



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 28, 2021

Mr. Steve Nason
Chief Executive Officer
Medical Packaging Corporation
941 Avenida Acaso
Camarillo, CA 93012

SUBJECT: MEDICAL PACKAGING CORPORATION, REQUEST FOR WRITTEN CONSENT TO
INDIRECT LICENSE TRANSFER

Dear Mr. Nason:

By letter dated February 18, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession Number ML21054A144), Medical Packaging Corporation (MPC) submitted to the U.S. Nuclear Regulatory Commission (NRC) a request for written consent to an indirect transfer of control of NRC Materials License number License # 04-23996-01E. In accordance with Section 184 of the Atomic Energy Act of 1954, as amended (AEA), and Title 10 of the *Code of Federal Regulations* (10 CFR) Section 30.34, the NRC consents to the transfer. Please review the enclosed documents carefully to ensure that you understand all the conditions. If there are any errors or questions, please contact me so that appropriate corrections or answers can be provided.

Medical Packaging Corporation is authorized by the NRC for the distribution of carbon-14 contained in calibration control kits from its facility located in Camarillo, California, under 10 CFR Part 32. By letter dated February 18, 2021, Medical Packaging Corporation requested written consent to the indirect transfer of control of its license to EW Group GmbH. Because the license was issued under 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," the NRC must find that the transfer is in accordance with the provisions of the AEA and, if so, must give its consent in writing prior to the transfer, in accordance with Section 184 of the AEA and 10 CFR 30.34(b), which applies to Part 32 licenses. Additionally, the NRC staff reviewed the indirect transfer of control request using the guidance in NUREG-1556, Volume 15, Revision 1, "Consolidated Guidance About Materials Licenses – Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated June 2016.

10 CFR 30.34(b) states:

- (1) No license issued or granted pursuant to the regulations in [parts 30] 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.

- (2) An application for transfer of license must include:
- (i) The identity, technical and financial qualifications of the proposed transferee; and
 - (ii) Financial assurance for decommissioning information required by [10 CFR] 30.35.

As described in ADAMS package accession number ML21054A144, the indirect transfer of control will result from an agreement between Hygiena Topco, MPC's parent company, and EW Group GmbH. The NRC staff finds that the licensee request adequately provides a complete and clear description of the proposed transaction, consistent with 10 CFR 30.34(b). The sufficiency of the description is evaluated below.

The request for an indirect transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2, Subpart M and as described in NRC's Regulatory Issue Summary 2014-08, Revision 1. No comments were received from members of the public.

In the request for an indirect transfer of ownership, Medical Packaging Corporation provided information regarding its current decommissioning funding plans. Based on the information provided, Medical Packaging Corporation is not required to have financial assurance for decommissioning because of the types and amount of material authorized in its license. The NRC staff finds that the licensee's request adequately provided information for financial assurance for decommissioning, consistent with 10 CFR 30.34(b) and Chapter 5 and Appendix E of NUREG-1556, Vol. 15, Rev. 1.

Further, the NRC conducted an inspection of Medical Packaging Corporation on April 27, 2016 at its Camarillo, California facility. The NRC identified no violations.

Additionally, as described in its request, Medical Packaging Corporation commits that it:

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

Based on these commitments, the NRC staff finds that the licensee request adequately documents the constraints, license conditions, requirements, representations, and commitments made by the transferee, consistent with 10 CFR 30.34(b) and Chapter 5 and Appendix E of NUREG-1556, Vol. 15, Rev. 1.

The indirect transfer of control will result from an agreement between Hygiena Topco, MPC's parent company, and EW Group GmbH. As part of its request for written consent, NRC staff virtually met with officials at EW Group because of the ongoing Covid-19 Public Health Emergency. In addition, during this meeting with the transferee, it was determined that EW Group GmbH is registered in Germany, and a legal certificate of the registration would be submitted after the communication. Subsequently, EW Group GmbH provided a certified

verification document (ML21152A118) to show that EW Group GmbH is in existence and duly incorporated under German law. Based on the submission of and meeting with EW Group, the NRC has reasonable assurance that the licensed material will be used for its intended purpose and not for malevolent use.

An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR 51.22(c)(21).

The staff has reviewed the request for an indirect transfer of control of License No. 04-23996-01E. The NRC staff finds that the indirect transfer of control is in accordance with Section 184 of the AEA and 10 CFR 30.34(b) and consents to the transfer. 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 sales agreement confirming completion of the transaction. If this planned sale has not been consummated within 30 days of the date of this letter, please notify us in writing.

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions specified in your NRC license, representations made in your license application, and other rules, regulations, and orders of the NRC, now or hereafter in effect, to include the following:

1. Comply with applicable NRC regulations in 10 CFR Part 30, "Rules of General Applicability to domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; and other applicable regulations.

NOTE: Licensees authorized to distribute or initially transfer products containing byproduct material must also possess a valid possession license issued either by NRC or an Agreement State(s) which authorizes possession and use of byproduct material.

2. Distribute only those products containing radioactive material which are specifically authorized in your license.
3. Notify NRC in writing within 30 days of any change in mailing address.
4. In accordance with 10 CFR 30.33, 30.34 and 30.38, please file appropriate documentation with the NRC prior to any changes to your organization, change locations of distribution of products containing radioactive material, facilities, equipment, procedures, change in the contact person or the person responsible for the quality assurance program for licensed activities, or any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with the NRC.
5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 60 days before the expiration date. Continued distribution of products containing radioactive material after your license expires is a violation of NRC regulations.
6. In accordance with 10 CFR 30.36, request termination of your license if you plan to permanently discontinue activities involving distribution of products containing radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in compliance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; proposed imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600).

Please be aware that, as a holder of an NRC license, you may be subject to the NRC's annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the Accounts Receivable Branch at (301) 415-7554.

Future changes in the licensee's name, licensed use, licensed materials, licensed location, persons responsible for licensed material, or other changes to the corporate organizational structure require submission of a request to amend the license or a request to transfer the license. NRC approval must be received prior to implementation of any such proposed change.

In accordance with 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's ADAMS. ADAMS is accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>. If you have any questions regarding this letter, please contact me at 301-415-7640 or via electronic mail at Shirley.Xu@nrc.gov.

Sincerely,

Materials Safety and Tribal Liaison Branch
Division of Materials Safety, Security, State,
and Tribal Program
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-38444
Mail Control No.: 624672

Enclosure:
License No. 04-23996-01E

SUBJECT: MEDICAL PACKAGING CORPORATION, REQUEST FOR WRITTEN CONSENT
TO INDIRECT LICENSE TRANSFER

DATE: June 28, 2021

ADAMS Accession No: ML21054A139

OFC	NMSS/MSST/MSTB	NMSS/MSST/MSTB	OGC/NLO	NMSS/MSST/MSTB
NAME	S Xu	M Pringle	I Irvin	S Xu
DATE	05/27/2021	06/28/2021	06/28/2021	06/28/2021

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