

SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE
NUMBER 47-15717-03, Charleston Radiation Therapy Consultants, PLLC also d/b/a
Charleston Brachytherapy Services, LLC

DATE: June 1, 2015

DOCKET NO.: 030-28869

LICENSE NO.: 47-15717-03

LICENSEE: Charleston Radiation Therapy Consultants, PLLC
also d/b/a Charleston Brachytherapy Services, LLC

TECHNICAL REVIEWER: Janice Nguyen

SUMMARY AND CONCLUSIONS

Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC is authorized by NRC License 47-15717-03 for Iridium 192 in a high dose rate remote afterloader unit and Strontium 90 for the calibration and checking of the licensee's instruments. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct transfer of ownership in the letter dated February 23, 2015 that resulted from a joint venture between Charleston Radiation Therapy Consultants, PLLC, Alliance Oncology, and Charleston Area Medical Center to form a new entity, Charleston Area Radiation Therapy Centers, LLC. The transaction took place on November 7, 2014. The original owner, Charleston Radiation Therapy Consultants, PLLC remains a partial owner of the new entity, and continues to operate as an individual entity. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML15071A362, which includes: letter dated February 23, 2015 (ML15071A406), letter with attachment dated April 30, 2015 (ML15134A094), and letter with attachment dated May 12, 2015.

The licensee's request for consent to a direct 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 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 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 Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC, Alliance Oncology, and Charleston Area Medical Center, sufficiently describes and documents the transaction and commitments made by all 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 3100 MacCorkle Avenue S.E., Suite B-1, Charleston, West Virginia, now operated by Charleston Area Radiation Therapy Centers, LLC 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 system, Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC has been an NRC licensee since December 2, 1985. The NRC conducted a main office inspection of Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC on July 17, 2013, and no violations were identified during the inspection. Charleston Area Medical Center, another partial owner of the new entity, Charleston Area Radiation Therapy Centers, LLC, has been an NRC licensee since March 26, 1973 (License No. 47-15473-01). The NRC conducted a main office inspection of Charleston Area Medical Center on December 9-11, 2014, and January 8, 2015, and two Severity Level IV violations were identified. The violations involved the licensee not maintaining sewer disposal records in accordance with 10 CFR 20.2108(a) and the licensee not calibrating instruments used for quantitative radiation measurements (e.g., bioassays) annually in accordance with 10 CFR 20.1501(b) and 10 CFR 35.61(a). The commitments made by Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC, Alliance Oncology, and Charleston Area Medical Center, state that absent NRC approval, the new entity Charleston Area Radiation Therapy Centers, LLC (License No. 47-15717-03):

- 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; and
- E. will keep regulatory required surveillance records and decommissioning records.

For security purposes, as described in letters dated February 23, April 30, and May 12, 2015 with their attachments, two of the three co-owners of the new entity, Charleston Area Radiation Therapy Centers, LLC (Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC and Charleston Area Medical Center), are considered known entities 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.

The licensee is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 47-15717-03.

REGULATORY FRAMEWORK

Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC, License No. 47-15717-03 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-1 556, 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. Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC’s request for consent describes a direct change of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in Agency Documents Access and Management System (ADAMS) package accession number ML15071A362, which includes: letter dated February 23, 2015 (ML15071A406), letter with attachment dated April 30, 2015 (ML15134A094), and letter with attachment dated May 12, 2015. The joint venture between Charleston Radiation Therapy Consultants, PLLC also d/b/a Charleston Brachytherapy Services, LLC, Alliance Oncology, and Charleston Area Medical Center will result in the formation of a new entity, Charleston Area Radiation Therapy Centers, LLC. Charleston Area Radiation Therapy Centers, LLC will be the licensee and control all licensed activities under Materials License No. 47-15717-03. 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 the licensee 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 a direct change of control of byproduct materials License No. 47-15717-03 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; 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.