

**SAFETY EVALUATION REPORT  
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE  
NUMBER 13-32622-01, BIOSTORAGE TECHNOLOGIES, INC.**

**DATE:** February 2, 2016

**DOCKET NO.:** 030-37223

**LICENSE NO.:** 13-32622-01

**LICENSEE:** BioStorage Technologies, Inc.  
2910 Fortune Circle West  
Suite E  
Indianapolis, IN 46241

**TECHNICAL REVIEWER:** Jennifer L. Bishop

**SUMMARY AND CONCLUSIONS**

BioStorage Technologies, Inc. is authorized by NRC License 13-32622-01 for the possession and use of byproduct material for purposes of storing labeled biological samples as a commercial service. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct license transfer submitted by BioStorage Technologies, Inc. that will result from a merger between BioStorage Technologies, Inc. and Brooks Automation, Inc. A wholly-owned subsidiary of Brooks Automation, Inc., which will merge with BioStorage Technologies, Inc., and will become a wholly-owned subsidiary of Brooks Automation, Inc. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML16020A533.

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 BioStorage Technologies, Inc. sufficiently describes and documents the transaction and commitments made by Brooks Automation, Inc. and BioStorage Technologies, Inc.

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, BioStorage Technologies, 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 promotes the security of licensed material.

**SAFETY AND SECURITY REVIEW**

According to data obtained from the NRC's Web Based Licensing (WBL) system, BioStorage Technologies, Inc. has been an NRC licensee since August 10, 2006. The NRC conducted a main office inspection of BioStorage Technologies, Inc. on February 15, 2015, and one Severity Level IV violation was identified. The commitments made by Brooks Automation, Inc. and

BioStorage Technologies, Inc. state that BioStorage Technologies, Inc. (*License No. 13-32622-01*):

- 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.

Brooks Automation, Inc. is a multinational corporation that has been incorporated since 1994 who has a license from the State of California to operate a tissue bank. Therefore, for security purposes, Brooks Automation, Inc. 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.

BioStorage Technologies, Inc. is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 13-32622-01.

## **REGULATORY FRAMEWORK**

BioStorage Technologies, Inc.'s License No. 13-32622-01, 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. BioStorage Technologies, Inc.'s request for consent describes direct change of control resulting from a planned merger between a wholly-owned subsidiary of Brooks Automation, Inc., which will merge with BioStorage Technologies, Inc., and

will become a wholly-owned subsidiary of Brooks Automation, Inc. and, as such, the transfer requires NRC consent.

### **DESCRIPTION OF TRANSACTION**

The transaction is described in ADAMS accession number ML16020A533. After completion of the merger, BioStorage Technologies, Inc. will continue as the licensee and remain in control of all licensed activities under Materials License No. 13-32622-01. 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 BioStorage Technologies, Inc. sufficiently describes and documents the commitments made by Brooks Automation, Inc. and BioStorage Technologies, Inc., 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 an indirect change of control of byproduct Materials License No. 13-32622-01 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.