



Mallinckrodt
Pharmaceuticals

January 17, 2014

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

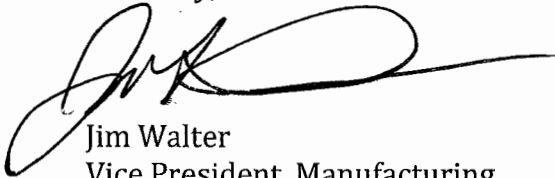
RE: License Numbers 24-04206-01, 24-04206-02, 24-04206-05MD

Dear Sir or Madam:

This letter is being written to inform you that Mallinckrodt LLC has changed the responsibility of several employees within our Manufacturing Operations. One of these changes includes the Site Director for the Maryland Heights Manufacturing Plant. Mr. Dexter Evans has been re-assigned to be the Site Director for the St. Louis Manufacturing Plant. He has been replaced at the Maryland Heights Site by Mr. Dale Eyman. Mr. Eyman previously served as the Interim Site Director at the Maryland Heights Plant and is familiar with the radiological operations performed there. Mr. Evans remains employed at Mallinckrodt in the St. Louis area and will be available to assist Mr. Eyman during this transitional period.

I appreciate your attention to this matter. If you have any questions, please contact Mr. Eyman at (314) 654-3923 or myself at (314) 654-1300.

Sincerely,



Jim Walter
Vice President, Manufacturing

cc: Eric Berry (via E-mail)
Ken Lambert (via E-mail)
Bryan Parker (via E-mail)
Jim Schuh (via E-mail)

January 21, 2014

Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: License Number 24-04206-01
Docket Number 030-00001

Dear Sir or Madam:

This letter constitutes a request for an amendment to Broad Scope Material License 24-04206-01. This license is issued to Mallinckrodt LLC to cover manufacturing and R&D activities at its Maryland Heights Facility. The purpose of this amendment request is to allow the appointment of Mr. Scott Surovi as Radiation Safety Office (RSO). Included with this letter is a completed NRC Form 313 (Attachment I), a copy of Mr. Surovi's resume (Attachment II), a signed delegation of authority from the Site Director (Attachment III), Mr. Surovi's acknowledgement of his responsibility as RSO (Attachment IV) and a revised organizational chart (Attachment V). On the organizational chart we have included the names of those currently holding the positions identified. We will amend the license in the event that the organizational structure changes, but will not amend the license for changes in the personnel holding those positions (except for the individual assigned the duties of the RSO).

Mr. Surovi was hired by Mallinckrodt in April, 1995 as Assistant Radiation Safety Officer for our Nuclear Pharmacy Operations and has held positions of increasing responsibility with Mallinckrodt since that time. As the Assistant Radiation Safety Officer he shared responsibility for the licensing associated with Mallinckrodt's Nuclear Pharmacy Operations. This included 42 pharmacies in both NRC and Agreement States.

One of the positions he served in at Mallinckrodt was the Supervisor of Health Physics for the Mallinckrodt Maryland Heights facility. In that role, he was responsible for implementing the site Radiation Protection Program (RPP) and directing the work of the Health Physics staff. This included supervising individuals in the use of kCi quantities of isotopes commonly used in nuclear medicine. He is very familiar with the radiological operations at our Maryland Heights facility.

Mr. Surovi has also served as the Radiation Safety Officer for Mallinckrodt's Nuclear Pharmacy located in Los Angeles, California where he was responsible for all aspects of implementing the RPP. He was also responsible for licensing associated



Prior to joining Mallinckrodt, Mr. Surovi served as a consultant where he audited licensees including the Mallinckrodt Maryland Heights Facility.

I appreciate your attention to this matter. If you have any questions, please contact Mr. Surovi at (314) 654-7444 or myself at (314) 654-3923.

Sincerely,

A handwritten signature in black ink that reads "Dale Eyman".

Dale Eyman
Site Director

cc: Eric Berry (via E-mail)
Tim Dowell (via E-mail)
Ken Lambert (via E-mail)
Bryan Parker (via E-mail)
Jim Schuh (via E-mail)
Scott Surovi (via E-mail)

APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER 24-04206-01

C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Mallinckrodt LLC
2703 Wagner Place
Maryland Heights, MO 63043

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

2703 Wagner Place
Maryland Heights, MO 63043

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Scott Surovi

BUSINESS TELEPHONE NUMBER (314) 654-7444	BUSINESS CELLULAR TELEPHONE NUMBER (314) 267-9142
BUSINESS EMAIL ADDRESS Scott.Surovi@Mallinckrodt.com	

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

9. FACILITIES AND EQUIPMENT.

11. WASTE MANAGEMENT.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

10. RADIATION SAFETY PROGRAM.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY	3A, 3L	AMOUNT ENCLOSED	\$ 0.00
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13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Dale Eyman, Site Director

SIGNATURE

Dale Eyman

DATE

1/21/14

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

Scott J. Surovi
675 McDonnell Boulevard
Hazelwood, Missouri 63042 USA
scott.surovi@mallinckrodt.com
(314) 654-7444

EDUCATION

- May 1988 **Bachelor of Science, Nuclear Medicine Technology**
Rochester Institute of Technology, Rochester, NY
- May 1986 **Associate in Science, Radiologic Technology**
Northampton College, Bethlehem, PA
- December 1985 **Associate in General Education**
Northampton College, Bethlehem, PA

PROFESSIONAL CREDENTIALS

- 2005, 2010 **Dangerous Goods Safety Advisor** (European Ground/Road Transport, all Classes)
Scottish Qualifications Authority/Department for Transport (Great Britain)
- 1996 **Medical Nuclear Radiological Physicist (#MNP 39) & Medical Health Physicist (#MHP 30)**
Florida Department of Health, Division of Medical Quality Assurance
- 1993 **Medical Health Physics & Radiological Health Physics (#MP0091)**
Texas Board of Licensure for Professional Medical Physicists
- 1988 **Certified Nuclear Medicine Technologist (#012215)**
Nuclear Medicine Technology Certification Board (NMTCB)
- 1988 **Registered Technologist – Nuclear Medicine (#207792)**
American Registry of Radiologic Technologists (ARRT)
- 1986 **Registered Technologist – Radiography (#207792)**
American Registry of Radiologic Technologists (ARRT)

EMPLOYEMENT HISTORY

- March 2011 – Present **Director, Transportation Compliance Programs**
Mallinckrodt Pharmaceuticals/Covidien, Hazelwood, MO
- March 2005 – March 2011 **Transportation Compliance Manager, North America**
Tyco Healthcare/Covidien/Mallinckrodt, Hazelwood, MO
- July 2003 – March 2005 **Supervisor, Health Physics**
Tyco Healthcare/Mallinckrodt, Maryland Heights, MO
- January 2003 – June 2003 **Radiation Safety Officer**
Tyco Healthcare/Mallinckrodt, Los Angeles, CA
- August 1996 – July 2003 **Senior Radiation Specialist**
Tyco Healthcare/Mallinckrodt, St. Louis, MO
- April 1995 – August 1996 **Assistant Radiation Safety Officer** (Radiopharmacy Operations)
Mallinckrodt, Inc., St. Louis, MO

EMPLOYMENT HISTORY *(continued...)*

June 1991 – April 1995	Senior Medical Physics Consultant NMA Medical Physics Consultation/Mallinckrodt, Inc., Folcroft, PA
November 1988 – June 1991	Medical Physics Consultant NMA Medical Physics Consultation/Mallinckrodt, Inc., Warren, MI / Folcroft, PA
June 1988 – November 1988	Staff Technologist, Nuclear Medicine Easton Hospital, Easton, PA
February 1988 – May 1988	Health Physics Internship University of Rochester, Rochester, NY
March 1986 – August 1986	Staff Technologist, Radiography Stefko MediCenter, Inc., Bethlehem, PA

PROFESSIONAL AFFILIATIONS

Health Physics Society (HPS) – Plenary Member (1998 – Present)

Greater St. Louis Health Physics Society (2000 – Present)

- Secretary (2003 – present)
- President (2006 – present)

Society of Nuclear Medicine - Molecular Imaging (SNM-MI)

- Technologist's Section (1988 – Present)

Missouri Valley Chapter, Society of Nuclear Medicine - Molecular Imaging

- Technologist Member (1996 – Present)

INDUSTRY AFFILIATIONS

Council on Radionuclides and Radiopharmaceuticals (CORAR)

- Co-Chairperson, Transportation Committee (December 2006 – present)
- Board of Directors - Secretary/Treasurer (December 2009 – December 2012)
- Board of Directors – Vice Chairman (December 2013 – present)
- Ad-hoc member representing CORAR, a Non-Government Organization (NGO), at the International Atomic Energy Agency (IAEA)
 - Annual General Conference/Scientific Forum (2007, 2008, 2009)
 - International Steering Committee on the Denial & Delay of Class 7 Consignments
 - Conference on the Safe & Secure Transportation of Radioactive Materials (October 2011)

Radiopharmaceutical Shippers & Carrier's Conference (RSCC)

- Vice Chairperson (December 2006 – December 2007; January 2011 – December 2011)
- Chairperson (December 2007 – December 2009; December 2011 – December 2013)

Nuclear Sector Coordinating Council – Radioisotopes (NSCC-R)

- Co-Chairperson (May 2006 – present)

Council on Safe Transportation of Hazardous Articles (COSTHA)

Society for Chemical and Hazardous Communication (SCHC)

PROFESSIONAL CONTRIBUTIONS

Author/Presenter: Department of Transportation (DOT) Hazardous Materials Transportation Regulatory Update, Gateway Society of Hazardous Materials Managers (St. Louis, MO; March 10, 2011)

Author/Presenter: Industry Initiatives on Transportation of Radioactive Materials, American Nuclear Society Meeting (Anaheim, CA; June 11, 2008)

Presenter: Denial of Shipment of Radioactive Materials, American Nuclear Society Meeting (Anaheim, CA; June 11, 2008)

Contributor: Review Questions for Nuclear Medicine: The Technology Registry Examination, A. M. Gallo-Foss (March 1997)

Item Writer: Nuclear Medicine Technologist certification board/registry exams

- The Nuclear Medicine Technology Certification Board (NMTCB) (May 1993 – February 2000)
- American Registry of Radiologic Technologists (ARRT) (May 1990 – April 1991)

OTHER ACCOMPLISHMENTS

Six-Sigma: Green Belt Certified – Tyco Healthcare (May 2004)

REFERENCES

Professional and Character References available upon request.

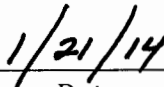
Attachment III**Delegation of Authority for Radiation Safety Officer**

Scott Surovi has been appointed Radiation Safety Officer (RSO) and is responsible for ensuring the safe use of radioactive material. The RSO is responsible for managing the radiation safety program; identifying radiation safety concerns; initiating, recommending, or providing correction action; verifying implementation of corrective actions; and ensuring compliance with regulations for the use of radioactive material. The Radiation Safety Officer is hereby delegated the authority necessary to meet these responsibilities.

The Radiation Safety Officer has the authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with NRC requirements.



Dale Eyman
Site Director

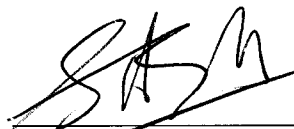


Date

Attachment IV

Acceptance of Responsibility for Radiation Safety Officer

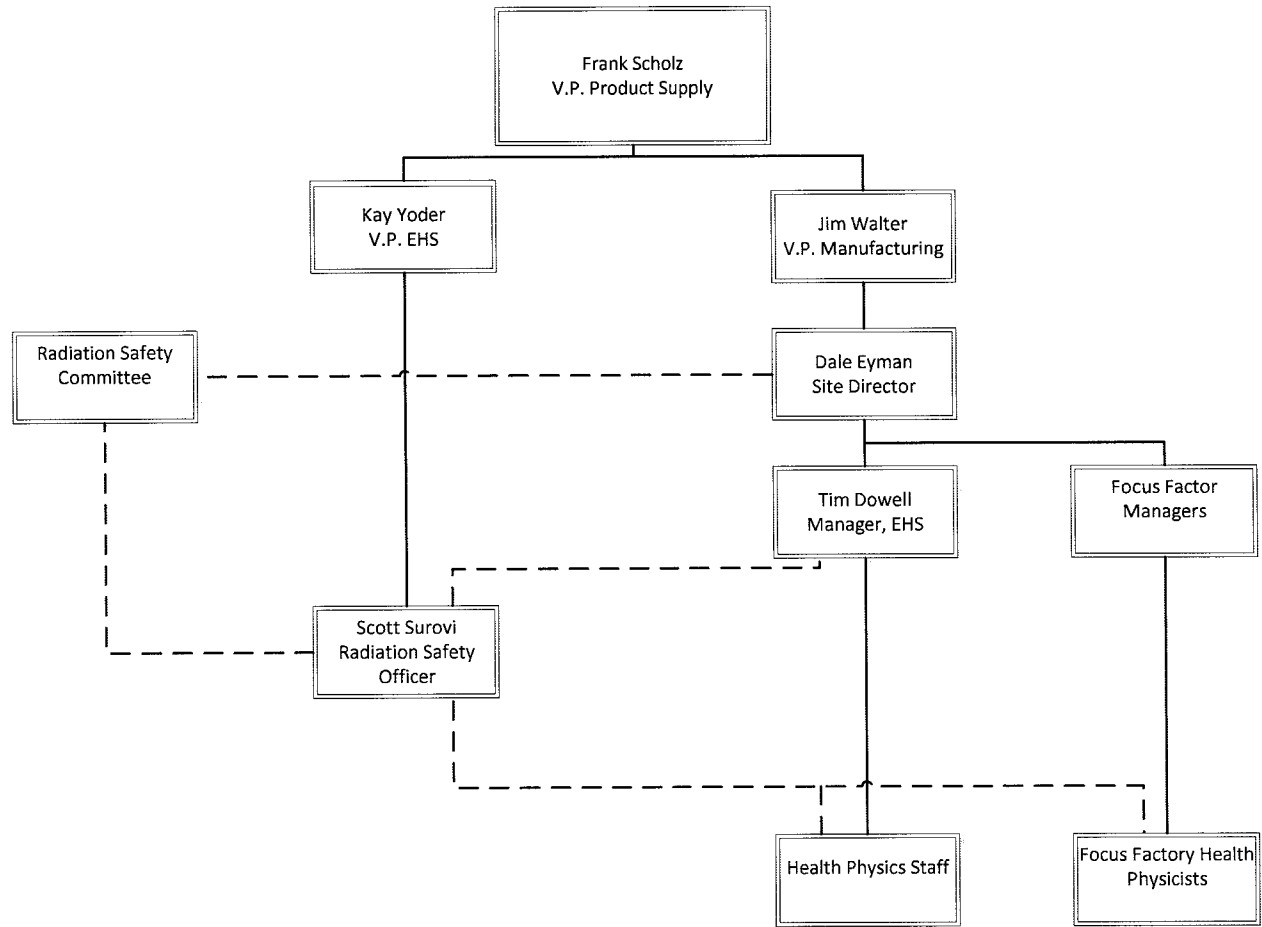
I have successfully completed education, training and experience sufficient to serve as Radiation Safety Officer for the three NRC licenses currently possessed by Mallinckrodt, LLC (24-04206-01, 24-04206-02 and 24-04206-05MD). This includes training and experience in radiation safety, regulatory issues, emergency procedures and specific license conditions associated with the uses covered by the three licenses listed above. I accept responsibility for insuring the safe use of radioactive materials; managing the radiation safety program; identifying radiation safety concerns; initiating, recommending or providing corrective actions; verifying implementation of corrective actions; and insuring compliance with regulations for the use of radioactive materials.



Scott Surovi
Director, Transportation Compliance Programs

21 JAN 2014

Date



Pelke, Patricia

From: Dowell, Tim <Tim.Dowell@mallinckrodt.com>
Sent: Tuesday, January 21, 2014 3:47 PM
To: Pelke, Patricia
Subject: FW: Carbon Copy for License amendments for 24-04206-01, 24-04206-02 and 24-04206-MD
Attachments: Mallinckrodt License Ammendment Jan 2014.zip

Patricia,

I am forwarding the below e-mail correspondence as a courtesy follow up to our telephone conversation (01/15/14) concerning a RSO change and subsequent License Amendment submission for the Mallinckrodt Pharmaceuticals manufacturing site.

If you have any questions or concerns, please free to call me at any time.

Regards,

Tim Dowell

Tim Dowell, CSP | EHS Manager
Mallinckrodt Pharmaceuticals
2703 Wagner Place | Maryland Heights, MO 63043 | USA
T: 314.654.7975
tim.dowell@mallinckrodt.com | www.mallinckrodt.com

This information may be confidential and/or privileged. Use of this information by anyone other than the intended recipient is prohibited. If you receive this in error, please inform the sender and remove any record of this message.

From: Dowell, Tim
Sent: Tuesday, January 21, 2014 2:56 PM
To: kenneth.lambert@nrc.gov; Bryan.Parker@nrc.gov
Cc: Berry, Eric; Schuh, James R; Dowell, Tim; Surovi, Scott J
Subject: Carbon Copy for License amendments for 24-04206-01, 24-04206-02 and 24-04206-MD

All,

Please reference attached electronic copies of licenses amendment requests for the above mentioned license numbers currently held by the Mallinckrodt Pharmaceutical site located in Maryland Heights, MO.

Additionally, contained in each file is a courtesy letter informing of recent company personnel changes at the site Director level.

Please note that hard copies (x2) have been sent to the Region III office via FEDEX.

If you have any questions, please free to contact me.

Regards,

Tim Dowell

Tim Dowell, CSP | EHS Manager
Mallinckrodt Pharmaceuticals
2703 Wagner Place | Maryland Heights, MO 63043 | USA
T: 314.654.7975
tim.dowell@mallinckrodt.com | www.mallinckrodt.com

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