Chapter 3
Obtaining an Authorization to Possess and Use Radioactive Material

As discussed in Chapter 1, the possession and use of radioactive material by UIC are regulated by the Illinois Emergency Management Agency (IEMA). As provided for in the IEMA regulations, radioactive material may be license exempt, generally licensed, or specifically licensed. The UIC Radiation Safety Manual specifies the policies that have been formulated to control these materials at UIC. These policies represent high standards for the safe and legal use of radioactive material.

Licenses, which are issued by regulatory agencies to UIC, should not be confused with radiation project authorizations, which are issued by the Radiation Safety Committee (RSC) or the Radiation Safety Section (RSS) to UIC personnel.

3.1 Requirements for Exempt and Generally Licensed Radioactive Materials

Exempt concentrations and quantities of radioactive material, and general licenses are frequently misunderstood. This has been caused in part by the various ways that regulatory agencies have interpreted the Nuclear Regulatory Commission (NRC) and agreement state regulations and how the regulations are applied to broad scope licensees. This section explains exempt and general licenses and establishes policies regarding the use of these materials at UIC.

3.1.1 Exempt Quantities and Concentrations

Exempt quantities and concentrations have a very low inherent potential to produce a significant radiation hazard. Obtaining an authorization from the RSS or the RSC is not necessary before acquiring or using exempt sources. Exempt sources should be registered with the RSS as soon as they are received by filing Form 8.2.224.

The IEMA, NRC, and corresponding regulatory agencies in the agreement states have exempted the possession and use of small quantities and low concentrations of certain radionuclides from the requirement to obtain a license. A small quantity of radioactive material may be exempt if it is below the limit published in the regulations *and* it was manufactured by authority of a license to distribute exempt sources. Examples of exempt quantity sources include:

- Reference or check sources;
- Timepieces, hands, or dials containing certain quantities of tritium (H-3), promethium-147, or radium-226;
- Certain gas and aerosol detectors containing radioactive materials;
- Incandescent gas mantles containing thorium; and
- Rare earth metals and compounds containing not more than 0.25% by weight of thorium or uranium.

The regulations regarding exempt quantities are not simple and a full explanation of them is beyond the scope of this manual. In general, the following rules apply:

- The recipient must follow special instructions accompanying the sources;

- Exempt quantities may not be combined to make larger sources;
- Exempt sources may not be incorporated into other products or materials unless a license to do so is obtained;
- Exempt sources may not be transferred for commercial purposes; and
- Disposal of exempt sources should be made in accordance with the regulations.

A table of exempt concentrations is published in the IEMA regulations. Radioactive material that is at or below the concentration limit can be declared exempt if necessary with the permission of the RSS. Once again, there are regulations that apply to the transfer of exempt concentrations. Contact an RSS Health Physicist for details.

3.1.2 Generally Licensed Radioactive Material

The use of a general license does not require the filing of an application to transfer, acquire, own, possess, or use generally licensed devices or equipment. General licenses are published directly in the regulations and specify the authorized licensees by categories such as physicians, commercial firms, medical institutions, physicians, etc. General licensees must maintain control of generally licensed devices at all times, and must dispose of them properly. Some generally licensed sources could be hazardous if mishandled or improperly stored. To mitigate this possibility at UIC, an RSS Health Physicist must evaluate the source and its intended use before a generally licensed source may be obtained. Registration of the source with the RSS is required, and a submission of an application to establish a radionuclide project may be required if warranted. Call and speak with an RSS Health Physicist before obtaining a generally licensed source.

Some of the general licenses that have been issued in the IEMA regulations are listed below:

- Anyone may possess static elimination devices containing up to 500 µCi of Po-210 and ion generating tubes that contain up to 500 µCi of Po-210 or 50 mCi of H-3.
- Research, educational, and medical institutions may use or transfer up to 15 pounds at any one time of natural (unenriched) uranium or thorium in any chemical or physical form. Up to 150 pounds may be received each calendar year.
- Research, educational, and medical institutions may possess and use generally licensed devices designed to qualitatively or quantitatively measure the chemical composition of matter. Examples of these devices include some gas chromatography units equipped with electron capture detectors containing Ni-63 or H-3 and liquid scintillation counters containing “external sources” of Cs-137, Ba-133, Ra-226, or Am-241.
- A general license to possess and use certain calibration and reference sources has been issued to all institutions or individuals that have been issued specific licenses.
- Physicians, veterinarians, clinical laboratories, and hospitals may receive, acquire, possess, transfer, or use certain in vitro clinical or laboratory tests containing small quantities of C-14, Co-57, H-3, I-125, mock I-125 (a mixture of I-129 and Am-241) I-131, Fe-59, and Se-75.

Distributors and manufacturers of generally licensed sources must obtain a specific license to manufacture and distribute them. While some generally licensed sources bear labels that declare them to be generally licensed, some do not. Manufacturers have distributed identical sources under

both a specific and general license. The only certain ways to identify generally licensed sources are by means of source labels or documentation provided by the source distributor or an appropriate regulatory agency.

The regulations pertaining to generally licensed sources are not simple, and a full discussion of them is beyond the scope of this manual. Some of the rules that may apply under a general license include:

- The general licensee may be required to register with the appropriate regulatory agency within a specified time following the receipt of a generally licensed source;
- Special instructions accompanying the source must be followed;
- Transfer of a generally licensed source to another recipient may require the reporting the transfer to the regulatory agency within a specified period;
- Generally licensed sealed sources may require periodic leak testing;
- Generally licensed sources cannot be incorporated into other products or materials unless a license to do so is obtained; and
- Disposal of generally licensed sources must be done in accordance with special instructions or regulations.

3.2 Specifically Licensed Radioactive Material

The IEMA has issued a Type A Specific License of Broad Scope to UIC. The license permits the use of any radioactive material with an atomic number of 1 through 104 in any chemical or physical form for research and development uses, medical research, instrument standardization and calibration. It also permits the use of several large sealed source irradiators, gas chromatography cells, and other types of radioactive material. The routine clinical uses that are permitted under the license are categorized as follows:

- Uptake, Dilution, and Excretion;
- Imaging and Localization;
- Radiopharmaceuticals for Therapy;
- Sealed Sources for Diagnosis; and
- Sealed Sources for Brachytherapy.

Details regarding the requirements for clinical human use of materials in these categories will be provided by the RSS upon request.

UIC personnel may use licensed radioactive material only after the proposed use is approved by the RSC or RSS. While the license allows the RSS and RSC to authorize a wide variety of human and nonhuman uses, it also places great responsibility on the RSS and the RSC to properly review proposed uses.

In this manual, individuals who are issued authorizations are referred to as project directors. Other individuals who are selected by the project director to work with radioactive material under an authorization are referred to as project personnel. The work conducted under the authorization is referred to as a radiation project.

3.2.1 Minimum Requirements for All Applications

Authorizations may be granted to faculty, staff, and visiting physicians and scientists. Project directors and project personnel must have a proper amount of training and experience. Facilities must be adequate to perform the proposed work safely. This section outlines the minimum requirements that must be met before an authorization may be issued.

The following criteria are used to evaluate all applications for the use of radioactive material:

- Requests for use of radioactive material must be typewritten and must include all the pertinent information on the application form.

- The applicant's proposed equipment and facilities must be adequate to protect health and minimize danger to life or property. Details on facilities and equipment can be found in Chapter 15 of this manual.

- The applicant must be qualified by training and experience to conduct the project in such a manner as to protect health and minimize danger to life or property. At the time an application is submitted, the training and experience of the applicant is reviewed as it relates to the requested radionuclide(s), quantity(ies), and proposed procedure(s). See Section 3.3 for further details. The applicant must have sufficient knowledge of the regulations, the permissible exposure limits, and safe methods of handling the particular radionuclide(s) to be used. See Section 3.2.3 for additional information regarding the training required for radionuclide project personnel.

- The applicant's proposed procedures are not likely to result in unacceptable radiation exposure of personnel.

- The applicant has adequate plans and procedures for storage, handling, and disposal or transfer of radioactive material.

- The proposed use is in compliance with all IEMA regulations, conditions of the UIC License, and UIC's policies.

The applicant should carefully review the application for completeness and correctness before submitting it to the RSS. Applications must be signed by the applicant and the applicant's department head. If a laboratory that is under the administrative control of another department is to be used, the head of that department must also sign the application.

3.2.2 Applying for a Nonhuman Use Authorization

Nonhuman use authorizations are by far the most numerous of the radioactive material authorizations granted at UIC. A wide variety of research and development projects utilizing radioactive material may be authorized. Proposed projects should be described on Form 8.2.038a, *Application for Non-Human Use of Radioactive Material,* which can be obtained from the RSS or by visiting the web site at http://www.uic.edu/depts/envh/radforms. The applicant should become familiar with applicable sections of this chapter before completing the application. If assistance is needed, the applicant should make an appointment with an RSS Health Physicist to discuss the proposed project.

Projects that propose to administer radioactive material to live animals must obtain authorizations from the RSS or the RSC and the Animal Care Committee (ACC). Submit applications to the ACC through the Biologic Resources Laboratory (BRL). The RSS and RSC require that all rules established by the ACC be followed.

3.2.3 Training Requirements for Radionuclide Project Personnel

All individuals who use radioactive material at UIC must be provided with appropriate radiation safety training before being allowed to perform the work. Individuals must request permission to use radioactive material by submitting Form 088a, *Request to Add Personnel to a Radionuclide Project.* When the individual and project director sign the form they are verifying that the following minimum training requirements have been satisfied:

- The individual has attended the 3 hour UIC Radiation Safety Lecture. The lecture, offered several times each year, is given in a three-hour session. An individual may be approved prior to fulfilling this requirement only if he or she agrees to attend the lecture the next time they are offered. **Failure to complete the lecture the next time offered will result in revocation of authorization to use radioactive material at UIC until the lecture is attended.**

- The individual has read and understood the project authorization documents, which consist of the radioactive material applications filed by the project director when establishing the authorization, the application review documents provided by the RSS, documents issued periodically to renew the authorization, all other documents in which conditions of authorization have been issued, and the Radiation Safety Data Sheets that are available for the approved radionuclides. Additional training requirements may also be included in the project authorization documents

- The project director has provided instruction in the specific handling techniques, laboratory procedures, safety practices, waste disposal procedures, record keeping, etc. to ensure the individual has sufficient knowledge and skills to safely perform any assigned work with radioactive materials.

- The individual has read and agrees to follow the *General Rules for Radioisotope Labs*, which are posted in every authorized radionuclide laboratory.

Individuals requesting to be added to the project and project directors are cautioned that in order to maintain regulatory compliance, these tasks *must* be completed *before* the form is signed.

3.2.4 Applying for Classroom Use of Radioactive Materials

Proposals for the nonhuman use of radioactive materials in the classroom should be submitted on an Application for Nonhuman Use of Radioactive Material. Instead of submitting a protocol, state the course number, and name, and provide a copy of the written laboratory exercises or procedures that the students will be expected to follow. Include the general and specific safety instructions to be provided to the students. Radiation safety precautions should be made an integral part of the exercises or procedures.

3.2.5 Applying for a Human Use Authorization

The RSS offers the following advice to prospective applicants of human use projects;

- Read this section and Sections 3.2, 3.2.1, and 3.2.6 completely;
- After reading, make an appointment with an RSS Health Physicist to discuss the proposed use; and
- Complete the appropriate application form AFTER taking the above actions.

Human use projects generally fall into one of two categories: clinical or research. Human research is defined by the FDA (21 CFR 361.1(a)) as "research projects intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry, but not intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug to humans for such purposes (i.e., to carry out a clinical trial)." Clinical uses are those that are not defined as research; generally those intended for diagnostic or therapeutic purposes.

! NOTE ! The FDA does not consider clinical trials to be categorized as human research. Before clinical trials may be undertaken, an Investigational New Drug (IND) application must be accepted by the FDA.

There are several regulatory requirements pertaining to the human uses of radioactive material that must be satisfied:

- Radiopharmaceuticals, reagent kits, and generators for the preparation of radiopharmaceuticals, and devices containing radioactive materials that are used for clinical purposes must be manufactured, labeled, packaged, and distributed in accordance with specific license(s) issued by the IEMA, NRC or agreement state.
- Radiopharmaceuticals, reagent kits, and generators used to prepare radiopharmaceuticals for clinical uses must be produced under an active New Drug Application (NDA) or an Investigational New Drug (IND) that has been accepted by the FDA. Devices (e.g., bone densitometers) containing radioactive materials that are used for clinical purposes must also be approved by the FDA.
- Applicants for human use authorizations do not need to be licensed physicians; however, license conditions require that administration of radioactive material to humans be performed by or under the supervision of a physician licensed by the State of Illinois, that the physician be listed on the project, and that the physician meet the training requirements that are discussed in the next section.
- Human research using radioactive materials may be permitted without an IND or NDA only under the following conditions:
  - The proposed use must meet the FDA's definition of research (above).
  - The proposed use must be approved by the UIC Institutional Review Board (IRB), and the UIC Radioactive Drug Research Committee (RDRC) as mandated by the FDA. The IRB and RDRC must adhere to strict FDA guidelines when reviewing proposed uses.
  - The proposed use must be approved by the Human Use Subcommittee of the RSC as required by the UIC Radioactive Material License.

! NOTE ! Apply to the IRB through the Section of the Vice Chancellor for Research. Apply to the RDRC and the Human Use Subcommittee simultaneously by completing an Application for Human Research Use of Radioactive Material and submitting it to the RSS. This form is designed to meet the needs of both the RDRC and the Human Use Subcommittee.

3.2.6 Training and Experience Requirements for Human Medical Use

The training and experience requirements for physicians who desire to use radioactive material in human medicine are specified in the IEMA regulations. Training and experience must be documented on a Preceptor Statement that was included with the application forms mentioned above. Physicians who apply for an authorization to perform a broad range of clinical procedures will be required to meet the current training qualifications established by the IEMA. Physicians who apply for an authorization to perform specific procedures but who do not satisfy the IEMA qualifications will be required to obtain training in basic radionuclide handling techniques and clinical experience commensurate with the types, quantities, and uses of the materials being requested. Requests will be examined on a case by case basis by the Human Use Subcommittee.
License conditions and the qualifications that the IEMA finds acceptable are subject to periodic revision. To review the currently acceptable qualifications, contact a Health Physicist from the UIC RSS.

3.3 Review and Approval of Applications

This section describes the system that is used to evaluate applications from new applicants and applications from project directors for the use of radionuclides that are not currently authorized. The review level is based upon the form and quantity of radioactive material being requested and the type of use that has been proposed.

3.3.1 Authorization Mechanism

After an application is filed with the RSS, a Health Physicist will discuss the proposed project with the applicant and prepare a written evaluation. The application and the evaluation are submitted for review and approval to the Radiation Safety Officer, the appropriate Radiation Control Subcommittee, or the main RSC depending on the review level. Table 3.1 lists the review levels that were established in the UIC broad scope license. If the application is approved, the project director is issued a project authorization document that lists the radionuclides, possession limits, authorized locations, project personnel, conditions of authorization, recommendations, and the authorization's expiration date.

The RSS, any member of the Committee or the Subcommittees, or the applicant may make an appeal to the Committee regarding the action taken on an application by the RSS, the Nonhuman Use Subcommittee or the Human Use Subcommittee. The decision of the RSC is final.

3.3.2 Review Level R (Radiation Safety Section Review)

Nonhuman use applications for quantities that do not exceed the values listed in Table 3.1 may be approved by the RSS. Applications are submitted to the RSS and are evaluated and augmented. The proposed project must meet the applicable provisions of Section 3.2 before an authorization may be issued. After review and evaluation of the application, approval may be granted by the Radiation Safety Officer or his authorized delegate. The RSC is informed of all authorizations

granted by the RSS.

TABLE 3.1 REVIEW LEVELS FOR RADIOACTIVE MATERIAL APPLICATIONS AT UIC

Type of Use Requested In Application	Quantity That May Be Approved			
	Radiation Safety Section	Nonhuman Use Subcommittee	Human Use Subcommittee	Radiation Safety Committee
Unsealed Sources for Nonhuman Use				
H-3 and C-14	50 mCi	500 mCi	- - - - - - -	>500 mCi
Alpha Emitters	1 mCi	10 mCi	- - - - - - -	>10 mCi
All Others	25 mCi	150 mCi	- - - - - - -	>150 mCi
Sealed Sources for Nonhuman Use				
Beta-Gamma Emitters	100 mCi	1,000 mCi	- - - - - - -	>1,000 mCi
Alpha Emitters	10 mCi	100 mCi	- - - - - - -	>100 mCi
Exempt Quantities, Source, and Concentrations for Nonhuman Use	All	- - - - - - -	- - - - - - -	- - - - - - -
Generally Licensed Sources for Nonhuman Use	All	- - - - - - -	- - - - - - -	- - - - - - -
Diagnostic and Therapeutic Human Use	- - - - - - -	- - - - - - -	All	- - - - - - -
Other Human Use	- - - - - - -	- - - - - - -	All	- - - - - - -

3.3.3 Review Level S (Subcommittee Review)

Nonhuman use applications for quantities indicated in Table 3.1 are reviewed for approval by the Nonhuman Use Subcommittee. All human use applications are reviewed for approval by the Human Use Subcommittee. Applications are initially submitted to the RSS for evaluation and augmentation. Recommendations regarding approval of each application are provided to the appropriate Subcommittee. The Subcommittees require that the application meet the criteria outlined in Section 3.2 before an authorization will be issued. Approval of an application must be recommended by simple majority of the Subcommittee members including the Radiation Safety Officer before the authorization will be issued. The RSC is informed of all authorizations granted by the Subcommittees.

3.3.4 Review Level C (Committee Review)

Applications for nonhuman use that request the use of activities exceeding the values in Table 3.1 may be approved only by the RSC. Applications are initially submitted to the RSS for evaluation and augmentation. Recommendations made by the RSS for each application are submitted to the RSC. The Committee will require that the application meet the criteria outlined in Section 3.2 before an authorization will be issued. Approval of an application must be recommended by a simple majority of the Committee members including the Radiation Safety Officer before an authorization will be issued.

3.4 Amendment of Authorizations

It is important for the project director to keep the project authorization current. Authorizations need to be amended for the following reasons:

- Addition of a radionuclide that is not currently authorized. Submit Form 8.2.038A, *Application for Non-Human Use of Radioactive Material*.
- Increase in possession limit of an authorized radionuclide. Submit Form 8.2.039, *Application to Change a Radioactive Material Possession Limit*.
- Significant new uses of a previously authorized radionuclide. Submit Form 8.2.038A, *Application for Non-Human Use of Radioactive Material*. Examples of significant new uses include administration of radioactive material to live animals, performing iodinations, generation of a waste form that is not provided for in the current authorization, etc. If in doubt, contact an RSS Health Physicist.
- Addition of project personnel, submit Form 8.2.088, *Request to Add an Individual to a Radionuclide Project*.
- Removal of project personnel, submit Form 8.2.130, *Request to Remove Individual(s) or Lab(s) from a Radiation Project Authorization*.
- Addition of authorized laboratories, submit Form 8.2.157, *Request to add Lab(s) to a Radiation Project Authorization*.
- Removal of authorized laboratories, submit Form 8.2.130, *Request to Remove Individual(s) or Lab(s) from a Radiation Project Authorization*.
- Updating of mailing addresses or telephone numbers, submit Form 8.2.221, *Change in Radiation Project Director Information*.

The addition of a radionuclide that is not currently authorized requires that a completed application form be filed with the RSS. Review will proceed as described in Section 3.3.

3.5 Authorization Renewals

A RSS Health Physicist will contact the project director about one month prior to the expiration date of the authorization. The Health Physicist will review the project's authorization documents, surveys, and monthly *Radionuclide Inventory Reports*. An interview and laboratory inspection will be performed with the project director. The Health Physicist will discuss the results of the review with the project director, make any amendments in the authorization that are necessary, and prepare the renewal documents for the approval of the RSO. A new expiration date is assigned that is based

upon the type and quantity of material that is authorized, complexity of the procedures being performed, and performance of the project since authorization or the last renewal.

In instances where numerous, repeated, or severe violations of the conditions of authorization have been identified, the renewal may be referred to the RSC or its designated Subcommittee.

3.6 Vacations, Sabbaticals, and Leaves of Absence

Project directors are responsible for maintaining the conditions of their authorizations at all times, even when they are not present to provide direct supervision. During an absence of any length, project directors should make provisions so that project personnel conduct their work safely and in accordance with the conditions of the authorization. Depending upon the length of the absence, the work being conducted, and the personnel involved, it may be necessary to appoint a qualified individual to act on behalf of the project director. For example, close supervision of inexperienced workers, performance of surveys at meaningful times, filing of inventory reports, and proper management of waste must continue.

If a project director plans to be absent from the University for longer than six weeks, an acting project director must be appointed. This individual may be a faculty member, a staff member, a post doctoral student, etc. Several weeks before the absence begins, the project director should do the following:

- Select a qualified individual;
- If the individual is not the project director of another radionuclide project, have the individual complete 8.2.038B, *Training and Experience of Radiation Project Director*; and
- Complete Form 8.2.183, *Request to Designate an Acting Project Director,* and send it with the training form (if required by the previous step) to the RSS.

The RSS will review the request and approve it if the individual is qualified. The name, address, and telephone extension of the acting project director will then be added to the RSS's database so that communication regarding the project will be with this individual during the absence.

3.7 Temporary Inactivation of an Authorization

Projects that are not expected to be active for a period of six months or more should be temporarily inactivated. Temporary inactivation of a project provides benefits to the project director and the RSS. Reactivation does not require the submission of new application forms.

Inactivation of a radiation project may be initiated in a written request to the RSS. A RSS Health Physicist will contact the project director to make further arrangements. Radioactive material in the inventory may be disposed of as radioactive waste or transferred to another project for storage. Waste and waste containers are also removed. During the period of inactivation authorized laboratories that are not shared by other radiation projects are released for unrestricted use (radiation safety restrictions will not be required). Additionally, *Monthly Inventory Reports* no longer have to be filed and radiation surveys are not performed. During the inactivation, the project may not acquire, possess, or use radioactive material.

To initiate reactivation, submit Form 8.2.226, *Request to Reactivate a Radionuclide Project*. An RSS Health Physicist will arrange for reopening of the laboratories and reactivation of the project authorization.

3.8 Termination of an Authorization

Authorizations should be terminated when the use of radioactive material is no longer needed. Individuals who are leaving UIC must terminate their authorization in a timely fashion by submitting a written request. An RSS Health Physicist will contact the project director and make arrangements to close laboratories, remove radioactive waste, and clear inventories. If the project director desires to transfer radioactive material to another institution in conjunction with the authorization termination, follow the instructions in Chapter 4, Section 4.11.

Project terminations are final. If the director of a terminated project desires to establish a radiation project in the future, new application forms must be filed and reviewed.