NRC FORM 313 **U.S. NUCLEAR REGULATORY COMMISSION**
(03-2013)
10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 05/31/2015**

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 Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet 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:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
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
- [x] B. AMENDMENT TO LICENSE NUMBER 24-17450-01
- [ ] C. RENEWAL OF LICENSE NUMBER

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

Mallinckrodt LLC
675 McDonnell Blvd
Hazelwood, MO 63042

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Mallinckrodt LLC
675 McDonnell Blvd
Hazelwood, MO 63042

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John Snider

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(314) 654-8563	(314) 713-5276

BUSINESS EMAIL ADDRESS
john.snider@covidien.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. maiximum 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 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, 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 C RIMINAL 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
Richard A. Roberts, Ph.D., Sr Director	Richard A. Roberts	11 Jun 2013

FOR NRC USE ONLY

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

RECEIVED JUN 1 2 2013

Mallinckrodt

June 10, 2013

United States Nuclear Regulatory Commission
Region III
Nuclear Materials Licensing Branch
2443 Warrenville Road, STE 210
Lisle, IL 60532-4352

RE: License No: 24-17450-01, Amendment Request 32

Mallinckrodt is requesting an amendment to license 24-17450-01 due to organization re-alignments to better facilitate development of new products. As part of this re-alignment, we are asking that the roles and responsibilities, previously undefined by the license, of the RSC Chairperson, RSC Management Representative, and Authorized User be added to item 7.

Attached are the updated organizational charts and roles and responsibilities.

Please feel free to contact me at (314)654-8563 if you have any questions or need further information.

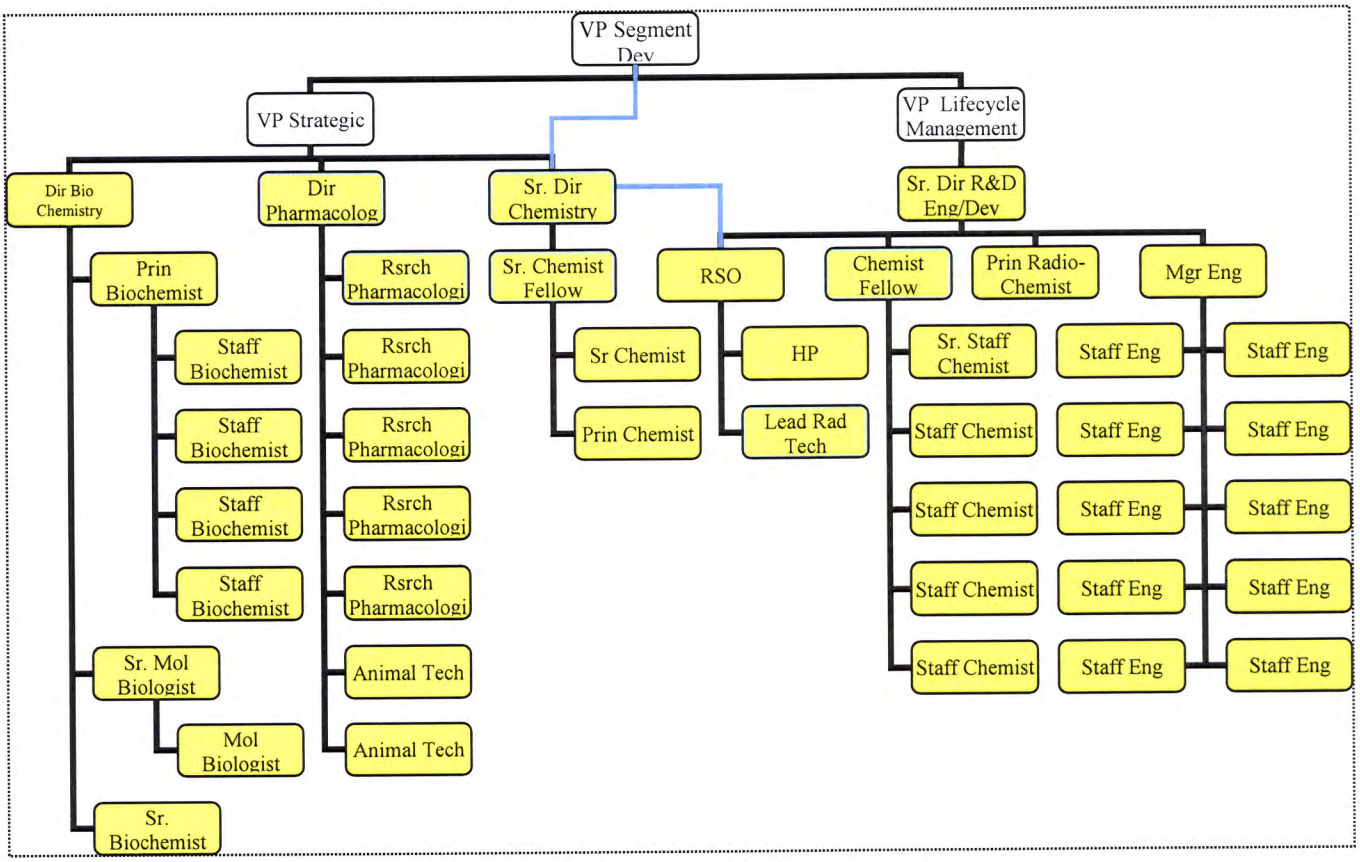
Thank you,

Sincerely,

John Snider
Radiation Safety Officer

Due to changes in the organizational structure to better facilitate development of new products please update the organization chart:

Radiation Safety Organizational Chart



Highlighted/shaded areas are positions that have direct responsibility for the management of persons using radioactive materials and/or directly use radioactive materials. Blue lines denote DOA. For purposes of radiation safety, the RSO will take direction from the RSC Management Representative.

Executive (Senior) Management Representative

The executive management representative is the individual that has been delegated the responsibility associated with managing the facility's radiation safety program and the activities associated with ensuring that the radiation safety program is maintaining doses as low as reasonably achievable. This individual represents the highest level of facility management and has the authority to delegate resources for the program and appropriate funds in a timely manner. The management representative must be:

1. Knowledgeable of radiation safety regulations and skilled in the art of radiation protection in order to assess if rates are as low as reasonably achievable.
2. Knowledgeable of the contents of the license application to ensure all conditions relating to maintaining doses are kept ALARA are being enforced.
3. Responsible for, and must sign, that the radiation safety records and any information provided to the NRC is complete and accurate, including the commitment to keep doses ALARA.
4. Must be capable and qualified to select and review the technical qualifications of employees to serve on the Radiation Safety Committee.
5. Must be capable and qualified to select and review the technical qualifications of employees to serve as the Radiation Safety Officer and if required, serve as the RSO when he/she is away for short periods due to illness, vacation, or for professional development.

This individual shall be available to facilitate effective and immediate action on behalf of management, the RSC, and the RSO, particularly in the event of an emergency. The executive management representative is to ensure that the RSC and RSO have the resources necessary to fulfill their roles. Both the RSC chairperson and RSO are to have access to and a direct line of communication with him/her to discuss radiation safety issues that need to be brought to management's attention.

The representative has the authority to make prompt decisions on the basis of the information available without having to consult with higher management officials, including the authority to take whatever action is necessary to ensure that all radiation safety practices are in accordance with the regulations and conditions of the license without having to consult with higher management officials. The management representative is to brief executive management, who has ultimate responsibility for the radiation safety program, to ensure executive management is knowledgeable of the programs.

The management representative is a vital member of the RSC and must attend Committee meetings to ensure all activities are in compliance with regulatory requirements and the conditions of the license, and that activities are being conducted in a safe manner that produce doses as low as reasonably achievable.

The management representative is involved in selecting the members of the RSC, and in selecting candidates for the RSO to be submitted to the NRC. He/she defines the role, duties, and responsibilities of the RSO and RSC.

The executive management representative is to ensure that the RSO has adequate time and resources to fulfill the role. Therefore, management, with assistance from the RSC, should accurately estimate time requirements associated with program management including time for the RSO to attend professional meetings, delegate the necessary authority to the RSO, and demonstrate support for the RSO to fulfill the role.

Authorized Users (Class I)
Authorized Users (also known as "principal investigators" or "Class I" users) are persons whose training and experience have been reviewed and approved by RSC and who use or directly supervise the use of licensed material. These individuals must be approved by the committee and are authorized to use materials unsupervised or directly supervise the use of radioactive materials within their area of responsibility.

The Authorized User's primary responsibility is to ensure that radioactive materials used in his or her particular lab, area, or listed on the protocols they help develop are used in a manner so as not to lead to unnecessary dose. The Authorized User needs to be onsite and available for consultation with the workers performing the work while it is occurring. More than one Authorized User may be listed on the protocol, with the intent that the Authorized Users as a group would share the responsibility of supervising the workers under the protocol. The Authorized User is also responsible to ensure that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

Under the direction of the RSO and RSC, Authorized Users maintain familiarity with and adhere to the requirements specified in the license documents, federal regulations, and licensee procedures.

Duties of an Authorized User include, but are not limited to:

- Assuring that personnel under their supervision are aware of, practice, and apply good radiation safety practices and are performing work to established standards and procedures as described in protocols;
- Ensuring that individuals performing experiments under their area of supervision have the appropriate level of training and are listed on the appropriate protocols;
- Implementing and enforcing work restriction directives issued by the RSO;
- Submitting written reports to the RSO describing circumstances resulting in work restrictions, unusual doses, and the corrective actions taken or proposed;
- Assisting with continuing on-the-job radiation safety training of personnel under their supervision;
- Stopping any operations under their supervision which threaten the safety of personnel, the general populace, or threaten the laboratory;
- Order radioactive material, with prior written authorization from the RSO.

Radiation Safety Committee (RSC)
The Radiation Safety Committee (RSC) is responsible for the implementation and review of the radiation safety program . This is accomplished by closely working with executive management and the Radiation Safety Officer (RSO) to establish policies and procedures for the safe handling of radioactive material so that exposures may be maintained as low as reasonably achievable (ALARA).

The RSC serves as a "window" to the licensed program through which management gains an overall picture of the licensed activities, and the respective roles of the RSO, RSC, and other responsible individuals, including Authorized Users.

One of the RSC's most important responsibilities is to evaluate the training and experience of applicants who request authorization to use radioactive material. The RSC reviews the applicant's training and experience documentation to determine if the applicant meets the license criteria. If the applicant is deemed qualified, the RSC imparts the authority to work with radioactive materials to the worker/user.

The RSC must include, at a minimum, a representative from each authorized area of use, the RSO, and a representative of executive management. The RSC is to keep abreast of the status of the program through the RSO to prevent a significant void of information in the event that the RSO discontinues service or is otherwise unavailable. Management, with assistance from the RSC, is to accurately estimate time requirements associated with program management, including time for the RSO and his staff to attend appropriate professional meetings to stay abreast of current industry practices and changes to regulations.

The RSC, including the executive management representative, shares the responsibility with the RSO for the conduct of periodic audits of the radiation safety program in order to ensure doses are as low as reasonably achievable. RSC members must review the results of the annual audits of the radiation safety program. Included in this audit are: the performance of Health Physics Staff in the performance of their duties, significant events, radiation exposure summaries, and overall compliance status achieved by Authorized Users. Possible trends are analyzed and suggestions for timely and effective corrective action are documented. The annual review concentrates on critical self-analysis to ensure that aggressive and timely corrective actions have been taken throughout the year. Problems should be clearly defined and tracked as "open items" until appropriate corrective action has been taken. Additionally, assessment of the effectiveness of the corrective actions occurs to help deter or eliminate future problems and violations.

The RSC must hold meetings at least quarterly. It may also be necessary for the RSC chairperson to schedule additional meetings to discuss issues that arise and demand early intervention or attention. The RSC is to discuss the aggregated dose reports and discuss if the doses can be lowered.

The RSC can conduct considerable business by mail, telephone, or email. For example, members can receive user applications or reports by email or mail and be ready to discuss them at an upcoming meeting. Voting is also permissible by telephone, mail, or email when necessary.

Specific duties include:

1. Ensuring that all of the required audits are performed.
2. Reviewing summaries of personnel dosimetry data, radiological surveys, air effluent levels, and releases to ensure they are ALARA.
3. Review significant actions such as spills, contamination events, areas of non compliance etc., to discuss causes, and to discuss and approve corrective actions plans designed to correct the issue and to prevent recurrence.
4. Review any audits of the radiation safety program and ensure that all findings are evaluated and corrective action plans have been formed.
5. Hear users, and any other individual involved with licensed materials, grievances against audit findings. The committee will resolve the grievances through a vote requiring a majority of votes to overturn an audit finding. The committee will draft a report of any audit finding overturned that indicates the stance of the majority and includes a dissenting opinion, in addition to the vote results.
6. Track and ensure that all corrective actions are implemented.
7. Review, recommend, and discuss changes to the radiation safety program where the license allows such flexibility. The review is to ensure that all regulatory and license conditions are met and that these changes enhance the effectiveness of the radiation safety program.
8. Review and approve all procedural changes impacting the program prior to implementation.
9. Review the qualifications of and approve Authorized Users and workers.
10. Review and approve new uses of, and new areas where, radioactive materials may be used.
11. Review of area release surveys to allow an area to be classified for unrestricted use.
12. Immediately terminate any work, in the representative's respective work area, that threatens the safety of personnel, members of the general public, or the facilities, and to terminate any activities that are in violation of any federal, state, or local regulations and/or NRC license requirements or RSC directive.

The RSC, where indicated in the license, has the flexibility to make changes to the program in the areas of: Training, Audit Program, Radiation Monitoring Instruments, Occupational Dose, Emergency Procedures, and Surveys without amendment from the NRC. Any such changes will be documented with an evaluation including:

1. The reason for the change.
2. A summary of radiation safety matters considered.
3. An evaluation of the change against the regulatory requirements to ensure the

change still satisfies the requirements.

4. An evaluation of the change against license conditions to ensure that existing license conditions are not changed or eliminated.
5. An evaluation that the change does not decrease the effectiveness of the radiation safety program.

A quorum of the RSC must sign the evaluation. Prior to implementing any changes, all affected users, workers, ancillary staff, and HP staff must be trained on the new procedure. Any changed procedures will be evaluated during the annual audit to ensure the change's effectiveness and to ensure that the new procedure has been properly implemented by staff.

Radiation Safety Committee Chairperson

The Radiation Safety Committee and its chairperson represent executive management in the formulation of policy for the radiation safety program in order to keep exposures as low as reasonably achievable; therefore, the chairperson is expected to guide the committee's agenda and to facilitate RSC meetings. A quorum of the RSC must include the chairperson, executive management representative, RSO, and as many other RSC members, that within the chairperson's professional opinion, would be required to adequately address the topics. The RSC chairperson is to decide when a quorum has been reached.

When the RSC needs to be expanded, the RSC chairperson, Executive Management Representative, and the RSO are to work together to appoint other people, who must be approved by vote of the RSC, who are interested in serving on the committee. The RSC chairperson, with the aid of the RSO, ensure that all RSC members are adequately trained or possess an appropriate level of knowledge of radiation safety to the degree necessary to be effective in their role.

The RSC chairperson, with the aid of the RSO, ensures that RSC members receive all necessary documents and information before each meeting so that the exchange of information and deliberations reached during the meeting are well researched. Meetings may be as formal or informal as desired by the chairperson. Although the RSO is expected to provide considerable information at the meetings and to be responsive to questions from RSC members, the RSO should not be the most prominent member. The RSO may not serve as the RSC Chairperson as it is possible there will be times when the best radiation safety policy for the institution is not the easiest for the RSO to implement; thus conflicts of interest may arise and additionally the committee is expected to hear users' grievances against audit findings performed by the RSO making it inappropriate for the RSO to serve as chairperson.

Radiation Safety Officer (RSO)

The primary responsibility of the RSO is to implement the radiation safety program with the assistance and support of the RSC and executive management. This individual oversees the day-to-day implementation of the radiation safety program and is

responsible for supervising any Health Physics Services performed that are required to maintain compliance with the license or regulations. The RSO is a member of the RSC and works closely with the RSC and executive management in implementing the radiation safety program. The RSO must ensure that radiation safety activities are being performed safely according to approved policies and procedures, and that all regulatory requirements are met.

The RSO assists the RSC in ensuring that radiation safety issues are addressed in a comprehensive and timely manner, audits are conducted as required, feedback mechanisms are in place to correct deficiencies, and that adequate resources are provided for implementing the radiation safety program or when modifications are needed.

The RSO performs audits of all areas of use and observes individuals who are authorized to use byproduct material to ensure work is done in accordance with the license, regulations, and RSC conditions. The RSO shall ensure that activities involving licensed materials are being performed according to approved policies and procedures, and that all regulatory requirements are complied with in the daily operation of the licensed program.

The highest priority for the RSO is to ensure that day-to-day operations involving radioactive material are conducted according to policies and procedures designed to adequately protect public health and safety by maintaining exposures ALARA. To accomplish this, the RSO must have unhampered access to all activities involving radioactive material. In addition, because of the consequences of actions taken by the RSO in response to emergency situations, the RSO is to be intimately familiar with the regulations, applicable regulatory guidance, and license commitments. Because of the unique training and experience requirements of the RSO, the RSO is to act as advisor to answer, or to find the answer to, most technical and regulatory questions. If the RSO discovers an activity involving radioactive material in which health and safety, in the RSO's professional judgment, appears to be compromised, the RSO has the authority to terminate the unsafe activity immediately without consulting with executive management or the RSC. However, at the next available opportunity, the RSO will brief executive management and the RSC chairperson about the event and the RSO's immediate response. The responsible parties will determine the cause of the problem, collectively identify effective corrective actions, and document such deliberations in the minutes of the RSC meeting.

The RSO works closely with the RSC chairperson, executive management representative, and Authorized Users on a continuing basis, rather than limiting this work to the RSC meetings. The RSC depends on the RSO to be extremely knowledgeable about the details of the day to day operation of the program and the regulatory requirements.

The RSO communicates with individuals at all levels while fulfilling the role of auditor and advisor. A portion of the RSO's time should be devoted to providing consultation on health physics matters and regulatory requirements to Authorized Users and other persons at all levels of responsibility within the organization who may have special needs or concerns.

Specific responsibilities include:

- Oversight of the day-to-day implementation of the radiation safety program.
- Communicating with senior management and the Radiation Safety Committee regarding program implementation and compliance status.
- The immediate termination of any activity judged to be a threat to health, safety, property, public health, and/or the environment, or a violation of federal, state, or local regulations and/or a condition of the NRC license.
- Act as liaison with NRC and other regulatory authorities.
- Ensure security of radioactive materials.
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal.
- Oversee the storage of radioactive materials not in current use, including waste.
- Ensure that licensed materials are transported in accordance with applicable NRC and DOT requirements.
- Supervise decontamination and recovery programs.
- Ensure that all users are properly trained.
- Ensure that licensed materials possessed by the licensee are limited to the types and quantities of materials listed on the license.
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments.
- Perform general surveillance over all activities involving radioactive material.
- Evaluate proposed new uses of radioactive materials and present recommendations to the Radiation Safety Committee.
- Present quarterly reports to the RSC indicating personnel exposures to radiation from the past quarter.
- Issue directives to appropriate supervisory personnel when work restrictions are necessary.

- Perform initial investigations to: overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers or disposals, and other deviations from the approved radiation safety practices and to ensure that corrective actions are implemented as necessary.

- Present information and data needed by the RSC to determine corrective actions for reports or responses to the NRC.

- Draft, review, and propose revisions to written policies and procedures for:
  Authorizing the purchase of radioactive material;
  Receiving and opening packages of radioactive material;
  Emergency response;
  Performing checks of survey instrumentation and other safety equipment;
  Disposing of radioactive waste;
  Training personnel to work in or who may frequent areas where radioactive material is used;
  Maintain copies of all records and reports required by the NRC.

- Prepare applications for new NRC licenses and license amendments.

- Supervise the overall radiation protection program to ensure compliance with established standards and procedures.

- Perform, or cause to perform, annual audits of the radiation safety program to ensure compliance with established regulations, policies, and procedures, and conditions or approval specified by the RSC.

- Maintain an understanding of, and up-to-date copies of, NRC regulations, the license, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, information, or commitments provided to the NRC during the licensing process.

- Supervise the health physics staff.

From: (314) 654-8563
JOHN SNIDER
Hornet
THC Mallinckrodt

Hazelwood, MO 63042

Origin ID: ALNA

FedEx Express

J13111302120326

Ship Date: 11JUN13
ActWgt: 1.0 LB
CAD: 3742267/INET3370

Delivery Address Bar Code

Ref # 0080114202866656
Invoice #
PO #
Dept #

SHIP TO: (630) 829-9500 BILL SENDER

Materials Licensing Branch
US Nuclear Regulatory Commission R3
2443 WARRENVILLE RD
STE 210
LISLE, IL 60532

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