

November 9, 2005

Steve T. Laflin
President and Chief Executive Officer
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, Idaho 83401

SUBJECT: REQUEST TO BECOME CERTIFICATE HOLDER FOR CERTIFICATE OF
COMPLIANCE NO. 5796 FOR THE MODEL NOS. 181375 AND 181361
PACKAGES

Dear Mr. Laflin:

By letter dated August 15, 2005, International Isotopes, Inc., (INIS) submitted an application requesting the U.S. Nuclear Regulatory Commission (NRC) transfer Certificate of Compliance (CoC) No. 5796 from Advanced Medical Systems, Inc., to INIS.

This letter is to inform you that prior to INIS becoming the Certificate Holder of CoC No. 5796, INIS should adequately address all the requirements of Part 71, Subpart H, "Quality Assurance." INIS' current user-only quality assurance program does appear to address the requirements of a Certificate Holder, for example, the requirements of 10 CFR 71.107, "Package Design Control."

To avoid termination of CoC No. 5796, if Advanced Medical Systems, Inc., will likely be out of business by the time INIS implements an NRC approved broad-scope quality assurance program, the staff is willing to discuss transfer of CoC No. 5796 to INIS that includes a condition in the certificate that the design and fabrication documentation is maintained and transport is not authorized. Please submit a written request if this is how INIS would like to proceed.

If you have any questions regarding this matter, you may contact me at (301) 415-8500.

Sincerely,

/RA/

Shawn Williams, Project Engineer
Licensing Section
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-5796
TAC No. L23888

cc: Advanced Medical Systems, Inc.

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DISTRIBUTION: (Closes TAC No. L23888)
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