19-11831-03 030-31743



#### DEPARTMENT OF THE ARMY

576492

U. S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES

1425 PORTER STREET FORT DETRICK, MARYLAND 21702-5011

Branch 2

January 11, 2012

G-5 MS-16

Ms. Betsy Ullrich Licensing Assistant Section U.S. Nuclear Regulatory Commission, Region 1 475 Allendale Road King of Prussia, Pennsylvania 19406-1415 19-11831-03 03031743

REGION 1

Dear Ms. Ullrich:

As you requested, enclosed are appendices from United States Army Medical Research Institute of Infectious Diseases (USAMRIID) Regulation 385- 11. The appendices explained the criteria that we use to approve new users of licensed materials, and new uses of licensed material.

For additional information and questions, please call me at 301-619-4626 or email Josephine. Esteban@us.army.mil.

Sincerely,

Josephine S. Esteban

U\$AMRIID, RSO

**Enclosure** 

### Appendix B

Initial Qualification of Radiation Worker(s), Approval of Technician(s), Trainee(s), Co-worker(s), X-ray and Irradiator Operator(s)

- 1. Initial qualification of radiation worker(s):
- The supervisor of the individual will request that the individual be added to the USAMRIID Authorized Radiation Workers List.
- b. The Radiation Safety Officer will assure that a USAMRIID Form 32, a DD Form 1952, and a history of prior occupational exposure are complete and a file established for each individual listed in the Authorized Radiation Workers List.
- c. The individual will be required to take the introductory USAMRIID Radiation Course to establish qualification to utilize ionizing radiation.
- d. The individual will be required to take the annual USAMRIID Radiation Course to maintain their qualification to utilize ionizing radiation.
- e. A certificate will be issued by the RSO to the individual and a photocopy of this certificate will be placed in the individual's radiation exposure file located in the Radiation Protection Office.
- Initial approval of technician(s):
  - a. The individual will be a qualified radiation worker.
- b. The individual will take the IRCC approved Introduction to Radiation Course. This is a one-time requirement.
- c. A co-worker will recommend the individual for inclusion on the Authorized Radioisotope Users List.
- d. A co-worker's recommendation will include the respective active protocol(s) on which the technician will work and be routed through the PRU and the Division Chief.
- e. After concurrence of the PRU and Division Chief, the RSO will approve the addition of the individual as an authorized radioisotope user. If the individual is disapproved, the RSO will inform the co-worker as to reason for disapproval and corrective action(s) required for obtaining approval.
- f. The RSO will notify the individual, co-worker, PRU, and Division Chief that the authorization to use radioisotopes has been approved.

### Appendix B (continued)



- a. The individual will be a qualified radiation worker and meet the training, recommendation, and approval requirements for a technician.
  - b. The individual will be approved by the IRCC as a trainee.
- 4. Initial approval of Co-worker(s):
- a. The individual will be a qualified radiation worker and meet the training, recommendation and approval requirements for a trainee.
  - b. The individual will be approved by the IRCC as a co-worker.
- 5. Initial qualification of X-ray personnel:
- a. The supervisor of the individual will request that the individual be added to the USAMRIID Authorized Radiation Workers List as an x-ray operator.
- b. The RSO will assure that Form 32, Form DD 1952 and history of prior occupational exposure are completed.
- c. The individual will be required to take the introductory USAMRIID Radiation Course for X-ray Use to establish qualification to utilize ionizing radiation.
- d. The individual will be required to take the annual USAMRIID Radiation Course for X-ray Use to maintain their qualification to utilize ionizing radiation.
- 6. Initial qualification of irradiator operator(s):
  - The Division Chief will recommend the individual to the RSO.
- b. The individual will complete five (5) irradiation "under instruction" runs monitored by the RSO or ARSO.
- c. At the discretion of the RSO, an oral or written examination may be administered during the fifth irradiation "under instruction" run.
- d. The individual will be approved by the IRCC as an "Authorized Irradiator Operator".



## Appendix B (continued)

- e. The individual will be required to attend the annual USAMRIID Radiation Training or an annual briefing on irradiator operation (provided by the RSO) to maintain their qualification to operate the irradiator(s).
  - f. The monitored runs and areas attributable to training will be documented.
- g. A certificate will be issued by the RSO to the individual and a photocopy of this certificate will be placed in the individual's radiation exposure file located in the Radiation Protection Office.



# Form DD 1952 (Page 1 of 2)

THIS COMMAND IN THE PAST?    YES		LICATION AND RECORD			XPOSURE		
DUTY SECTION (Dople, Ward, Unit, etc.)   5. JOB TITLE   6. DUTY PHONE					CURITY NUMBER		
PAY GRADE  8. HAVE YOU WORN A DOSIMETER ISSUED BY THIS COMMAND IN THE PAST?  YES NO  D. DUTY STATUS  F. TRANSIENT SHOW MAILING ADDRESS (street address, city, state, sip code) OF LOCATIO HEALTH RECORDS  EXPOSURE INFORMATION (ITEMS 11 TEROUGH 20 FOR HEALTH PHYSICS USE ONLY)  1. CLASSIFICATION OF EXPOSURE  EXTERNAL  NEUTRON  NEUTRON  13. TLD REQUIRED  WRIST  WHOLE-BODY FINGER  4. BIDASSAYS REQUIRED WHOLE-BODY NEUTRON  WRIST  WHOLE-BODY FINGER  4. BIDASSAYS REQUIRED WHOLE-BODY FINGER  16. DD FORMIS) 1141 INITIATED  TO DOSIMETER(S) ISSUED  16. DD FORMIS) 1141 INITIATED  TO DOSIMETER(S) ISSUED  NOTE: This section only applies to the individual who has worked with radiation-producing devices or racioisotopes in a permantance.  NAME OF ENDI OVER  ADDRESS  FROM  TO  Do not write  TO Do not write  ADDRESS  FROM  TO  DO not write	And tenter from the tenter				3. SOCIAL SECURITY NUMBER		
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YES		8. HAVE YOU WORN A I	OSIMETER ISSUED		9. DATE OF RADIATION PHYSICAL		
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REMARKS	MARKS		,				



## Appendix C (continued)

### Form DD 1952

#### PRIVACY ACT STATEMENT DATA REQUIRED BY THE PRIVACY ACT OF 1974 (5 USC 552a)

- 1. TITLE OF FORM: Dosimeter Application and Record of Occupational Radiation Exposure.
- 2. PRESCRIBING DIRECTIVE: AR 40-14 and DLAR 4145.24.
- 3. AUTHORITY: 5 USC 301 Departmental Regulation; 10 USC 1071, Medical and Dental Care, Purposes; 42 USC 2073, 2093, 2095, 2111, 2133, 2134, 2201(b), and 2201(c). The authority for soliciting the social security number is 10 CFR 20; 44 USC 3101 Record Management by Agency Heads, General Duties.
- 4. PRINCIPAL PURPOSE(S): To establish qualification of personnel monitoring and document previous exposure history. The information is used in the evaluation of risk of exposure to ionizing radiation or radioactive materials. The data permits meaningful comparison of both current (short-term) and long-term exposure to ionizing radiation or radioactive material. Data on your exposure to ionizing radiation or radioactive material is available to you upon request.
- 5. ROUTINE USES: The information may be used to provide data to other Federal agencies, academic institutions, and non-governmental agencies, such as the National Council on Radiation Protection and Measurement and the National Research Council, involved in monitoring/evaluating exposures of individuals to ionizing radiation or radioactive materials who are employed as radiation workers on a permanent or temporary basis and exposure received by monitored visitors. The information may also be disclosed to appropriate authorities in the event the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding.
- 6. MANDATORY OR VOLUNTARY DISCLOSURE AND EFFECT ON INDIVIDUAL NOT PROVIDING INFORMATION: It is voluntary that you furnish the requested information, including social security number; however, the installation or activity must maintain a competed DD Form 1141 on each individual occupationally exposed to ionizing radiation or radioactive material as required by 10 CFR 20, 29 CFR 1910.96 and AR 40-14/DLAR 4145.24. If information is not furnished, individual may not become a radiation worker. The social security number is used to assure that the Army/Agency has accurate identifier not subject to the coincidence of similar names or birthdates among the large number of persons on whom exposure data is maintained.

#### STATEMENT

Under the provisions of 10 CFR 19.13, 29 CFR 1910.96 and the Privacy Act of 1974, I hereby authorized the release of, and request that all of my radiation exposure records be furnished to appropriate authorities in accordance with the "Routine Uses" portion of the above Privacy Act Statement. As a radiation worker, I have been provided instructions in radiation protection as required by 10 CFR 19.12 and 29 CFR 1910.96. As a female radiation worker, I have been informed of the biological effects and the risks from ionizing radiation on the embro-fetus and received a copy of NRC (Nuclear Regulatory Commission) guide 8.13. I will contact my supervisor or the radiation protection officer if I have any questions. I hereby certify that the exposure history listed on the obverse is correct and complete, to the best of my knowledge and belief. I have read and understand the above Privacy Act Statement.

Date (YYMMDD)	Signature of Applicant

DD Form 1952 Reverse, NOV 81

USAPPC V1.00







# Appendix D

# USAMRIID Form 32 (Page 1 of 2)

# TRAINING AND EXPERIENCE OF AUTHORIZED RADIOISOTOPE USERS

1. Name o	of the Authorized Us	er (Last, First, M	II) Rank/Grade	Organiz	ation Division	Bldg./Room #		
	AL EDUCATION ner Education Institut Attended	tions Typ	HIGHEST ACADEMIC DEGREE ATTAINES Type of Program Pursued and Dates of Attendance			D Degree, Diploma, or Certificate Received and Date		
а								
b. ——	b							
с								
d	3 TRAIN	ING RECEIVED II	N BASIC BADIOIS	OTOPE H	ANDLING TECHNIQUE	<u> </u>		
	0. 110.11	ING RECEIVED II	TEASIC TABION	30101011		ENGTH OF TRAINING		
FIELD	OF TRAINING A		LOCATION AND DATE(S) OF TRAINING (Include course title if known) B			SUPERVISED LABORATORY EXPERIENCE (Hours) D		
	TION PHYSICS RUMENTATION							
b. RADIATION PROTECTION								
	NG TO THE USE SUREMENT OF							
d. RADIAT	TION BIOLOGY							
e. RADIOF	PHARMACEUTICAL RY			7				
4. EXPERIENCE WITH RADIATION (Actual use of Radioisotopes) (Sealed or unsealed source)								
ISOTOPE MAXIMUM AMOUNT		WHERE EX	WHERE EXPERIENCE WAS GAINED DURATE		URATION OF EXPERI	ENCE TYPE OF USE		

USAMRIID Form 32 (dated 6 May 1988)



# Appendix D (continued)

# USAMRIID Form 32 (Page 2 of 2)

4.	EXPE	RIENCE WITH RAD	PIATION (Actual use of Ra	adioisotopes)	(Sealed or unsealed source)	(Continued)	
ISOTOPE	MA)	CIMUM AMOUNT	WHERE EXPERIENCE WA	AS GAINED	DURATION OF EXPERIENCE	E TYPE OF USE	
		E EVERDIENCE	MITTI DADIATION COORDINA				
DEVIC			MITH RADIATION PROL		ICES (X-ray, Irradiators, etc.	TYPE OF USE	
6. CERTIFICATION:  I certify that the information provided hereon is true and complete to the best of my knowledge.  (Date signed)  (Signature of Applicant)							



## Appendix E



- 1. Approval process for a new Protocol for Radioisotope Usage (USAMRIID Form 35).
- a. The co-worker shall review protocol(s) to be submitted in their area of responsibility.
- b. A separate protocol will be submitted for each radioisotope. Note: All co-worker(s), trainee(s) and technician(s) will be current, qualified radiation worker(s) and authorized radioisotope user(s).
  - c. The proposed protocol will include the following information:
    - (1) Radioisotope.
    - (2) Beginning and ending dates (maximum of three years).
    - (3) Maximum amount (mCi) of reagent to be used per experiment.
    - (4) Maximum amount (mCi) of reagent to be maintained in inventory.
- (5) Maximum amount (mCi) to be held as reagent, radioactive research material and radioactive waste.
  - (6) Building and room designations for all work and storage locations.
  - (7) A summary of the research procedure.
- (8) Statements addressing handling, labeling, transportation, room survey(s), animal usage (if applicable) and adherence to the As Low As Reasonably Achievable (ALARA) policy will be incorporated in the body of the form. Note: research protocol number and isotope usage number will be provided by the Radiation Safety Officer (RSO).
- d. The co-worker will submit the new protocol to the division principal radioisotope user (PRU).
- e. After review and concurrence by the PRU, the new protocol will be forwarded to the Division Chief.
- f. After review and concurrence by the Division Chief, the new protocol will be forwarded to the RSO.



## Appendix E (continued)

- g. After review and concurrence by the RSO, the new protocol will be forwarded to the lonizing Radiation Control Committee (IRCC) Chairman.
  - h. All new protocol(s) will be approved by the IRCC.
- i. A photocopy of the signed protocol will be provided to the co-worker and respective PRU for their records.
- 2. Interim approval (not to exceed 120 days) of new protocol(s) may be granted by the RSO and IRCC Chairman.
- a. Interim approval(s) may be granted for protocol(s) that have completed steps 1a. through 1g above.
  - a. Interim approval(s) will not be extended beyond the initial 120-day period.
- b. A memorandum, signed by the RSO and IRCC Chairman, will be provided to the co-worker and PRU to indicate interim approval.
  - c. Formal approval of the new protocol will occur at the next IRCC meeting.