MATERIALS LICENSE

Amendment No. 33

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Genome Therapeutics Corporation

2. 100 Beaver Street
Waltham, Massachusetts 02154

In accordance with application dated April 4, 1995,

3. License Number 20-11124-01 is amended in its entirety to read as follows:

4. Expiration Date May 31, 1998

5. Docket or Reference No. 030-04696

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Phosphorus 32	A. Any	A. 500 millicuries
B. Phosphorus 33	B. Any	B. 100 millicuries
C. Sulfur 35	C. Any	C. 100 millicuries
D. Iodine 125	D. Labelled compounds	D. 50 millicuries
E. Cesium 137	E. Sealed source (E. I. DuPont Model C-316B)	E. 10 millicuries

9. Authorized use

A. through E. For research and development as defined in 10 CFR 30.4.
F. For instrument calibration.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 1365 Main Street or 100 Beaver Street, Waltham, Massachusetts.

11. A. Licensed material shall be used by, or under the supervision of, Dennis R. Dumais, Thomas C. Gravius, Dana D. Torrey, and Kristina Serino.

    B. The Radiation Safety Officer for this license is Dennis Dumais.

12. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

OFFICIAL RECORD COPY ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 20-11124-01
Docket or Reference number 030-04696
Amendment No. 33

(Continued)

CONDITIONS

13. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen 3; or

(ii) they contain only a gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken.

NRC Form 374A (5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 20-11124-01

Docket or Reference number: 030-04696

Amendment No. 33

(13. continued) CONDITIONS

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

14. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.

15. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory.

16. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Letter dated January 30, 1992
B. Letter dated January 26, 1993
C. Letter dated April 1, 1993
D. Letter dated April 4, 1995

For the U.S. Nuclear Regulatory Commission

Date OCT 11 1995

By Original Signed By: John R. McGrath

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

OCT 11 1995

Dennis R. Dumais
Radiation Safety Officer
Genome Therapeutics Corporation
100 Beaver Street
Waltham, MA 02154

Dear Mr. Dumais:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I office, the Licensing Assistance Section, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:

John R. McGrath
Senior Health Physicist
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

License No. 20-11124-01
Docket No. 030-04696
Control No. 121628

Enclosures:
1. Amendment No. 33
2. 10 CFR Parts 2, 19, 20, 30, and 170
3. NRC Form 3 and 313

DOCUMENT NAME: R:\WPS\MLTR\L2011124.01
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DRSS/RI	N	/		/			
NAME	McGrath JRM							
DATE	04/21/95		04/ /95		04/ /95		04/ /95	

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ML10

Genome Therapeutics Corporation

100 Beaver Street, Waltham, MA 02154
617/893-5007

030-04696

September 29, 1995

U.S. Nuclear Regulatory Commission, Region I
Nuclear Materials Section
475 Allendale Road
King of Prussia, PA 19406-1415

Reference: License No. 20-11124-01
Mail Control No. 121628

Dear Materials License Reviewer,

This letter is a request to increase the radioisotope possession limit of P-32 on Genome Therapeutics Corporation's Materials License (no. 20-11124-01) from 200 mCi to [illegible]00 mCi due to a projected increase in use. We request that this change be included as part of the review process for the amendment application dated April 4, 1995 (mail control no. 121628) under current review by the NRC.

If you require additional information, I may be reached at (617) 893-5007.

Sincerely,

Dennis R. Dumais

Dennis R. Dumais, RSO

OFFICIAL RECORD COPY

ML 10

121628
OCT - 2 1995

NAME CHANGE

Genome Therapeutics Corporation

100 Beaver Street, Waltham, MA 02154
617/893-5007

030-04696

April 4, 1995

U.S. Nuclear Regulatory Commission, Region I
Nuclear Materials Section
475 Allendale Road
King of Prussia, PA 19406-1415

Reference: License No. 20-11124-01

Dear Materials License Reviewer,

This letter is a request for an amendment of our current Materials License # 20-11124-01. A description of requested changes follows.

1. Company Name Change: We recently changed the company name from Collaborative Research, Inc. to Genome Therapeutics Corporation (GTC). (This name change is not due to a change in ownership.) Corporate headquarters are located at 100 Beaver Street, Waltham, MA, and all future correspondence from the NRC should be sent to this address. Radioactive material is still used at both facilities listed on our Materials License (100 Beaver St., and 1365 Main St., both in Waltham, MA). In addition, GTC's new telephone number is (617) 893-5007.

2. Authorized Users: Remove Lance S. Davidow from the list of authorized users since he is no longer with the company.

3. Removal of Tritium (Hydrogen-3) from Materials License: We no longer use tritium and request its removal from GTC's Materials License. Tritium has never been used, stored, or received by GTC at the 100 Beaver Street facility. All tritium at 1365 Main Street was properly disposed of in 1991, and there has been no use, storage, or receipt of tritium since that time.

4. Decay-In-Storage of Sulfur-35 Waste: We would like permission to place S-35 in storage decay on the premises in order to minimize costs for waste management at GTC. Although we are not currently generating S-35 waste, a shift in research efforts could result in the generation of up to 45 cubic feet per year (6 x 7.5 cubic foot barrels). Instructions to employees concerning the segregation of radioactive waste are included in the GTC Radiation Safety Manual, appendix IV, part III. Whenever possible, we will dedicate separate laboratory space for S-35 use. In the event that another isotope must be used at the same location, any radioactive waste generated at that location will be collected, stored and decayed for a minimum of 10 half-lives based on the half-life of the S-35. All radioactive waste collection containers are clearly labeled to identify the radioisotope(s) permitted for disposal. Radioactive waste is transferred from the laboratory collection containers, (by or under the supervision of radiation protection personnel), to 55-gallon

steel drums. The drums are cleary identified by radioisotope content and activity, sealed, and dated for decay-in-storage. An inventory list is maintained of all decay-in-storage waste. Prior to disposal as normal trash and after a minimum of ten half lives, the material will be surveyed in a low background area with an appropriate survey instrument (Ludlum Model 44-9 pancake GM detector or equivalent). Survey results must be background before any material is disposed of as normal trash. The S-35 decay-in-storage waste will be stored in the same areas at each facility previously approved by the NRC for decay-in-storage of radioactive material with a half-life less than 65 days.

5. Bioassays: Since H-3 is no longer used on the premises, we would like to eliminate periodic urinalysis testing except in the event of a suspected uptake.

6. Instrumentation: We no longer possess a gamma counter (ICN Micromedic Systems, Inc., model no. 280118) as previously mentioned in a letter to the NRC dated January 26, 1993. The instrument was included in the sale of our diagnostics division to Dianon Systems, Inc. of Stratford, CT on June 27, 1993.

7. Updated Safety Manual: The GTC Safety Manual has been updated to reflect the above changes as well as to clarify instructions to workers. The updated manual is attached for your review.

If further information is required, I may be reached at (617) 893-5007.

Sincerely,

Dennis R. Dumais

Dennis R. Dumais
Radiation Safety Officer

NRC FORM 313 (9-90)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB NO. 3150-0120
EXPIRES 6-20-93

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 3.25 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503

APPLICATION FOR MATERIAL LICENSE

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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 JURISDICTION.

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

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 20-11124-01
- [ ] C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Genome Therapeutics Corporation
100 Beaver Street
Waltham, MA 02154

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Genome Therapeutics Corporation
100 Beaver Street
Waltham, MA 02154

Genome Therapeutics Corporation
1365 Main Street
Waltham, MA 02154

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dennis R. Dumais, Radiation Safety Officer

TELEPHONE NUMBER (617) 893-5007

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 3-M
AMOUNT ENCLOSED $ 690

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, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Fenel M Eloi	Fenel M. Eloi	Vice President - Finance, Treasurer and Chief Financial Officer	4/4/95

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS
Amd	Apr 12 #65	3B	& Refunded $90

AMOUNT RECEIVED	CHECK NUMBER
$690	018684

APPROVED BY	DATE
[signature]	4/24/95

NRC FORM 313 (9-90)

OFFICIAL RECORD COPY ML 10 121628 APR 12 1995

GENOME THERAPEUTICS CORPORATION

Radiation Safety Plan

April 4, 1995

TABLE OF CONTENTS

I. PURPOSE

A. The required procedures contained in this document have been established for the following purposes:

(1) To provide Genome Therapeutics employees and the general public with protection against the radiation hazards associated with the possession, use, transportation and disposal of radioactive material.

(2) To insure compliance with applicable radiation protection regulations of governmental agencies.

II. DELEGATION OF RESPONSIBILITIES

A. GENOME THERAPEUTICS MANAGEMENT

(1) Management is responsible for providing adequate facilities, equipment and instruments for the purpose of maintaining radiation exposures as low as reasonably achievable to workers and the population.

(2) Management requires compliance, by its workers, with the procedures in this document.

B. RADIATION PROTECTION STAFF

The Radiation Protection Staff consists of the Radiation Protection Safety Officer and research scientists as listed on the NRC Material License and in the Genome Therapeutics Employee Safety Manual. Duties listed in this Radiation Safety Plan which are delegated to the Radiation Protection Staff are routinely carried out by the Radiation Protection Officer or as otherwise designated. The Radiation Protection Staff is responsible for the following:

(1) Implementing the radiation protection program.

(2) Providing such services as may be required for radiation protection and compliance with governmental regulations.

The services include the following:

(a) Registration and instruction of radiation workers.

(b) Personnel monitoring of internal and external radiation exposure.

(c) Radioisotope laboratory inspections and radiation surveys.

(d) Radioactive waste collection and disposal.

(e) Calibration and repair of radiation protection instruments.

(f) Environmental monitoring.

(g) Monitoring of outgoing radioactive waste.

(h) Supervision of radiation emergencies and decontamination operations.

(i) Maintenance of radiation protection records.

(j) Maintenance of an adequate inventory of radioactive material possessed.

(k) Consultation on laboratory design, shielding, and other radiation protection control methods.

(l) Providing lectures and training on radiation protection techniques, and overseeing the on-the-job radiation protection training provided by supervisors.

C. EACH SUPERVISOR POSSESSING OR USING RADIOACTIVE MATERIAL IS RESPONSIBLE FOR

(1) Allowing only those persons who are registered with the radiation protection staff to use radioactive material.

(2) Ensuring that personnel keep adequate records of disposal of radioactive materials.

(3) Requiring non-registered personnel who wish to enter a radiation lab to receive prior approval from the radiation protection staff.

(4) Informing the radiation protection officer of new radioactive material work, or changes in existing work which may increase radiation exposure.

(5) Ensuring that personnel wear personal monitoring devices during periods of possible radiation exposure.

(6) Ensuring compliance with the caution sign and labeling requirements of 10 C.F.R. part 20.

(7) Establishing a daily radioisotope lab 'close-down' procedure to ensure that at the end of the work day:

(a) Survey-meter measurements are taken to establish that external radiation levels are as low as reasonably achievable and contamination levels are within permissible limits.

(b) Radiation sources are properly labeled and stored.

(c) Experiments that will be in progress after work hours will be attended or adequately contained.

(8) Providing on the job radiation protection training for workers using radioactive material.

(9) Maintaining radiation exposure as low as reasonably achievable.

III. REQUIRED PROCEDURES PERTAINING TO RADIOACTIVE MATERIAL

A. Scope: These procedures apply to all persons that receive, possess, use, transport or dispose of radioactive material.

B. Control of Radiation Exposure and Contamination

(1) Exposure to ionizing radiation shall be kept as low as is reasonably achievable.

(2) Occupational external and internal exposure from radioactive material shall be controlled such that no individual shall receive a radiation dose in excess of the values listed in Appendix 1.

C. Compliance with Regulations of Government Agencies

The use, storage, transportation, and disposal of radioactive material must conform to the applicable regulations of the U.S. Nuclear Regulatory Commission, the Massachusetts Department of Labor and Industry, and the U.S. Department of Transportation.

The applicable regulations are as follows:

AGENCY	REGULATION
Nuclear Regulatory Commission	CFR-10
MA. Dept. of Labor & Industry	"Rules and Regulations to Control the Radiation Hazards of Radioactive Material and of Machines Which Emit Ionizing radiation." Section 5B, Chapter III, General Laws
U.S. Dept. of Transportation	CFR-49

D. Registration and Authorization

(1) Prior to possessing or using radioactive material, authorization must be obtained from the Radiation Protection Staff.

(2) Each room or laboratory in which radioactive material is to be handled or stored must be registered and approved for such use by the Radiation Protection Staff.

(3) Each person who may handle radioactive material must register with the Radiation Protection Staff and receive a radiation protection instruction-interview.

(4) Each user must be approved for a proposed use of radioactive material with specific regard to the adequacy of his or her training and experience.

E. Bioassay Tests, Including In Vivo Measurements

(1) Depending on radiation exposure history and proposed work, persons registering with the Radiation Protection Staff may be given appropriate bioassay tests to determine body burden of radioactive material. Subsequently, as required by the Radiation Protection Staff, periodic bioassay tests shall be performed.

(2) In the event of accidental internal deposition of radioactive material, bioassay tests shall be performed as appropriate.

F. **Radiation Laboratory Maintenance**

(1) Registered radiation lab workers are responsible for the proper disposal and monitoring of all waste material, the cleaning of all laboratory equipment, benches and hoods, and the clean up of any radioactive contamination under the direction of the Radiation Protection Staff. The Housekeeping Group is responsible for the general cleaning of the radiation laboratories under the direction of the Radiation Protection Staff.

G. **Radiation Surveys and Monitoring**

(1) Unless deemed unnecessary by the Radiation Protection Staff, each laboratory using radioactive material must have appropriate radiation detection instruments.

(2) Personnel shall use an appropriate radiation detection instrument or wipe test to establish that radiation exposure and removable contamination are being adequately controlled.

(3) Each radiation worker who may receive a radiation dose in excess of 10% (5% for persons under the age of 18) of the values indicated in Appendix I will be provided with appropriate personnel monitoring badges.

(4) When provided, personal monitoring badges shall be worn in the manner specified by the Radiation Protection Staff, whenever occupational radiation exposure may be received. When not being worn, the badges shall be stored in a location where they will receive minimal radiation exposure above background.

(5) Appropriate air samples will be taken to determine air concentrations from various operations involving radioactive materials.

H. **Procurement of Radioactive Material**

(1) Procurement of radioactive material must be in accordance with the provisions of Appendix II.

I. **Receiving Packages Containing Radioisotopes**

(1) Packages containing Radioisotopes must be received in accordance with the provisions of Appendix III.

J. **Storage of Radioactive Material**

Radioactive Material shall be kept or stored in a manner that:

(1) Provides adequate radiation shielding.

(2) Provides adequate protection against fire, explosion or flooding.

(3) Provides adequate protection against accidental breakage of primary storage containers.

(4) Provides adequate protection against unauthorized removal.

K. Shipment of Radioactive Material

No radioactive material may be shipped from Genome Therapeutics unless:

(1) The Radiation Protection Staff has a current copy of the destination facilities' Radioactive Material License that authorizes that facility to possess such material.

(2) The shipment is sent according to the Department of Transportation regulations (Title 49CFR) and the Nuclear Regulatory Commission regulations (10CFR part 71). (The Radiation Protection Staff has shipping information.)

(3) Approval is obtained from the Radiation Protection Staff.

L. Disposal of Radioactive Material

(1) Radioactive material must be disposed of in accordance with the provisions of Appendix IV.

M. Caution Signs and Labels

(1) Caution Signs and Emergency Notification

Each laboratory storing or using radioactive material shall be posted by the Radiation Protection Staff with appropriate caution signs in conformance with 10 C.F.R. part 20. These signs shall be removed only by, or with the approval of, the Radiation Protection Staff. In addition, these laboratories will be posted with signs on which emergency notification information is listed. It is the Radiation Protection Staff's responsibility to ensure that the appropriate emergency notification information is kept up to date.

(2) Labaling of Containers

Each container of radioactive material will be labeled by the user in conformance with the following procedures, which meet state and federal regulations:

(a) Each container of radioactive material in excess of those quantities listed below must have a durable, clearly visible label bearing the radiation caution symbol and the words:

"CAUTION RADIOACTIVE MATERIALS"

(Color and design of label are specified in 10 C.F.R. part 20.) These labels must also state the quantities and kinds of radioactive materials in the containers and the date for which the activity is estimated.

Title 10 C.F.R. Part 20 Appendix C
Reference List of Radionuclides

Phosphorus-32	1000 uCi
Phosphorus-33	10 uCi
Sulfur-35	100 uCi
Iodine-125	1 uCi

Note: These are the only radioisotopes used at Genome Therapeutics.

(b) Labeling is not required for laboratory containers, such as beakers, flasks, and test tubes used transiently during laboratory procedures while the user is present.

(c) Containers of lesser amounts of radioactive materials should be marked with a "Caution Radioactive Material" label along with the identity of the isotope.

N. General Radiation Protection Requirements and Precautions

(1) There shall be no smoking, eating, storage of food, or use of cosmetics in any area where unsealed radioactive materials are being used, handled, transferred, or stored.

(2) Use paper tissues in place of ordinary handkerchiefs when working with radioactive material.

(3) Safety glasses and a lab coat must be worn in all radiation laboratories. Protective gloves shall be worn during operations involving the handling of any unsealed radioactive material. Any cuts or breaks in the skin, particularly on the hands or forearms, should be protected when working with unsealed radioactive material.

(4) Body badges shall be worn for all radioactive work, with the exception of the low energy β-emitting radionuclides ^{33}P, and ^{35}S. Finger ring badges must be worn when handling millicurie quantities of ^{32}P.

(5) There will be no mouth pipetting of radioactive solutions.

(6) Radioactive work should be separated from non radioactive work as far as reasonably possible. Unsealed radioactive material may only be used in the radiation laboratories and in specially designated areas approved by the Radiation Protection Staff.

(7) Always work over plastic backed absorbent paper or a spill tray when using unsealed radioactive material.

(8) Always use the minimum quantity of radioactivity compatible with the objectives of the experiment.

(9) Whenever practical, the user should perform a trial experiment run using stable (or low activity) material to establish the adequacy of procedures and equipment. Use plastic lab ware in place of glassware whenever possible. The use of needles should be avoided. Any new procedure from which there is potential for a significant increase in exposure should be reviewed and observed by the Radiation Protection Staff.

(10) Prior to performing an operation on a source of radioactive material, radiation levels will be measured. To minimize the dose to the extremities, handling tongs, or a suitable remote handling device must be used for handling a source or container which emits a dose rate, at contact, in excess of 1 rem/hr. Appropriately shielded containers shall be used when transporting radioactivity within and between lab areas.

(11) When performing operations that might produce airborne contamination (i.e., evaporation, sanding or grinding, transfer of unsealed powdered or volatile radioactive material), approved* exhaust ventilation shall be used. When recommended by the Radiation Protection Staff, appropriate filtration for effluent air shall be provided.

* Note: Approved exhaust ventilation means a hood, glove box or local exhaust ventilation that is (1) registered with the Radiation Protection Staff and (2) approved for adequacy of ventilation.

(12) Always work in a manner which minimizes radiation exposure to yourself and others in the lab. Time, distance, and shielding are the best methods for reducing exposures.

(a) Time: Work efficiently to minimize the time spent working with radioactive materials.

(b) Distance: Distance is a very effective means to reduce radiation exposure. For point sources, the exposure received is inversely proportional to the square of the distance from the source (Inverse Square law). Thus, if the distance is doubled between you and the source of radiation, you will reduce the radiation dose by a factor of four.

(c) Shielding: Use proper shielding to reduce exposure. Consult the Isotope data sheets or the Radiation Protection Staff to determine the appropriate shielding material for the isotope being used.

(13) Always monitor your work area, protective clothing and gloves during, and after the use of radioactive material. Contaminated surfaces should be decontaminated immediately to minimize exposure and the spread of radiation. For continuing operations, e.g. electrophoresis, check the radiation levels around the equipment for adequacy of shielding when the apparatus is set up.

(14) Always monitor, remove, and dispose of gloves properly whenever leaving a radiation work area.

(15) Label any newly generated containers of radioactive material before storing as outlined in Section III.M. of this manual.

(16) Radioactive waste must be disposed of in accordance with the guidelines set in Appendix IV.

(17) Radiation work areas shall be kept clean and orderly by all users in order to maintain a safe work environment. It is the user's responsibility to notify the Radiation Protection Staff of any potentially unsafe or hazardous conditions in or near any radioactive work areas.

(18) After handling unsealed radioactive material, exposed skin, hair, and clothing shall be surveyed for contamination, and hands shall be washed and remonitored before leaving the laboratory. The Radiation Protection Staff shall be notified immediately if, after decontamination, residual contamination of skin, hair or personal clothing is detected.

(19) Objects, equipment, and clothing that may have been contaminated with radioactive material shall be surveyed for exterior surface contamination. If surface contamination is detected and cannot be removed, notify the Radiation Protection Staff for proper guidance. Shielding or decay storage may be necessary to minimize exposure to workers in the area. Contaminated objects shall not be removed from the radiation laboratory without the authorization of the Radiation Protection Staff.

M. Emergency Procedures

The Radiation Protection Staff shall be notified immediately if any of the following circumstances is known or suspected:

(1) Exposure to external radiation in excess of the values in Appendix I.

(2) Accidental exposure by inhalation, ingestion, or injection of radioactive material.

(3) Accidental release of radioactive material to laboratory atmosphere, surfaces, drains, or ventilation system. For accidental releases, follow the procedures outlined below:

(a) If alone, notify someone for help.

(b) Remain at the scene; have someone immediately notify the Radiation Protection Staff.

(c) Mark off the contaminated area.

(d) Wearing gloves, contain the spill as much as possible.

(e) If it is known that the radioactive material is volatile, evacuate the area and wait for assistance.

(f) Wait for a member of the Radiation Protection Staff to arrive for monitoring and decontamination.

Appendix I

DOSE LIMITS

(A) Occupational dose limits for adults

(1) The annual limit for the whole body effective dose equivalent shall not exceed 5 rems (0.05 Sv) .

(2) The annual limits to the lens of the eye, to the skin, and to the extremities shall not exceed:

(a) An eye dose equivalent of 15 rems and

(b) A shallow-dose equivalent of 50 rems to the skin or to any extremity.

(B) Occupational dose limits for minors

(1) The annual occupational dose limits for minors are 10% of the annual body dose limits specified for adult workers.

(C) Dose to an embryo/fetus

(1) The deep-dose equivalent to the declared pregnant woman, and the dose to the embryo/fetus from radionuclides in the embryo/fetus and in the pregnant woman, shall not exceed a total dose of 0.5 rems. (See the Genome Therapeutics Pregnancy Policy.)

(D) Dose limits for individual member of the public

Each licensee shall conduct operations so that:

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem in a year.

Additional information is in 10 C.F.R. Part 20.

Appendix II

PROCEDURE FOR PROCUREMENT OF RADIOACTIVE MATERIAL

The limit of possession of radioactive materials at this facility is the following:

^{32}P	200 mCi	Any chemical (liquid)
^{33}P	100 mCi	Any chemical (liquid)
^{35}S	100 mCi	Any chemical (liquid)
^{125}I	50 mCi	Labeled compounds only (liquid)

(1) When an order for a radioisotope is placed, the requisition is forwarded to the Radiation Safety Officer for approval. This approval is based on the possession limit and whether the user is qualified to receive such material.

(2) No phone orders are to be made without prior approval of the Radiation Protection Staff.

Appendix III

PROCEDURES FOR RECEIVING PACKAGES CONTAINING RADIOISOTOPES

(1) Visual Observation

Before handling the package, check it for obvious deformation or wet spots. If any obvious damage has occurred during shipment, notify the Radiation Protection Staff.

(2) Delivery

All packages are to be delivered to the radioisotope laboratory unopened, and must be surveyed and logged in within 3 hours of receipt.

(3) Logging the Package

Remove the packing slip from the package. Record the receipt in the receiving log. After all of the procedures below have been properly completed, make a copy of the packing slip and forward it to the radiation safety officer so that the radioisotope inventory log may be updated. The original packing slip is then sent to the GTC receiving department.

(4) Survey and Storage

(a) Prior to opening the package, all surfaces must be monitored for contamination and radiation levels. Use the technique appropriate to the isotope, e.g. end-window Geiger-Mueller counter for ^{32}P, NaI crystal monitor for ^{125}I, and wipe testing with scintillation counting for all other isotopes.

(b) If contamination is found to be less than 2200 dpm/100 cm^2, open the package. Observe the contents. If the inner container appears undamaged, store the container in the place appropriate to its form and radiation level after item (d) has been completed.

(c) Discrepancies between the quantity of radiochemicals received and the quantity listed on the packing slip must be reported to the Radiation Protection Staff immediately.

(d) Survey the packaging material using the instrument appropriate to the isotope. If the packaging materials are found to be uncontaminated, obliterate the radioactive markings and discard them.

(e) Record the results of swipe tests and survey readings of packing material in the receipt log book.

(5) Procedure if Contaminated Packing Material is Found

If surveys at any point indicate contamination of the packing materials through leakage of the contents of the inner container:

(a) Secure all materials associated with the shipment.

(b) Notify the Radiation Protection Staff immediately so that a survey may be directed to ascertain the extent of the contamination.

(c) If contamination and/or radiation levels exceed authorized limits, immediate notification must be made as stated in CFR Title 10 Part 20.

Appendix IV

RADIOACTIVE WASTE DISPOSAL

I. Sanitary Sewer

Limited quantities of aqueous liquid waste may be discarded into the sinks in the radioisotope laboratories for the isotopes listed below:

^{32}P, ^{33}P, ^{35}S, & ^{125}I

These limits are posted at the sinks and are based on the monthly sanitary sewerage concentration limits in CFR Title 10 Part 20 Appendix B as diluted by the average monthly sewerage release. Genome Therapeutic's ALARA goal for sanitary sewerage release is 10% of the yearly release limit of 1 Curie per year for all radioisotopes combined. A log for recording disposal of liquid waste is located near each sink. Large quantities of ^{32}P, ^{33}P, ^{35}S, and ^{125}I should not be discarded into the sinks. Facilities for decay storage are provided.

II. Scintillation Vials - Decay-Storage

Scintillation cocktails containing radioisotopes are considered radioactive. These vials are placed in decay storage (decay for ten half-life's) and then disposed of as chemical waste.

III. Decay-Storage of Waste

(1) The following radioisotopes are placed in decay storage: ^{32}P, ^{33}P, ^{35}S, and ^{125}I. Waste must be separated by radioisotope. Radioactive waste collection containers are clearly labeled to indicate the acceptable radioisotope for disposal. If any radioactive waste is disposed of incorrectly, the Radiation Protection Staff must be informed immediately.

(2) All sharps and needles are separated from other waste and are disposed of in accordance with federal and state guidelines. All waste receptacles are clearly labeled.

(3) **No lead containers may be placed in this waste.** Lead must be disposed of as hazardous waste and may not be placed with radioactive or nonradioactive waste. Contaminated lead must be stored separately from other radioactive waste for decay storage prior to hazardous waste disposal.

(4) Deface all radioactive material labels prior to disposal.

(5) Drums designated for storage and decay are sealed, monitored, labeled and marked as to its activity, isotopes, and date.

(6) A minimum decay storage time of ten half-lifes is required for this waste. After decay storage, the contents of the drum are surveyed in a low background area with a low-level survey meter and with all shielding removed. If no activity above background is detected, the material is disposed of as deregulated waste.

PHOSPHORUS-32

Decay Mode: Beta Emission (β^-)

Maximum Beta Energy: 1.71 MeV (100%)

Maximum Range of Beta: 6 m in Air
8 mm in Water
6 mm in Plastic
0.6 mm in Lead

Dose Rate at Mouth of Open Vial: 22 rem/hour per mCi in 1 ml liquid

Radioactive Half-Life ($t_{1/2}$): 14.29 days

Annual Limit on Intake (ALI): 400 μCi

Derived Air Concentration (DAC): 2×10^{-7} μCi/ml

Dosimetry: The bone is the critical organ for intake of transportable compounds of ^{32}P. Phosphorus metabolism is complex; 30% is rapidly eliminated from the body, 40% possesses a 19-day biological half life, and the remaining 30% is reduced by radioactive decay. The lung and lower large intestine are the critical organs for inhalation and ingestion, respectively, of non-transportable ^{32}P compounds. The high-energy beta emissions can present a substantial skin dose hazard.

Detection: End-window Geiger-Mueller detectors, or liquid scintillation counter for ^{32}P.

Handling Precautions: Since the dose rate from ^{32}P is not attenuated significantly by air, shielding materials should be used. The best material is 1 cm thick Plexiglas. It will absorb the beta particles while generating little secondary radiation. For millicurie amounts of ^{32}P, lead (3-6 mm thick) should be added to the exterior of the Plexiglas shield to absorb the more penetrating secondary radiation. Lead should only be used as a secondary shield.

A high local dose can be received if the radioactive material is touched and allowed to remain on the skin or gloves. Both the hands and face can receive a considerable dose of radiation near an open container of ^{32}P, particularly if the radioactivity is in a concentrated form. Therefore, never work over an open container of ^{32}P.

Phosphorus-32 Decay Data Table Physical Half Life: 14.29 Days

Days	0.0	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5
0	1.000	0.976	0.953	0.930	0.908	0.886	0.865	0.844	0.824	0.804
5	0.785	0.766	0.748	0.730	0.712	0.695	0.678	0.662	0.646	0.631
10	0.616	0.601	0.587	0.573	0.559	0.545	0.532	0.520	0.507	0.495
15	0.483	0.472	0.460	0.449	0.438	0.428	0.418	0.408	0.398	0.388
20	0.379	0.370	0.361	0.353	0.344	0.336	0.328	0.320	0.312	0.305
25	0.297	0.290	0.283	0.277	0.270	0.264	0.257	0.251	0.245	0.239
30	0.233	0.228	0.222	0.217	0.212	0.207	0.202	0.197	0.192	0.188
35	0.183	0.179	0.174	0.170	0.166	0.162	0.158	0.155	0.151	0.147
40	0.144	0.140	0.137	0.134	0.130	0.127	0.124	0.121	0.118	0.116
45	0.113	0.110	0.107	0.105	0.102	0.100	0.098	0.095	0.093	0.091
50	0.088	0.086	0.084	0.082	0.080	0.078	0.077	0.075	0.073	0.071
55	0.069	0.068	0.066	0.065	0.063	0.062	0.060	0.059	0.057	0.056
60	0.054	0.053	0.052	0.051	0.049	0.048	0.047	0.046	0.045	0.044

PHOSPHORUS-33

Decay Mode: Beta Emission (β^-)

Maximum Beta Energy: 0.249 MeV (100%)

Maximum Range of Beta: 46 cm

Radioactive Half-Life ($t_{1/2}$): 25.4 days

Annual Limit on Intake (ALI): 3 mCi

Derived Air Concentration (DAC): 1×10^{-6} µCi/ml

Dosimetry: Millicurie quantities of ^{33}P do not present a significant external exposure hazard because the low energy betas emitted barely penetrate gloves and the outer dead layer of skin. The bone is the critical organ for intake of transportable compounds of ^{33}P. Phosphorus metabolism is complex; 30% is rapidly eliminated from the body, 40% possesses a 19 day biological half-life and the remaining 30% is reduced by radioactive decay. The lung and the lower large intestine are the critical organs for inhalation and ingestion, respectively, of non transportable ^{33}P compounds.

Detection: End-window Geiger-Mueller detector or liquid scintillation counter for ^{33}P.

PHOSPHORUS-33 DECAY TABLE
PHYSICAL HALF-LIFE = 25.4 DAYS

days	0	1	2	3	4	5	6	7	8	9
0	1.000	0.973	0.947	0.921	0.897	0.872	0.849	0.826	0.804	0.782
10	0.761	0.741	0.721	0.701	0.683	0.664	0.646	0.629	0.612	0.595
20	0.579	0.564	0.549	0.534	0.520	0.506	0.492	0.479	0.466	0.453
30	0.441	0.429	0.418	0.406	0.395	0.385	0.374	0.364	0.355	0.345
40	0.336	0.327	0.318	0.309	0.301	0.293	0.285	0.277	0.270	0.263
50	0.256	0.249	0.242	0.236	0.229	0.223	0.217	0.211	0.205	0.200
60	0.195	0.189	0.184	0.179	0.174	0.170	0.165	0.161	0.156	0.152
70	0.148	0.144	0.140	0.136	0.133	0.129	0.126	0.122	0.119	0.116
80	0.113	0.110	0.107	0.104	0.101	0.098	0.096	0.093	0.091	0.088
90	0.086	0.084	0.081	0.079	0.077	0.075	0.073	0.071	0.069	0.067
100	0.065	0.064	0.062	0.060	0.059	0.057	0.055	0.054	0.053	0.051
110	0.050	0.048	0.047	0.046	0.045	0.043	0.042	0.041	0.040	0.039
120	0.038	0.037	0.036	0.035	0.034	0.033	0.032	0.031	0.030	0.030

SULFUR-35

Decay Mode: Beta Emission (β^-)

Maximum Beta Energy: 0.167 MeV (100%)

Maximum Range of Beta: 24 cm

Radioactive Half-Life ($t_{1/2}$): 87.4 days

Annual Limit on Intake (ALI): 2 mCi

Derived Air Concentration (DAC): 9×10^{-7} μCi/ml

Dosimetry: Millicurie quantities of ^{35}S do not present a significant external exposure hazard since the low-energy emissions barely penetrate the outer dead layer of skin. The critical organ for ^{35}S is the whole body. The elimination rate of ^{35}S depends on the chemical form. Most ^{35}S labeled compounds are eliminated via the urine with 90 days being an acceptably conservative biological half life.

Detection: End-window Geiger-Mueller detector or liquid scintillation counter for ^{35}S.

Handling Precautions: Some ^{35}S compounds, including Methionine, generate volatile fractions particularly during lyophilization or incubation. Any work with such compounds must be cleared with the Radiation Protection officer to ensure that appropriate safety precautions are observed.

Sulfur-35 Decay Table Physical Half Life: 87.4 Days

Days	0	3	6	9	12	15	18	21	24	27
0	1.000	0.976	0.954	0.931	0.909	0.888	0.867	0.847	0.827	0.807
30	0.788	0.770	0.752	0.734	0.717	0.700	0.683	0.667	0.652	0.636
60	0.621	0.607	0.592	0.579	0.565	0.552	0.539	0.526	0.514	0.502
90	0.490	0.478	0.467	0.456	0.445	0.435	0.425	0.415	0.405	0.395
120	0.386	0.377	0.368	0.359	0.351	0.343	0.335	0.327	0.319	0.312
150	0.304	0.297	0.290	0.283	0.277	0.270	0.264	0.258	0.252	0.246
180	0.240	0.234	0.229	0.223	0.218	0.213	0.208	0.203	0.198	0.194
210	0.189	0.185	0.180	0.176	0.172	0.168	0.164	0.160	0.156	0.153
240	0.149	0.146	0.142	0.139	0.136	0.132	0.129	0.126	0.123	0.120
270	0.118	0.115	0.112	0.109	0.107	0.104	0.102	0.099	0.097	0.095
300	0.093	0.090	0.088	0.086	0.084	0.082	0.080	0.078	0.077	0.075
330	0.073	0.071	0.070	0.068	0.066	0.065	0.063	0.062	0.060	0.059
360	0.058	0.056	0.055	0.054	0.052	0.051	0.050	0.049	0.048	0.046

IODINE-125

Decay Mode: Electron Capture (e⁻)

Principal Radiation Emissions: Gamma (γ): 0.035 MeV (6.5%)
X-Rays: 0.027 MeV (112.5%)
0.031 MeV (25.4%)

Half-Value Layer for Lead Shielding: 0.02 mm

Unshielded Exposure Rate: 1.4 rad/hour per mCi at 1 cm

Radioactive Half-Life ($t_{1/2}$): 60.2 days

Annual Limit on Intake (ALI): 60 µCi

Derived Air Concentration (DAC): 3×10^{-8} µCi/ml

Dosimetry: The thyroid is the critical organ for ^{125}I uptake. Individual uptake and subsequent metabolism vary over a wide range. The thyroid may be assumed to accumulate 30% of soluble radioiodine uptake to the body and retain iodine with a 138 day biological half life (42 effective half life). All radioiodine in the body can be assumed to be eliminated via the urine.

Detection: NaI detector or liquid scintillation counter for ^{125}I.

Handling Precautions: Some radioiodine compounds may penetrate gloves and skin. Therefore, these compounds should be handled indirectly by using tools and wearing two pairs of gloves. The outer layer of gloves should be changed frequently and whenever they are suspected to be contaminated.

Iodine-125 Decay Data Table Physical Half Life: 60.14 Days

Days \ Days	0	2	4	6	8	10	12	14	16	18
0	1.000	0.977	0.955	0.933	0.912	0.891	0.871	0.851	0.831	0.812
20	0.794	0.776	0.758	0.741	0.724	0.707	0.691	0.675	0.660	0.645
40	0.630	0.616	0.602	0.588	0.574	0.561	0.548	0.536	0.524	0.512
60	0.500	0.489	0.477	0.467	0.456	0.445	0.435	0.425	0.416	0.406
80	0.397	0.388	0.379	0.370	0.362	0.354	0.345	0.338	0.330	0.322
100	0.315	0.308	0.301	0.294	0.287	0.281	0.274	0.268	0.262	0.256
120	0.250	0.244	0.239	0.233	0.228	0.223	0.218	0.213	0.208	0.203
140	0.198	0.194	0.189	0.185	0.181	0.177	0.173	0.169	0.165	0.161
160	0.157	0.154	0.150	0.147	0.144	0.140	0.137	0.134	0.131	0.128
180	0.125	0.122	0.119	0.117	0.114	0.111	0.109	0.106	0.104	0.102
200	0.099	0.097	0.095	0.093	0.090	0.088	0.086	0.084	0.082	0.081
220	0.079	0.077	0.075	0.073	0.072	0.070	0.069	0.067	0.065	0.064
240	0.063	0.061	0.060	0.058	0.057	0.056	0.054	0.053	0.052	0.051

DEFINITIONS

Absorbed Dose: The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

Activity: The rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

Adult: An individual 18 or more years of age.

ALARA: Acronym for "as low as reasonably achievable" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Alpha Decay: Radioactive decay in which an alpha particle (α) is emitted. This lowers the atomic number of the nucleus by two and its mass number by four.

Alpha Particle (α): A positively-charged particle emitted by certain radioactive materials. Consisting of two neutrons and two protons bound together, it is identical to the nucleus of a helium atom. The least penetrating of the three common types of radiation, the α particle is generally not harmful to animals or humans, unless the α-emitting substance enters the body. Alpha particles can be stopped by a few sheets of paper.

Annual Limit on Intake (ALI): The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue.

Assay (Radioactivity): To determine the quantity of radioactivity present in a substance.

Atom: The basic component of all matter; the smallest part of an element that has all the chemical properties of that element. Atoms are made up of protons, neutrons, and electrons.

Background Radiation: Radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by the NRC.

Becquerel (Bq): The SI unit of activity equal to one nuclear transformation (disintegration) per second. One curie is exactly equal to 3.7×10^{10} becquerels.

Beta Decay: Radioactive decay in which a beta particle (β) is emitted or in which orbital electron capture occurs.

Beta Particle (β): An elementary particle emitted from a nucleus during radioactive decay. It has a single electrical charge and a mass equivalent to 1/1,837 that of a proton. A negatively-charged β particle is identical to an electron; a positively-charged β particle is called a positron.

Bioassay: The determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

Body Burden: The total quantity of a radionuclide present in the body.

Capture: A process by which an atomic or nuclear system acquires an additional particle.

CFR: Code of Federal Regulations

Committed Dose Equivalent ($H_{T,50}$): The dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50 year period following the intake.

`**Committed Effective Dose Equivalent ($H_{E,50}$):** The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma W_T H_{T,50}$).

Contamination, Radioactive: Deposition of radioactive material where it may be contacted by persons without their knowledge, ruin experiments or make products or equipment unsuitable or unsafe for a specific use.

Controlled Area: (1) An area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. (2) A specified area in which exposure of personnel to radiation or radioactive material is controlled and which is under the supervision of a person who has knowledge of the appropriate radiation protection practices, including pertinent regulations, and who has responsibility for applying them.

Cosmic Radiation: Radiation of many sorts, but mostly protons with very high energies originating beyond the earth's atmosphere. Cosmic radiation is part of the natural background radiation.

Count (radiation counters): (1) A Pulse that has been registered, corresponding either to an ionizing event or to an extraneous disturbance (spurious count). (2) The number of pulses recorded in a specific period.

Counter (Radiation): A general designation applied to radiation detection instruments or survey meters that detect and measure radiation in terms of individual ionizations, displaying them as either the accumulated total or as their rate of occurrence.

Counter (Scintillation): See **Scintillation Counter**.

Counter Tube, Geiger-Mueller: A gas filled radiation counter tube operated in that range of applied voltage in which the charge collected per isolated count is independent of the charge liberated by the initial ionizing event, that is, the Geiger-Mueller region.

Counter Tube, Proportional: A gas filled radiation counter tube operated in that range of applied voltage in which the charge collected per isolated count is proportional to the charge liberated by the original ionizing event. The range of applied voltage depends upon the type and energy of the incident radiation.

Counting Efficiency: The ratio or the observed counts per minute (cpm) to the theoretical disintegrations per minute (dpm).

CPM: Counts per minute.

Critical Organ: That organ (or tissue) in which the dose equivalent would be the most significant due to a combination of the organ's radiosensitivity and a particular dose pattern throughout the body.

Curie (Ci): The basic unit of activity used to describe the quantity of radiation given off by a sample of radioactive material over a defined length of time (total decay rate). The curie is equal to 3.70×10^{10} nuclear transformations (disintegrations) per second (2.22×10^{12} disintegrations per minute). One Curie is approximately the rate of decay of one gram of radium.

Decay Product: A nuclide, stable or radioactive, formed by radioactive decay.

Decay, Radioactive: Elements that give off radiation are in an unstable state. They continue to give off radiation until they reach a stable, non radioactive state. This process is known as radioactive decay. An unstable element may become one or a string of different elements as it undergoes radioactive decay.

Declared Pregnant Woman: A woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

Decontamination (Radiation): Removal or reduction of radioactive contamination.

Deep Dose Equivalent (H_d): Applies to external whole-body exposure and is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

Derived Air Concentration (DAC): The concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI.

Derived Air Concentration-Hour (DAC-Hour): The product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose the equivalent of 5 rems (0.05 Sv).

Disintegration, Nuclear: Transformation of a nucleus, involving a splitting into more nuclei or the emission of particles.

Dose or Radiation Dose: A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

Dose, Accumulated: The sum of the absorbed doses received by the system considered regardless of whether it is exposed to radiation in a continuous or discontinuous fashion.

Dose Equivalent (H_T): The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

Dosimeter: A device, such as a body badge, which can be worn and used to measure the radiation dosage a person receives over a period of time.

DPM: Disintegrations per minute.

DPS: Disintegrations per second.

Effective Dose Equivalent (H_E): The sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

Electromagnetic Radiation: Radiation consisting of associated and interacting electric and magnetic waves that travel at the speed of light, including: radio waves, γ-rays and X-rays.

Electron: A subatomic particle with a unit negative electric charge and a mass equivalent to 1/1,837 that of a proton. Electrons surround the positively-charged nucleus and their arrangement determines the chemical properties of the element.

Embryo/Fetus: The developing human organism from conception until the time of birth.

Exposure: (1) For X or gamma radiation in air, the sum of the electrical charges of all the ions of one sign produced in air when all electrons liberated by photons in a suitably small element of volume of air are completely stopped in air, divided by the mass of the air in the volume element. It is commonly expressed in roentgens. (2) The incidence of radiation on living or inanimate material, by accident or intent. (See irradiation.)

Exposure Rate: The exposure per unit of time.

External Dose: The portion of the dose equivalent received from radiation sources outside the body.

Extremity: Hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

Eye Dose Equivalent: The external exposure of the lens of the eye, taken as the dose equivalent at a tissue depth of 0.3 centimeter.

Gamma Rays (γ): High-energy, short-wavelength electromagnetic radiation. Highly penetrating γ-rays are best stopped or shielded against by dense materials, such as lead, water, or concrete. γ-rays are similar to X-rays; however, they are of nuclear origin and are usually more energetic.

Geiger Counter: An instrument for detecting and measuring beta and gamma radiation.

Geiger-Mueller Region: The range of applied voltage in a gas filled counter tube in which the charge collected per ionizing event is constant and independent of the charge liberated by that event.

Gray (Gy): The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

Half-Life, Biological: The time required for the amount of a particular substance in a biological system to be reduced to one half of its value by biological process when the rate of removal is approximately exponential.

Half-Life, Effective: The time required for the amount of a particular radionuclide in a system to be reduced to half its value as a consequence of both radioactive decay and other processes such as biological elimination and burnup when the rate of removal is approximately exponential.

Half-Life, Radioactive: For a single radioactive decay process, the time required for the activity to decrease to half its value by that process.

Half-Value Layer: The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the value of a specified radiation quantity by one-half. It is sometimes expressed in terms of mass per unit area. (Also called half-value thickness.)

Health Physics: The science concerned with recognition, evaluation and control of health hazards from ionizing radiation.

Hot: An expression commonly used to mean "highly radioactive".

Internal Dose: The portion of the dose equivalent received from radioactive material taken into the body.

Ion: An atom or molecule that has lost or gained one or more electrons, thus becoming electrically charged.

Ionization: Any process by which an atom, molecule, or ion gains or loses electrons.

Ionization Chamber: A gas filled enclosure for measuring radiation by means of ions produced therein.

Ionizing Radiation: Any radiation that displaces electrons from atoms or molecules, thereby producing ions. Examples include α, β, and γ radiation.

Irradiation: Exposure to ionizing radiation. (see Exposure (2))

Isotope: One of two or more atoms with the same atomic number (the same chemical element), but a different atomic weight.

License: A license issued under the regulations of 10 C.F.R. Part 20.

Licensee: The holder of a license.

Limits (Dose Limits): The permissible upper bounds of radiation doses.

Measurements, Radiation: This table is a summary of various units used in the measurement of radiation.

MEASUREMENT	DESCRIPTION	UNIT	SI UNIT
Activity	Rate of Decay	Curie (Ci)	Bequerel (Bq)
Exposure	Ionizations in Air	Roentgen (R)	-
Absorbed Dose	Energy Absorbed	RAD	Gray (Gy)
Dose Equivalent	Effective Biological Dose	REM	Sievert (Sv)

Member of The Public: An individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

Minor: An individual less than 18 years of age.

Monitor, Radiation: A radiation detector whose purpose is to measure the level of ionizing radiation (or quantity of radioactive material) and possibly give warning when it exceeds a prescribed amount. It may also give quantitative information on dose or dose rate. The term is frequently prefixed with a word indicating the purpose of the monitor, such as: area monitor, air particle monitor.

Monitoring (Radiation Monitoring): The measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurement to evaluate potential exposures and doses.

Monitoring, Individual: (1) The assessment of dose equivalent by the use of devices designed to be worn by an individual; (2) The assessment of committed effective dose equivalent by bioassay (see bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or (3) The assessment of dose equivalent by the use of survey data.

Monitoring Devices, Individual: Devices designed to be worn by a single individual for the assessment of dose equivalent. These include film badges, themoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

Neutron (n): An uncharged elementary particle with a mass slightly greater than that of the proton and found in the nucleus of every atom heavier than hydrogen.

Nonstochastic Effect: Health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

NRC: Nuclear Regulatory Commission or its duly authorized representatives.

Nucleon: A protcn or neutron.

Nucleus: The small, positively charged core of an atom containing the protons and/or neutrons. Although the nucleus is only approximately 1/10,000 of the diameter of an atom, it contains nearly all the atom's mass.

Nuclide: (1) A species of atom characterized by its mass number, atomic number, and energy state, provided that the mean life in that state is long enough to be observable. (2) One of two or more atoms with the same atomic number (the same chemical element), but a different atomic weight.

Occupational Dose: The dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received form background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

Orbital Electron Capture: A radioactive transformation in which the nucleus captures an orbital electron.

Photon: A particle, without mass, that transfers electromagnetic energy.

Proportional Region: The range of applied voltage in a radiation counter tube in which the charge collected per ionizing event is proportional to the charge liberated by that event.

Proton: A subatomic particle with a positive electric charge and a mass 1,873 times that of an electron.

Public Dose: The dose received by a member of the public from exposure to radiation and to radioactive material released by a licensee, or to another source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

Quality Factor (Q): The modifying factor that is used to derive dose equivalent from absorbed dose. The absorbed dose which will produce a particular biological effect varies considerably from one type of radiation to another. In general, particles which produce many ionizations are more effective in producing biological damage. Studies have shown that one rad resulting from alpha or neutron radiation results in greater biological damage than one rad of gamma radiation. The Rem is the unit used to equalize the biological consequences which result from equal absorbed doses of radiation. This is done by applying a "correction factor" to the Rad. This factor is called the Quality Factor (QF). Some quality factors are listed below.

Quality Factors and Absorbed Dose Equivalencies

Type of Radiation	Quality Factor	Absorbed Dose Equal to a Unit Dose Equivalent*
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

* Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

Radiation (ionizing radiation): Alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this manual, does not include non-ionizing radiation, such as radio or microwaves, or visible, infrared, or ultraviolet light.

Rad (Radiation Absorbed Dose): The basic unit of absorbed dose of ionizing radiation. A dose of one rad is equal to the absorption of 100 ergs of radiation energy per gram of absorbing material, or 0.01 joule/kilogram (0.01 gray).

Radiation Area: An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Radioactive: Exhibiting radioactivity.

Radioactive Decay: The spontaneous transformation of one isotope into a different isotope or into a different energy state of the same isotope. The process results in a decrease, with time, in the number of original radioactive atoms in a sample. A single transformation, called a disintegration, may result in the emission of one or more charged particles and/or photons, such as alpha (α), beta (β), gamma (γ), or X-ray.

Radioactivity: The property of certain isotopes that causes them to emit radiation as a result of changes in the nuclei of atoms of the element.

Radiochemical: Any chemical containing one or more radioactive atoms.

Radioisotope: An unstable nuclide of an element that decays or disintegrates spontaneously emitting radiation.

Radiolabel: To incorporate a radioisotope into a molecule.

Radionuclide: An unstable isotope of an element that decays or disintegrates spontaneously emitting radiation; a radioactive atom that exists for a measurable amount of time before decay occurs.

Range: The distance that a charged particle penetrates a material before it ceases to ionize.

Reference Man: A hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

Rem (Roentgen Equivalent Man): (1) The basic unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). (2) A measure of radiation exposure that indicates the potential biological impact on human cells.

Restricted Area: An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.

Roentgen (R): The basic unit of measurement of the ionization produced in air by X or gamma radiation. One roentgen is equal to 2.54×10^{-4} coulombs per kilogram of air.

Scintillation Counter: An instrument that detects and measures ionizing radiation by counting the light flashes (scintillations) caused by radiation impinging on certain materials. The light flashes are converted into electrical pulses by a photo-multiplier tube.

Shallow-Dose Equivalent (H_S): Applied to the external exposure of the skin or an extremity, and is taken as the dose equivalent at a tissue depth of 0.007 centimeters (7mg/cm^2 averaged over an area of 1 square centimeter).

Shield: Material intended to reduce the intensity of radiation entering a region.

Shield, Biological: A shield whose primary purpose is to reduce ionizing radiation to biologically permissible levels.

Shielding: The use of shields. Also the material of which a shield is composed.

Sievert: The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

Source, Radiation: An apparatus or a material emitting or capable of emitting ionizing radiation.

Source, Sealed: A radioactive source sealed in a container or having a bonded cover, the container or cover being strong enough to prevent contact with and dispersion of the radioactive material under the conditions of use and wear for which it was designed.

Source, Unsealed: A radioactive source which is not a sealed source.

Specific Activity: (1) In a given sample, the activity of a radionuclide divided by the mass of the element whose radionuclide is being considered. (2) The activity of a material divided by its mass. (3) Often abbreviated as S.A., it is usually measured in Ci/mmol in radiochemistry.

Stochastic Effects: The health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

Survey: An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Swipe Test: A procedure in which a swab is rubbed on a surface and its radioactivity measured to determine if the surface is contaminated with loose radioactive material.

Total Effective Dose Equivalent (TEDE): The sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unrestricted Area: An area, access to which is neither limited nor controlled by the licensee.

Weighting Factor (W_T): For an organ or tissue (T), W_T is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly.

Whole Body: For purposes of external exposure, means, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

EQUATIONS AND CONVERSIONS

Decay Equation

$$A_t = A_o e^{-\lambda t}$$

Where: A_o = Activity at t (time) = O (original activity)

$\lambda = \ln 2 / T_{1/2} = 0.693 / T_{1/2}$ (decay constant)

$T_{1/2}$ = Half life of isotope of concern

A_t = Activity remaining after some period of time ("t" in the exponent)

All values given in the decay tables are derived from the above equation.

Counting Efficiency

= cpm (counts per minute)/dpm (disintegrations per minute)

Units and Conversions

1 curie (Ci) = 2.22×10^{12} dpm (disintegrations/minute) = 3.7×10^{10} dps (disintegrations/second)

1 becquerel (Bq) = 1 nuclear transformation/second

1 curie (Ci) = 3.7×10^{10} becquerels (exactly)

Time Conversion Factors

1 year = 5.26×10^5 minutes = 3.16×10^7 seconds
1 day = 1.44×10^3 minutes = 8.64×10^4 seconds

Metric Prefixes:

tera (T)	10^{12}
giga (G)	10^9
mega (M)	10^6
kilo (k)	10^3
centi (c)	10^{-2}
milli (m)	10^{-3}
micro (μ)	10^{-6}
nano (n)	10^{-9}
pico (p)	10^{-12}

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