January 27, 2005

MEMORANDUM TO: Tim Harris, Section Leader

Materials Safety and Inspection Branch, IMNS

FROM: Tomas Herrera /RA/

Materials Safety and Inspection Branch, IMNS

SUBJECT: SUMMARY OF MEETING WITH INTERNATIONAL

ISOTOPES INC., JANUARY 25, 2005

International Isotopes Inc. representatives requested a meeting with NRC staff, on January 25, 2005, to discuss their application for irradiator and teletherapy sources.

The meeting addressed International Isotopes Inc.'s draft response to the NRC request for additional information. The topics included:

- prototype testing;
- construction of the device;
- manufacturing procedures;
- quality assurance program;
- conditions of use;
- guidelines for withholding proprietary information.

The NRC participants outlined the type of responses that the NRC would deem acceptable to the request for additional information.

The objective of the meeting was to answer any questions that the representatives from International Isotopes Inc., had regarding the request for additional information and NRCs expectations on the responses that it would accept from International Isotopes Inc.

A copy of the meeting agenda is attached.

Attachments: As stated

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NRC Staff:

Nima Ashkeboussi Tomas Herrera

International Isotopes Inc.:

Stephen Laflin John Miller

<u>Distribution:</u> NMSS r/f THarris/IMNS JJankovich/IMNS

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January 25, 2005 Location: 09B6

Time: 10:00am to 12:00pm
Public Meeting: International Isotopes Inc.

INTRODUCTIONS

PURPOSE

- International Isotopes Inc. requested the meeting to discuss their sealed source and device application
- The NRC does not expect any commitments or answers to the request for additional information

OUTCOME

- International Isotopes Inc. understands what the basis for the NRC requests are.
- International Isotopes Inc. understands what the NRC expects regarding a response to the request for additional information.

PROCESS

- NRC staff will discuss any questions the International Isotopes Inc. representatives have regarding NRC's request for additional information
- NRC will discuss what areas need to be addressed when International Isotopes Inc. prepares a response

CLOSURE