

SAFETY EVALUATION REPORT
PROPOSED TRANSFER OF CONTROL FOR BYPRODUCT MATERIALS LICENSE
NUMBERS 45-25221-01MD/45-25221-05, IBA MOLECULAR NORTH AMERICA, INC.

DATE: July 15, 2015

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LICENSE NO.: 45-25221-01MD
45-25221-05

LICENSEE: IBA Molecular North America, Inc.
21000 Atlantic Boulevard, Suite 730
Dulles, Virginia 20166

TECHNICAL REVIEWERS: Tara L. Weidner, Senior Health Physicist, Region I
Jennifer L. Bishop, Health Physicist, Region III

SUMMARY AND CONCLUSIONS

IBA Molecular North America, Inc. is authorized by NRC License 45-25221-05 for the preparation and distribution of radiochemicals and NRC License 45-25221-01MD for the possession and use of byproduct material for the purposes of preparation, distribution, and redistribution of radioactive drugs and radiochemicals to authorized recipients for medical use. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by IBA Molecular North America, Inc., a wholly-owned subsidiary of GRD US PET Operations, Inc. (GRD). GRD is a wholly-owned subsidiary of Rose Holdings, S.a.r.l. (Rose). The indirect transfer will result from a sale between Rose and C-Molecular, Inc. (C-Molecular), which is wholly owned by Illinois Health & Science. Under the planned transaction, Rose will sell 100% of its shares in GRD to C-Molecular, Inc. Following the sale, GRD will be a wholly owned subsidiary of C-Molecular and IBA Molecular North America, Inc. will remain a wholly owned subsidiary of GRD. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number and ML15146A046 ML15128A543.

The licensee's request for consent to an indirect transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2 and following the guidance provided in the NRC's Regulatory Issue Summary 2014-08. No comments were received from members of the public.

The request for consent was reviewed by NRC staff for an indirect transfer of control of a 10 CFR Part 30 license using the guidance in NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses: Program-Specific 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 IBA Molecular North America, Inc. sufficiently describes and documents the transaction and commitments made by the licensee.

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 transfer of control

is in accordance with the Act. The staff finds that, after the transfer of control, IBA Molecular North America, Inc. 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 promote the common defense and security.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing system, IBA Molecular North America, Inc. has been an NRC licensee since February 4, 1993 for License No. 45-25221-01MD and since November 9, 2009 for License No. 45-25221-05. The NRC conducted an inspection of the cyclotron facility associated with License No. 45-25221-05 on March 26, 2015, and no violations were identified. With respect to License No. 45-25221-01MD, the NRC conducted inspections at the Kansas City, Missouri location on March 26, 2015 and identified one violation for a failure to perform linearity testing on the dose calibrator and on November 22, 2013 at the Morgantown, West Virginia location a posting violation was identified. The commitments made by IBA Molecular North America, Inc. and Illinois Health & Science state that there will be:

- A. no change to the radiation safety officer listed on the NRC licenses;
- B. no change in personnel involved in licensed activities;
- C. no change in the locations, facilities, and equipment authorized in the NRC license;
- D. no change in the radiation safety program authorized in the NRC license;
- E. no change in the organization's name listed in the NRC license; and
- F. the licensee will keep regulatory required surveillance records and decommissioning records.

For security purposes, IBA Molecular North America, Inc. and Illinois Health & Science, the ultimate parent post-closing, are considered to be known entities following the guidance provided by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS)¹ "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.

IBA Molecular North America, Inc. is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 45-25221-01MD. However, IBA Molecular North America, Inc. is required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 45-25221-05.

REGULATORY FRAMEWORK

¹ Previously the Office of Federal and State Materials and Environment Management Programs (FSME)

IBA Molecular North America, Inc.'s License Nos. 45-25221-05 and 45-25221-01MD were 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 transfer 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. IBA Molecular North America, Inc.'s request for consent describes an indirect transfer of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession numbers ML15128A543 and ML15146A046. After completion of the sale, IBA Molecular North America, Inc. will continue as the licensee and remain in control of all licensed activities under Materials License Nos. 45-25221-05 and 45-25221-01MD. 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 IBA Molecular North America, Inc. sufficiently describes and documents the commitments made 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)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by the licensee with regard to an indirect transfer of control of byproduct materials license Nos. 45-25221-05 and 45-25221-01MD and consents to the transaction pursuant to 10 CFR 30.34(b).

The submitted information sufficiently describes the transaction; documents the understanding of the license and commitments of the transferee; and 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 transfer of 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.