

**SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE
NUMBER 09-31177-01, 21ST CENTURY ONCOLOGY**

DATE: April 29, 2020

DOCKET NO.: 03037316

LICENSE NO.: 09-31177-01

LICENSEE: 21st Century Oncology
2270 Colonial Boulevard
Fort Myers, FL 33907

TECHNICAL REVIEWER: Tara L. Weidner

SUMMARY AND CONCLUSIONS

21st Century Oncology is authorized by NRC License 09-31177-01 for the possession and use of byproduct material for the purpose of medical therapy. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by 21st Century Oncology and Orion US Holdings, Inc. Specifically, Orion Merger Sub, Inc. (Orion Merger Sub), a wholly-owned subsidiary of Orion US Holdings, Inc. (Orion US Holdings), will merge with 21st Century Oncology Holdings, Inc. 21st Century Oncology Holdings, Inc. will remain the surviving entity. Orion US Holdings is a wholly-owned subsidiary of Genesis Specialist Care UK Limited, which is, in turn, a wholly-owned subsidiary of Genesis Care Finance Pty Ltd. Genesis Care Finance Pty Ltd. is a wholly-owned subsidiary of GenesisCare Pty, Ltd., an Australian proprietary limited company. Following the transaction, 21st Century Holdings, Inc. will continue to own 21st Century Oncology. The name, mailing address, and contact information will not change as a result of the transaction.

The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML20021A161.

The request for consent was reviewed by NRC staff for an indirect change of control of a 10 CFR Part 30 license using the guidance in NUREG-1556, Volume 15, Revision 1, "Consolidated Guidance About Materials Licenses - Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated June 2016. The NRC staff finds that the information submitted by 21st Century Oncology sufficiently describes and documents the transactions and commitments made by 21st Century Oncology and Orion U.S. Holdings.

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff have reviewed the application and find that the proposed change of control is in accordance with the Act. The staff finds that, after the change of control, 21st Century Oncology 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 Agencywide Documents Access and Management System (ADAMS) and Web Based Licensing System (WBL), 21st Century Oncology has been an NRC licensee since October 13, 2006. The NRC conducted an inspection of 21st Century Oncology on November 30, 2018, and no violations or items of concern were identified.

Review of the transactions completed by all parties described above confirmed that 21st Century Oncology (License No. 09-31177-01):

- A. did not change the radiation safety officer listed in the NRC license;
- B. did not change the personnel involved in licensed activities;
- C. did not change the locations, facilities, and equipment authorized in the NRC license;
- D. did not change the radiation safety program authorized in the NRC license;
- E. did not change the organization's name listed in the NRC license; and
- F. has kept regulatory required surveillance records and decommissioning records.

Orion Merger Sub, a wholly-owned subsidiary of Orion US Holdings, will merge with 21st Century Oncology Holdings, Inc. 21st Century Oncology Holdings, Inc. will remain the surviving entity. Following the transaction, 21st Century Holdings, Inc. will continue to own 21st Century Oncology. Orion US Holdings is the parent company of the following Agreement State licensees: Carolina Regional Cancer Center, LLC (License No. 515), a South Carolina licensee, and 21st Century/Louisville (License No. 202-352-27), a Kentucky licensee. Therefore, for security purposes, Orion US Holdings, Inc., is considered a known entity following the guidance provided by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) "Checklist to Provide a Basis for Confidence that Radioactive Materials Will be Used as Specified on the Application," January 29, 2019. 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.

21st Century Oncology is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 09-31177-01.

REGULATORY FRAMEWORK

21st Century Oncology's License No. 09-31177-01, was issued under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." The NRC 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)(1) 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, Revision 1. The central issue is whether the authority over the license has changed. 21st Century Oncology's request for consent describes an indirect change of control resulting from a merger between Orion US Holdings, Inc. and 21st Century Oncology Holdings, Inc. and, as such, the transfer required NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS package accession number ML20021A161. 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 E of NUREG-1556, Volume 15, Revision 1.

TRANSFeree'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the information submitted by 21st Century Oncology and Orion US Holdings, Inc. sufficiently describes and documents the commitments made by the transferee and is consistent with the guidance in NUREG-1556, Volume 15, Revision 1.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required because the approval of the described transfer of control and the associated administrative license amendment are categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by all parties, with regards to an indirect change of control of byproduct materials license No. 09-31177-01 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, Revision 1.

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.