MD:		
17	**11/9/99**	**Add H-3 and C-14 for distribution as research drugs to be used in FDA approved clinical trials.**
For 29-00139-08:		
2	**9/18/97**	**Decrease item 8.A. to read 2000 curies. Change item 9.A. to read "for use in J.L. Shepherd Mark 1 Model 25 irradiator."**
3	**6/14/99**	**Change of RSO.**

2.	**INSPECTION AND ENFORCEMENT HISTORY**
Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders.	
For 29-00129-02 - 99-001 and 97-001 were clear. For 29-00129-04MD - 97-001 and 94-001 were clear. For 29-00129-08 - Initial inspection 94-001 was clear.	

3.	INCIDENT/EVENT HISTORY

List any incidents or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.

The inspector checked ADAMS and NMED. One event report for the -02 license was identified. On July 19, 1999, the licensee identified that a package containing 4.9 mCi of I-131 was apparently missing. The package held two containers, each with one capsule of I-131 and was to be delivered to North Shore University Hospital. When the courier arrived to pick-up the package, it was determined to be missing and was later found to have been picked up by mistake earlier in the day by another courier. The package was located late on July 19, 1999 and recovered on July 20, 1999. A PN was issued on July 20, 1999.

The licensee's corrective actions included a change in procedure. The courier must have a purchase order number supplied by Squibb in order for Squibb to release the package. This ensures that the courier retrieves the correct package.

PART II - INSPECTION DOCUMENTATION

NOTE: References that correspond to each inspection documentation topic are in Inspection Procedure 87111, Appendix B, "Materials Processor/Manufacturer Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in this part are required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1.	ORGANIZATION AND SCOPE OF PROGRAM

Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use.

The RSO changed a month after the last inspection in May 1999. The RSO, Michael Vala, reports to the Director of Environmental Health and Safety (EHS), Craig Woodard, who reports to the Sr. Director of EHS, Susan Voight. The -02 Manufacturing and Broad Scope R&D license has 4 authorized locations of use: New Brunswick, Lawrenceville, Pennington, and Hamilton, New Jersey. All of the activities for the medical distribution -04MD license are at the New Brunswick, NJ location. All of the activities for the irradiator -08 license are at the Lawrenceville, NJ location. The licensee has approximately 700 authorized users. There is animal use at New Brunswick, Lawrenceville and Pennington including rodents, dogs and primates.

The licensee's manufacturing and distribution program has diminished in recent years. The licensee ultimately plans to eliminate manufacturing and distribution altogether and to shift their emphasis to R&D. They plan to change their -02 license to Broad R&D and terminate their -04MD license. They do plan to continue preparing and distributing C-14 and H-3 for human use metabolic research studies on the -02 license by applying for an exemption to **10 CFR 32.72(a)(2), in order to manufacture and distribute drugs containing byproduct material, pursuant to 10 CFR 32.72, to authorized recipients for human use research.**

New Brunswick

All of the licensee's manufacturing and distribution is done from their New Brunswick, NJ facility. Manufacturing and distribution is done in building 124. Manufacturing of Cr-51 ceased in November 2000, however the licensee still distributes Cr-51. They receive approximately 60 mCi of Cr-51 every 4 weeks from Nycomed Amersham in the UK. Manufacturing of Strontium/Rubidium generators (not byproduct material) ceased in April 2001. The only manufacturing at the time of the inspection was I-131 which they plan to stop by the end of June 2001. The licensee has been receiving 45-50 Ci of I-131 a week and processed it into oral solutions and capsules for medical distribution. Manufacturing occurs 2 - 3X per week on Mondays, Tuesdays and Thursdays. The licensee's main Radiation Safety Office is located in building 124. The licensee plans to decommission building 124 in the near future. The inspector discussed the need for the licensee to provide notification of their decision to cease activities in building 124 and the need for them to submit a decommissioning plan for NRC review. The licensee will relocate their Radiation Safety Office to either the Lawrenceville or Pennington sites during the last quarter of 2001.

Other than the manufacturing/distribution facilities in building 124, the New Brunswick location has approximately 20-30 other laboratories where radioactive materials are used including an iodination laboratory in building 80. Iodinations are performed infrequently, with the last use approximately one year ago. The group that has performed iodinations plans to move to the Lawrenceville location.

Radiosynthesis using C-14 and H-3 is also done in a laboratory in building 107 at New Brunswick. In addition to other work, this laboratory prepares H-3 and C-14 labeled compounds intended for human use metabolic research studies. The radiosynthesis lab will be moved to Lawrenceville in the second quarter of 2002.

The licensee has submitted an amendment request regarding their interim waste storage facility which was located in Building 81. With the exception of a mixed waste storage area and approximately 500 square feet of adjoining warehouse space, the building 81 waste storage area has been decommissioned in accordance with MARSSIM guidelines.

Building 122 is currently used to store radioactive waste for the facility.

Other buildings used for radioactive materials use in New Brunswick are buildings 105, 80, 83, and 92.

Lawrenceville/Princeton

The facility at Lawrenceville is a large connected building with several modules. Modules K and H are the primary areas where radioactive material is used. There are approximately 125 active laboratories at the facility conducting R&D and this number is expected to increase in the future. The most common R&D isotopes in use are C-14, H-3, P-32, P-33 S-35 and I-125. Iodinations have not been conducted for the last two years. Iodinations are restricted to a specific authorized laboratory. Waste is stored in two areas in the basement of the F module. One area contains only dry waste and the second area contains all other types of radioactive waste (liquids, liquid scintillation vials, etc.)

(b)(7)(F)

Pennington/Hopewell

Approximately 80% of all the R&D work at this site is done in building 21. There are approximately 90 active laboratories at the facility conducting R&D and this number is expected to increase in the future. The most common R&D isotopes in use are C-14, H-3, P-32, P-33 S-35 and I-125. Iodinations are not conducted at this facility. Waste is stored primarily in the basement of building 21 with smaller amounts being stored in buildings 10 and 3.

Hamilton

This facility had one clinical pharmacology scientist (Ph.D.) with a small support staff overseeing the use of H-3 and C-14 labeled compounds. In addition, RIA research, using prepackaged kits, is conducted to determine efficacy of drugs. This facility is located next to Hamilton Hospital where the H-3 and C-14 labeled compounds made by the radiosynthesis group at New Brunswick are administered to human research subjects as part of a joint research venture with Robert Wood Johnson Hospital. Waste at the Hamilton facility is stored in a separate room within a locked cage.

This inspection included visits to each of the four facilities described above.

2.	MANAGEMENT OVERSIGHT

Management support to radiation safety; Radiation Safety Committee; Radiation Safety Officer; program audits, including annual reviews; as low as is reasonably achievable (ALARA) reviews; control and supervision by authorized users.

The licensee's Radiation Safety Committee meets bimonthly. The inspectors reviewed Radiation Safety Committee meeting minutes from May 1999 to April 2001. The meetings were consistently held with a quorum of members including the senior management representative. The meetings focused on items appropriate to the program such as authorizations/renewals of users, deviation reports, results and corrective actions of internal and external audits, decommissioning issues, and licensing issues.

Radiation Safety staff generally conduct monthly audits of laboratories. Audit frequency is increased for users of higher activities or when contamination frequency or levels becomes a concern in a laboratory.

Annual audits of the licensee's radiation safety program were conducted in 1999 by QMI and in 2000 by NDL Organization. The inspector reviewed documentation of the 1999 and 2000 audits. The licensee formally documents corrective actions for each of the audit's findings.

The RSO believes that management is supportive of the radiation safety program.

Control and supervision of authorized users is as required.

3.	FACILITIES

Facilities as described; uses; control of access; engineering controls; calibration facilities; shielding; air flow:

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High radiation areas are locked, posted, monitored by area radiation monitors and have red alarming lights at the entrances and peripheries as appropriate.

Breathing air sampling is conducted in the following areas: manufacturing, waste storage, rooms housing ventilation ducts from manufacturing, and iodination facilities. The licensee exchanges rotameters every six months for calibration. Rotameters are sent to Alnor for calibration. Average readings indicate 1% of the DAC of $2E^{-8}$ uCi/ml for I-131 with occasional spikes in concentration.

The licensee also conducts continuous air sampling before and after the charcoal filters for manufacturing exhaust ventilation. There is also a radiation monitor in the manufacturing exhaust stack which alarms in the HP office.

4.	EQUIPMENT AND INSTRUMENTATION
Operable survey instruments; procedures; 10 CFR Part 21 procedures; process and storage systems.	
The inspectors observed, through sampling approximately 70 meters, that the licensee maintains and uses properly calibrated and functional survey instruments for the types and quantities of material in use. Instruments used by the health physics staff were verified to have been calibrated at least every six months and those in the possession of authorized users were observed to have been calibrated at least annually. The licensee maintains approximately 25 extra survey instruments to provide to users that have malfunctioning or inoperable meters. In addition, these meters are provided to individual lab groups during the annual calibration of their instruments.	

5.	MATERIAL USE, CONTROL, AND TRANSFER

Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material.

Orders for radioactive materials may only be placed by users after the approval of the Radiation Safety Staff through forms available on the licensee's LAN. The form must have Radiation Safety approval or the purchasing agent will not approve it for purchase. All radioactive materials purchases are done by one purchasing agent for all 4 of the licensee's locations of use.

Radioactive material is delivered to one receiving dock at each of the licensee's four locations of use. Receiving is done by a contractor (Pitney Bowes) at the licensee's Pennington and Lawrenceville facilities and by licensee staff at New Brunswick and Hamilton. Contractors are trained to identify packages containing radioactive materials and to place them in a specific location and to call Health Physics (HP) staff to receive the packages. According to loading dock personnel, since deliveries occur at specific times, HP staff are usually present when the packages arrive at the facility. An HP technician performs required surveys of packages, opens the package and verifies the contents, and then delivers packages to the researchers.

Outgoing packages of radioactive materials are prepared for shipment by HazMat trained personnel.

For outgoing deliveries for medical distribution, the licensee prepares a bill of lading to transfer the material to DelMed. DelMed takes responsibility as shipper and prepares shipping papers. DelMed delivers all packages from Boston to Baltimore on the East Coast. For deliveries of packages which do not require labeling going to other areas of the country, DelMed prepares shipping papers and UPS or FedEx makes deliveries.

6.	AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses.

VIOLATION - 29-00139-02

The licensee has committed that operational contamination surveys in R&D areas will be performed daily, as practical, by researchers when unsealed sources of radioactive material are used. Through observations and discussions with licensee personnel in laboratories, the inspectors determined that contamination surveys were not always performed following use of unsealed materials. Specifically, contamination wipe surveys following use of unsealed H-3 and C-14 in several laboratories were not performed. The laboratory workers stated that Health Physics staff performed wipe testing of their labs monthly and relied on these surveys to determine if contamination was present.

Health physics staff perform monthly surveys/audits of R&D laboratories and daily surveys of manufacturing/distribution areas.

To monitor dose to individual members of the public, the licensee monitors dose at their fenceline, performs air sampling of the manufacturing stack and samples liquid effluent from their New Brunswick site.

The inspector reviewed results of fenceline monitoring and determined that no dose to individual members of the public exceeds 100 mrem per year. The highest fenceline exposures are near building 122 where the fenceline is located near the building. Building 122 houses expired radioactive products and there is a high radiation area located within the building.

The inspector reviewed records of manufacturing stack releases. Average releases were 4 - 8% of Part 20 limit for I-131 of 2×10^{-10} uCi/ml with occasional spikes in activity.

The licensee performs breathing air sampling. See section 3 for full description. Average readings indicate 1% of the DAC of 2×10^{-8} uCi/ml for I-131 with occasional spikes in concentration.

Leak tests and inventories are conducted by the health physics staff every six months for sealed sources. Records were reviewed for calendar years 1999 and 2000. The inventory records indicate that the licensee possesses approximately 67 sealed sources, the majority of which are used as check sources. The remaining sources are used in gas chromatagraphs, for instrument calibration and in the two J.L. Shepherd Mark I irradiators.

Inventories of unsealed sources used for research and development are conducted monthly. Selected records were reviewed for calendar years 1999 and 2000. In general, the activities present were 10 to 20 percent of the limits specified on the license. The health physics staff rely on the authorized users to report the quantities in their possession. Each authorized user maintains a user log for each vial of material. The health physics staff provide standard inventory log sheets to each user for each vial of material. The inspectors visited approximately 30 different laboratories and observed that most researchers use the forms provided by the health physics staff and post them on the outside of the storage location of the material. Some individuals used computer based tracking while others relied on their experiment log books. The health physics staff plan to conduct quarterly spot checks of a sampling of authorized users' log books to ensure that the users are properly tracking and accounting for use of material under their control. In all laboratories visited, the researchers were able to locate the material under their control.

7.	TRAINING AND INSTRUCTIONS TO WORKERS

Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency situations; and supervision by authorized users.

Initial radiation safety training is provided to new workers prior to beginning work with radioactive material. Refresher training is scheduled on a frequent basis and is provided during staff meetings to ensure that all workers received the required retraining at least annually.

The inspector reviewed training records for workers who were interviewed during the course of the inspection. Interviews and observations of the workers indicated they were knowledgeable of Squibb routine and emergency procedures and NRC requirements. Records indicated that these workers were trained as required.

The inspector reviewed selected records of individuals who prepare packages containing radioactive material for transport and verified that HazMat training is provided every three years as required.

The inspector reviewed records of training for several irradiator users. The inspector randomly chose users indicated indicated by the irradiator use logs. Users had been trained as required.

The inspector noted that the licensee had done training on the Mallinkrodt extremity exposure incident for manufacturing staff.

8.	RADIATION PROTECTION

Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications.

The licensee performs thyroid bioassay for iodine (manufacturing), and urine bioassay for H-3 and C-14 (radiosynthesis laboratory). The licensee performs thyroid bioassay and has appropriate calibrated equipment to do so including a neck phantom and mock iodine check source. Thyroid bioassays are performed at least twice a week for all persons working in manufacturing. Urine (H-3 and C-14) samples are sent to RSI for analysis. Bioassay results indicate that readings are below the MDA for H-3 and C-14 and that no doses to the thyroid exceeding 10% of the allowable limits have been received since the last inspection received.

Maximum CDE 305 mrem Organ: Thyroid The calculated uptake was 0.282 uCi as a result of a contamination in the manufacturing area.

The licensee uses ICN to provide dosimetry.

Dosimetry is exchanged weekly (manufacturing), monthly (x-ray users), and quarterly (everyone else) dependent upon work duties.

Maximum whole body dose, DDE, for 2000 was 1.51 rem received by an individual who works in the manufacturing department. Maximum extremity dose, SDE, for 2000 was 19.2 rem received by an individual who also works in the manufacturing department.

Maximum whole body dose, DDE, for the first quarter of 2001 was 557 rem received by an individual who works in the manufacturing department. Maximum extremity dose, SDE, for the first quarter of 2001 was 10.8 rem received by an individual who also works in the manufacturing department.

See also the TI for 2800/031 attached.

The licensee receives approximately four to five written declarations of pregnancy annually. Workers are provided a copy of the licensee's policy during training which includes a summary of the applicable regulations, the workers' right (not requirement) to seek reassignment to activities that do not involve radioactive material, and a form for declaring their pregnancy. Declared pregnant females are offered the opportunity to speak to a counselor and/or physician to discuss the risks associated with exposure to the fetus. Over the course of the gestation period, the declared pregnant females' radiation badges are read every week. No one has ever approached the 500 mrem limit.

The licensee currently badges almost everyone who uses any radioactive materials at their facilities. They plan to reduce the number of dosimeters in the future.

9.	RADIOACTIVE WASTE MANAGEMENT

Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents and compactors; license conditions for special disposal method.

See section 1 for locations where radioactive waste is stored. The license segregates waste according to half life and also separates liquids, mixed wastes and deregulated scintillation vials. Waste at all facilities is picked up and consolidated for transfer to licensed waste disposal facilities.

The licensee has not used its compactors in approximately 5 years. Their dry waste is ultimately incinerated by Duratek who prefers to receive uncompacted waste which burns more efficiently. Since Duratek charges by the pound and not by the cubic foot, the licensee has no incentive to compact their waste.

Air effluent - The licensee consistently maintains release to less than 20% of the Part 20 limit.

Waste has been transferred for disposal approximately 2-3 times per year for the last several years. With the decommissioning of most of building 81 and the loss of this waste storage space, the licensee will have to transfer waste more frequently and believes they will transfer 4-5 times per year.

The licensee has four sewer collection tanks at the New Brunswick facility. The tanks are sampled prior to discharge to the sanitary sewer to ensure that the requirements of 10 CFR 20.2003 are met. To ensure that they get a representative sample of liquid effluent, the licensee aerates the tanks to mix liquid waste prior to sampling it.

There is no release of liquid radioactive waste to the sanitary sewer from the Lawrenceville, Pennington, or Hamilton sites. At these sites all liquid waste is collected and held for decay or eventual transfer.

10.	DECOMMISSIONING

Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted.

Records important to decommissioning are maintained in an identifiable location.

License condition No. 24 requires that the licensee submit a decommissioning funding plan to the NRC by June 1, 2001. See section 19.

11.	TRANSPORTATION
Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports.	
The licensee transports limited quantities and Type A quantities of radioactive materials. Persons preparing packages containing radioactive materials for transport have received HazMat training - see section 7. The inspector observed licensee staff preparing packages for distribution. Packages were surveyed and labeled as required.	

12.	NOTIFICATIONS AND REPORTS
Reporting and followup of theft; loss; incidents; overexposures; change in RSO; authorized user; and radiation exposure reports to individuals.	
The licensee reported a change in RSO in June 1999. See amendment No. 96 for the -02 license and amendment No. 3 for the -08 license. (The medical distribution license -04MD does not list an RSO.) In addition, the licensee reported one event concerning the -02 license (See section 3). On July 19, 1999, the licensee identified the loss of a package containing 4.9 mCi of I-131. The package was located the same day. Aside from the above, there have not been any reportable incidents.	

13.	POSTING AND LABELING
Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licenses material.	
The inspectors observed NRC Form 3 posted in appropriate areas at all of the licensee's facilities. The doors to rooms where radioactive materials are used were posted with "Caution Radioactive Materials" signs as required. In addition, containers of radioactive materials, waste, storage areas including refrigerators and freezers were labeled/posted as required.	

14.	INDEPENDENT AND CONFIRMATORY MEASUREMENTS

Areas surveyed and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date.

The inspectors used a Ludlum 14C with end window (NRC SN 33509) last calibrated on July 13, 2000 and an Eberline Model E-120 geiger counter with a thin end window (NRC 000906) last calibrated on July 13, 2000, to conduct independent measurements of the licensee's facility.

In R&D laboratory areas, the inspectors surveyed floors, benchtops, sinks, telephones, calculators and laboratory equipment. All readings were at background (0.02 - 0.04 mR/hr).

15.	VIOLATIONS, NON-CITED VIOLATIONS (NCVs), AND OTHER SAFETY ISSUES

State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.

For license No. 29-00139-02:
License condition 25 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in documents listed below the condition which includes the application dated February 18, 1997. Page 22, Paragraph 12 of the application dated February 18, 1997 states, "Operational contamination surveys in R&D areas will be performed daily, as practical, by researchers when unsealed sources of radioactive material area used." Contrary to the above, contamination surveys were not always performed following use of unsealed materials. Specifically, contamination wipe surveys following use of unsealed H-3 and C-14 in several laboratories were not performed.

No safety significant items were identified for license Nos. 29-00139-04MD or 29-00139-08.

16.	SOURCE OR DEVICE REVIEW

Device registration documents; changes; quality assurance/quality control program. Contact Material Safety Branch (NMSS/IMNS) and supervisor if unregistered equipment is identified.

NA - The licensee does not manufacture or distribute sealed sources.

17.	PERSONNEL CONTACTED

Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).
Use # to indicate individual present at entrance meeting.
Use * to indicate individual present at exit meeting.

Name	Title	Phone No.	In Person or By phone
#*Michael J. Vala, Jr.	Radiation Safety Officer	(732) 519-2987	In person
#*Larry Gaines	Manager, Radiation Safety, Pennington	(609) 818-3520	In person
#*Deborah A. Silva	Health Physics Supervisor, Lawrenceville	(609) 252-7119	In person
#*Jerry Bonanno	Environmental Health and Safety Specialist	(609) 252-4657	In person
#*John Frankowski	Senior Manager, Radiodiagnostics Operations	(908) 519-2341	In person
*Cynthia Salamon	Director QC/QA	(732) 519-2987	In person
*Marlene Rathnum	Associate Director Research Operations	(732) 519-2987	By phone
*Susan Voigt	Senior Director Environmental Health & Safety	(732) 519-2987	In person
*Bonnie Lubuiewski	Senior Administrative Associate, Health Physics	(732) 519-2987	In person
*Craig Woodard	Director, Environmental Health & Safety	(732) 519-2987	By phone
*Thomas Primm	Vice President, Strategy	(732) 519-2987	In person
Mark Ogan	Radiochemist	(732) 519-2987	In person
Sam Bonacorsi	Radiochemist	(732) 519-2987	In person

Frank Eads	Manufacturing Tech	(732) 519-2987	In person
Don Staback	QC Manager	(732) 519-2987	In person
Tim Harper, Ph.D.	Senior Research Investigator	(609) 252-4538	In person
Praveen Baliman, Ph.D.	Research Investigator	(609) 252-4538	In person
Nicholas McKinly	Supervisor, Loading Dock	(609) 252-4538	In person
John Pfeil	HP Lab Tech	(609) 252-4538	In person
Tony Hensperger	HP Lab Tech	(609) 252-4538	In person
Linda Stadnick	Research Scientist II	(609) 252-4538	In person
Becky Dendler	Research Scientist	(609) 252-4538	In person
Kurt Gregor	Junior Scientist	(609) 252-4538	In person
Debbie Lee	Research Scientist	(609) 252-4538	In person
Rebecca Penhalow	Research Scientist	(609) 252-4538	In person
Carrie Seachord	Research Scientist	(609) 252-4538	In person
Stephanie Kurt	Research Scientist	(609) 252-4538	In person
Khalid Senbatoul	Research Scientist	(609) 252-4538	In person
Marco Gottardis	Director of Oncology Discovery	(609) 252-4538	In person
Jieping Geng	Research Scientist	(609) 252-4538	In person
Steve Mortillo	Research Scientist	(609) 252-4538	In person
Steven Skoloda	Clinical Scientist	(609) 689-4000	In person
Haris Jamil, Ph.D.	Senior Research Scientist	(609) 818-3520	In person
Xiao Dong	Associate Scientist	(609) 818-3520	In person
Michele French	Associate Research Scientist	(609) 818-3520	In person
Neil Flynn	Associate Scientist	(609) 818-3520	In person
Tom Harrity	Senior Research Scientist II	(609) 818-3520	In person
Maureen Morgan	Research Scientist	(609) 818-3520	In person

Dan Longhi	Research Scientist	(609) 818-3520	In person

18.	PERFORMANCE EVALUATION FACTORS						
A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight.			Y		N	X
B.	RSO too busy with other assignments.			Y		N	X
C.	Insufficient staffing.			Y		N	X
D.	RSC fails to meet or functions inadequately.	N/A		Y		N	X
E.	Inadequate consulting services or inadequate audits conducted.	N/A		Y		N	X

REMARKS :(Consider the above assessment and/or other pertinent Performance Evaluation Factors (PEFs) with regard to the licensee's oversight of the radiation safety program)

The licensee's program appears sound. The licensee is proactive in identifying and correcting weaknesses in their program.

19.	SPECIAL CONDITIONS OR ISSUES
NONE	Special license conditions

License Condition 24 of the 29-00139-02 license requires submission of a decommissioning funding plan by June 1, 2001.

The licensee plans to request an extension for submission of the funding plan. The licensee plans to submit a decommissioning plan and decommission building 124 in the near future. After discussing this with NRC management (Frank Costello), it was decided that the licensee should wait until after building 124 is decommissioned before submitting the funding plan. That way the funding plan need only address the remaining facilities and the licensee's R&D program.

PART III - POST- INSPECTION ACTIVITIES	
1.	REGIONAL FOLLOWUP ON PEFs
None required.	

2.	DEBRIEF WITH REGIONAL STAFF
Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer.	
The inspector's branch chief reviews this inspection report.	

APPENDIX A - ATTACHMENT A			
RADIOACTIVE DRUG DISTRIBUTORS			
Licensee:	E. R. Squibb & Sons, Inc.	Date of Inspection:	May 8-10, 2001

1.	Indicate type of operation:					
	A.	Registered or licensed with U.S. Food and Drug Administration as a drug manufacturer:	Y	X	N	

APPENDIX A - ATTACHMENT A							
RADIOACTIVE DRUG DISTRIBUTORS							
Licensee:	E. R. Squibb & Sons, Inc.		Date of Inspection:	May 8-10, 2001			
	B.	Registered or licensed with State Agency as a Drug Manufacturer:	Y		N	X
2.	Licensee distributes:					
	•	Sealed Sources	Y		N	X
	•	Alpha and beta emitters	Y	X	N	
	•	Generators	Y		N	X
	•	Photon emitters	Y	X	N	
Basis for Findings:	Observations and discussions with licensee staff.					

3.	Licensee periodically reviews work of supervised individuals preparing drugs, and records kept to reflect work. [License condition(L/C)]	Y	X	N	
Basis for findings:	The licensee has bimonthly good manufacturing procedures meetings. The licensee had three manufacturing technicians at the time of the inspection				

4.	Radioactive drugs are measured (assayed) by direct measurement or combination of measurement and calculation before commercial distribution. [10 CFR 32.72(c)]	Y	X	N	
Basis for findings:	Observations and discussions with licensee staff.				

5.	Instrumentation Used to measure Radioactivity of Drugs					
	A.	List type of equipment used to assay alpha and beta particles:				
	NA- The licensee's beta emitting radionuclides also emit gamma (I-131). Therefore the licensee assays the gammas.					
	B.	Procedures for instrument use developed and implemented. [10CFR 32.72(c)]	Y	X	N	
	C.	Calibration tests performed before initial use, periodically, and following repair for accuracy, linearity, and geometry dependence, as appropriate for use of the instrument. [10 CFR 32.72(c)(1); L/C]	Y	X	N	
	D.	Adjustment to instrumentation made when necessary. [10CFR 32,72(c)(1); L/C]	Y	X	N	
	E.	Instruments are checked for constancy and proper operation at the beginning of each day of use. [10 CFR 32.72(c)(2); L/C]	Y	X	N	
Basis for findings:	Observations and discussions with licensee staff.					

6.	Transport radiation shield (on transfers for distribution) labeled with radiation symbol, "CAUTION [or DANGER] RADIOACTIVE MATERIAL", name, and quantity at specified date and time*: [10 CFR 32.72(a)(4)(I); L/C] *Time may be omitted for drugs with a half-life > 100 days.	Y	X	N	
Basis for findings:	Observations and discussions with licensee staff.				

7.	Syringes, vials, or other containers labeled with radiation symbol,"CAUTION [or DANGER] RADIOACTIVE MATERIAL," and an identifier to correlate with the information on the transport radiation shield label: [10 CFR 32.72(a)(4)(ii); L/C]	Y	X	N	
Basis for findings:	Observations and discussions with licensee staff. Licensee uses vials to contain capsules and liquid I-131. No syringes are distributed.				

TO ADVANCE TO NEXT SECTION OF FORM - PRESS PAGE DOWN KEY

APPENDIX A - ATTACHMENT B DECOMMISSIONING TIMELINESS INSPECTION ATTACHMENT			
Licensee:	E.R. Squibb & Sons, Inc.	Date of Inspection:	May 8-10, 2001

1.	COMPLIANCE WITH DECOMMISSIONING TIMELINESS RULE					
(NOTE: Repeat the answers given in Section 12 of the main body of the inspection record. The issues in subsequent sections are dependent on the answers to these questions.)						
	A.	License to conduct a *principal activity* has expired or been revoked:	Y		N	X
	B.	Licensee has made a decision to permanently cease *principal activities* at the entire site, or any separate buildings, or any outdoor areas, including inactive burial grounds:	Y		N	X
	C.	A 24-month duration has passed in which no *principal activities* have been conducted under the license at the site, or at any separate buildings, or any outdoor areas, including inactive burial grounds:	Y		N	X
	D.	If "Yes" to either A or B or C above:				
		(1) Identify Site/Bldg./Area:	Note: Licensee plans to cease manufacturing and distribution activities by June 2001 and to decommission Bldg. 124. Licensee will notify NRC of their decision to permanently cease principal activities in Bldg. 124 as required.			
		(2) Date of occurrence of A, B, or C:	B - TBD			
2.	NOTIFICATION REQUIREMENTS					
	A.	Licensee has provided written notification to U.S. NRC within 60 days of the occurrence of 1.A., 1.B., or 1.C. above.	Y		N	X
	If "Yes," date of notification:					
	B.	If the licensee is requesting to delay initiation of the decommissioning process, the licensee has provided written notification to NRC within 30 days of occurrence of 1.A., 1.B., or 1.C. above:	N/A	X	Y		N	

	If "Yes," date of notification:									
Basis for Findings:	Discussions with licensee staff.									
3.	DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS									
	A.	Licensee is required to submit a decommissioning plan per 10 CFR 30.36(g), 40.42(g), 70.38(g), or 10 CFR Part 72?	N/A		Y	X	N	
	If "No" to 3.A., answer the following items B - F:									
	B.	The decommissioning work scope is covered by current license conditions.			Y		N	
	C.	Decommissioning has been initiated within 60 days of notification to NRC, or NRC has granted a delay.			Y		N	
	D.	If licensee has initiated decommissioning, give date the decommissioning was initiated:						
	E.	If decommissioning has been completed, it was completed within 24 months of notification to NRC.	N/A		Y		N	
	F.	If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months of notification to NRC.	N/A		Y		N	
Basis for Findings:	Discussions with NRC management (Costello and Kinneman) have determined that a decommissioning plan for Bldg. 124 must be submitted.									
	If "Yes" to 3.A., answer the following items G - J:									
	G.	The decommissioning plan has been submitted to NRC within 12 months of notification.			Y		N	X		
	If "Yes," date of submittal:									
	If NRC approved, date of NRC approval:									
	H.	Has the licensee submitted an alternative schedule request?			Y		N	X		
	If "Yes," date of submittal:									
	I.	If decommissioning has been completed, it was completed within 24 months after approval of the decommissioning plan.	N/A		Y		N			
	J.	If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months after approval of the decommissioning plan.	N/A		Y		N			
Basis for Findings:	Discussions with licensee staff.									
Violations Identified, if any:	None.									

END

EXTREMITY EXPOSURE MONITORING
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