



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

August 4, 2015

Thomas K. Spencer
Radiation Safety Officer
Sigma-Aldrich Company
P.O. Box 14508
St. Louis, MO 63178

SUBJECT: REQUEST FOR CONSENT TO DIRECT LICENSE TRANSFER

Dear Mr. Spencer:

By letter dated May 12, 2015, Sigma-Aldrich Company and Merck KGaA, submitted to the U. S. Nuclear Regulatory Commission (NRC) a Request for Consent to Direct License Transfer of NRC Materials Licenses issued to Sigma-Aldrich Company. The affected licenses noted in that letter were License Nos. 24-16607-03 and 24-16273-01.

Based on the information provided, we understand that as a result of a purchase of stock from Sigma-Aldrich Company, by Merck KGaA, control will be directly transferred to Merck KGaA. We further understand that this transfer will not result in any change to the licensee's name, licensed materials, persons using the license material, location of use of licensed material, or persons responsible for the licensee's radiation safety program.

Based on the above understandings and as more fully detailed in the enclosed NRC staff's Safety Evaluation Report which documents the NRC staff's review of the request, the NRC consents to the proposed direct transfer of control. Please note that you will need to notify us promptly, in writing, after the transaction has been finalized and include a signed copy of the final agreement confirming completion of the transaction. Please also include information to support other necessary changes such as a name change. With this information, we can issue an administrative amendment to your NRC license to reflect the transaction, if necessary. Please contact Jennifer L. Bishop at 630-829-9607, or by e-mail at: jennifer.dalzell-bishop@nrc.gov if you have any questions regarding this letter.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

T. Spencer

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In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/RA/

Jennifer L. Bishop
Materials Licensing Branch
Division of Nuclear Materials Safety

License Nos. 24-16607-03; 24-16273-01
Docket Nos. 030-28992; 030-10716

Enclosure: Safety Evaluation Report

T. Spencer

-2-

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Enclosure: Safety Evaluation Report

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George Alexander
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**SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS
LICENSE NUMBERS 24-16607-03 and 24-16273-01, Sigma-Aldrich Company**

DATE: August 4, 2015

DOCKET NO.: 030-28992 and 030-10716

LICENSE NO.: 24-16607-03 and 24-16273-01

LICENSEE: Sigma-Aldrich Company
3050 Spruce Street
St. Louis, MO 83103

TECHNICAL REVIEWER: Jennifer L. Bishop

SUMMARY AND CONCLUSIONS

Sigma-Aldrich Company is authorized by NRC License Number 24-16607-03 for the possession and use of byproduct material for purposes of testing biochemical products and by NRC License Number 24-16273-01 for the possession of byproduct material for the purpose of decommissioning. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct license transfer submitted by Sigma-Aldrich Company that will result from Merck KGaA purchasing shares of Sigma-Aldrich Company. Sigma-Aldrich Company will become a wholly-owned subsidiary of Merck KGaA. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML15146A471.

The request for consent was reviewed by NRC staff for direct change in control of a 10 CFR Part 30 license using the guidance in NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses - Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated November 2000. The NRC staff finds that the information submitted by Sigma-Aldrich Company sufficiently describes and documents the transaction and commitments made by Merck KGaA and Sigma-Aldrich Company.

As required by 10 CFR 30.34 and Section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff has reviewed the application and finds that the proposed change in control is in accordance with the Act. The staff finds that, after the change of control, Sigma-Aldrich Company will remain qualified to use byproduct material for the purpose requested, and will continue to have the equipment, facilities, and procedures needed to protect public health and safety, and promotes the security of licensed material.

Enclosure

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing system, Sigma-Aldrich Company has been an NRC licensee since March 27, 1986, for License No. 24-16607-03 and since November 11, 1974 for License No. 24-16273-01. The NRC conducted an inspection of the facility for License No. 24-16607-03 from September 12, 2011, through October 13, 2011, and no violations were identified. With respect to License No. 24-16273-01, the NRC conducted an inspection from April 21, 2014, through July 7, 2014, and no violations were identified. The commitments made by Merck KGaA and Sigma-Aldrich Company state that Sigma-Aldrich Company (License Nos. 24-16607-03 and 24-16273-01):

- A. will not change the radiation safety officer listed in the NRC license;
- B. will not change the personnel involved in licensed activities;
- C. will not change the locations, facilities, and equipment authorized in the NRC license;
- D. will not change the radiation safety program authorized in the NRC license;
- E. will not change the organization's name listed in the NRC license; and
- F. will keep regulatory required surveillance records and decommissioning records.

Merck KGaA currently owns EMD Millipore, who is authorized to possess and use byproduct material under NRC License Number 24-26445-01. Therefore, for security purposes, Merck KGaA is considered a known entity following the guidance provided by the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the license", September 3, 2008 revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants or NRC licensees transferring control of licensed activities that the licensed material will be used for its intended purpose and not for malevolent use.

Sigma-Aldrich Company is required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 24-16607-03 and 24-16273-01. Any changes required of the licensee regarding their financial assurance will be submitted and reviewed following the completion of the transaction.

REGULATORY FRAMEWORK

Sigma-Aldrich Company's License No. 24-16607-03 and 24-16273-01, was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The Commission is required by 10 CFR 30.34 to determine if the change of control is in accordance with the provisions of the Act and give its consent in writing.

10 CFR 30.34(b) states: "No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full

information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.”

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15. As discussed in NUREG-1556, Volume 15, NRC is generally using the term “change of control” rather than the statutory term “transfer” to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed. Sigma-Aldrich Company’s request for consent describes direct change of control resulting from a planned purchase of company shares by Merck KGaA of Sigma-Aldrich Company. As a result, Sigma-Aldrich Company will become a wholly-owned subsidiary of Merck KGaA and, as such, the change requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession number ML15146A471. After completion of the merger, Sigma-Aldrich Company will continue as the licensee and remain in control of all licensed activities under Materials License Nos. 24-16607-03 and 24-16273-01. The NRC staff finds that the request for consent adequately provides a complete and clear description of the transaction, and is consistent with the guidance provided in Appendix F of NUREG-1556, Volume 15.

TRANSFeree’S COMMITMENT TO ABIDE BY THE TRANSFEROR’S COMMITMENTS

The NRC staff finds that the information submitted by Sigma-Aldrich Company sufficiently describes and documents the commitments made by Merck KGaA and Sigma-Aldrich Company, and is consistent with the guidance in NUREG-1556, Volume 15.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(14)(xi).

CONCLUSION

The staff has reviewed the request for consent submitted by both parties with regard to a direct change of control of byproduct materials License Nos. 24-16607-03 and 24-16273-01 and approves the application pursuant to 10 CFR 30.34(b).

The submitted information sufficiently describes the transaction; documents the understanding of the license and commitments; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they will maintain the existing records; and, in the future, will abide by all existing commitments to the license, consistent with the guidance in NUREG-1556, Volume 15.

Therefore, the staff concludes that the proposed change in control would not alter the previous findings, made under 10 CFR Part 30, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.