

**SAFETY EVALUATION REPORT**  
**PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE**  
**NUMBERS**  
**06-30657-01 PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut**  
**and**  
**06-30537-01 PriMed, LLC d/b/a Connecticut Heart & Vascular Center**

**DATE:** September 16, 2014

**DOCKET NO.:** 030-35779 and 030-35233

**LICENSE NO.:** 06-30657-01 and 06-30537-01

**LICENSEE:** PriMed, LLC  
d/b/a Heart Specialists, PC of Southern Connecticut  
Four Corporate Drive, Suite 100  
Shelton, Connecticut 06484

PriMed, LLC  
d/b/a Connecticut Heart & Vascular Center  
112 Quarry Road, Suite 400  
Trumbull, Connecticut 06611

**TECHNICAL REVIEWER:** Janice Nguyen

**SUMMARY AND CONCLUSIONS**

PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut (PM-HSSC) and PriMed, LLC d/b/a Connecticut Heart & Vascular Center (PM-CHVC) are authorized by NRC Licenses 06-30657-01 and 06-30537-01 for the possession and use of byproduct material for the purpose of imaging and localization studies permitted by 10 CFR 35.200 at Four Corporate Drive, Suite 100, Shelton, Connecticut and 112 Quarry Road, Suite 400, Trumbull, Connecticut. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct license transfer submitted by PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut (PM-HSSC) and PriMed, LLC d/b/a Connecticut Heart & Vascular Center (PM-CHVC) that will result from a sale between PM-HSSC and PM-CHVC and Northeast Medical Group, Inc. (NEMG). NEMG is owned by Yale-New Haven Health Services Corporation d/b/a Yale-New Haven Health System. The assets of PM-HSSC and PM-CHVC were purchased by Northeast Medical Group, Inc. on June 1, 2014. Both locations of use will be merged onto the PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut (PM-HSSC) license under the new name Northeast Medical Group, Inc. and the PriMed, LLC d/b/a Connecticut Heart & Vascular Center (PM-CHVC) license will be terminated. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML14184B313. The ADAMS package consists of the following agency documents: letter dated June 17, 2014 (ML14184B316), telephone conversation record dated August 5, 2014 (ML14224A313), letter dated September 2, 2014 (ML14259A503), telephone conversation record dated September 11, 2014, and letter dated September 16, 2014.

The request for consent was reviewed by NRC staff for a 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 PriMed, LLC and Northeast Medical Group, Inc. sufficiently describes and documents the transaction and commitments made by both parties.

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, the facilities at Four Corporate Drive, Suite 100, Shelton, Connecticut and 112 Quarry Road, Suite 400, Trumbull, Connecticut, now operated by Northeast Medical Group, 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 security of licensed material.

### **SAFETY AND SECURITY REVIEW**

Northeast Medical Group, Inc. does not currently hold a NRC license, but they are directly owned by Yale-New Haven Health Services Corporation d/b/a Yale New Haven Health System. Yale-New Haven Health System owns and operates an integrated medical services delivery system in Connecticut, eastern New York, and Southern Rhode Island, including three NRC licensees Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital. According to data obtained from the NRC's Licensing Tracking System (LTS), Yale-New Haven Hospital has been an NRC licensee since August 13, 1985. The NRC conducted a main office inspection of Yale-New Haven Hospital on June 23-27, 2014, with an exit meeting on July 22, 2014, and three Severity Level IV violations were identified. The three violations involved the following: as of June 23, 2014, Yale-New Haven Hospital did not periodically (at least annually) review the radiation protection content and implementation as required by 10 CFR 20.1101(c), include a representative from the nursing service on the Radiation Safety Committee as required by 10 CFR 35.24(f), and include the determination of the length of the source transfer tubes and the lengths of the applicators in the full calibration measurements on the remote afterloader unit at St. Raphael's Campus as required by 10 CFR 35.633(b). The commitments made by PriMed, LLC and Northeast Medical Group, Inc. (NEMG) (License No. 06-30657-01) state the following:

- A. PriMed, LLC (PM-CHVC) Radiation Safety Officer (RSO) will continue to serve as the NEMG Radiation Safety Officer (RSO) and will oversee the locations at Four Corporate Drive, Suite 100, Shelton, Connecticut and 112 Quarry Road, Suite 400, Trumbull, Connecticut; the other PriMed, LLC (PM-HSSC) RSO will remain as an authorized users (AU);
- B. NEMG will not change the personnel involved in licensed activities;
- C. NEMG will not change the locations, facilities, and equipment authorized in the NRC license;
- D. NEMG will not change the radiation safety program authorized in the NRC license;

- E. The locations at Four Corporate Drive, Suite 100, Shelton, Connecticut and 112 Quarry Road, Suite 400, Trumbull, Connecticut will be known as Northeast Medical Group, Inc.
- F. NEMG will keep regulatory required surveillance records and decommissioning records.

Northeast Medical Group, Inc. does not currently hold a NRC license, but they are directly owned by Yale-New Haven Health Services Corporation d/b/a Yale New Haven Health System. Yale-New Haven Health System owns and operates three hospitals with NRC licenses, including Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital. Yale-New Haven Hospital (YNHH) has an active NRC license (License No. 06-00819-03). YNHH is a medical broad scope license, authoring multiple modalities of medical use of diagnostic studies and therapy procedures. Therefore, for security purposes, Northeast Medical Group, the daughter company of Yale-New Haven Health Services Corporation, 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.

PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut (PM-HSSC) and PriMed, LLC d/b/a Connecticut Heart & Vascular Center (PM-CHVC) are not required to have decommissioning financial assurance based on the types and amount of material authorized in License Nos. 06-30657-01 and 06-30537-01.

## **REGULATORY FRAMEWORK**

The PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut (PM-HSSC) NRC License No. 06-30657-01 and PriMed, LLC d/b/a Connecticut Heart & Vascular Center (PM-CHVC) NRC License No. 06-30537-01 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 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-I 556, 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. PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut (PM-HSSC)'s and PriMed, LLC d/b/a

Connecticut Heart & Vascular Center (PM-CHVC)'s request for consent describes a direct change of control resulting from a planned sale between Northeast Medical Group, Inc. (NEMG), PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut (PM-HSSC), and PriMed, LLC d/b/a Connecticut Heart & Vascular Center (PM-CHVC). Following the completion of the sale, the locations at Four Corporate Drive, Suite 100, Shelton, Connecticut and 112 Quarry Road, Suite 400, Trumbull, Connecticut will become locations of use for Northeast Medical Group, Inc., and, as such, the transfer requires NRC consent.

## **DESCRIPTION OF TRANSACTION**

The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML14184B313. The ADAMS package consists of the following agency documents: letter dated June 17, 2014 (ML14184B316), telephone conversation record dated August 5, 2014 (ML14224A313), letter dated September 2, 2014 (ML14259A503), telephone conversation record dated September 11, 2014, and letter dated September 16, 2014.

After completion of the sale, the locations at Four Corporate Drive, Suite 100, Shelton, Connecticut and 112 Quarry Road, Suite 400, Trumbull, Connecticut, will become locations of use for Northeast Medical Group, Inc. under the merged Materials License No. 06-30657-01 and the PriMed, LLC d/b/a Connecticut Heart & Vascular Center (PM-CHVC) NRC License No. 06-30537-01 will be terminated. 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 PriMed, LLC d/b/a Heart Specialists, PC of Southern Connecticut (PM-HSSC) and PriMed, LLC d/b/a Connecticut Heart & Vascular Center (PM-CHVC) sufficiently describes and documents the commitments made by Northeast Medical Group, Inc. and PriMed, LLC 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 direct change of control of byproduct materials license No. 06-30657-01 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.