FORM 374
(9-89)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 84

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. E. R. Squibb and Sons, Inc. One Squibb Drive 2. P. O. Box 191 New Brunswick, New Jersey 08903-0191	In accordance with letter dated December 11, 1990, 3. License number 29-00139-02 is amended in its entirety to read as follows: 4. Expiration date April 30, 1997 5. Docket or Reference No 030-05222

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with Atomic Nos. 1-83 inclusive, except Strontium 90	A. Any	A. 5 curies per radionuclide and 1000 curies total
B. Iodine 131	B. Any	B. 150 curies
C. Molybdenum 99/Technetium 99m	C. Any	C. 500 curies
D. Any byproduct material with Atomic Nos. 1-83 inclusive, except Strontium 90	D. Any	D. 200 millicuries per radionuclide and 6 curies total
E. Hydrogen 3	E. Any	E. 5 curies
F. Carbon 14	F. Any	F. 4 curies
G. Sulfur 35	G. Any	G. 2 curies
H. Any byproduct with Atomic Nos. 1-83 inclusive, except Strontium 90	H. Any	H. Not to exceed 10 millicuries per radionuclide and 1 curie total
I. Hydrogen 3	I. Any	I. 40 millicuries
J. Carbon 14	J. Any	J. 40 millicuries
K. Phosphorus 32	K. Any	K. 100 millicuries
L. Sulfur 35	L. Any	L. 300 millicuries
M. Iodine 125	M. Any	M. 20 millicuries
N. Nickel 63	N. Plated sources in detector cells	N. Not to exceed 15 millicuries per source and 750 millicuries total

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
29-00139-02

Docket or Reference number
030-05222

Amendment No. 84

9. Authorized use:

A., B., and C. (1) Research and development as defined in 10 CFR 30.4.
(2) For possession use and processing incident to the manufacture of radiochemicals and radiopharmaceuticals.
(3) For storage prior to distribution of manufactured radiochemicals and radiopharmaceuticals.
(4) For packaging and distribution of manufactured radiochemicals and radiopharmaceuticals to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.

D. through N. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. A. Licensed material in Items 6.A., B., C. and N. may only be used at licensee's facilities at One Squibb Drive, New Brunswick, New Jersey.

B. Licensed material in Items 6.D., E., F., G., and N. may only be used at licensee's facilities at Route 206 and Provinceline Road, Lawrenceville, New Jersey.

C. Licensed material in Items 6. H. and N, may only be used at licensee's facilities, Princeton House, 905 Herrontown Road, Princeton, New Jersey.

D. Licensed material in Item 6.K., L., M. and N. may be used only at the licensee's facilities at 675 College Road East, Princeton Forrestal Center, Plainsboro, New Jersey.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee.

B. The Radiation Safety Officer for this license is Daniel K. Balkunow.

12. This license does not authorized commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR 31 or to persons exempt from licensing pursuant to 10 CFR 30.18.

13. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

14. Experimental animals administered licensed materials or their products shall not be used for human consumption.

15. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 29-00139-02
Docket or Reference number: 030-05222
Amendment No. 84

(15. Continued) CONDITIONS

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen 3; or

(ii) they contain only a gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for a[illegible]/sis by the licensee. Alternatively, tests for leakage and/or contaminat[illegible] may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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030-05222

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(Continued) CONDITIONS

16. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in 10 CFR 20.203(a)(1), the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols.

17. Detector cells containing a titanium tritide foil or a scandium tritride foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding that specified by the manufacturer.

18. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.

19. The licensee shall not acquire licensed material in a sealed source or in a device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

20. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

21. The licensee shall maintain and execute the response measures of his Radiological Emergency Contingency Plan submitted to the Commission on March 28, 1990. The licensee shall also maintain procedures as necessary to implement the plan. The licensee shall make no change in his Radiological Emergency Contingency Plan that would decrease the response effectiveness of the plan without prior Commission approval as evidenced by license amendment. The licensee may make changes to his Radiological Emergency Contingency Plan without prior Commission approval if the changes do not decrease the response effectiveness of the plan, and shall maintain records of changes that are made to the plan without prior approval for period of two years from the date of the changes and shall furnish the Chief, Nuclear Materials Safety Branch, Division of Radiation Safety and Safeguards, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, a report containing a description of each change within six months after the change is made.

22. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days and sulfur-35, scandium-46, strontium-85, and tin-113 for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
29-00139-02
Docket or Reference number
030-05222
Amendment No. 84

(Continued) CONDITIONS

23. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated February 28, 1989
B. Letter dated June 16, 1989
C. Letter dated October 4, 1989
D. Radiological Contingency Plan dated March 28, 1990
E. Letter dated May 17, 1990
F. Letter dated May 24, 1990
G. Letter dated July 24, 1990
H. Letter dated April 15, 1991
I. Letter dated November 25, 1991
J. Letter dated December 11, 1990
K. Letter dated March 23, 1992
L. Letter dated May 8, 1992

Date JUN 2 6 1992

For the U.S. Nuclear Regulatory Commission
Original Signed By:
By Francis M. Costello
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

JUN 2 6 1992

License No. 29-00139-02
Docket No. 030-05222
Control No. 114080

E. R. Squibb & Sons, Inc.
ATTN: Larry Gaines
One Squibb Drive
P. O. Box 191
New Brunswick, New Jersey 08903-0191

Dear Mr. Gaines:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

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ML 10

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Francis M. Costello

Francis M. Costello, Chief
Research, Development and
Decommissioning Section
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 84
2. Requirements for Materials Licensees

DRSS:RI
Dimitriadis/men
06/25/92

DRSS:RI
Costello
06/26/92

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Bristol-Myers Squibb Company
Pharmaceutical Group Technical Operations
One Squibb Drive P.O. Box 191 New Brunswick, NJ 08903-0191 201 519-2000

MS 16
K8

May 8, 1992

Mr. A. Demitriadis
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

RE: LICENSE NO. 29-00139-02
DOCKET NO. 030-05222
CONTROL NO. 114080

AMENDMENT REQUEST

Dear Mr. Demitriadis:

As discussed, attached is the additional information you had requested concerning the Bristol-Myers Squib amendment request dated December 11, 1990, the NRC information request (Docket No. 030-05222; Control No. 114080) and the Bristol-Myers Squibb response dated March 23, 1992.

Sincerely,

Daniel K. Balkunow
Radiation Safety Officer

DKB:bl

Attachment

cc: Mr. J. P. Gresh
Health Physics Staff
RSC

114080

MAY 13 1992

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NRC Request A, (February 18, 1992):

A brief statement of why the increase is necessary. The particular isotopes which necessitate the increase should be stated. The volume of contaminated waste to be produced should be estimated.

Response (March 23, 1992):

It will enable us to include five additional radionuclides that produced from 300-500 ft^3 of low-level radioactive waste annually in the storage and decay process. These nuclides are essential in our research and development operation. They include:

Nuclide	T½
^{35}S	87 days
^{46}Sc	83.8 days
^{85}Sr	65.2 days
^{88}Y	106.6 days
^{113}Sn	115 days

Future R&D projects most likely will include other nuclides that would fall within the 65- to 120-day T½ time frame.

Additional information on last point of response to NRC Request A (May 8, 1992):

Listed below is the projected amount of waste by the number of drums of all categories that could possibly be stored in an interim waste storage facility. These numbers are extremely conservative and the actual numbers will be dependent upon:

- The overall continued expansion of radioactive material users
- Revision of the storage and decay program to include radionuclides with half lives of 65 days to 120 days
- Limited access to a disposal facility for some categories of waste
- Federal, state and local regulatory pressures

BRISTOL-MYERS SQUIBB RADIOACTIVE WASTE GENERATION
Projection for 1993 through 1998
Number of 55-Gallon Drums

Waste Category	1993	1994	1995	1996	1997	1998
Dry Waste	137	150	161	169	176	184
Absorbed Liquid	137	150	161	169	176	184
Animal Carcasses	231	252	273	285	297	311
Aqueous Vials	5	5	5	6	6	6
Total Drums Per Year	510	557	600	629	655	685
Cumulative Total Drums	510	1069	1671	2302	2960	3648

NRC Request D, (February 18, 1992):

A description of the instrumentation and the monitoring procedure that will be used to determine that the waste is free of radioactive contamination at the end of the storage period. This must include an explicit statement of the MDA which will be achieved.

Response (March 23, 1992):

The instrumentation used to determine that the waste is free of radioactive contamination will be the most sensitive detector that is designed for the measurement or detection of the types of radiation associated with the radioactive waste being held for decay.

After 10 or more half lives have occurred, the waste will be removed from storage, the waste container opened and the contents will be monitored for residual contamination in a low background area.

If any detectable activity above background is noted, the radioactive material and generator will be identified, the waste repackaged and returned to storage.

Additional Information (May 8, 1992):

The detectors/monitoring equipment that will be used to monitor for residual contamination will have an MDA/LLD sensitive enough to detect and comply with the recommended "Beta Gamma" contamination levels described in Table 1 of the NRC "Guidelines for decontamination of facilities and equipment prior to release for unrestricted use or termination of licenses for byproduct, source or special nuclear material."

Examples of detectors/equipment and anticipated MDA/LLD that will be used for final surveys are as follows:

look at Reg. Guide 1.86

DIRECT SURVEY INSTRUMENTATION		
Type of Radiation	**Instrumentation***	**Anticipated MDA/LLD**
Low Energy β (S^{35})	Eberline HP100A gas proportional	800 dpm/100 cm^2
Low Energy γ (I^{125})	Eberline LEG-1	5000 dpm/100 cm^2
Medium to High Energy γ (I^{131}, Sn^{113})	HP210 Pancake	5000 dpm/100 cm^2
Medium to High Energy γ (I^{131}, Sn^{113})	μR meter	10 μR/hr
REMOVABLE SURVEY INSTRUMENTATION		
Low Energy β/γ (S^{35}, I^{125})	Liquid Scintillation Counter	25 dpm/100 cm^2
Medium to High Energy γ	Solid Scintillator or Pancake Probe	100 dpm/100 cm^2

*or equivalent

ML 10 114080

CONVERSATION RECORD

TIME 4:35pm | DATE 4/15/92

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Daniel Balkanow	Bristol-Meyers-Squibb	201-519-2009 ext-2451

SUBJECT: Amendment No. 82

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Q1.) Do they want 120 days or less (or) do they want the 5 isotopes listed in their response to be listed on their license?

A1.) They want everything with T1/2 of 120 days or less. period.

Q2.) We need ~~an~~ information and an explicit statement of the MDA of the instrumentation which will be used to achieve the goals outlined for decay-in-storage.

ACTION REQUIRED

RESPONSE TO DEFICIENCY Phone Call.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
DIMITRIADIS	A. Dimitriadis	4/15/92

ACTION TAKEN

SIGNATURE	TITLE	DATE

MS-16
K-8

Bristol-Myers Squibb Company
Pharmaceutical Group Technical Operations
One Squibb Drive P.O. Box 191 New Brunswick, NJ 08903-0191 201 519-2000

2451
908-519-2451

March 23, 1992

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

ATTN: Mr. Francis M. Costello, Chief
Research, Development and Decommissioning Section
Division of Radiation Safety and Safeguards

RE: LICENSE NO. 29-00139-02
DOCKET NO. 030-05222
CONTROL NO. 114080

Dear Mr. Costello:

As requested, attached is the additional information required in your letter dated February 18, 1992, concerning the Bristol-Myers Squibb 1990 amendment for modification to the decay and storage program, in conjunction with state mandated interim waste storage.

Sincerely,

Daniel K. Balkunow
Radiation Safety Officer

DKB:bl

cc: L. Gaines
J. P. Gresh
RSC

'92 MAR 25 P1:07
RECEIVED-REGION 1

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114080
MAR 25 1992

NRC Request A.:

A brief statement of why the increase is necessary. The particular isotopes which necessitate the increase should be stated. The volume of contaminated waste to be produced should be estimated.

Response:

As you are aware, we are currently authorized by the NRC to hold radioactive materials with a physical half life of < 65 days for decay in storage before disposal in ordinary trash, provided: (1) material is held for a minimum of 10 half lives; (2) it is surveyed and found it to be less than background; (3) all radiation labels are removed or obliterated; and (4) records are maintained of the final survey results.

The State of New Jersey has also authorized us to hold radioactive material with a physical half life of < 300 days for decay in storage before disposal as ordinary trash under the same conditions identified above by the NRC.

(1) We wish to include radioactive materials with physical half lives of $\leq$ 120 days in our storage and decay program for the following reasons:

- There will be no approved burial site in the State of New Jersey or our Compact for disposal of radioactive waste beginning January 1, 1993.
- The three existing disposal sites will no longer be available to radioactive waste generators outside their Compacts and/or States in which the burial sites reside.
- To significantly reduce the amount of space necessary during the interim storage period.
- To reduce the volume of radioactive waste that will be stored during the interim storage period.
- It will enable us to include five additional radionuclides that produced from 300-500 ft^3 of low-level radioactive waste annually in the storage and decay process. These nuclides are essential in our research and development operation. They include:

Nuclide	T½
^{35}S	87 days
^{46}Sc	83.8 days
^{85}Sr	65.2 days
^{88}Y	106.6 days
^{113}Sn	115 days

Future R&D projects most likely will include other nuclides that would fall within the 65- to 120-day T½ time frame.

NRC Request B.:

A copy of the instructions which will be provided to employees concerning the segregation of radioactive waste. These procedures shall provide a high degree of assurance that long-lived isotopes will not be included with those of shorter half-life and will be adequate to assure that the waste is properly labelled or identified, especially with regard to isotope.

Response:

Attached is an operating procedure designed to provide guidance to employees who will generate waste which must be segregated by form and half life (T½) [see Attachment 1].

NRC Request C.:

A description of the records that will be maintained and/or the labelling that will be used to track and identify the waste as it is placed in storage and removed for disposal.

Response:

All containers that are to be placed in interim storage will be labelled and identified with the following information:

a) Isotope
b) Activity in millicuries
c) Date
d) Half life of radionuclide(s) the container holds
e) Date placed in storage (may be the same as c)
f) All containers will be marked with conventional radioactive warning labels
g) Identification number or bar code

Radioactive waste placed in storage will be identified by drum number, waste form and any other information that might be needed for tracking purposes. This information will be maintained in some type of log, be it a computer data acquisition system or an actual book.

NRC Request D.:

A description of the instrumentation and the monitoring procedure that will be used to determine that the waste is free of radioactive contamination at the end of the storage period. This must include an explicit statement of the MDA which will be achieved.

Response:

The instrumentation used to determine that the waste is free of radioactive contamination will be the most sensitive detector that is designed for the measurement or detection of the types of radiation associated with the radioactive waste.

After 10 or more half lives have occurred, the waste will be removed from storage, the waste container opened and the contents will be monitored for residual contamination in a low background area.

If any detectable activity above background is noted, the radioactive material and generator will be identified, the waste repackaged and returned to storage.

NRC Request E.:

A description of the containers in which the waste will be stored and an evaluation that they are appropriate to the waste form and are likely to survive the proposed storage interval.

Response:

All containers used for the storage of this radioactive waste will be DOT 17H steel containers with standard 7A specification. In order to maintain the life expectancy of the containers, they will be stored in an environment whose temperature and humidity are regulated to avoid the extremes of these parameters.

NRC Request F.:

A description of the storage facility, including security and fire protection features and data, demonstrating that it is large enough to hold the expected volume of waste for a reasonable time period into the future, and adequate to protect the waste containers from deterioration due to environmental conditions.

Response:

The facility will be a 14,000 sq. ft. single-story metal structure with the potential for future expansion. The building is located on the New Brunswick site. It has been designed to store raw waste forms for a period of seven years and will include volume reduction applications, including but not necessarily limited to a storage and decay program, compaction and segregation.

A fire protection system will be installed that will encompass the potential fire hazard associated with this particular type of waste and in accordance with NFPA and applicable New Jersey uniform construction codes.

Security of the building will be designed to limit access and egress of only authorized personnel. The proposed security monitoring system will be capable of providing surveillance when the building is not occupied.

All of the building areas that are to be inhabited by operational personnel will have a one-pass air system which will be exhausted through appropriate filters before being released into the general environment. The drum storage area will be equipped with an emergency auxiliary exhaust system that if necessary can be bypassed to provide a true one-pass recirculating system. In any mode, the ventilation system will exhaust to the general environment through appropriate filters.

All exhausted air from the building will be properly monitored to ensure all releases are in compliance with NRC regulatory requirements.

The temperature and humidity within the facility will be controlled to provide a comfortable level for operational personnel, while at the same time achieving a suitable environment appropriate for the long-term storage of various forms of radioactive waste, that will be stored in sealed radioactive waste storage container.

Remote area radiation monitors will be located throughout the facility where appropriate.

All activities involving the processing and storage of radioactive materials at this facility will be conducted in accordance with Bristol-Myers Squibb's radiation safety program, under the control of the Radiation Safety Officer and the Radiation Safety Committee.

BRISTOL-MYERS SQUIBB COMPANY
STANDARD OPERATING PROCEDURE
FOR
GOOD MANUFACTURING PRACTICES

BMS-PG 457

Department: Health Physics		Subject: Radioactive Waste - Segregation Instructions		
Procedure No: GRP-21	New Procedure [X]	Revised Procedure [ ]	Replaces Procedure # of / /	Originator D. K. Balkunow
Reviewed By: L. Gaines	H.P. Approval D. K. Balkunow / /			Effective Date / /

I. PURPOSE

To provide a uniform procedure for the segregation of radioactive waste within designated parameters of half life.

II. RESPONSIBILITY

It is the responsibility of all generators to segregate their radioactive waste according to half life (T½) and waste form.

III. PROCEDURE

A. Segregate all radioactive waste with T½ less than a 120 days

Under no circumstances should radioactive waste with a half life greater than 120 days be combined with waste whose T½ is less than 120 days.

B. Obtain the appropriate laboratory radioactive waste containers to hold the particular waste form (e.g., Category "R", "W", "L", etc.).

C. If you intend to generate radioactive waste that could result in material with a T½ less than 120 days and T½ greater than 120 days, obtain a suitable number of containers to successfully achieve the segregation task.

D. Add radioactive waste to the container(s) according to the procedure outlined for the particular waste form insuring that waste with a T½ less than 120 days is placed in containers designated for that particular half life and waste form.

E. Record the radioactivity, date of disposal, isotope and half life on the Radioactive Waste Disposal Record Card(s).

F. When full, properly seal and remove the container to the radioactive waste consolidation area.

BMS-PO 457

Department: Health Physics		Subject: Radioactive Waste - Segregation Instructions		
Procedure No: GRP-21	New Procedure [X]	Revised Procedure [ ]	Replaces Procedure # of / /	Originator D. K. Balkunow
Reviewed By: L. Gaines	H.P. Approval D. K. Balkunow / /			Effective Date / /

VI. WASTE CONSOLIDATION PROCEDURE

A. Responsible waste consolidation personnel will accept the segregated waste if:

1. The laboratory radioactive waste container used is appropriate.
2. Waste material is in a sealed clear 4-mil plastic bag or other appropriate container.
3. No mixed waste forms are evident.
4. Radioactive Waste Disposal Record Card is properly and legibly completed and indicates that the T½ of the materials are within designated parameters.
5. Lids are securely fit onto container.
6. No surface of the laboratory radioactive waste container exceeds 30 mR/hr.

B. If the container is found to be acceptable based upon above monitoring procedure, the responsible waste person will authorize the transfer of waste to the 55-gallon drum designated for the appropriate radioactive material half life (T½). Prior to transferring sealed bags, the room number from which the waste was generated must be recorded on the plastic liner or equivalent waste form container.

C. The Radioactive Waste Disposal Record Card from each lab container must be removed from the 5-gallon cover and attached to the 55-gallon drum in which the waste is being discarded. Only nuclides with suitable half lives shall be placed into the same 55-gallon waste drum.

D. When the 55-gallon drum is filled, the responsible waste person will transcribe the information from each lab container record card onto a final Waste Disposal Record Card attached to the cover of the 55-gallon drum. The amount of activity for each isotope may be totalled and transcribed as a single entry after allowing for decay to a common date (the date the drum is scheduled for shipment or placed in storage).

BRISTOL-MYERS SQUIBB COMPANY
STANDARD OPERATING PROCEDURE
FOR
GOOD MANUFACTURING PRACTICES

BMS-PG 457

Department: Health Physics		Subject: Radioactive Waste - Segregation Instructions		
Procedure No: GRP-21	New Procedure [X]	Revised Procedure [ ]	Replaces Procedure # of / /	Originator D. K. Balkunow
Reviewed By: L. Gaines	H.P. Approval D. K. Balkunow / /			Effective Date / /

E. Label each 5-gallon Radioactive Waste Disposal Record Card with the drum number of the 55-gallon waste container in which its contents were discarded.

F. Place all Radioactive Waste Disposal Record Cards which were removed from the 5-gallon containers in an envelope and maintain on file.

G. Secure the 55-gallon waste consolidation container with a bolt and ring.

H. Remove to a staging area in preparation for removal by a contractor, for further processing/compaction or for storage in the interim waste storage facility.

CONVERSATION RECORD

TIME 14:29 | DATE MARCH 19, 1992

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau etc.)	TELEPHONE NO.
DAN BULKANOW	BRISTOL-MYERS SQUIBB	

SUBJECT: Amendment no. 3.

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Needs an extension for reply to deficiency letter.

I gave him an extension.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
DIMITRIADI	[signature]	3/19/92

ACTION TAKEN

SIGNATURE	TITLE	DATE

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FEB 18 1992

License No. 29-00139-02
Docket No. 030-05222
Control No. 114080

E. R. Squibb and Sons, Inc.
Squibb Institute for Medical Research
ATTN: Daniel K. Balkunow
Radiation Safety Officer
One Squibb Drive
P. O. Box 191
New Brunswick, New Jersey 08903-0191

Dear Mr. Balkunow:

This is in reference to your application dated December 11, 1990 to amend License No. 29-00139-02.

Please describe your procedures for your decay-in-storage program in more detail. We need some additional information before we can process your application.

Please describe the following:

a. A brief statement of why the increase is necessary. The particular isotopes which necessitate the increase should be stated. The volume of contaminated waste to be produced should be estimated.

b. A copy of the instructions which will be provided to employees concerning the segregation of radioactive waste. These procedures must provide a high degree of assurance that long-lived isotopes will not be included with those of shorter half-life and must be adequate to assure that the waste is properly labelled or identified, especially with regard to isotope.

c. A description of the records that will be maintained and/or the labelling that will be used to track and identify the waste as it is placed in storage and removed for disposal.

d. A description of the instrumentation and the monitoring procedure that will be used to determine that the waste is free of radioactive contamination at the end of the storage period. This must include an explicit statement of the MDA which will be achieved.

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02/14/92
ML 10

e. A description of the containers in which the waste will be stored and an evaluation that they are appropriate to the waste form and are likely to survive the proposed storage interval.

f. A description of the storage facility, including security and fire protection features and data, demonstrating that it is large enough to hold the expected volume of waste for a reasonable time period into the future, and adequate to protect the waste containers from deterioration due to environmental conditions.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I office and refer to Mail Control No. 114080. The reviewer for this licensing action is Anthony Dimitriadis. If you have any technical questions regarding this deficiency letter please call the reviewer at (215) 337-6953.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:
Francis M. Costello

Francis M. Costello, Chief
Research, Development &
Decommissioning Section
Division of Radiation Safety
and Safeguards

FMC

RI:DRSS
Dimitriadis/gc
02/15/92

RI:DRSS
Costello
02/17/92

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02/14/92

030-05222

Bristol-Myers Squibb Company
Pharmaceutical Group Technical Operations
One Squibb Drive P.O. Box 191 New Brunswick, NJ 08903-0191 201 519 2000

December 11, 1990

Log Feb. 13
Remitter
Check No. 551548
Amount 150
Category 3A
Fee AMD
Check
Empl.

Mr. Francis Costello
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

RE: License Amendment
License #29-00139-02

Dear Mr. Costello:

This is a letter to request an amendment to E. R. Squibb & Sons radioactive material license to reflect the following items:

1) Dr. A. Tobia will no longer be a member of the Radiation Safety Committee and has been replaced by Mr. Robert Endries. Attached is Mr. Endries' biographical profile.

2) Ms. Christine M. Tuday, currently an alternate member of the Radiation Committee, will replace Dr. P. Fernandes on the Committee. Attached is Ms. Tuday's biographical profile.

3) Mr. William H. Gaylord III has been appointed as a member of the Radiation Safety Committee. Attached is Mr. Gaylord's biographical profile.

4) Currently, E. R. Squibb & Sons is licensed to store and decay radionuclides with half lives of 65 days for a minimum of 10 half lives, monitor for any residual radioactivity and if acceptable, dispose of as nonradioactive trash. In order to aid in the future reduction of radioactive waste volume, it would be more advantageous to our operations if the 65 day half life radionuclide criteria was changed to include radionuclides with half lives of 120 days. Would you please amend our license to include radionuclides with half lives of 120 days.

11 1080

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5) The current individual possession limit for Hydrogen-3 at Squibb's facilities in Lawrenceville, NJ and 675 College Road East, Princeton Forrestal Center, Plainsboro, NJ, is two curies. Please increase this limit from two to five curies (Part 6, Section E). In addition, please increase the "total possession" limit for these facilities from the current five to six curies (Part 6, Section D).

I trust this information is adequate and clear. Should you have any questions regarding the above requests, please contact me.

Included is a check for $180.00 to cover the fee for the license amendment.

Daniel K. Balkunow
Radiation Safety Officer
Health Physics Department

DKB:bl

dkb\license.amd

cc: Mr. L. Gaines
Mr. J. P. Gresh
Ms. D. Silva
R.S.C.

Attachments (4)

ROBERT H. EMERELS

BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NEW JERSEY 08540
609-921-5700

EXPERIENCE

Vice President - Senior Counsel Pharmaceutical Group Technical Operations and Human Resources	1990 - Present

BRISTOL-MYERS COMPANY
NEW YORK, NEW YORK

Vice President - Licensing Counsel Science and Technology Group	1988 - 1990
Vice President - Counsel U.S. Pharmaceutical Group	1986 - 1988
Vice President - Counsel Bristol Laboratories Division	1974 - 1986
Counsel Westwood Pharmaceuticals	1972 - 1974
Staff Attorney Bristol Laboratories	1966 - 1974

STATE OF NEW YORK
NORWICH, NEW YORK

Confidential Clerk	1965 - 1966

EDUCATION

LL.B.	Syracuse University College of Law International Legal Studies	(b)(6)
A.B.	Cornell University Economics	

ROBERT N. ENDRES

BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NEW JERSEY 08540
609-921-5720

ARMED FORCES

U.S. Marine Corps	Captain (USMCR)	1958 - 1962

PROFESSIONAL AFFILIATIONS

Bar of the State of New York	Admitted 1965
Pharmaceutical Manufacturers Association - Law Section	1974 to date
American Bar Association	
New York Bar Association	

COMMUNITY AFFILIATIONS

Board of Visitors, Syracuse University College of Law	
Member	1974 to date
Vice Chairman	1983 to date
Annual Giving Chairman Syracuse University College of Law	1984 - 1986

Christine M. Todaro
(b)(6)
Work: (609) 921-5107
Home: (b)(6)

EDUCATION

(b)(6)

B.S. Biological Sciences
New York Institute of Technology
Old Westbury, NY
Cum Laude

EMPLOYMENT

1982 - Present — Bristol-Myers Squibb Pharmaceutical Research Institute
Lawrenceville, NJ
Microbial Molecular Biology

1987 - Present — Assistant Research Investigator
Primary Responsibilities
- Isolating of a wide variety of microorganisms from environmental products.
- Supervising world wide sample collection.
- Providing pure cultures to screening group.
- Maintaining soil importation permits by reporting to U.S. Department of Agriculture.
- Acting as departmental safety officer.
- Member Bristol-Myers Squibb Corporate Radiation Safety Committee

1982 - 1987 — Research Associate
Primary Responsibilities
- Screening microorganisms for targeted activities in anti-infective drug discovery program.
- Optomizing fermentation conditions to enhance activity.
- Performing preliminary organic extractions and chromatographic characterization.

1987 - Acting as temporary Curator for the Squibb Culture Collection - Training new curator.

1980-1982 — National Starch and Chemical Corporation
Bridgewater, NJ
Natural Products Division

Technical Assistant
Primary Responsibility
- Chemical modification of various types of starch to optimize commercially useful properties.
- Organic synthesis and characterization.
- Trouble-shooting a compound used in the pilot plant.

1979-1980 Children's Hospital Harvard Medical School
Boston, MA

Collaboration of Cell Biology - Endocrinology
Juvenile Diabetes Research Division

Research Assistant
Primary Responsibilities
- Radiolabelling, purifying and assaying of pancreatic and other hormones.
- Isolating and characterizing of human proinsulin and human antibodies to insulin.
- Trouble-shooting iodination procedures.
(attended Radioisotope handling course, Harvard School of Public Health)

1978-1979 Hempstead General Hospital
Hempstead, NY

Clinical Laboratory Intern
Primary Responsibilities
- Performing diagnostic assays in all areas: manual bench chemistry, special chemistry (radioimmunoassay) hematology, blood bank, serology, and microbiology. Hired as part-time staff during rotation.
- Phlebotomy.

PROFESSIONAL SOCIETY

American Society for Microbiology

ACCOMPLISHMENTS

My microorganism isolation work has lead to the following Bristol-Myers Squibb anti-infective compounds for which patents are applied:

Scopularin
Culpin No. 4,914,245
Peptifluorin
Neopeptifluorin

WILLIAM H. GAYLORD III

[illegible]

OBJECTIVE

General Facility Administration and Research Administration management

SUMMARY

[illegible] responsibility in Facilities Administration for multiple departments providing services covering fifteen different locations. Financial control and management of services and supplies in excess of $8 million, capital control in excess of $1.5 million per year and manpower supervision of fifty. In addition, significant responsibilities include compliance with Federal, State and Local regulations covering hazardous waste disposal and medical waste disposal

EXPERIENCE

BRISTOL-MYERS SQUIBB, Princeton, New Jersey. 1985 to Present
(formerly Squibb Corporation)

FACILITY SERVICES MANAGER March 1987 to Present
Worldwide Facilities Administration

Facility and administrative management, expense and capital budget preparation and financial control for services to Squibb world headquarters and 19 satellite facilities. Services include Research Laboratory support, in-Plant printing and reprographics, In-Plant micrographics, inventory control for supply stores and hazardous waste disposal compliance and management. Responsible for the conduction of site approvals for disposal facilities, contract negotiations, insurance evaluations and assurance of Legal review.

RESEARCH SERVICES MANAGER June 1985 to March 1987

Management of support services to Research and Development, including preparation of sterile culture media, sterile glassware, decontamination of patnological agents and glassware washing services. Provide consumable materials for research use through Research Supply Store. Supervision of 17 union employees.

STATE OF CONNECTICUT, Newtown, Connecticut. 1984 to 1985
Fairfield Hills Hospital

PHYSICIAN ASSISTANT INTERNAL MEDICINE

Responsible for evaluation and treatment of acute and chronic medical problems in hospitalized patients. Performance of physical examinations, medical histories and evaluation of diagnostic tests under supervision of physician. Acted as infection control coordinator responsible for identification, treatment and prevention of infectious outbreaks in hospitalized population.

(b)(6)

GUILFORD BOARD OF EDUCATION, Guilford, Connecticut
Guilford High School

Responsible for teaching advanced inorganic, advanced organic and general [illegible], [illegible] to [illegible] college bound students per year. Also, responsible for chemical preparation of laboratory experiments and Departmental safety program and procedures.

EDUCATION

[illegible] University, New Haven, Connecticut; (b)(6)

Bachelor of Science, Southern Connecticut State University, New Haven, Connecticut (b)(6)

CERTIFICATION

Physician Assistant, National Commission on Certification of Physician Assistants, Inc. 1981

Teaching Certificate: Biology, Chemistry, General Science. Connecticut State Board of Education. 1978.

CPR Instructor: Red Cross and American Heart Association. 1986

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 2
FEE CATEGORY: 3A
EXP. DATE: 19890331
FEE COMMENTS:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: E. R. SQUIBB & SONS, INC.
RECEIVED DATE: 901213
DOCKET NO: 3005222
CONTROL NO.: 114080
LICENSE NO.: 29-00139-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 150.00
CHECK NO.: 5454R

3. COMMENTS

SIGNED TMH
DATE 091791

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED ✓)

1. FEE CATEGORY AND AMOUNT: 3A $ 180

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL
LICENSE

3. OTHER

SIGNED
DATE 9/19/91