

MATERIALS LICENSE

Amendment No. 30

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, 36, 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.

OFFICIAL RECORD COPY

Licensee

1. Du Pont Merck Pharmaceutical Company
2. 331 Treble Cove Road
North Billerica, Massachusetts 01862

In accordance with the letter dated
August 21, 1996,

3. License Number 20-00320-19 is amended in
its entirety to read as follows:

4. Expiration Date September 30, 2004

5. Docket or
Reference No. 030-13288

6. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

A. Phosphorus 32

A. Prepackaged organic
salts in aqueous
solutions

A. 10 curies

B. Molybdenum 99/
Technetium 99m

B. In Tc99m Generators

B. 300 curies

C. Xenon 133

C. Gas Calidose refills

C. 160 curies

9. Authorized use

- A. through C. For possession, storage, and packaging incident to distribution to persons authorized to receive the licensed material pursuant to terms and conditions of a specific license issued by the Nuclear Regulatory Commission or any Agreement State.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 1909 Beltway Drive, Overland, Missouri; 0555 Sweet Valley Drive, Valley View, Ohio; Ronson Aviation, Inc., Mercer County Airport, Trenton, New Jersey; and 100 Wade Avenue, South Plainfield, New Jersey.
11. A. Licensed material shall be used by, or under the supervision of, J. Michael Blake or individuals designated by the Radiopharmaceutical Division's Manager of Safety and Environmental Engineering.
- B. The Radiation Safety Officer for this license is J. Michael Blake.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

20-00320-19

Docket or Reference Number

030-13288

Amendment No. 30

12. 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. Letter dated July 11, 1986
- B. Letter dated June 16, 1989
- C. Letter dated October 29, 1991
- D. Letter dated June 9, 1992
- E. Letter dated August 25, 1992
- F. Letter dated February 25, 1993
- G. Letter dated April 4, 1993
- H. Facsimile dated September 23, 1994
- I. Letter dated April 14, 1995
- J. Letter dated August 21, 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By:

Francis M. Costello

By

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Date SEP 10 1996

SEP 10 1996

Francis E. Roy, Jr.
Senior Health Physicist
Du Pont Merck Pharmaceutical Company
331 Treble Cove Road
North Billerica, Massachusetts 01862

Dear Mr. Roy:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

This amendment gives you the authority to possess, store and package licensed material incident to distribution at your new facility located at 100 Wade Avenue, South Plainfield, New Jersey. After you complete a comprehensive close-out survey of your facility located in Trenton, New Jersey, please submit a completed NRC Form 314 (enclosed), including the survey results, to Region I. Please verify that all radioactive material and "Caution Radioactive Materials" signs and labels have been removed from the Trenton, New Jersey facility. In this correspondence, refer to Mail Control No. 123592.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:

Francis M. Costello, Chief
Nuclear Materials Safety Branch 3
Division of Nuclear Materials Safety

License No. 20-00320-19
Docket No. 030-13288
Control No. 123592

Enclosures:

1. Amendment No. 30
2. NRC Form 314

OFFICIAL RECORD COPY **ML 10**

F. E. Roy, Jr.
Du Pont Merck Pharmaceutical Company

-2-

DOCUMENT NAME: R:\WPS\MLTR\20-00320.19

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	Dolce\kd1	<input checked="" type="checkbox"/>	Costello	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DATE	09/02/96	<input checked="" type="checkbox"/>	09/ 7 /96	09/ /96	09/ /96	<input type="checkbox"/>

OFFICIAL RECORD COPY

August 23, 1996

030-13288

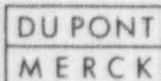
U.S. Nuclear Regulatory Commission

ATTN.: Elizabeth Ullrich

Region I

475 Allendale Road

King of Prussia, PA 19406



Reference: Materials License #20-00320-19

Dear Ms. Ullrich:

This is written to correct a typographical error I made in our license amendment request dated August 21, 1996.

In the request for a license amendment to move the Distribution Center from Trenton to South Plainfield NJ the statement concerning the size of the space for the facility, at approximately 45,000 ft², is incorrect. It turns out that the size of the entire Del-Med warehouse facility at 100 Wade Avenue is approximately this size. The area to be occupied by DuPont Merck is approximately 1,000 ft² as indicated on the attached sketch.

I apologize for any confusion this may have created. Please contact me if you require any additional information.

Sincerely,

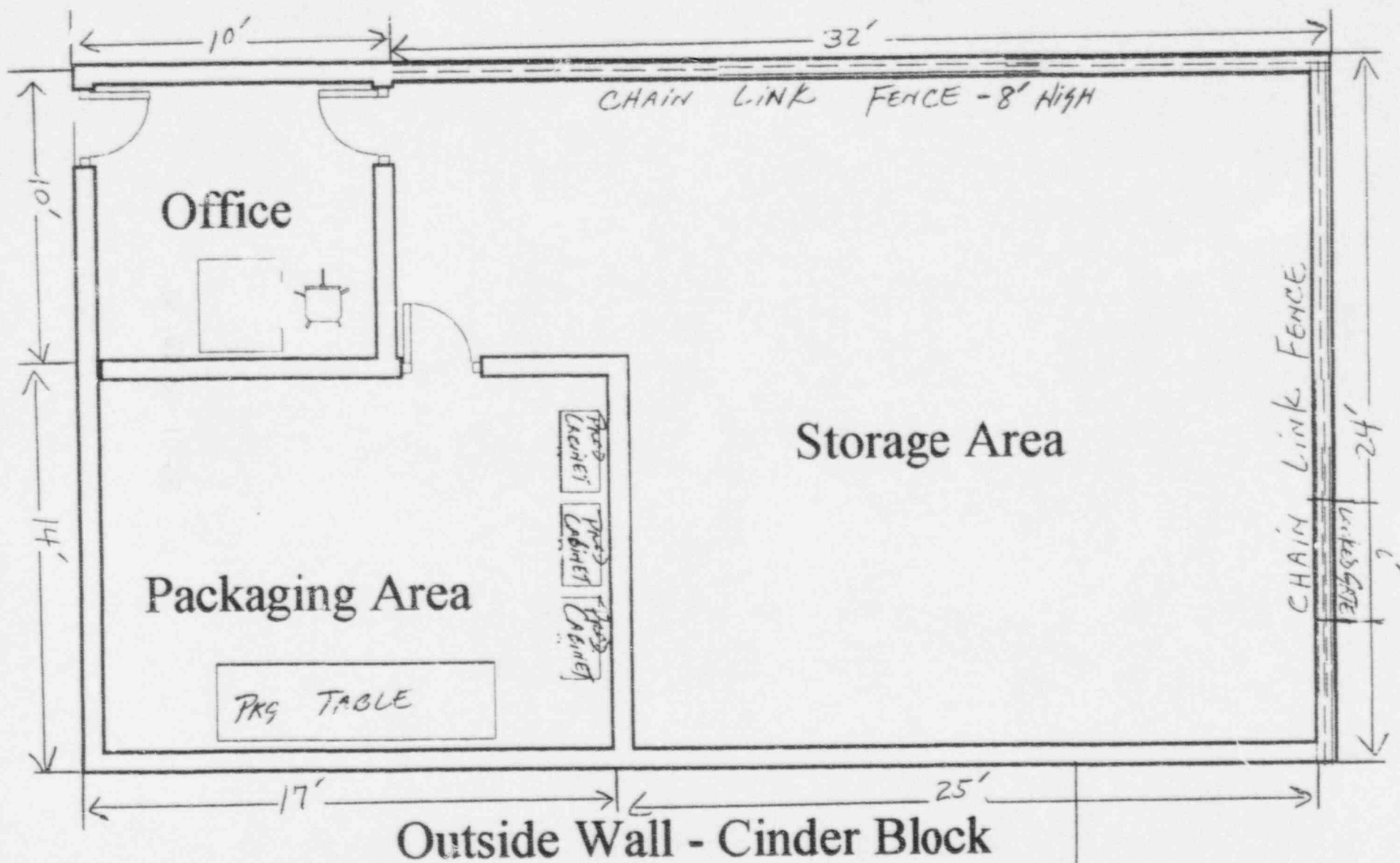
A handwritten signature in cursive script that reads "Francis E. Roy, Jr.".

Francis E. Roy, Jr. (Skip)

Senior Health Physicist

123592

AUG 26 1996



August 21, 1996

030-13288



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

Reference: Materials License #20-00320-19

Dear Ms. Ullrich:

This is written to request an amendment to the above-referenced Materials License. We request authorization to relocate the New Jersey Distribution Center to a new address and to change the Radiation Safety Officer for this license.

With regards to relocation we ask that the following address be added to our license:

Del-Med, Inc.
100 Wade Avenue
South Plainfield, NJ 07080

During the month of September we propose to move the existing distribution operation in Trenton, New Jersey to the new address in South Plainfield. With the addition of the new address on our license we will be able to move the operation and then perform the required close-out surveys at the existing facility. A separate amendment submittal will then be forwarded to your office with the results of our close-out survey and request to delete the Trenton facility from the license.

A sketch of the proposed facility in South Plainfield is attached for your review. The DuPont Merck facility will consist of an approximately 45,000 ft² secured area within the Del-Med, Inc. warehouse. The office and packaging area will be enclosed in floor to ceiling partitions and the storage area used for the staging of the outgoing shipments will be secured with an 8 foot high chain link fence. The entire Del-Med building is on an alarmed security system and the DuPont Merck distribution facility within this building will be on its own secured zone. The product cabinets are kept individually locked and the storage area and packaging area will be kept locked whenever the area is unattended. All existing Radiation Protection procedures as currently licensed will be carried over into the new facility.

We also request a change in the Radiation Safety Officer for this license. Michael Rielly the existing RSO has been assigned new job duties within the Customer Service/Distribution organization and is becoming less involved in the Distribution Center operations. In his place we request that Michael Blake be authorized as the new Radiation Safety Officer for this license. Documentation regarding Mr. Blake's training and experience are attached for



123592
AUG 22 1996

August 21, 1996

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

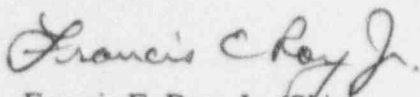
Reference: Materials License #20-00320-19

Page 2

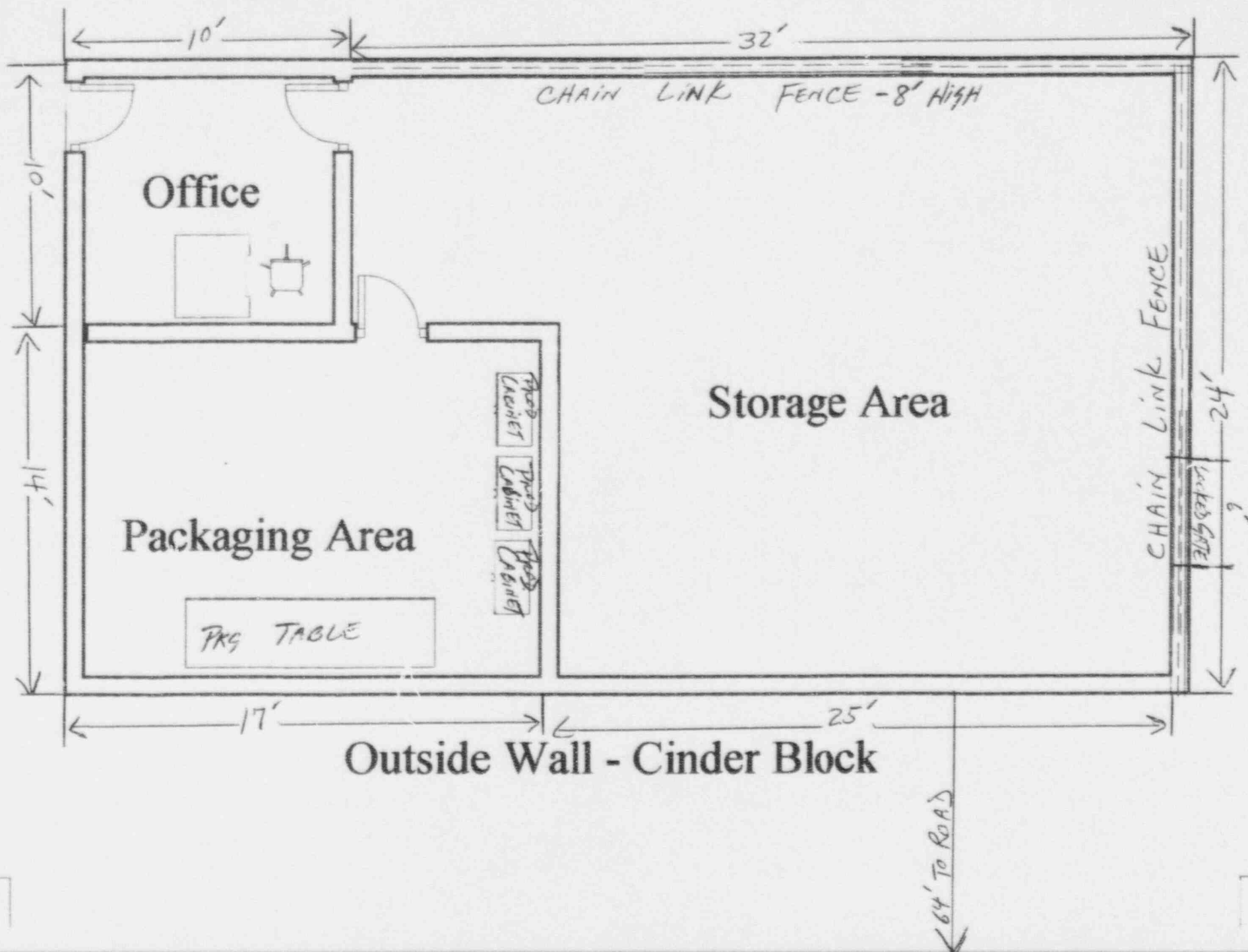
your review. Currently Mike Blake is the supervisor of the Distribution Centers and each operator reports directly to Mike. Mike Blake began his experience with the Distribution Center operations in 1986, and until 1989 worked at the facility in Texas. From 1989 to the present, Mike has operated the Atlanta Distribution Center and within the past year attained supervisory responsibilities for all Distribution Center personnel. Mike is eminently qualified to act as Radiation Safety Officer for this licensed operation.

A check is enclosed in the amount of \$300 in payment of the license amendment fee specified for Fee Category 3P in Title 10 CFR Part 170, §170.31. Please contact me if you require any additional information.

Sincerely,



Francis E. Roy, Jr. (Skip)
Senior Health Physicist



COVER SHEET

This is to certify and document my training file that

I have read and understood the attached STANDARD

OPERATING PROCEDURES on (date) 9-12-94

Signed: Michael Black

COMMENTS:

SUGGESTIONS:

RETURN TO: DUPONT MERCK
8555 SWEET VALLEY DR.
VALLEY VIEW, OH 44125
ATTN: J.D. ADAMS



CHEYENNE MOUNTAIN CONFERENCE RESORT

1994 Annual Radiation Safety Training for Distribution Center Personnel MAY 21, 1994

NAME

1. Vandelia Trejo
2. Becky Parmelee
3. Bob Fontaine
4. Jim Lowright
5. Jim Anderson
6. Mark Gatewood
7. Don Pulk
8. Tom Rooney
9. Gary Staggs
10. Charles Jeffus
11. Ray Noble
12. Mike Blake
13. Dave Zydiak
14. Ken Carlson
15. Vernon Cairns
16. Rose Adams
17. Dave Adams
18. Boyd Olson
19. Randall Hansen
- (dup) 20. VERNON D CAIRNS
- (dup) 21. Charles Jeffus
22. J. MICHAEL BLAKE
23. MICHAEL RIELLY

SIGNATURE

Vandelia Trejo
 Becky Parmelee
 Bob Fontaine
 Jim Lowright
 Jim Anderson
 Mark Gatewood
 Don Pulk
 Tom Rooney
 Gary Staggs
 Charles Jeffus
 Ray Noble
 Mike Blake
 Dave Zydiak
 Ken Carlson
 Vernon D Cairns
 Rose Adams
 Dave Adams
 Boyd Olson
 Randall J Hansen
 Vernon D Cairns
 Charles Jeffus
 J. Michael Blake
 Michael RIELLY

Radiation Safety Training

Agenda

Lectures and Discussions:

- **Basic Radiation Safety**
 - Radiation and Radioactivity**
 - How Radiation Exposure Occurs**
 - Possible Health Risks**
 - The ALARA Principle**
 - How to Minimize Radiation Exposure**
 - Radiological Posting and Labeling**
 - Detecting Radioactive Contamination**
 - Measuring Radiation Exposure Rates**
 - Use of Radiological Survey Instruments**
 - Use and Storage of Personal Dosimetry**
 - Daily Radiation Safety Actions**
- **10 CFR Part 20, Standards for Radiation Protection**
 - What is "10 CFR Part 20"**
 - Major Areas of Change Effective 1/1/94**
 - Dose Limits**
 - ALARA Emphasis**
 - Hazard Posting Requirements**
 - Radioactive Materials Package Receipt**
- **Billerica Site Handbook of Radiation Protection**
 - Revised April 20, 1994**
 - ALARA Commitment**
 - Radiation Protection Responsibilities**
 - Authorization to Handle Radioactive Materials**
 - Required Procedures**
 - Radiation Safety Rules**
- **Compliance**
 - Discussion of Facilities' Licenses**
 - Review Internal & Regulatory Agency Inspections**

MERCK

Title Documentation of Training	Number 05-001-002	Issue Date Mar. 13, 1994	Page 7 of 7 Pages
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GROUP TRAINING RECORD

FORM 1 OF 1

Title of Presentation and/or brief description of activity: Dec 1993 Annual Radiation Safety training materials covering 1994 Revision to RegulationsDepartment Name: DistributionCourse Code No. (If Applicable): _____ Date: 3/24/94Training Type: _____ Job _____ GMP ☒ SafetyFormat: ☒ Instructor _____ Self-InstructionInstructor Name
(Please Print)Roy GreavesOrganization/Company
(Please Print)Radiation Protection
Office

Signature

Roy Greaves

Employee Name (Please Print)

Tim Anderson

Social Security Number

021-50-7852

Signature

Tim AndersonJ. Michael Blake462-90-4904J. Michael Blake

Certificate of

TRAINING

U.S. DEPARTMENT OF TRANSPORTATION

Mike Blake

GENERAL HAZARDOUS MATERIALS REGULATIONS
AND RADIOPHARMACEUTICAL SHIPMENTS

Ernest De Maria
Ernest DeMARIA

MAY 1993

DUPONT MERCK PHARMACEUTICAL COMPANY
SAFETY AND ENVIRONMENTAL AFFAIRS
RADIATION PROTECTION OFFICE

DIB
Rev 11/91

TRAINING SESSION ATTENDANCE

Date: May 21, 1993

Instructor(s): Skip Roy

Time: 12:45 PM to 3:15 PM

Training session description: Annual Radiation Safety Training for
the Distribution Centers (see attached agenda)

Please print your name, employee number, and supervisors name in the spaces below.

EMPLOYEE NAME (PLEASE PRINT)	EMP #	SUPERVISOR
1. <u>Jim Anderson</u>		<u>Mike Blake</u>
2. <u>J. MICHAEL BLAKE</u>		<u>Michael P. Kelly</u>
3. <u>RICHARD P. SCHENA</u>		<u>MIKE BLAKE</u>
4. <u>DONALD R PULK</u>		<u>MIKE BLAKE</u>
5. <u>RICHARD RADZYCKI</u>		<u>MIKE BLAKE</u>
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27.		

RADIATION SAFETY TRAINING

for the

DISTRIBUTION CENTERS

Date: May 21, 1993

Trainer: Skip Roy

Location: Brewster, Massachusetts

AGENDA

12:45 PM to 3:15 PM

Basic Radiation Safety (70 minutes)

**Video Radiation Naturally, by the U.S. Council for
Energy Awareness (30 minutes)**

Lecture/Discussion (40 minutes)

**Radiation Exposure
Half-Life, Activity
Contamination Detection
Dose (Regulatory Limits and Natural Levels)
Low Level Effects
Controlling Exposure
Posting
Dosimetry**

Compliance (60 minutes)

Discussion of the Facilities' Licenses

**Review of Selected Internal and Regulatory Audit
Findings**

Review and Questions (20 minutes)

Individual Training Record

Last Name

First Name

Blake

Jerry

Middle Init

M

Active/Inactive

A

ASD

Functional Group

Customer Service Distribution

Supervisor

Rielly, Michael

Job Title

Regional Supervisor, Atlanta DC

Location

BRI 200-2

Tot Hrs

22

Code

Training Description

Hours

Date

Instructors

2240

Customer Work Group App. Skills Training

2

8-22-02

D. O'Brien

2241

Customer Work Group App. Technology

2

8-24-02

D. O'Brien, J. Smith

2242

Customer Work Group App. Skills Training

2

8-21-02

D. O'Brien

GMP Training Record

Customer Service/Distribution

Supervisor Rielly, Michael

<u>Name</u>	<u>Training Description</u>	<u>Hours</u>	<u>Date</u>	<u>Tot Hrs</u>
Adams James	CustomWork Group Appl. GMP Rqmts	2	6/27/92	22
	cGMP's & Cleanroom Technology	16	10/5,6/93	
	CustomWork Group Appl. GMP Rqmts	4	5/21/93	
Adams Rose	CustomWork Group Appl. GMP Rqmts	2	6/27/92	6
	CustomWork Group Appl. GMP Rqmts	4	5/21/93	
Anderson James	CustomWork Group Appl. GMP Rqmts	2	6/27/92	6
	CustomWork Group Appl. GMP Rqmts	4	5/21/93	
Blake Jeri	CustomWork Group Appl. GMP Rqmts	2	6/27/92	22
	cGMP's & Cleanroom Technology	16	10/5,6/92	
	CustomWork Group Appl. GMP Rqmts	4	5/21/93	

Du Pont Merck Radiopharmaceuticals

presents this certificate

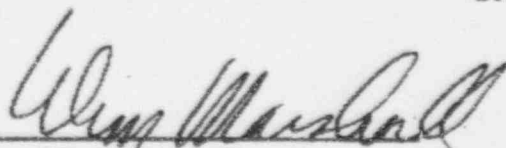
to

J. Michael Blake

For participation in the cGMP Training Program

On October 5 and 6, 1992

**In the Du Pont Merck Learning Center
N. Billerica, MA**



W. Marshall



W. O'Connor

Title Documentation of Training	Number 05-001-002	Issue Date Sep. 23, 1987	Page 4 of 5 Pages
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GROUP TRAINING RECORD

Page 1 of 2

Department Name Development & Training

Date(s) of Presentation: 6/27/82

Type of Training: Job — GMP — Safety

Title of presentation or brief description of program:

Toto eGMP's for Cost Service Distribution

Signature of Trainer(s):

W.F. O'Connor

Name(s) Typed:

William F. O'Connor

Signature of Attendee(s):

J. Michael Blakis

Name(s) Typed: J. Michael Blakis

J. Michael Blakis

Donald R. Pulk

DONALD R. PULK Donald R. Pulk

Richard P. Schena

RICHARD P. SCHENA Richard Scher

Donna C. Perlak

DONNA C. PERLAK Donna C. Perl

Bill Helfrich

BILL HELFRICH Bill Helfrich

Bill Mulvana

BILL MULVANA (Daniel Trucking) Bill Mulvana

Fred Wolman

FRED WOLMAN (Conson Aviat) Fred Wolman

Richard Radzycki

RICHARD RADZYCKI Richard Raduzy

James D. Adams

JAMES D. ADAMS James D. Adams

Rose A. Adams

ROSE A. ADAMS Rose A. Adams

Wendi Fox

WENDI FOX Wendi Fox

Pamela E. Davis

PAMELA E. DAVIS Pamela E. Davi

Charles Grant

CHARLES GRANT Charles Grant

Boyd Olson

BOYD OLSON (Synchron) Boyd Olson

Gary Staggs

GARY STAGGS (Medival Navigation Inc) Gary Staggs

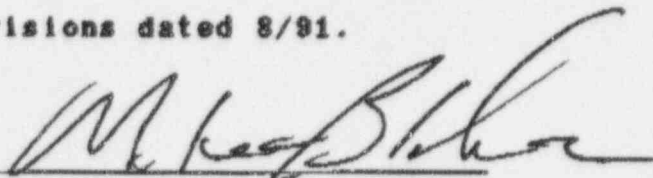
Michael Rielly

MICHAEL RIELLY Michael Rielly

MIKE BLAKE

The following is a signed statement attesting that
I have read and understood all the Distribution Center
Survey Procedure revisions dated 8/91.

By: _____



Distribution Center _____

Atlanta

Date _____

1-9-92

J. MICHAEL BLAKE

HOME ADDRESS

MARITAL STATUS

HOBBIES

Outside activities

Current Position:

DuPont Medical Products
Distribution Supervisor
Houston, TX

Training:

Health Physics Training 7/86
On the job training with Mike Rielly, DuPont Safety
Officer 7/86 - 8/86.

Have open communication with Customer Service and
Carriers to complete delivery of material from order
input to destination. Maintain adequate inventory for
emergency delivery. Take daily inventory to maintain
proper records for audits.

Previous Experience:
6/76 - 7/86

Customer Service Representative
DuPont Photo Products
Irving, TX

Determine needs of customers with whom DuPont Photo
Products does business and maintain a working
relationship with customers, interacting in a way which
would satisfy their needs to the greatest extent.
Prepared customer orders received by mail or telephone
and provided the necessary follow-up on those requiring
special attention. Maintained adequate inventory
levels to give good customer service.

6/75 - 6/76

Dispatcher
DuPont Photo Products
Dallas, TX

Routed orders to destination. Double checked outgoing
orders before shipment.

6/73 - 6/75

Warehouseman
DuPont Photo Products
Dallas, TX

Pulled and checked orders. Put up stock.

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

[illegible]

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: DU PONT MERCK PHARMACEUTICAL CO.
RECEIVED DATE: 960822
DOCKET NO: 3013288
CONTROL NO.: 123592
LICENSE NO.: 20-00320-19
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: 300.00
CHECK NO.: 204922

3. COMMENTS

SIGNED
DATE

M. A. Perkins
8/26/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 4 / 1)

1. FEE CATEGORY AND AMOUNT:

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT ☒
 RENEWAL ☐
 LICENSE ☐

3. OTHER

SIGNED
DATE

AC 9/3/96

Log Aug 15 I
Remitter _____
Check No. 204922
Amount \$300
Fee Category 3P
Type of Fee AmD
Date Check Rec'd 8/29/96
Date Completed 9/3/96
By: SC