International Isotopes Inc.

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APR 28 2016
DNMS

PUBLIC
☐ Immediate Release
☐ Normal Release

NON-PUBLIC
☒ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:_____

Reviewer: RITC Date: 5-2-16

April 26, 2016

US NRC Region IV,
ATTN: Mr. Jack Whitten
1600 East Lamar Boulevard
Arlington, Texas 76011-4511

Subject: Request to Amend NRC License 11-27680-01MD

Dear Mr. Whitten,

International Isotopes Inc. (INIS) is requesting to amend NRC license 11-27680-01MD to update the reference to OP-QMS-011 Revision B in Blocks 9 Land M (iii).

Sources may be transferred between devices not specifically listed in paragraph (ii) directly into a transportation package utilizing the International Isotopes, Inc. (INIS) mobile hot cell so long as the compatibility of the device with the mobile hot cell is evaluated and approved by the International Isotopes, Inc. ALARA Safety Committee and this evaluation and approval is conducted and documented in accordance with International Isotopes, Inc. procedure OP-QMS-011 Revision ~~B~~ C, Product and Equipment Development and Design Control as described in letter dated ~~December 6, 2013~~ April 14, 2016.

This procedure has been revised to incorporate corrective actions to address NRC findings identified in NRC Inspection Report 030-35486/2015-001. INIS will continue to utilize Revision B of the procedure until 11-27680-01MD has been updated to reflect Revision C.

The following items are included to support this request:

- Completed NRC Form 3.
- Blocks 5-11 of NRC Form 3
- Copy of red-lined revision to OP-QMS-011, Revision B and a copy of the final version of OP-QMS-011, Revision C.

Please contact me at 208.524.5300 or via email at jjmiller@intisoid.com if you have any questions or comments regarding this request.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer
JJM-2016-12

4137 Commerce Circle, Idaho Falls, Idaho 83401
Phone: 208-524-5300, 800-699-3108 Fax: 208-524-1411
Website: www.intisoid.com

ML590764

NRC FORM 313 (04-2016)
10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 04/30/2016

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☑ B. AMENDMENT TO LICENSE NUMBER 11-27680-01MD
- ☐ C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

International Isotopes Inc.
4137 Commerce Circle
Idaho Falls, ID, 83401

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4137 Commerce Circle
Idaho Falls, ID 83401

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John J. Miller

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(208) 524-5300	(208) 589-1580

BUSINESS EMAIL ADDRESS
jjmiller@intisoid.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY _____ AMOUNT ENCLOSED $ _____

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
John J. Miller, CHP Radiation Safety and Regulatory Compliance Officer		4/26/16

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

International Isotopes Inc.

TITLE:	Number:	Revision:
Product & Equipment Development and Design Control	OP-QMS-011	~~B~~C
		Effective Date
		~~4/18/2012~~TBD

PRI Signature and Date:	Document Control Signature and Date:	Quality Assurance Signature and Date:
/s/ Steve Laflin ~~4/18/2012~~	~~/s/Dominique Kauer 4/18/2012~~	/s/Audrey Nelson ~~4/18/2012~~

1.0 Purpose

To provide a flexible set of instructions on how to document product and equipment development and implement the design controls associated with new products or new pieces of equipment relied on for safety or when design changes are necessary for existing products or existing pieces of equipment.

2.0 Potential Hazards

Not applicable.

3.0 Applicability ~~And~~ and Limitations

3.1 This procedure applies to all products under INIS design authority, including those that may be manufactured by an outside source.

~~3.1~~3.2 This procedure applies to Product or Safety Significant Equipment (PSSE) that the ALARA Committee has determined the design control process applies.

4.0 Definitions

4.1 Design Controls – an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances.

4.2 Design Input – the physical and performance requirements of a device that are used as a basis for device design.

4.3 Design Output – the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

4.4 Design Review – a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

4.5 Specification – any requirement with which a product, process, service, or other activity must conform.

4.6 Validation – confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

4.6.1 *Process Validation* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

4.6.2 *Design Validation* means establishing by objective evidence that device specifications conform with user needs and intended use(s).

4.7 Verification – confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

4.8 Design Transfer – the act of translating the device design into production specifications through the use of process procedures.

4.9 Design History File – a compilation of records which describes the design history of a finished product or device.

5.0 Responsibilities

5.1 Product Manager: Develops an initial description and desired function of the proposed product. Leads the Management Team through the design and development process, through design transfer. Compiles the Design History File and ensures subsequent design changes are controlled in accordance with this procedure.

5.2 Design Engineer: Develops design specifications, process technologies and equipment and facility requirements needed to ensure design transfer results in the development of a process that will achieve product specification.

5.3 Management Team: Reviews and evaluates new product designs and subsequent design changes to existing products in accordance with this procedure.

5.4 Health and Safety Manager: As a member of the Management Team, evaluates the design and identifies health and safety hazards that must be addressed during design transfer and subsequent production including inherent hazards associated with the finished product and the controls necessary to reduce the health and safety risk to the end user.

5.5 Quality Assurance Manager: As a member of the Management Team, ensures the design control process is conducted in accordance with applicable regulation and that the Design History File is maintained as a living document throughout the life of the product.

6.0 Equipment and Materials

Form F-240 Product Development and Design Control

7.0 Procedure

7.1 Design and Development Planning:

7.1.1 Project Manager - initiate F-240 Product Development and Design Control for new products being developed, when new models to existing products are proposed or when a product design change is necessary.

7.1.2 Complete Blocks 1 through ~~10~~11 of Section 7.1 of Form-F-240 taking into consideration the elements listed below.

- Description of the goals and objectives of the design and development program; i.e., what is to be developed;
- Delineation of organizational responsibilities with respect to assuring quality during the design and development phase, to include interface with any contractors;
- Identification of the major tasks to be undertaken, deliverables for each task, and individual or organizational responsibilities (staff and resources) for completing each task;
- Identification of potential risks resulting from failure of or improper use of the product or PSSE and measures to mitigate identified risks;
- Scheduling of major tasks to meet overall program time constraints;
- Identification of major reviews and decision points;
- Selection of reviewers, the composition of review teams, and procedures to be followed by reviewers;
- Controls for design documentation;
- Notification activities.

7.1.3 Forward Form-F-240 Product Development and Design Control to the Quality Assurance Manager.

7.2 Design Input:

7.2.1 Quality Control Manager: review Section 7.1 of Form F-240 and determine if the information provided by the Project Manager provides enough initial detail to support the design control process. If Section 7.1 is considered incomplete, ambiguous, or contains conflicting requirements then return the Form F-240 to the Project Manager to be revised.

7.2.2 If the Form-F-240 is submitted to initiate a design change, evaluate the proposed design change against the design control criteria and determine if the design control process is necessary. If the design control process is not necessary then inform the Project Manager as such and implement the change in a different manner.

7.2.3 If the design control process is necessary then coordinate with the Project Manager, Design Engineer and Management Team to develop design inputs.

7.2.4 Management/Design Team –Identify and develop a comprehensive set of design input requirements assigned to the following categories:

- Functional requirements – specify what the device does, focusing on the operational capabilities of the device and processing of inputs and the resultant outputs.
- Performance requirements – specify how much or how well the device must perform, addressing issues such as speed, strength, response times, accuracy, limits of operation, etc. This includes a quantitative characterization of the use environment, including, for example, temperature, humidity, shock, vibration, and electromagnetic compatibility. Requirements concerning device reliability and safety also fit into this category.
- Safety and Effectiveness requirements – specify measures to; identify and reduce risks inherent with the device, provide protection, minimize the hazard of potential failures, not deteriorate under normal use to such a degree that health or safety is adversely affected, ensure materials used in the manufacture shall be compatible with every other material with which it interacts.
- Interface requirements – specify characteristics of the device which are critical to compatibility with external systems; specifically, those characteristics which are mandated by external systems and outside the control of the developers.

7.2.5 Management/Design Team – Document Design Input in Section 7.2 of Form F-240, include environmental extremes, manufacturing tolerances, material properties etc. Include supporting documentation such as drawings, schematics, Material Safety Data Sheets, etc. with the Form F-240, supporting documents will be incorporated into the Design History File.

7.3 Design Output:

As a general rule, an item is a "design output" if it is a work product or deliverable item of a design task listed in the design and development plan, and the item defines describes or elaborates an element of the design implementation. Design output includes production specifications as well as descriptive materials which define and characterize the design.

7.3.1 Management/Design Team – Develop design outputs necessary in order for product to achieve functional objectives.

7.3.2 Document Design Outputs on Form-F-240. When possible link a specific design output to a design input. For example, if design output achieves the design input recorded in Function Requirement block a. then annotate the design output to correlate to the design input i.e. FR-a. Note that more than one Design Output may be needed to meet a specific design input and a single design output may satisfy multiple design inputs.

7.3.3 Maintain documentation of design outputs such as safety evaluations, product drawings and schematics, material specifications in the Product Design History File.

7.3.4 Perform a Product Hazard Analysis and Risk Assessment in accordance with the OP-QMS-012 Failure Mode and Effects Analysis Procedure, and include the results as a design output.

7.4 Design Verification and Review:

Design Verification is intended to confirm through tests, inspections and analyses that the Design Output meets the Design Input requirements. The Design Verification process will be conducted in conjunction with the first of two Design Reviews.

7.4.1 Management/Design Team – Identify Design Verification methods for specific Design Outputs and document on Form F-240.

7.4.2 Identify reviewers and their review responsibility(ies) on Form F-240.

7.4.3 Design Reviewers – Review intended application/use of the product against the Design Inputs and Design Outputs as assigned. Evaluate the Design Verification methods and results against product conformance requirements. Provide feedback as needed to the Management and Design Team when design changes may be warranted.

7.4.4 Indicate approval of the design at this point in the development stage by signing Form F-240.

7.4.5 Project Manager – When external design verification and/or reviews are conducted, compile external documents for Management and Design Team review and subsequent inclusion in the Design History File.

7.4.6 Annotate an External Design Verification and/or Review on Form F-240 by including the name of the company or consultant performing the activity. External Design Verifications and/or Reviews must be reviewed and accepted by the Management and Design Team. The Project Manager will indicate acceptance by signing Form F-240 in the approval block for the external party.

7.5 Design Validation and Review:

Whereas verification is a detailed examination of aspects of a design at various stages in the development, design validation is a cumulative summation of all efforts to assure that the design will conform with user needs and intended use(s), given expected variations in components, materials, manufacturing processes, and the use environment. The Design Validation process will be conducted in conjunction with the second of two Design Reviews.

7.5.1 Management/Design Team – Identify Design Validation methods for specific Design Outputs and document on Form F-240 Product Development and Design Control.

7.5.2 Identify reviewers and their review responsibility(ies) on Form F-240 Product Development and Design Control.

7.5.3 Design Reviewers – Review intended application/use of the product against the Design Inputs and Design Outputs as assigned. Evaluate the Design Validation methods and results against product conformance requirements. Provide feedback as needed to the Management and Design Team when design changes may be warranted.

7.5.4 Indicate approval of the design at this point in the development stage by signing Form F-240 Product Development and Design Control.

7.5.5 Project Manager – When external design validation and/or reviews are conducted, compile external documents for Management and Design Team review and subsequent inclusion in the Design History File.

7.5.6 Annotate an External Design Validations and/or Reviews on Form F-240 Product Development and Design Control by including the name of the company or consultant performing the activity. External Design Verifications and/or Reviews must be reviewed and accepted by the Management and Design

Team. The Project Manager will indicate acceptance by signing Form F-240 in the approval block for the external party.

7.6 Design Transfer

Design Transfer translates the design into product or PSSE specifications. Production specifications must ensure that manufactured devices are repeatedly and reliably produced within product and process capabilities. The level of detail necessary to accomplish this objective varies widely, based on the type of device, the relationship between the design and manufacturing organizations, and the knowledge, experience, and skills of production workers. Documents developed during the Design Transfer Process will be approved in accordance with OP-ADM-002 INIS Document Change Procedure and/or OP-QMS-037 INIS Equipment Evaluation and Change Control Procedure.

7.6.1 Management and Design Team – Develop new or approve earlier product or PSSE -specification documents that ensure product or PSSE performance objectives are met.

7.6.2 Develop product drawings ensuring that materials of construction and tolerances are addressed.

7.6.3 Identify those materials required to be provided by a qualified supplier and the supplier(s) that have been qualified.

7.6.4 Identify critical equipment necessary to manufacture the product, such as welders, cameras, assay instrumentation etc. Include purchasing information as needed or in the case of custom fabricated equipment such as jigs then include drawings or documentation that would be useful if the piece of equipment requires replacement. Document this information on Form F-240 Product Development and Design Control.

7.6.5 Operations – Evaluate specification documents, drawings and equipment requirements and develop a procedure specific to the product being manufactured. In some cases product evaluation, packaging and handling procedures may be needed in addition to the production procedure.

7.6.6 Document procedures developed to produce the product, including procedures that support production or to operate the PSSE on Form F-240 Product Development and Design Control.

7.7 Design Change

Design changes will be documented on Form F-240 Product Development and Design Control. The extent at which the design change is evaluated verified and validated depends on the magnitude of the change.

7.7.1 Project Manager - initiate Design Control Form, F-240 when a product design change is necessary. Complete Steps 7.1 through 7.6. Mark portions of the form as "No Change Required" as appropriate. For example if the design change does not require a change in the supplier list then mark this section of the Form as "No Change Required"

7.8 Procedural changes supporting the design change will be performed in accordance with the INIS document control system, specifically procedure OP-ADM-002 INIS Document Change Procedure.

7.9 Design History File

A Design History File is a living document that compiles the records supporting the product design during the life of the product line.

7.9.1 Project Manager – Prepare a Design History File for product or PSSE.

7.9.1.1 The Design History File will include complete Form F-240 for the development of the product and subsequent Design Changes.

7.9.1.2 When possible the design history file will include all documentation supporting the design, such as test reports, photographs, calculation sheets, design meeting notes, etc.

7.9.1.3 Items that support the design such as specification documents, manufacturing procedures, drawings will be referenced in the design file so that they are easily retrievable when needed.

7.9.2 Forward completed Design History Files to the Quality Assurance Manager for record retention.

8.0 References

8.1 F-240 Product Development and Design Control

8.2 OP-ADM-002 INIS Document Change Procedure.

8.3 OP-QMS-037 INIS Equipment Evaluation and Change Control Procedure

~~8.3~~8.4 OP-QMS-012 Failure Mode and Effects Analysis Procedure

~~8.4~~8.5 International Standard, ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes

~~8.5~~8.6 International Standard, ISO 9001:2008 Quality management systems — Requirements

~~8.6~~8.7 Technical Information Report, ANSI/AAMI/ISO TIR14969:2004 Medical devices— Quality management systems— Guidance on the application of ISO 13485:2003

~~8.7~~8.8 FDA Center for Device and Radiological Health, Design Control Guidance for Medical Device Manufacturers, March 11, 1997

~~8.8~~8.9 Canadian Medical Device Regulations, SOR/98-282, December 16, 2011

9.0 Attachments

None

International Isotopes Inc.

TITLE:	Number:	Revision:
Product & Equipment Development and Design Control	OP-QMS-011	C
		Effective Date

PRI Signature and Date:	Document Control Signature and Date:	Quality Assurance Signature and Date:

1.0 Purpose

To provide a flexible set of instructions on how to document product and equipment development and implement the design controls associated with new products or new pieces of equipment relied on for safety or when design changes are necessary for existing products or existing pieces of equipment.

2.0 Potential Hazards

Not applicable.

3.0 Applicability and Limitations

3.1 This procedure applies to all products under INIS design authority, including those that may be manufactured by an outside source.

3.2 This procedure applies to Product or Safety Significant Equipment (PSSE) that the ALARA Committee has determined the design control process applies.

4.0 Definitions

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5.4 Health and Safety Manager: As a member of the Management Team, evaluates the design and identifies health and safety hazards that must be addressed during design transfer and subsequent production including inherent hazards associated with the finished product and the controls necessary to reduce the health and safety risk to the end user.

5.5 Quality Assurance Manager: As a member of the Management Team, ensures the design control process is conducted in accordance with applicable regulation and that the Design History File is maintained as a living document throughout the life of the product.

6.0 Equipment and Materials

Form F-240 Product Development and Design Control

7.0 Procedure

7.1 Design and Development Planning:

7.1.1 Project Manager - initiate F-240 Product Development and Design Control Product Development and Design Control for new products being developed, when new models to existing products are proposed or when a product design change is necessary.

7.1.2 Complete Blocks 1 through 11 of Section 7.1 of Form-F-240 Product Development and Design Control taking into consideration the elements listed below.

- Description of the goals and objectives of the design and development program; i.e., what is to be developed;
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- Scheduling of major tasks to meet overall program time constraints;
- Identification of major reviews and decision points;
- Selection of reviewers, the composition of review teams, and procedures to be followed by reviewers;
- Controls for design documentation;
- Notification activities.

7.1.3 Forward Form-F-240 Product Development and Design Control to the Quality Assurance Manager.

7.2 Design Input:

7.2.1 Quality Control Manager: review Section 7.1 of Form F-240 Product Development and Design Control and determine if the information provided by the Project Manager provides enough initial detail to support the design control process. If Section 7.1 is considered incomplete,

ambiguous, or contains conflicting requirements then return the Form F-240 Product Development and Design Control to the Project Manager to be revised.

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7.2.3 If the design control process is necessary then coordinate with the Project Manager, Design Engineer and Management Team to develop design inputs.

7.2.4 Management/Design Team –Identify and develop a comprehensive set of design input requirements assigned to the following categories:

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- Safety and Effectiveness requirements – specify measures to; identify and reduce risks inherent with the device, provide protection, minimize the hazard of potential failures, not deteriorate under normal use to such a degree that health or safety is adversely affected, ensure materials used in the manufacture shall be compatible with every other material with which it interacts.
- Interface requirements – specify characteristics of the device which are critical to compatibility with external systems; specifically, those characteristics which are mandated by external systems and outside the control of the developers.

7.2.5 Management/Design Team – Document Design Input in Section 7.2 of Form F-240 Product Development and Design Control, include

environmental extremes, manufacturing tolerances, material properties etc. Include supporting documentation such as drawings, schematics, Material Safety Data Sheets, etc. with the Form F-240 Product Development and Design Control, supporting documents will be incorporated into the Design History File.

7.3 Design Output:

As a general rule, an item is a "design output" if it is a work product or deliverable item of a design task listed in the design and development plan, and the item defines describes or elaborates an element of the design implementation. Design output includes production specifications as well as descriptive materials which define and characterize the design.

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7.3.4 Perform a Product Hazard Analysis and Risk Assessment in accordance with the OP-QMS-012 Failure Mode and Effects Analysis Procedure, and include the results as a design output.

7.4 Design Verification and Review:

Design Verification is intended to confirm through tests, inspections and analyses that the Design Output meets the Design Input requirements. The Design Verification process will be conducted in conjunction with the first of two Design Reviews.

7.4.1 Management/Design Team – Identify Design Verification methods for specific Design Outputs and document on Form F-240 Product Development and Design Control.

7.4.2 Identify reviewers and their review responsibility(ies) on Form F-240 Product Development and Design Control.

7.4.3 Design Reviewers – Review intended application/use of the product against the Design Inputs and Design Outputs as assigned. Evaluate the Design Verification methods and results against product conformance requirements. Provide feedback as needed to the Management and Design Team when design changes may be warranted.

7.4.4 Indicate approval of the design at this point in the development stage by signing Form F-240 Product Development and Design Control.

7.4.5 Project Manager – When external design verification and/or reviews are conducted, compile external documents for Management and Design Team review and subsequent inclusion in the Design History File.

7.4.6 Annotate an External Design Verification and/or Review on Form F-240 Product Development and Design Control by including the name of the company or consultant performing the activity. External Design Verifications and/or Reviews must be reviewed and accepted by the Management and Design Team. The Project Manager will indicate acceptance by signing Form F-240 Product Development and Design Control in the approval block for the external party.

7.5 Design Validation and Review:

Whereas verification is a detailed examination of aspects of a design at various stages in the development, design validation is a cumulative summation of all efforts to assure that the design will conform with user needs and intended use(s), given expected variations in components, materials, manufacturing processes, and the use environment. The Design Validation process will be conducted in conjunction with the second of two Design Reviews.

7.5.1 Management/Design Team – Identify Design Validation methods for specific Design Outputs and document on Form F-240 Product Development and Design Control.

7.5.2 Identify reviewers and their review responsibility(ies) on Form F-240 Product Development and Design Control.

7.5.3 Design Reviewers – Review intended application/use of the product against the Design Inputs and Design Outputs as assigned. Evaluate the Design Validation methods and results against product conformance

requirements. Provide feedback as needed to the Management and Design Team when design changes may be warranted.

7.5.4 Indicate approval of the design at this point in the development stage by signing Form F-240 Product Development and Design Control.

7.5.5 Project Manager – When external design validation and/or reviews are conducted, compile external documents for Management and Design Team review and subsequent inclusion in the Design History File.

7.5.6 Annotate an External Design Validations and/or Reviews on Form F-240 Product Development and Design Control by including the name of the company or consultant performing the activity. External Design Verifications and/or Reviews must be reviewed and accepted by the Management and Design Team. The Project Manager will indicate acceptance by signing Form F-240 Product Development and Design Control in the approval block for the external party.

7.6 Design Transfer

Design Transfer translates the design into product or PSSE specifications. Production specifications must ensure that manufactured devices are repeatedly and reliably produced within product and process capabilities. The level of detail necessary to accomplish this objective varies widely, based on the type of device, the relationship between the design and manufacturing organizations, and the knowledge, experience, and skills of production workers. Documents developed during the Design Transfer Process will be approved in accordance with OP-ADM-002 INIS Document Change Procedure and/or OP-QMS-037 INIS Equipment Evaluation and Change Control Procedure.

7.6.1 Management and Design Team – Develop new or approve earlier product or PSSE specification documents that ensure product or PSSE performance objectives are met.

7.6.2 Develop product drawings ensuring that materials of construction and tolerances are addressed.

7.6.3 Identify those materials required to be provided by a qualified supplier and the supplier(s) that have been qualified.

7.6.4 Identify critical equipment necessary to manufacture the product, such as welders, cameras, assay instrumentation etc. Include purchasing information as needed or in the case of custom fabricated equipment such as jigs then include drawings or documentation that would be useful if the

piece of equipment requires replacement. Document this information on Form F-240 Product Development and Design Control.

7.6.5 Operations – Evaluate specification documents, drawings and equipment requirements and develop a procedure specific to the product being manufactured. In some cases product evaluation, packaging and handling procedures may be needed in addition to the production procedure.

7.6.6 Document procedures developed to produce the product, including procedures that support production or to operate the PSSE on Form F-240 Product Development and Design Control.

7.7 Design Change

Design changes will be documented on Form F-240 Product Development and Design Control. The extent at which the design change is evaluated verified and validated depends on the magnitude of the change.

7.7.1 Project Manager - initiate Design Control Form, F-240 Product Development and Design Control when a product design change is necessary. Complete Steps 7.1 through 7.6. Mark portions of the form as "No Change Required" as appropriate. For example if the design change does not require a change in the supplier list then mark this section of the Form as "No Change Required"

7.8 Procedural changes supporting the design change will be performed in accordance with the INIS document control system, specifically procedure OP-ADM-002 INIS Document Change Procedure.

7.9 Design History File

A Design History File is a living document that compiles the records supporting the product design during the life of the product line.

7.9.1 Project Manager – Prepare a Design History File for product or PSSE.

7.9.1.1 The Design History File will include complete Form F-240 Product Development and Design Control for the development of the product and subsequent Design Changes.

7.9.1.2 When possible the design history file will include all documentation supporting the design, such as test reports, photographs, calculation sheets, design meeting notes, etc.

№ 5 9 0 7 6 4

7.9.1.3 Items that support the design such as specification documents, manufacturing procedures, drawings will be referenced in the design file so that they are easily retrievable when needed.

7.9.2 Forward completed Design History Files to the Quality Assurance Manager for record retention.

8.0 References

8.1 F-240 Product Development and Design Control

8.2 OP-ADM-002 INIS Document Change Procedure.

8.3 OP-QMS-037 INIS Equipment Evaluation and Change Control Procedure

8.4 OP-QMS-012 Failure Mode and Effects Analysis Procedure

8.5 International Standard, ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes

8.6 International Standard, ISO 9001:2008 Quality management systems — Requirements

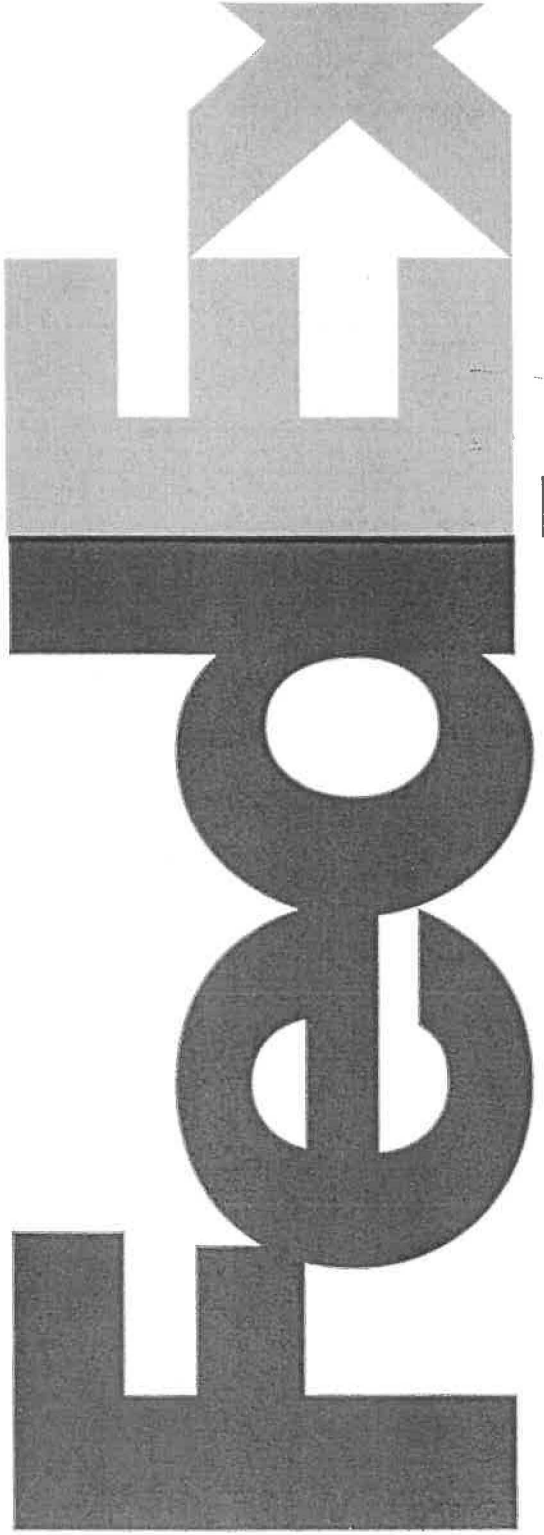
8.7 Technical Information Report, ANSI/AAMI/ISO TIR14969:2004 Medical devices—Quality management systems— Guidance on the application of ISO 13485:2003

8.8 FDA Center for Device and Radiological Health, Design Control Guidance for Medical Device Manufacturers, March 11, 1997

8.9 Canadian Medical Device Regulations, SOR/98-282, December 16, 2011

9.0 Attachments

None



Express

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ATTN JACK WHITTEN
1600 EAST LAMAR BLVD

ARLINGTON
TX 76011

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658323747064

26Apr16
** 2DAY **

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ATTN ~~JACK WHITTEN~~
US NRC REGION IV
1600 EAST LAMAR BLVD

ARLINGTON TX 76011

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NRC FORM 532
(1-2012)

U. S. NUCLEAR REGULATORY COMMISSION

DATE

04/28/2016

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
Mr. John J. Miller, CHP Radiation Safety Officer International Isotopes, Inc. 4137 Commerce Circle Idaho Falls, ID 83401	11-27680-01MD
	MAIL CONTROL NUMBER 590764
	LICENSING AND/OR TECHNICAL REVIEWER CH

This is to acknowledge the receipt of your:

☑ LETTER and/or ☐ APPLICATION DATED: 04/26/2016

The initial processing, which included an administrative review, has been performed.

☑ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

☐ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER.** When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1140

NRC FORM 532
(1-2012)

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 03211
Status Code: Pending Amendment
Fee Category: 3A 3L 3N
Exp. Date:
Fee Comments:
Decom Fin Assur Reqd: Y

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	INTERNATIONAL ISOTOPES INC.
Received Date:	04/28/2016
Docket Number:	3035486
Mail Control Number:	590764
License Number:	11-27680-01MD
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Carol L Hess

Date: 4/28/16

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER_____

_____

Signed: _____

Date: _____