

K4
Branch 2



2012 FEB -6 AM 9:32

RECEIVED
REGION I

February 1, 2012

Commercial and R&D Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: Request for Written Consent to Indirect Change of Control Pursuant to 10 CFR 30.34(b)
IBA Molecular North America, Inc.
NRC License Nos. 45-25221-01MD and 45-25221-05
03032974 and 03038113

To Whom It May Concern:

IBA Molecular North America, Inc. (IBA Molecular NA), hereby requests that the NRC grant written consent to a pending indirect change of control of the above referenced materials licenses. IBA Molecular NA operates two facilities that are licensed by the NRC to produce and distribute various radioactive materials, which are primarily distributed to medical use licensees.

Please note that the 45-25221-01MD license covers two facilities under NRC jurisdiction: Morgantown, WV; and Kansas City, MO. The Kansas City, MO, facility is also covered under NRC materials license 45-25221-05, administered through NRC Region III. As such, duplicate consent requests are being sent to both the Region I and Region III offices. We request that this licensing action be coordinated between the two Regional offices.

The intent is to close the transaction on or by March 31, 2012. Based on the timeline and the requirement for prior NRC consent, we respectfully request that the NRC perform an expedited review of this request.

Please find below the information identified in NUREG 1556, Vol. 15, sections 5.1 through 5.6:

5.1. Description of Transaction

- A. Please find in Attachment 1 a description of the current and post-closing corporate structure. Please also find in Attachment 1 diagrams of the current and post-closing corporate structures.
- B. The name of the licensed entity will not change. The name will remain IBA Molecular North America, Inc.
- C. The licensee contact(s) will not change. The primary point of contact remains David Pellicciarini, Vice President RA/QA/EHS, phone number (424) 206-2480.

5.2. Changes of Personnel

- A. No new individuals having control over licensed activities (i.e., authorized users or authorized nuclear pharmacists) are to be added to the license as a result of the planned transaction.

IBA Molecular

576887
NMSS/RGN1 MATERIALS-002

- B. There is no change in the Radiation Safety Officer (RSO). The RSO will remain David Pellicciarini.

5.3. Changes of Location, Equipment & Procedures

- A. From the level of the President, IBA Molecular NA, to the Site RSO, no changes are planned in the organization that exercises control over licensed material as a result of this transaction.
- B. As a result of this transaction, there will be no changes to the place of use of licensed materials.
- C. As a result of this transaction, there will be no changes to the facilities where licensed materials are used.
- D. As a result of this transaction, there will be no changes to the equipment associated with the use of licensed materials.
- E. As a result of this transaction, there will be no changes to the procedures associated with the use of licensed materials.
- F. As noted above, there will be no additional authorized users or authorized nuclear pharmacists added to the license at this time as a result of this transaction. Also, the RSO listed on the materials license is not changing.

5.4. Surveillance Records

- A. All required surveillance activities have been performed, documented and reviewed.

5.5. Decommissioning and Related Records Transfers

- A. As there are no changes to the facilities, equipment and storage location of records as a result of this transaction, required records will continue to remain available at the sites (i.e., current locations of use) post-transfer.
- B. IBA Molecular NA commits to maintaining the relevant decommissioning and related records.
- C. IBA Molecular NA operates two facilities under NRC jurisdiction, one in Kansas City, MO, and one in Morgantown, WV. Contamination and ambient radiation levels are consistent with those expected at operating facilities that produce and distribute the types and quantities of radioactive materials that are handled at these sites. Contamination and ambient radiation levels are in compliance with the regulations and license requirements.
- D. There will not be any decontamination to prepare the facility for decommissioning prior to the change of control.
- E. Decommissioning of these two sites is not planned at this time, i.e., it is the intent to continue to operate these sites for the foreseeable future following the change of

control. Contamination levels, including activation products, are consistent with those expected at facilities that produce and distribute the types and quantities of radioactive materials that are handled at these sites. Contamination and ambient radiation levels are in compliance with the regulations and license requirements. The transferee is knowledgeable of the extent and levels of contamination and applicable decommissioning requirements.

- F. IBA Molecular NA continues to accept full responsibility for the decommissioning of the sites, including any contaminated facilities and equipment, post-transfer of control.

5.6. Transferee's Commitment to Abide by the Transferor's Commitments

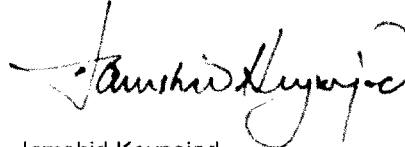
- A. As the continuing holder of the licenses, IBA Molecular NA continues to agree to abide by all constraints, license conditions, requirements, representations and commitments identified in and attributed to the existing NRC materials licenses.
- B. At this time there are no open inspection or enforcement issues. The Morgantown, WV, facility was recently inspected by the NRC, and we anticipate a Notice of Violation (NOV) based upon weaknesses in the equipment calibration program. Once the NOV is received, the transferee commits to resolving any open inspection issues as listed in the NOV.

We appreciate your assistance with this transaction. If you have any questions about this notification, please contact me at (424) 206-2480.

Sincerely,



David W. Pellicciarini, CHP
Vice President, RA/QA/EHS
IBA Molecular North America, Inc



Jamshid Keynejad
Managing Director – SK Capital Partners III
Sole Manager – SK Rose S.a.r.l.

cc: Jim Kostka, RAM License Admin
Gregory Hisel, Director, Health Physics
Todd Bejian, Corporate Legal Counsel, IBA Molecular NA
Michael Hickey, President
Mark Delevie, General Counsel, SK Capital

Attachment 1

CORPORATE STRUCTURE

The *current* corporate structure, as relevant to the radioactive materials licensee, IBA Molecular North America, Inc.,¹ is as follows: The licensee, IBA Molecular North America, Inc., is a U.S. Corporation organized under the laws of the State of Delaware, wholly owned by Molecular Imaging SA, a Belgian corporation. Molecular Imaging SA is owned (99.9%) by IBA Pharma SA, a Belgian corporation, and (0.10%) by IBA Participations SPRL, a Belgian corporation. IBA Pharma SA is owned by IBA Molecular Holding SA, a Belgian corporation (14.39%), and Ion Beam Applications SA ("IBA"), also a Belgian corporation (85.61%). IBA Molecular Holding SA is wholly owned by IBA. The current, relevant corporate structure is depicted in Figure 1.

After the closing on the transaction (which will be implemented pursuant to a share purchase agreement), the corporate structure, as relevant to the radioactive materials licensee² will be as follows: IBA Molecular North America, Inc. will *remain* the responsible radioactive materials licensee. It will be wholly owned by a new U.S. corporation, GRD US PET Operations, Inc., organized under the laws of the State of Delaware. That company will be wholly owned by Rose Holdings SARL, a Luxembourg corporation. Rose Holdings SARL will be 60% owned by SK Rose SARL, a Luxembourg corporation and 40% owned by IBA Molecular Holding SA, an existing Belgian corporation. SK Rose SARL will be wholly owned by SKCP III Rose AIV, LP, a Cayman limited partnership. IBA Molecular Holding SA will continue, as before the transaction, to be wholly owned by IBA. The relevant, post-closing corporate structure is depicted in Figure 2.

¹ The licensee and its parent companies own other companies not relevant to this request for consent, and are not reflected in this description.

² The licensee and its parent companies will continue to own other companies not relevant to this request for consent, which are not reflected in this description.

Figure 1

Current Relevant, Corporate Structure

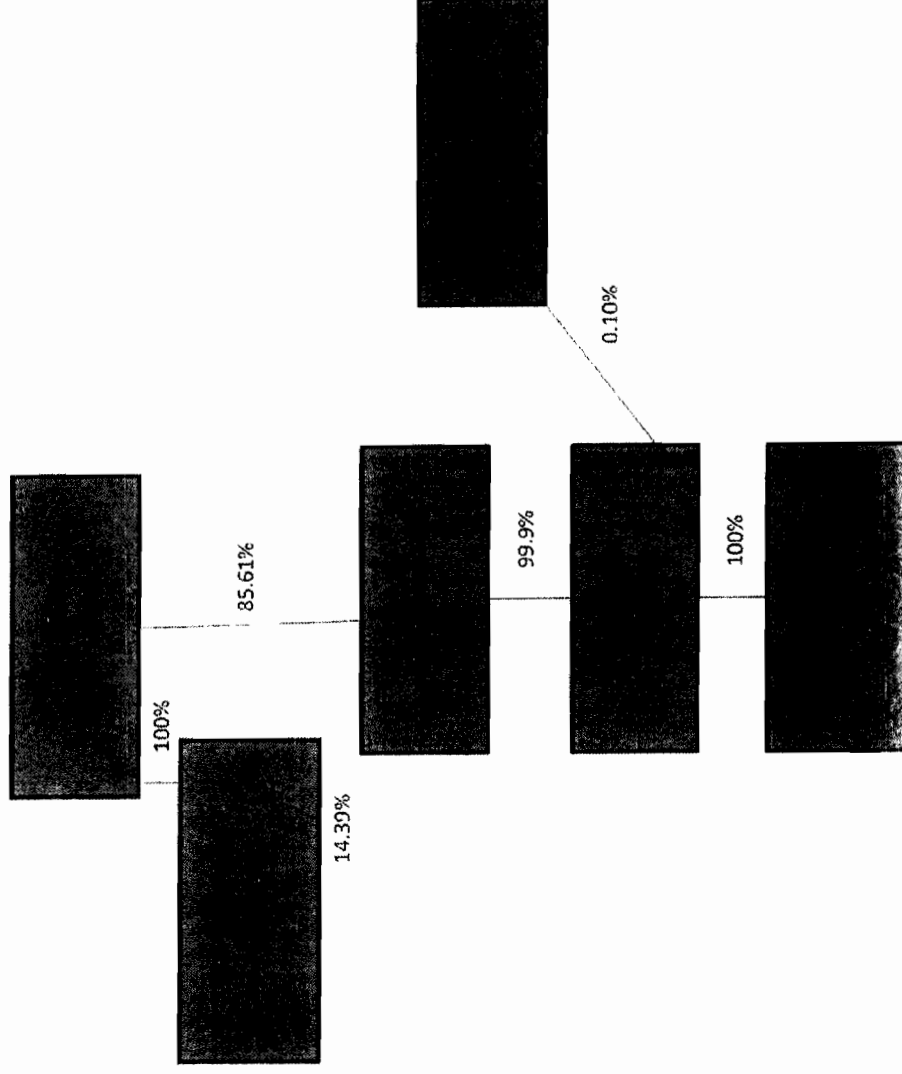
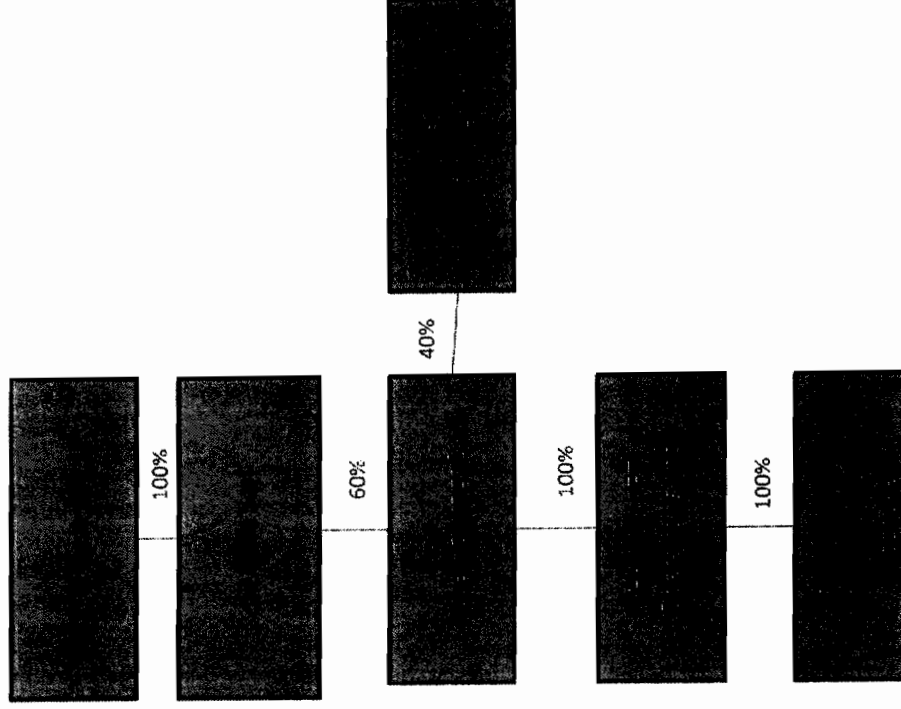


Figure 2

Relevant Post-Closing Corporate Structure



This is to acknowledge the receipt of your letter application dated

02/01/2012, and to inform you that the initial processing which includes an administrative review has been performed.

Notification (45-25221-01MD)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 576887.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.