



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

October 20, 2015

Cornelis J. Van der Schyf, B.Pharm., D.Sc., DTE
Vice President for Research and Dean of the Graduate School
Idaho State University, Office of Research
921 South 8th Avenue, Stop 8130
Pocatello, ID 83209

Dear Dr. Van der Schyf:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter of July 23, 2015, requesting an annual fee waiver under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 171.11 for production and distribution of radio-chemicals by the Idaho Accelerator Center (IAC) at Idaho State University (ISU).

The NRC has established regulations for the granting of fee exemptions under 10 CFR 171.11, "Exemptions," for which licensees may apply in accordance to 10 CFR 171.9, "Communications." The NRC has reviewed your request based on the following requirements:

- 10 CFR 171.11, Exemptions. (c) The Commission may, upon application by an interested person or on its own initiative, grant an exemption from the requirements of this part that it determines is authorized by law or otherwise in the public interest. The NRC acknowledges the IAC is permitted to produce and process accelerator-produced radionuclides, ⁶⁷Cu, for commercial distribution. The NRC further notes that the IAC receives an insignificant amount of revenues from the remunerated distributions of ⁶⁷Cu, and it does not have any other radio-isotope distribution program or revenue source. In its first year (fiscal year 2015) of the program, the IAC had a total of \$1,900 in revenues; yet it would be obligated for a total of \$88,100 in a flat annual fee under category Part 171, 3A and 3S. The NRC recognizes that IAC continuing its program is conditional on its ability to maintain a low cost-structure, and such a discrepancy between its revenue and the regulatory fee could have a significant impact to the operation. The NRC agrees with the IAC that providing inexpensive radionuclides to researchers at cancer research centers and universities nationwide to produce life enhancing drugs benefits the public, and, therefore, the public interest is served by granting IAC an annual fee exemption that allows for continued radionuclide production. Further, granting a fee exemption is authorized by the Omnibus Budget Reconciliation Act of 1990, which requires the NRC to ensure that its annual fees are fair and equitable; here, fairness and equity is served by calibrating IAC's annual fees with its actual revenues. The NRC, therefore, concludes that IAC activities meet this regulation.
- 10 CFR 171.9, Communications, All communications concerning the regulations in this part should be addressed to the NRC's Chief Financial Officer, either by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, via

Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to MSHD.Resource@nrc.gov; or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. The IAC's fee exemption request was submitted in writing; therefore, it meets this regulation.

The NRC concludes IAC radionuclides production and distribution activities meet the criteria for receiving an annual fee exemption, as established under 10 CFR 171.11(c) and 10 CFR 171.9; therefore, your fee-exemption request is approved for a full exemption. If you have any questions regarding this matter, please contact Ms. Arlette Howard, of my staff, at 301-415-1481.

Sincerely,

/RA/

Maureen E. Wylie
Chief Financial Officer

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/RA/

Maureen E. Wylie
Chief Financial Officer

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Adams: Yes No Initials: EK SUNSI Review: EK

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*NLO via email attached

ADAMS Accession No: ML15274A346

***via e-mail CFO-0009**

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