RADIATION USE APPLICATION

PURPOSE

This procedure specifies the requirements that must be met and the information that must be provided to the Radiation Safety Committee in support of an application to use ionizing radiation sources of any kind at the University of Utah.

POLICY

The Radiation Safety Committee is the governing body for all aspects of radiation protection within the University, including all affiliated research, clinical, instructional and service units utilizing radiation sources in facilities owned or controlled by the University. Each proposed use of radioactive materials, x-ray or other radiation generating machines must be submitted to the Committee, via the Radiation Safety Officer (RSO), for review before implementation. Specific forms and data to be submitted are prescribed in the attachments to this procedure. The descriptions of facilities and equipment, the training and experience of the user, and the operating or handling procedures shall be provided in sufficient detail to permit the Committee to evaluate the safety of the proposed use.

To assure that all records related to radiation sources, users and conditions of use are accurate and up-to-date, the RSO may require that parts or all of the application be verified or resubmitted periodically. If the updated information includes changes that are significant to safety, the application will be submitted to the Committee for reauthorization.

DEFINITIONS

Healing arts screening: Use of diagnostic x-rays on a population to find disease in asymptomatic individuals.

Human use: The use of any radiation source in or on humans.

Responsible User: An individual authorized by the Radiation Safety Committee to acquire and use specific radiation sources and to supervise such use by others, based on a determination by the Committee that the individual has had sufficient training and experience and is in a position of sufficient authority to assure the safety and financial support of the proposed use.

INITIAL APPLICATIONS

A first-time applicant to become a Responsible User should obtain a current copy of the Radiation Safety Policy Manual from the RSO. The index to all current Radiation Procedures and Records should be reviewed to identify any that may be applicable to the planned radiation use; these should be obtained from the RSO.

After becoming thoroughly familiar with the pertinent requirements, the applicant should complete the appropriate checklists and forms attached to this procedure and submit them to the RSO. Allow 2-4 weeks to receive notification of the Committee's action.

INFORMATION TO BE SUBMITTED

All applicants for authorization to be a Responsible User must submit the RESPONSIBLE USER'S TRAINING & EXPERIENCE form (RPR 2A) **and** a RADIATION USER PERSONAL DATA form (RPR 1), if not previously provided.

Applicants for unsealed, radioactive materials not to be used in or on humans must also submit the RADIOACTIVE MATERIAL USE APPLICATION form (RPR 2B). The categories of proposed uses on the first page of the application provide initial guidance on the requirements for inventory control, contamination surveys, sealed-source leak tests, and individual monitoring for the materials to be acquired. Adjustments will be made to these requirements based on actual use as the work progresses.

Use categories identified with a category code "D" indicate materials that pose risks of intake as well as external exposure. Most nuclides that are used as biomedical tracers in millicurie quantities require some degree of individual monitoring. The monitoring codes column indicates default monitoring methods; the monitoring subsequently required will depend on the quantities of materials actually acquired and used.

Use categories identified with a category code "N" refer to materials that are normally not likely to be dispersed in a form that can be readily taken up by the body and, therefore, do not require intake monitoring.

Use categories identified with a category code "G" refer to uses that do not require specific license or authorizations by the Committee, but must be identified and tracked by the RSO. The radiation risks associated with generally licensed materials are low and do not require individual monitoring, although some generally licensed sources require periodic leak testing and all require proper disposal.

Applicants should check in the left-hand column of RPR 2B each use category for which approval is sought. The most commonly used radionuclides in each category are indicated in the *Nuclide(s)* column. If approval is sought for a radionuclide not listed, the applicant should write in its identity. The *Reviewing Level* column indicates quantities per purchase within each category above which the RSO will review the purchase order for safety and ALARA considerations. Review quantities are not intended to be a limit on purchases, but rather they provide the Radiation Safety Committee assurance that radionuclide procurements are being monitored.

Applicants for radiation generating machines or self-shielded irradiators not to be used on humans must submit the RADIATION MACHINE USE APPLICATION form (RPR 2C).

Applicants for use of any source of radiation on or in humans must submit the APPLICATION FOR USE OF RADIATION IN OR ON HUMANS form (RPR 2D) and AUTHORIZED TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION form (Utah Form DRC-02A). The clinical categories of use listed on the application form are defined in the Utah Radiation Control Rules and/or 10 CFR 35, together with specific certification and/or training requirements applicable to each category. The applicant should review those requirements before submitting the application forms to the Committee.

SPECIAL PROCEDURES FOR USE OF RADIATION IN OR ON HUMANS

An applicant **for clinical or research use of any radioactive materials applied to humans <u>or</u> for screening or research use of machine-generated radiation applied to humans** must first be approved as a responsible user by the Radiation Safety Committee; use all appropriate application forms (RPR 1A, 2A, 2D and DRC-02A).

An application for any research use of a radioactive drug must be submitted to the **Radioactive Drug Research Committee (RDRC)** for review and approval. The RDRC is constituted in accordance with, and specifically approved by, the Food and Drug Administration (FDA). This Committee also serves as the **Human Use Subcommittee (HUS) of the Radiation Safety Committee** to review and approve any experimental use of radiation in research on human subjects. Certain protocols involving radioactive drugs are submitted to the FDA, and all experimental protocols approved by the RDRC-HUS are reported to the Radiation Safety Committee.

Application forms for research use of radiation in human subjects are contained in RDRC - HUMAN USE SUBCOMMITTEE (RPR 48).

In addition to Radiation Safety Committee approval, an applicant for **the use of diagnostic x-rays for healing arts screening** must obtain approval from the Human Use Subcommittee. The screening program information required for approval is described in UDRC rule R313-28-400. A copy of the rule and instructions for submission of a screening program application can be obtained from the RSO.

REVISIONS TO AUTHORIZATIONS

Any desired revisions to an authorization should be discussed with the RSO. If the RSO determines that the proposed revision does not involve any change from the initial safety evaluation, and is within the intent of the initial authorization, the revision may be approved by the RSO without further Committee action. The RSO may, however, require additional information before granting approval.

If a proposed revision to an initial authorization involves significant changes in sources or conditions of use from those specified initially, the proposal must be resubmitted to the Committee for authorization.

RENEWAL OF AUTHORIZATION

Responsible user authorizations do not expire as long as the user continues in the same categories of use and complies with all radiation protection requirements, including periodic refresher training for all personnel as scheduled by the RSO.

REGULATORY BASIS

Utah Division of Radiation Control:

Utah Radiation Control Rules:

Specific Licenses, R313-22.

Use of X-Rays in the Healing Arts, R313-28.

Medical Use of Radioactive Material, R313-32.

Radiation Safety Requirements for Analytical X-ray Equipment, R313-40.

Radiation Safety Requirements for Particle Accelerators, R313-44.

Nuclear Regulatory Commission:

Code of Federal Regulations, Title 10 part 35, Medical Use of Byproduct Material.

Consolidated Guidance About Materials Licenses, Program Specific Guidance About Medical Use Licenses. NUREG 1556, Volume 9.

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RPR 2A. RESPONSIBLE USER'S TRAINING & EXPERIENCE

(Please type or print legibly)

Surname: _____ Initials: ____ UNID: _____

Training in Basic Radiation Sciences		Type and Hours of Training	
Subjects	**Location and Dates**	**Formal Courses (Hours)**	**Supervised On-the-Job (Hours)**
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics of Radioactivity			
Biological Effects of Radiation			
Radiopharmaceutical Chemistry (Medical users only)			

Work or Practical Experience With Radiation			
Description of Experience	**Name of Supervising Individual**	**Location and Materials License Number**	**Dates and Numbers of Hours of Experience**

All applicants who will use radiation on or in humans must also complete RPR 2D and Utah Form DRC-02A.

The information above is accurate and complete.

Signature _____ Date _____

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RPR 2B. RADIOACTIVE MATERIAL USE APPLICATION

Surname: _____ Initial:_____ UNID:_____

USE CATEGORIES: Check each proposed Use Category; circle and/or add nuclide information where requested.

☐	Cat.	Uses Categories and Forms	Nuclide(s) (Circle or write-in)	Review Level[1]	Monitoring Codes[2]
		GENERALLY LICENSED CATEGORIES			
	G-1	U or Th compounds, e.g. for electron microscopy	Natural U, Th	None	None
	G-2	Ionization sources, spark gap irradiators, ionization detector cells, e.g. gas chromatograph, ECDs	^{3}H ^{63}Ni ^{210}Po ^{147}Pm	None	None
	G-3	Self-luminous products & luminous dials	^{3}H ^{85}Kr ^{147}Pm	None	None
	G-4	Calibration and check sources, including LSC built-in standardization sources (<10 μCi α; <100 μCi β-γ)	Nuclide:	None	None
		NON-DISPERSIBLE CATEGORIES			
	N-1	Sealed sources (≥10 μCi α; ≥100 μCi β-γ)	^{57}Co ^{60}Co ^{125}I ^{137}Cs Other:	10 mCi	B*
	N-2	Microspheres for cardiovascular or respiratory studies in animals	^{85}Sr ^{95}Nb ^{103}Ru ^{109}Cd ^{141}Ce ^{86}Rb ^{113}Sn ^{46}Sc ^{153}Gd ^{114M}In ^{57}Co ^{111}In	10 mCi	R*
		DISPERSIBLE CATEGORIES			
	D-1	Pre-packaged Assay kits	^{3}H ^{125}I ^{59}Fe ^{75}Se	None	None
	D-2	Nuclides for labeling, or as labeled biological compounds to be used directly as molecular or cellular tracers, for DNA sequencing, for metabolic studies in animals, etc.	^{3}H ^{51}Cr ^{14}C ^{33}P ^{35}S ^{36}Cl ^{55}Fe	25 mCi 10 mCi	U* U*
	D-3		^{32}P	10 mCi	U*, R*
	D-4		^{22}Na ^{24}Na ^{59}Fe	10 mCi	U*, R*
	D-5		^{125}I	10 mCi	T*
	D-6	Orthophosphoric acid or other **high-activity** solutions for use in synthesizing labeled compounds	^{32}P Other:	10 mCi	U, R
	D-7	Sodium iodide for iodination	^{125}I ^{131}I	25 mCi	R, B*, T
	D-8	Preparation or administration of radiopharmaceutical	^{99m}Tc ^{131}I and any radiopharmaceutical	N/A	U, R, B, T
	D-9	Nuclides as the element or an inorganic compound used for chemical/physical tracer studies	Nuclide: Activity:	N/A	U*, R*, B*, T*
	D-10	Production and handling of activated samples or compounds in an accelerator or nuclear reactor	Any activation or fission products	N/A	U*, R, B

1 Individual purchase orders exceeding the review level are reviewed by the Radiation Safety Officer.
2 Monitoring codes: B = body badge; R = finger ring badge; T = thyroid counting; U = urinalysis.
* Monitoring requirements depend on actual quantities acquired and used.

RPR 2B. RADIOACTIVE MATERIAL USE APPLICATION

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PERSONNEL:

List all individuals who will work with the above materials in the same location (faculty, staff, students). Unless a current record is on file with the Radiological Health Department, attach "RADIATION USER TRAINING & PERSONAL DATA" form (RPR 1A) for each listed individual.

Name of Individual		University ID # (UNID)

FACILITIES:

Location - Building: _____ Room Numbers: _____

Fume hood available in room: _____ Waste will be stored in room: _____

INSTRUMENTS:

Contamination survey meter; Make & Model: _____

Liquid scintillation counter, if needed, in room: _____

ANIMALS:

☐ None

☐ Animals will be used; attach description giving type, number, individual doses, holding facilities and handling methods. Refer to "HOUSING AND HANDLING OF RADIOACTIVE ANIMALS" (RPR 15).

CHEMICALS:

List brand names of liquid scintillation fluor(s), tissue solubilizers, if any that will be used with radioactive materials:

_____

Written justification must be provided for any fluors other than "NHNT". See "LIQUID SCINTILLATION MEDIA" on page 10.

RPR 2B. RADIOACTIVE MATERIAL USE APPLICATION

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WASTES:

List any chemicals listed by the EPA as hazardous (e.g. flammable solvents, toxic or poisonous chemicals, etc.) that will contain radioactive materials. For each, give the chemical name and the EPA hazardous material identification number (see the Material Safety Data Sheet for that chemical, or EPA/State hazardous waste regulations). Written justification must also be provided for generation of any "mixed wastes", i.e. radioactivity mixed with materials classified as hazardous by the EPA.

Indicate the types and quantities of radioactive and mixed wastes you expect to generate.

Dry, compactable waste:	_____ kg/month
Sharps in puncture-proof containers:	_____ kg/month
Animal carcasses, excreta, bedding:	_____ kg/month
Non-hazardous, non-toxic aqueous liquids:	_____ L/month
Flammable or combustible liquids:*	_____ L/month
Toxic, nonflammable, hazardous liquids:*	_____ L/month
Other (describe):	_____

* Written justification must be provided for any mixed wastes you expect to generate, and you may be required to pay for the disposal costs for such wastes.

I have read the University's Radiation Safety Policy Manual and understand the conditions and regulations contained in it. With respect to the requested radiation sources and proposed uses, I acknowledge and accept the responsibility for:

- radiation protection instruction for all involved personnel;
- acquisition of the equipment, supplies and/or services necessary for radiation protection;
- security to prevent misuse or theft of radioactive materials;
- maintaining accurate records of acquisitions and dispositions;
- regular contamination and/or exposure surveys and records;
- notification of the RSO of any accident or abnormal incident;
- arranging for authorization of another individual to assume the preceding responsibilities, or to suspend or terminate all radiation uses, prior to any extended absence.

Signature of Responsible User: _____ Date: _____

LIQUID SCINTILLATION MEDIA

Fluors containing non-hazardous, non-toxic (NHNT) solvents are required unless a specific exception is obtained from the RSO or the Radiation Safety Committee. Examples of such fluors are:

Fluor (Mfgr.)	^{3}H Efficiency* Mean ± SD (N)	Flow* (sec)	Fluor (Mfgr.)	^{3}H Efficiency* Mean ± SD (N)	Flow* (sec)
BCS (AMER)			**Betamax-ES** (MPBio)	45.1 ± 7.9 (6)	2.6
Bio-Safe II (RPI)	38.1 ± 5.2 (24)	4.1	**Bio-safe NA** (RPI)	43.9 ± 9.8 (6)	2.5
Cytoscint-ES (MPBio)	43.7 ± 4.0 (24)	3.7	**Ecolite(+)** (MPBio)	32.1 ± 5.1 (24)	5.3
Ecolume (MPBio)	36.6 ± 6.0 (24)	4.9	**Ecoscint A** (NAT)	40.2 ± 4.5 (24)	3.7
Ecoscint H (NAT)	45.8 ± 5.0 (24)	2.7	**Ecoscint O** (NAT)	45.1 ± 6.7 (6)	2.8
Envirosafe (ANOR)	35.4 ± 4.6 (24)	4.2	**Mono Flow 5** (NAT)	35.6 ± 3.7 (24)	2.7
Opti-Fluor** (PE)	39.7 ± 5.5 (24)	3.2	**Opti-Fluor O** (PE)		
OrganicSolv 3 (ANOR)	42.2 ± 9.7 (6)	2.5	**Poly-Fluor** (PE)		
Ready Safe (BECK)	40.6 ± 4.2 (24)	7.2	**Solvent-Free** (PE)		
Ultima Gold (PE)	43.1 ± 2.1 (24)	5.5	**Universol-ES** (ICN)		

Fluors containing toxic or flammable solvents may not be purchased without prior approval from the RSO. Examples are:

CP, HP, HP/b, EP, MP, NA, Ready Micro, Ready Solv, Ready Protein, Ready Gel, Ready Value, Ready Organic, Ready Flow II, Ready Flow III (BECK)

Universall (ICN)

Betafluor, Hydrofluor, Liquiscint, Monoflow 4, Ultraflow (NAT)

Aquasol, Aquasol-2, Econofluor, Econofluor-2, Formula 963, Liquifluor, Omnifluor, Atomlight, Aquasure, Biofluor, Riafluor, and all "NEF" numbers (NEN)

Insta-Gel XF, Scint-A XF, Pico-Aqua, Pico-Fluor 15, Pico-Fluor 40, Hionic Fluor, Filter-Count, Pico-Fluor LLT, Insta-Fluor, Permafluor V, Monophase S, Flo-Scint I, II, III, IV, and V (PE)

***** Tritium counting efficiencies are based on 0.1 mL sample in 4.0 mL fluor; "Flow" represents the time for a fixed volume to flow from a pipette and is inversely proportional to viscosity; data from Klein, RC and Gershey, EL, 'Biodegradable' liquid scintillation counting cocktails, Health Physics 59:461-470, 1990.

****** Available from U of U, Stores and Receiving, 581-8671

AMER = Amersham Corp., Arlington Heights, IL 800-526-3593

ANOR = Anorak Scientific, South Hackensack, NJ
BECK = Beckman Instruments, Fullerton, CA 800-742-2345
MPBio = MP Biomedicals, Solon, OH 800-854-0530
NEN = DuPont-NEN Products, Boston, MA 800-551-2121
NAT = National Diagnostics, Manville, NJ 800-526-3867
PE =PerkinElmer, Downers Grove, IL 800-323-5891
RPI = Research Products International Corp., Mount Prospect, IL 800-323-9814

RPR 2C. RADIATION MACHINE USE APPLICATION

(X-RAY MACHINES, PARTICLE ACCELERATORS AND SEALED-SOURCE IRRADIATORS NOT TO BE USED ON HUMANS)

PERSONNEL: Responsible User: _____ UNID:_____

Attach a list of all individuals (faculty, staff, students) who will work with the same machine, including full names and UNID numbers. Unless a current record is on file with the Radiological Health Department, attach "RADIATION USER TRAINING & PERSONAL DATA" form (RPR 1A) for each listed individual.

LOCATION: Building: _____ Room Number: _____

MACHINE: For all analytical x-ray machines, accelerators, irradiators, etc. complete the following:

Type: _____

Manufacturer, Model & Ser. No. _____

Radiation survey meter; Make & Model:_____

All applicants must attach the following:

- Description of the machine, including safety devices, interlocks, warning lights, shutter indicators (open-closed) x-ray tube status (on-off).
- Description of the facility where the machine will be used, including shielding, security arrangements, etc.; include diagram of layout as appropriate.
- Step by step operating procedures to be used by all personnel while operating equipment.
- Outline of instruction to be given to all users addressing items such as possible hazards, significance of safety devices, operating procedures, symptoms of acute localized exposure, and procedures to be followed in reporting suspected or actual exposure. (No person will be permitted to use equipment without this instruction.)

I have read the University's Radiation Safety Manual and understand the conditions and regulations contained in it. With respect to the requested radiation sources and proposed uses, I acknowledge and accept the responsibility for:

(a) radiation protection instruction for all involved personnel;
(b) acquisition of the equipment, supplies and/or services necessary for radiation protection;
(c) notification of the RSO of any accident or abnormal incident;
(d) arranging for authorization of another individual to assume the preceding responsibilities, or to suspend or terminate all radiation uses, prior to any extended absence.

Signature of Responsible User: _____ Date: _____

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RPR 2C-CL. ANALYTICAL X-RAY MACHINE CHECKLIST

PORTS AND SHUTTERS

Unused ports on radiation source housing shall be secured in the "closed" position in a manner that will prevent casual opening, i.e. without the use of tools **Yes No NA**

On equipment installed after November 1983, open beam units shall have ports equipped with a shutter that cannot be opened unless a local component has been connected **Yes No NA**

OPERATING REQUIREMENTS

Are written operating procedures available to all users of x-ray equipment? **Yes No NA**

PERSONNEL REQUIREMENTS

Have all persons who operate the x-ray equipment received the training for analytical x-ray users provided by the RSO and on-the-job instruction and demonstrated adequate knowledge of:

radiation hazards associated with use of equipment; **Yes No NA**

significance of radiation warning and safety devices; **Yes No NA**

operating procedures; **Yes No NA**

symptoms of acute localized exposure; and **Yes No NA**

procedure for reporting actual or suspected exposure? **Yes No NA**

Personnel Monitoring

For open-beam systems, have personal monitoring devices (ring badges) been issued? **Yes No NA**

If "Yes", are they used in compliance with University requirements? **Yes No NA**

RADIATION SURVEY EQUIPMENT

Radiation survey meter(s) available at facility:

Make/Model: _____ Ser. No.: _____ Calibration Date: _____

Make/Model: _____ Ser. No.: _____ Calibration Date: _____

Completed by: _____ Date: _____

Upon completion, send this checklist with the Radiation Machine Use Application to: Radiological Health Department, 75 S 2000 E, Room 322

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RPR 2D. APPLICATION FOR USE OF RADIATION IN OR ON HUMANS

Surname: _____ Initials: _____ UNID: _____

In addition to the RESPONSIBLE USER'S TRAINING & EXPERIENCE form (RPR 2A) and the RADIATION USER PERSONAL DATA form (RPR 1A), submit the following:

*Check each category and type of **clinical** use of radiation for which you are applying, and for each checked category provide evidence of board certification and Authorized Training and Experience and Preceptor Attestation form* (DRC-02A).

☐	**Radiation Producing Machines**		☐	**Sealed Source Use**	
	☐	Operator of diagnostic x-ray equipment (R313-28-350)		☐	Use of manual brachytherapy sources (10 CFR 35.490)
	☐	Use of diagnostic x-rays for healing arts screening (R313-28-400)		☐	Ophthalmic use of strontium-90 (10 CFR 35.491)
	☐	Therapeutic use of linear accelerator, Physician (R313-30-3)		☐	Use of sealed sources for diagnosis (10 CFR 35.590)
	☐	Radiation Therapy Physicist (R313-30-3)		☐	HDR therapeutic medical devices (10 CFR 35.690)
☐	**Unsealed Byproduct Material**			☐	Microsphere Brachytherapy (10 CFR 35.1000)
	☐	Uptake, dilution and excretion studies (10 CFR 35.190)	☐	Other Medical Uses of Byproduct Material (10 CFR 35.1000) Describe Proposed Use:	
	☐	Imaging and localization studies (10 CFR 35.290)	☐		
	☐	Therapeutic use of radiopharmaceuticals (10 CFR 35.390)	☐		
	☐	Treatment of hyperthyroidism (10 CFR 35.392)	☐	Authorized user (10 CFR 35.2 and 59)	
	☐	Treatment of thyroid carcinoma (10 CFR 35.394)	☐	Authorized medical physicist (10 CFR 35.51 and 59)	
	☐	Parenteral administrations of unsealed byproduct material (10 CFR 35.396)	☐	Authorized nuclear pharmacist (10 CFR 35.55 and 59)	

*Check each category of **research** use of radiation in or on humans for which you are applying;* separate applications for each new protocol or project must be submitted to the Radioactive Drug Research Committee - Human Use Subcommittee.

☐ Research using radioactive materials

☐ Research using machine-generated radiation (i.e., x-rays, electrons)

Acknowledgement:

I have read the University's Radiation Safety Manual and understand the conditions and regulations contained in it. With respect to the requested radiation sources and proposed uses, I acknowledge and accept the responsibility for:

(a) radiation protection instruction for all involved personnel;
(b) acquisition of the equipment, supplies and/or services necessary for radiation protection;
(c) notification of the RSO of any medical event (10 CFR 35.3045 and 3047), accident or abnormal incident.

Signature of Responsible User: _____ Date: _____

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