VOID SHEET

03034216

TO: License Fee Management Branch

FROM: Region I

SUBJECT: VOIDED APPLICATION

Aug 8 123526

Control Number: 123526

Applicant: Charles River Pharmservices

Date Voided: 3/11/97

Reason for Void: Massachusetts becoming a new agreement state. Action to be sent to Massachusetts for processing. After review. License No. New Application (030-34216).

M. A. Perkins 3/11/97
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

Refund Authorized and processed

No Refund Due

Fee Exempt or Fee Not Required

Comments: After Review

Log completed

Processed by: AS

97 JAN 12 PM 3:08

0/1

030093

OFFICIAL RECORD COPY ML 10

9707080409 970311
PDR ADOCK 03034216
B PDR

March 10, 1997

MEMORANDUM FOR: John D. Kinneman, Chief
Nuclear Materials Safety Branch 2

FROM: Sattar Lodhi

SUBJECT: Charles River PharmServices' License Application
Mail Control No. 123526

Approximately 95 % of the review of the application is complete. The only remaining item is the issue of the authorized user and the RSO. The applicant initially requested that Dr. Mary Ball be named as the authorized user and the RSO on the license. However, Dr. Ball did not have any training in the use of radioisotopes, and the applicant was advised that she did not meet the criteria to be an authorized user or the RSO. Later, she attended a radiation safety training course. However, this course did not provide her with any hands-on training in the use of radioisotopes. This is an important item because the applicant is planning to use large quantities (several hundred millicuries) of byproduct material in animals, and such use needs to be supervised by an experienced person.

The applicant then stated that Mr. Mitchell Gallanek will be supervising her use of radioisotopes, and every new use of radioisotopes will be closely supervised by Mr. Gallanek. However, Mr. Gallanek declined to assume the responsibility of the RSO.

The applicant then contacted Mr. Joseph Bekanauskus to be the authorized user and the RSO. Apparently this arrangement also fell through. Finally, the name of Dr. Sassan Abdollahzadeh was submitted to be the authorized user and the RSO for this license. This individual is employed by the University of Massachusetts (Worcester), and is associated with the applicant as a consultant. A letter dated February 20, 1997, was sent to the applicant to provide details of his association with the licensee and the control and amount of time the consultant will provide to the applicant.

The applicant was called on March 10, 1997, to respond to the deficiency letter, but as of 3:00 p.m. on March 10, 1997, no response was received from the applicant.

It is recommended that this action be voided because the review can not be completed before the licenses are transferred to the Commonwealth of Massachusetts.

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DNMS TELEPHONE CONVERSATION RECORD

Person Called:	Terry Fisher	**Phone No.:** (508) 765 9580
Person Calling:	Sattar Lodhi	**Date:** 3/10/97
Facility Name:	Charles River PharmServices Southbridge, MA	**Time:** 11:40 a.m.
License No.	New Application	**Docket No.** 030-34216

Subject: Response to Deficiency Letter

Summary: I called Mr. Fisher to remind him that they need to send their response to the deficiency letter dated February 25, 1997. Mr. Fisher was not available and Dr. Mary Ball responded to my call. I explained to her that we must have their response today in order to complete the review of their application otherwise the entire package will be transferred to the commonwealth of Massachusetts. She stated that she will relay the message to Mr. Fisher and he will call me back. I gave her the Fax number and my telephone number.

Action Required/Taken: Document

Signature: Sattar Lodhi

Mail Control No. 123526

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ML 10

FEB 20 1997

Docket No. 030-34216
Control No. 123526

Robert F. Doolin
President and General Manager
Charles River PharmServices
236 Blackmer Road
Southbridge, MA 01550

Dear Mr. Doolin:

This is in reference to your application dated July 30, 1996, for a Nuclear Regulatory Commission License. In order to continue our review, we need the following additional information:

1. In your letter dated February 14, 1997, you have requested that Dr. Sassan Abdollahzadeh be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:

   a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

   b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

   c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

   d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

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e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

2. In your letters dated October 7, 1996, and January 28, 1997, you stated that another consultant, Mr. Mitchell Gelanek will supervise the use of licensed material. Please provide details of how the supervision will be coordinated by the two consultants.

3. Because Dr. Mary Ball does not meet the requirements to be an authorized user, please state which of these two consultants is to be named the authorized user.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123526. If you have any technical questions regarding this deficiency letter, please call Dr. Sattar Lodhi at (610) 337-5364.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original Signed By:

Pamela J. Henderson
Senior Health Physicist
Division of Nuclear Materials Safety

Docket No. 030-34216
Control No. 123526

Enclosures:
1. Letter dated October 7, 1996
2. Letter dated January 28, 1997

DOCUMENT NAME: R:\WPS\DLTR\L2030331.01

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	DNMS/RI	N	DNMS/RI					
NAME	SLodhi		PHenderson					
DATE	02/20/97		02/ /97		02/ /97		02/ /97	

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Charles River
PHARMSERVICES

M516
Q-2

February 14, 1997

Dr. Sattar Lodhi
U.S. Nuclear Regulatory Commission
Region 1
575 Allendale Road
King of Prussia, PA 19406-1415

Dear Dr. Lodhi:

Charles River has hired Dr. Sassan Abdollahzadeh as our Radiation Safety Officer. Information on his training and experience is enclosed. As a faculty member of the University of Massachusetts Medical Center Dr. Abdollahzadeh has full consulting privileges and flexible scheduling allowing him to be present at our Southbridge facility as necessary. He will be directly involved in the planning of each project using licensed material and will be present for the initial run of each project involving 1 mCi or more of radioactive material. In addition he will directly participate in all staff training.

As you know, Dr. Mary Ball has been to the training course. Mary will be prepared to assist him and begin gaining more experience.

We trust that this action removes the last obstacle from issuance of the initial license to Charles River. Please let me know if any further information is required.

Regards,

Robert F. Doolin
President and General Manager

RFD/pmd
attachments

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ML 10

123526

P.O. Box 727, 236 Blackmer Road, Southbridge, MA 01550 (508) 765-9580 FAX (508) 765-1288
A Division of Charles River Laboratories

FEB 14 1997

FAX REC'D

CURRICULUM VITAE

NAME: Sassan Abdoltahzadeh, Ph.D.

CURRENT POSITION Assistant Radiation Safety Officer & Assistant Professor of Family and Community Medicine at The University of Massachusetts Medical Center

HOME ADDRESS: 105 Longfellow Rd.
Worcester, MA 01602
TEL: (508)791-9590

WORK ADDRESS: Radiation Safety Office
University of Massachusetts Medical Center
55 Lake Avenue
Worcester, MA 01655
TEL: (508)856-2416 or 856-3208

EDUCATION:

1987-1992 Ph.D., Environmental Health Sciences/Health Physics.
Clark University, Worcester, Massachusetts.
Thesis: Influence of Modeling Uncertainties on the Dose from the Unattached Fraction of Radon Decay Products.

1983-1986 M. S., Health Physics.
University of Kansas, Lawrence, Kansas
Thesis: Analysis of Radionuclides in Ground Water Around a Waste Disposal Site.

1979-1983 B.S., Physics.
University of Massachusetts, Amherst, Massachusetts.

TEACHING EXPERIENCE:

1992-present Radiation Protection for users of radioactive material
Health Physics for Nuclear Medicine Technologists
Radiation Protection for Radiation Oncologist
Radiation & Health (ionizing and non-ionizing), graduate school classes for MPH program and medical school residents

1988 Laboratory classes in Environmental Health Sciences at Clark University.

1987 Discussion section classes for Nuclear Radiation Classes.

PROFESSIONAL EXPERIENCE:

March, 1994 to present

ASSISTANT RADIATION SAFETY OFFICER
Radiation Safety Office/University of Massachusetts Medical Center
Developed and conducted formal training program for users of radioactive material. Developed and conducted training program for Radiation Safety Staff. Developed and implemented standardized record keeping system. Other responsibilities included environmental monitoring, radiation hazard evaluation and day to day business for a broad scope medical licence.

January, 1995 to present

ASSISTANT PROFESSOR
Department of Family and Community Medicine/University of Massachusetts Medical Center
Conducted research on the validity of electromagnetic field exposure assessment methodologies for use in epidemiological studies. Developed graduate school classes for MPH program and Medical School Residents.

May, 1992 to March, 1994

POSTDOCTORAL FELLOW
Department of Family and Community Medicine/University of Massachusetts Medical Center
Participated in collection, interpretation and publication of data obtained in an epidemiological study (the Semiconductor Health Study). Provided assistance in writing proposals for future grants. Investigated connection between exposure to electromagnetic fields and health effects. Provided assistance in teaching of ionizing and non-ionizing sections of occupational health classes in Occupational Health program.

1988-1992

RESEARCH ASSISTANT/HEALTH PHYSICIST
Department of Family and Community Medicine/University of Massachusetts Medical Center.
Coordinated and conducted ionizing and non-ionizing exposure assessment for more than 4000 individuals participating in 3 epidemiological studies known as Semiconductor Health Study. Developed protocols for ionizing (α and x-rays) and non-ionizing (extremely low frequency electromagnetic fields and radio frequencies) radiation measurements, supervised collection, organization and management of measurements, and developed computer models for interpretation of and use of the obtained data for epidemiological analysis.

1987-1988

RESEARCH ASSISTANCE
Clark University.
Developed a dosimetric model to predict lung dose from deposition of radon decay products inside lung. This project provided the necessary research for completion of my Ph.D. thesis. I was also involved in other projects such as: dosimetry calculations for Three Mile Island and Seabrook projects, risk analysis for disposal of high level radioactive waste in underground facilities, measurement of radon inside buildings and assessment of deposition of acidic particles inside lungs

1987-1988

TEACHING ASSISTANT
Clark University
Assist in teaching and conducting laboratory classes.

1983-1986

RESEARCH ASSISTANT/ASSISTANT HEALTH PHYSICIST
University of Kansas
Provided technical assistance to the University's radiation safety officer for determination of the compliance of the University's waste disposal site to the Code of Federal Regulations. Other duties included assisting the radiation safety officer in routine duties such as calibrations, inspections, inventories and emergency planning.

GRANTS:

"Development of a Validated Exposure Assessment Methodology for Epidemiological Studies of Health Effects of VDT use.
Source: The Johns Hopkins Center for VDT and Health Research
Period: May 1, 1994 - April 30, 1996
Amount: $43,356
Role: Principal Investigator

PUBLICATIONS:

Abdollahzadeh S.; Hammond S.K.; and Schenker M.B., A model for assessing occupational exposure to low frequency magnetic fields inside semiconductor fabrication rooms. **Am. J. Ind. Med.** 28(6):723-734, 1995.

S. Katharine Hammond, Cynthia J. Hines, Marilyn F. Hallock, Susan R. Woskie, Sassan Abdollahzadeh, C. Robert Iden, Ellen Anson, Fred Ramsey and Marc B. Schenker. Tiered Exposure-Assessment Strategy in the Semiconductor Health Study. **Am. J. Ind. Med.** 28(6):661-680, 1995.

Abdollahzadeh S., Hammond S.K.; and Schenker M.B., Validity of surrogates for determination of magnetic field exposure for video display terminal users in office settings. **Bioelectromagnetics** 17:406-410, 1996.

Paul M.E.; Hammond S.K. and Abdollahzadeh S.; Assessment of exposure to low frequency magnetic fields in neonatal intensive care nursery. **Bioelectromagnetics** 15:519-529, 1994.

Epidemiologic Study of Reproductive and other Health Effects Among Workers Employed in the Manufacture of Semiconductors. **Final report to the Semiconductor Industry Association**. December 1992.

Rosenthal F. S., Abdollahzadeh, S.; Assessment of Extremely Low Frequency (ELF) Electric and Magnetic Fields in Microelectronics Fabrication Rooms. **Appl. Occup. Environ. Hyg.** 6:777-784; 1991.

Hattis D.; Abdollahzadeh S.; and Franklin C. A.; Strategies for Testing the "Irritation-signaling" Model for Chronic Lung Effects of Fine Acid Particles. **J. Air Waste Manage. Assoc.** 40: 322-330, 1990.

SOCIETIES:

1985-present	Health Physics Society
1983-1992	Sigma Pi Sigma, The National Physics Honor Society

REFERENCES:

Furnished upon request

EXPERIENCE WITH RADIATION

ISOTOPE	MAXIMUM AMOUNT (mCi)	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE
H-3	10	Univ. of Kansas	9 months
C-14	10	Univ. of Kansas	9 months
P-32	10	Univ. of Kansas	9 months
S-35	10	Univ. of Kansas	9 months
Ga 67	10	Univ. of Mass	3 years
Tc-99m	1350	Univ. of Mass	3 years
I-123	0.2	Univ. of Mass	3 years
I-125	10	Univ. of Mass	3 Years
I-131	100	Univ. of Mass	3 Years
Cs-137	25	Univ. of Mass	3 Years

DNMS TELEPHONE CONVERSATION RECORD

Person Called:	Terry Fisher	**Phone No.:** (508) 765 9580
Person Calling:	Sattar Lodhi	**Date:** 2/5/97
Facility Name:	Charles River PharmServices Southbridge, MA	**Time:** 3:30 p.m.
License No.	New Application	**Docket No.** 030-34216

Subject: Authorized user

Summary: Mr. Fisher called to inform that Mitch Gelanek will not be able to serve as the RSO and the AU on their license because of his inability to be present at site. I again explained to him that because Dr. Ball does not have any hands-on experience in the use of radioisotopes, she does not meet the qualifications to be an authorized user or the RSO.

He stated that they are trying to seek some one from a nearby university to be put as the AU and the RSO. I informed him that as long as that individual meets the qualifications criteria for an AU and RSO, and he/she can devote sufficient time to their radiation safety program, this arrangement could be an alternative.

I again explained to him that the NRC can not approve any individual if the individual does not meet the qualifications criteria at the time of application, and reminded him that the RSO may delegate some of his tasks to others but he/she can not delegate the responsibility under the license.

Action Required/Taken: Document

Signature: Sattar Lodhi

Mail Control No. 123526

ML 10

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DNMS TELEPHONE CONVERSATION RECORD

Person Called: Mary Ball, DMV **Phone No.:** (508) 765 9580

Person Calling: Sattar Lodhi **Date:** 1/30/97

Facility Name: Charles River PharmServices Southbridge, MA **Time:** 10:30 a.m.

License No. New Application **Docket No.** 030-34216

Subject: Authorized user

Summary: I called Dr. Ball to inform her that because she does not have hands on experience of using radioisotopes, she does not meet the qualifications to be an authorized user or the RSO, and therefore she could not be listed as such on their license. I informed her that Mitchell Gelanek may be listed as the authorized user and he could also function as the RSO until she gets sufficient experience, at which time they could request an amendment to change the AU and the RSO. I also requested that future correspondence be signed by the President or the CEO. She would discuss it with management and respond later.

I also informed her that we do not list any one as a qualified user on the license.

Action Required/Taken: Document

Signature: Sattar Lodhi Mail Control No. 123526

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Charles River
PHARMSERVICES

M516
Q-2

January 28, 1997

Dr. Sattar Lodhi
U.S. Nuclear Regulatory Commission
Region 1
575 Allendale Road
King of Prussia, PA 19406-1415

Dear Dr. Lodhi:

In response to your phone call yesterday, I am providing the following information:

We are requesting 1 curie of Rhenium 186. Each pig will receive a dose of 125 millicuries. Due to the short half-life and the number of pigs required to make the study statistically valid, we require 1 curie.

Please list Mitch Galanek, and Mary Ball on our application as qualified users. Dr. Mary Ball will be listed as the Radiation Safety Officer but will be supervised by Mitch Galenek. Because Mr. Galenek is a consultant, we cannot list him as our RSO.

We thank you for the time and effort you have put into assisting us with licensing.

Sincerely,

Mary M. Ball, V.M.D., M.S.

MMB/pmd

123526

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FAX REC'D JAN 29 1997

P.O. Box 727, 236 Blacksmith Road, Southbridge, MA 01550 (508) 765-9580 FAX (508) 765-1288
A Division of Charles River Laboratories

DNMS TELEPHONE CONVERSATION RECORD

Person Called:	Mary Ball, DMV	**Phone No.:** (508) 765 9580
Person Calling:	Sattar Lodhi	**Date:** 1/27/97
Facility Name:	Charles River PharmServices Southbridge, MA	**Time:** 9:15 a.m.
License No.	New Application	**Docket No.** 030-34216

Subject: Authorized user and amount of Rh-186

Summary: I called Dr. Ball to inform her that from the documents submitted to us about her training, it does not appear that she has practical training of using radioisotopes. She stated that Mitch Gelanek will supervise her work in the initial stages. I informed her that:

1. Because Massachusetts is becoming an agreement state in a very near future, we need to resolve this licensing action very soon;

2. A supervised individual can not be listed as an authorized user, and because Mr. Gelanek is going to be supervising her work, they may consider listing him as the authorized user and the RSO.

3. They need to specify total amount of Rh-186 and its use

She stated that they need to have this license soon, and it will be acceptable to her to have Mr. Gelanek as the authorized user and the RSO. She will respond soon.

Action Required/Taken: Document

Signature: Sattar Lodhi Mail Control No. 123526

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Charles River
PHARMSERVICES

January 21, 1997

030-34216

Dr. Sattar Lodhi
U.S. Nuclear Regulatory Commission
Region 1
575 Allendale Road
King of Prussia, PA 19406-1415

Dear Dr. Lodhi:

Attached please the course outline and credentials for Mary Ball's training as Nuclear Regulatory Officer for Charles River PharmServices.

Further please be advised that Mitch Galanek will review each project and train staff prior to the beginning of each project. He will also direct hands on work at the beginning of each project. He will conduct follow-up visits during the project to monitor techniques, records, and waste handling. Mr. Galanek will also be available on call as necessary.

Details of individuals projects and their protocols will be forwarded on a project to project basis for your review.

Please feel free to contact me for any additional information necessary.

Sincerely,

Mary M. Ball, V.M.D., M.S.

MMB\pmd
attachment
cc: Mitch Galanek
Robert Doolin

OFFICIAL RECORD COPY ML 10 123526

P.O. Box 727, 236 Blackmer Road, Southbridge, MA 01550 (508) 765-9580 FAX (508) 765-1288
A Division of Charles River Laboratories

JAN 21 1997
FAX REC'D

RADIATION SAFETY OFFICER-COURSE OUTLINE

THE ATOM
- Atomic Structure
- Elements
- Isotopes

TYPES OF RADIATION
- Radiation
- Alpha Particles
- Beta Particles
- Gamma and X rays
- Neutrons
- Units of Radiation Energy

RADIOACTIVITY AND DECAY
- Radioactivity
- Decay
  - Half-life: the rate of radioactive decay
  - Decay constant
- Decay Equation
- Conservation of Mass, Charge, and Energy
- Methods Of Radioactive Decay
  - Alpha decay
  - Beta decay
  - Beta minus
  - Positrons
  - Gamma rays
  - X rays
  - Isomeric transition
  - Internal conversion
  - Auger electrons
  - Electron capture
- Chart of the Nuclides
- Decay Data Tables
- Radioactive Series

UNITS OF MEASURE
- Radioactivity
  - The curie
  - Submits of the curie
- Radiation
  - Radiation exposure vs. radiation dose
  - Radiation exposure: the roentgen
  - Absorbed dose: the rad
  - Dose equivalent: the rem
  - Dose and dose rate
  - Determination of dose and dose rate
- Source Activity Vs. Gamma Exposure Rate
- Cpm Vs. Dpm
- Specific Activity
- SI Units

RADIATION INTERACTIONS WITH MATTER
- Charged Particle Interactions
  - Ionization
  - Excitation
  - Bremsstrahlung
- Photons
  - Photoelectric effect
  - Compton scattering
  - Pair production
- Neutron Interactions
  - Fast/slow neutron interactions

BACKGROUND RADIATION
- Introduction
- Cosmic Radiation
- Radioactivity of the Earth
- Radioactivity Of Air
- Radioactivity Of Water
- Radioactivity in the Human Body
- Artificial (Manmade) Radioactivity
  - Medical and dental exposures
  - Nuclear reactors
  - Transportation
  - Low level waste storage
  - Nuclear reactor accidents
- Summary

APPLICATIONS
- X Ray Machines
  - Production
  - Filtering
- Medical Radionuclides
  - Diagnosis
  - Therapy (radiation oncology)
- Linear accelerators
- Nuclear Reactors
  - Boiling water reactor
  - Pressurized water reactor
  - Nuclear fuel
  - Safety
- Radiation Sterilization
- Other Industrial Sources
  - Isotopic neutron sources
  - Oil well logging
  - Level and density gauges

BIOLOGICAL EFFECTS
- Introduction
- Cell Damage
- Acute And Delayed Effects

Radiation Safety Associates, Inc.
P.O. BOX 107 • HEBRON, CONNECTICUT 06248 • (203) 228-0487

Somatic And Genetic Effects
Linear Or Threshold
Stochastic And Nonstochastic Effects
Summary

PERSONAL DOSIMETRY
Dose Limits
Definitions
10 CFR 20 occupational dose limits
Pregnant workers
Minors
Non-radiation workers
Violations
ALARA
Personal Dosimetry
Badge placement
Film badge
Thermoluminescent dosimeter (TLD)
Pocket ion chambers
Chirpers and alarming dosimeters
Neutron dosimeters
Control badges
Regulatory Guide 8.13

RADIATION DETECTION AND MEASUREMENT
Gas filled Detectors
Pulse size considerations
Ionization chambers
Proportional counters
Limited proportionality region
Geiger-Müeller (GM)
Continuous discharge region
Solid State Detectors
Scintillation detectors
Semiconductor detectors
Detector Applications
Portable survey meters
Calibration programs
Laboratory instruments
Portal monitors
Personnel contamination monitors
Whole body counters
Basic Radiation Spectroscopy
Spectrometer
Single and multi-channel analyzers

REGULATIONS AND GUIDES
History Of Protective Standards
ICRU, ICRP, and NCRP
Radiation exposure concerns
Basic recommendations
Federal policy
Regulating agencies
Other Organizations
Regulations And Guides
10 CFR 19
10 CFR 20
10 CFR 30
10 CFR 40
10 CFR 70
10 CFR 71
10 CFR 74
Regulatory guides
NUREGs
American National Standards Institute (ANSI) Standards
Information notices

EXTERNAL EXPOSURE CONTROL AND SURVEYS
ALARA
10 CFR 20
Current ALARA-related regulatory guides
Radiation Exposure Control
Time
Distance
Shielding
Administrative Controls
Radiation work permits
Access Control
10 CFR 20
Posting and Control
10 CFR 20
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DISTANCE AND SHIELDING
Distance
Point sources
Line sources
Plane sources
Shielding
Beta
Gamma
Neutron

CONTAMINATION CONTROL
Radiation Vs. Contamination
Survey Methods
Loose contamination
Total contamination
Wipe Test Evaluation
Statistical Considerations in a Counting Program
Accuracy and precision
Normal probability distribution

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- Standard deviation
- Confidence levels
- Minimum detectable count rate (MDCR)
- Minimum detectable activity (MDA)
- Changing the MDA

Survey Frequency And Limits
Protective Clothing
Self-Frisk
Personnel Decontamination
Skin Dose Assessment
- Skin dose calculation
- Documentation

Survey Documentation
Posting and Control of Contaminated Areas
Equipment And Area Decontamination

AIR SAMPLING AND EVALUATION
Types Of Airborne Contaminants
Sample Collection
Air Sample Accuracy
- Total sample volume
- Efficiency of collection medium
- Counting efficiency
- Representative sample

Calculation Of Airborne Concentrations
Lower Limit Of Detection (LLD)

INTERNAL EXPOSURE CONTROL AND DOSE ASSESSMENT
ALARA
Annual Limit On Intake (ALI)
Derived Air Concentration
- Derived air concentration-hour

Assessing Body Burden
Bioassay Methods
- Whole body counting
- Radioanalysis
- Fecal analysis

Bioassay Programs
Calculating Internal Dose
Examples of Dose Calculations
Removing Internal Contamination
Required Postings
- Airborne radioactivity area

Regulatory Guide 8.20
Regulatory Guide 8.32

SOURCE HANDLING TECHNIQUES/RADIOACTIVE MATERIAL CONTROL AND DISPOSAL
Definitions
- Sealed source
- Source material
- Special nuclear material

Regulations And Procedures
- 10 CFR 20
- 10 CFR 30
- 10 CFR 40
- 10 CFR 70/74

Exempt vs. Nonexempt Quantities of Radioactive Material
Responsibilities
Use And Precautions
Labeling
Master Index
Leak Testing
Storage Limitations
Disposal
Receiving Packages
Container Labels
Exemptions From Labeling Requirements
Disposal Of Empty Radioactive Material Containers
Storage And Control
Posting
Exceptions From Posting Requirements
Loss or Theft of Licensed Material
Industry Events
Radioactive Waste - Definition
Radwaste Minimization
Radwaste Treatment
- Storage for decay
- Evaporation
- Dilution and release
- Filtration and deionization
- Incineration
- Compaction
- Solidification

Waste Disposal
- Disposal facilities

Packaging
- Physical form
- Strong tight containers
- Type A containers
- Type B containers
- Warning labels on packages
- Contamination limits on packages
- Radiation limits during transport
- Vehicle placarding
- Other methods

Source Handling Incidents
NRC Information Notice 88-32
NRC Information Notice 90-35

Radiation Safety Associates, Inc.
P.O. BOX 107 • HEBRON, CONNECTICUT 06248 • (203) 228-0487

LICENSE REQUIREMENTS AND THE RADIATION PROTECTION PROGRAM
- Notice Of Expiration
- Application-NRC Form 313
- Radiation Protection Program
  - ALARA
  - Procedures
  - Training
  - Document Posting
  - Surveys
  - Legal Aspects
- Procedural Compliance
  - Fundamentals of excellence
  - Pitfalls
- Ways for Health Physicists to Minimize the Chances of Being Sued

EMERGENCY PLANNING
- Introduction
- The Emergency Plan
- Emergency Response Organization
- Characterization of Installation and Facilities
- Licensed Activities
- Emergency Plan Implementation
- Response Actions
  - Assessment Actions
  - Protective Actions
  - Corrective Actions
- Facilities And Equipment
- Offsite Agreements And Support
- Re-entry And Recovery
- Maintaining Emergency Preparedness
- Notifications

AUDITS
- Introduction
- In-House Audits
- Who Should Audit?
- What Should Be Audited?
- Performing An Audit
  - Audit Preparation
  - Audit Performance
- Audit Follow-Up
- Suggested Audit Finding Format
- Closing Out Previous Audits
- Dealing With Findings
- Handling A Regulatory Audit
- Other Regulatory Action
- General Comments

Radiation Safety Associates, Inc.
P.O. BOX 107 • HEBRON, CONNECTICUT 06248 • (203) 228-0487

Charles River
PHARMSERVICES

MS 16
Q-2

January 13, 1997

030-34216

Dr. Sattar Lodhi
U.S. Nuclear Regulatory Commission
Region 1
575 Allendale Road
King of Prussia, PA 19406-1415

Dear Dr. Lodhi:

This letter is in reference to Control #123526. We will be using our consultant, Mitch Galanek on our initial projects as you have requested. We would also like to add the isotope Re-186 to our application at this time. I hope that this information will be adequate to finalize our application. Please call if you have any other questions. Thank you.

Sincerely,

Mary M. Ball /pmd

Mary M. Ball
Radiation Safety Officer

MMB/pmd

OFFICIAL RECORD COPY ML 10

123526

JAN 17 1997

P.O. Box 727, 236 Blackmer Road, Southbridge, MA 01550 (508) 765-9580 FAX (508) 765-1288
A Division of Charles River Laboratories

DNMS TELEPHONE CONVERSATION RECORD

Person Called:	Mary Ball, DMV	**Phone No.:** (508) 765 9580
Person Calling:	Sattar Lodhi	**Date:** 12/11/96
Facility Name:	Charles River Pharmservices Southbridge, MA	**Time:** 2:30 a.m.
License No.	New License	**Docket No.** 030-34216

Subject: Additiona information

Summary: I called Dr. Ball again today (12-12-96) to get the following information:

1. The details of her training;
2. Supervision by Mitch Gelanek (at least three initial uses of each isotope)
3. Transportation of materials from clients to their facility will be in accordance with regulatory requirements.

She stated that they will agree to have the first three uses of each isotope supervised by Mitch Gelanek, the training details will be provided and commitment to follow transporation regulations. She will fax this information soon. She stated that they also want authorization to use Rh-186.

Action Required/Taken: Document/wait for response

Signature: Sattar Lodhi

Mail Control No. ~~123654~~ 123526

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DEC-02-1996 12:44 CHARLES RIVER PHARMSEA SECTION COPY 508 765 1288 P.02

MS-16
92

CERTIFICATE OF ACHIEVEMENT

This is to Certify that

MARY M. BALL, VMD

Has Completed 40 Hours of

Radiation Safety Officer Training

November 18-22, 1996

Radiation Safety Associates, Inc.

David J. Durkee

Tom Hasselbacher
Radiation Safety Associates, Inc.

DEC -2 1996 TOTAL P.02 123526

DNMS TELEPHONE CONVERSATION RECORD

Person Called:	Robert Doolin, President	**Phone No.:** (508) 765 9580
Person Calling:	Sattar Lodhi	**Date:** 11/18/96
Facility Name:	Charles River Pharmservices Southbridge, MA	**Time:** 9:00 a.m.
License No.	New License	**Docket No.** 030-34216

Subject: Completion of Training of Dr. Ball (RSO and AU)

Summary: I called Dr. Ball to remind her that we have not received the confirmation of completion of her radiation safety training. Dr. Ball was attending the week long training and was unavailable, but Mr. Doolin took the call, with a colleague on the speaker phone. He stated that Dr. Ball is in Connecticut attending the Radiation Safety Training. They will send the confirmation of the completion of training upon her return (at the end of next week).

Action Required/Taken: Document/wait for response

Signature: Sattar Lodhi

Mail Control No. 123526

OFFICIAL RECORD COPY ML 10

Charles River
PHARMSERVICES
Formerly East Acres Biologicals

MS-16
Q2

October 7, 1996

Dr. Sattar Lodhi
US Nuclear Regulatory Commission
Region 1
475 Allendale Rd.
King of Prussia, PA 19406-1415

Dear Dr. Lodhi,

The following is the additional information requested to complete the review of our application for an NRC license:

1. Dr. Ball will attend a formal training seminar prior to any licensed material being used. The training will cover principles and practices of radiation protection, radioactivity measurements, standardization, monitoring techniques, and instrumentation, mathematics and calculations basic to the use and measurements of radioactivity, and biological effects of radiation. In addition, the seminar will cover a complete review of applicable regulations, emergency response procedures, waste disposal and management techniques, and any other topics important to the safe storage and use of licensed material by Charles River Pharmservices' radiation workers.

   The training will be provided by our consultant, Mitchell Galanek, a certified health physicist from MIT. It is expected the formal training will take approximately one day. In addition, Mr. Galanek will completely review all of all the radiation protection requirements of our proposed program. Once this training is complete, Mr. Galanek will be present and assist Dr. Ball during the initial period of use of radioactive material. All initial experiments will be monitored by Mr. Galanek until Dr. Ball is experienced to manage the radiation protection program and the experimental uses of licensed material on her own.

   Documentation of Dr. Ball's completed formal training along with a written review of the initial experiments with licensed material will be submitted to the Commission after it is completed.

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P.O. Box 727, 236 Blackmer Road, Southbridge, MA 01550 (508) 765-9580 FAX (508) 765-1288
A Division of Charles River Laboratories

123526
OCT 11 1996

2. Dr. Ball, our Radiation Safety Officer, will be responsible for:
   a. ensuring that the use of the licensed material is by or under the direct supervision of individuals specifically listed on our license.

   b. ensuring that the use of licensed materials are secured against unauthorized removal at all times when not in use.

   c. will perform routine inspections of all laboratories using or storing license materials and the required periodic radiation surveys of the laboratories.

3. As required by the NRC regulations, an annual review of the radiation protection program will be performed by our consultant health physicist, Mr. Mitchell Galanek. The review will include the performance of the Radiation Safety Officer. At the completion of the annual review, the consultant will meet with senior management to discuss the results of the audits and to assist in the implementation of any corrective actions deemed necessary. Senior management will be briefed regularly by the Radiation Safety Officer or our consultant on an as needed basis with regard to any substantial changes in NRC regulations or policies. At a minimum, our consultant and the Radiation Safety Officer will meet with senior management at the time of the annual audit.

4. TLD type personnel dosimeters will be supplied for worker external dose assessment measurements. The badges will be supplied by Landauer Corporation, a NVLAP accredited processor, and will have a quarterly exchange frequency.

5. There will be no disposal of liquid radioactive waste into the public sanitary sewerage system. There is no plan for disposal of liquid radioactive waste into our private septic system. If it becomes necessary to release liquid radioactive waste into our private septic system, we will monitor the liquid effluent to ensure that levels are below the limits in Table 2, Column 2 of Appendix V of 10 CFR part 20. Records of any releases will be maintained by the Radiation Safety Officer.

6. One of our proposed uses of licensed material is the use of this material in animal studies. It will be necessary at times to have the licensed material supplied by a client contracting us to perform the animal experiments. Whenever this is necessary, the Radiation Safety Officer will obtain a copy of the client's license to possess and use licensed material and will supply the client with a copy of Charles River PharmServices NRC license.

I hope the above information will be sufficient to complete the review of our license application. If additional information is necessary, please contact Dr. Mary Ball directly. Thank you in advance for your help in this licensing matter.

Sincerely,

Robert F. Doolin
President/General Manager
Charles River PharmServices, Inc.

OFFICIAL RECORD COPY ML 10

123526

SEP 18 1996

Docket No. 030-34216
Control No. 123526

Robert F. Doolin
President/General Manager
Charles River PharmServices
236 Blackmer Road
Southbridge, MA 01550

Dear Mr. Doolin:

This is in reference to your application dated July 1, 1996, requesting a Nuclear Regulatory Commission (NRC) License. In order to continue our review, we need the following additional information:

1. Prior to authorizing an individual to use radioisotopes and/or to be a Radiation Safety Officer, that person must have on-the-job or formal training and experience in the use of radioisotopes. This training should cover (a) principles and practices of radiation protection, (b) radioactivity measurements, standardization, and monitoring techniques and instruments (c) mathematics and calculations basic to the use and measurement of radioactivity, and (d) biological effects of radiation. The individual must also have hands-on experience using radioisotopes of similar type, activities and using techniques identical or similar in nature to those being requested by the applicant. Please submit documentation of Dr. Ball's completed training and experience with your response to this letter. In addition, since Dr. Ball has not had any previous experience with radioisotopes, please confirm that for a specified initial period of time her use of radioactive materials will be directly monitored by an experienced health physicist.

2. Please confirm that the your Radiation Safety Officer would also be responsible for:

   a. Ensuring that the use of licensed material is by or under the direct supervision of individuals specifically listed on your license.

   b. Ensuring that licensed materials are properly secured against unauthorized removal at all times when not in use.

   c. Performing routine inspections of all laboratories using or storing licensed materials, and performing the required periodic radiation surveys of the laboratories.

OFFICIAL RECORD COPY NML 10

3. 10 CFR 20.1101(c) requires that the licensee review the radiation protection program content and implementation at least annually. Submit a description of your program for performing the required annual review. It should include the following criteria:

   a. Senior management oversight of the radiation protection program. Specify the mechanisms that will be used by senior management to ensure that they are aware of NRC regulations, the provisions of the license, and the compliance status of the institution's licensed program.

   b. Review of the Radiation Safety Officer and staff performance. Specify the minimum qualifications for an individual who will perform this review, and confirm that the results will be reported to senior management.

4. Please specify the type of personnel dosimetry (film badge or TLDs) you provide, and the frequency for changing the whole body dosimeters. Confirm that film badges will be exchanged at least monthly, and that dosimetry will be processed and evaluated by a NVLAP-accredited processor as required by 10 CFR 20.1501(c).

5. Please confirm that there will be no disposal of liquid radioactive waste into the public sanitary sewerage system. Please clarify whether there will be disposal of liquid radioactive waste into your private septic system. If so, please describe how you will monitor radioactive materials in liquid effluent to ensure that you do not exceed the limits in Table 2, Column 2 of Appendix B of 10 CFR Part 20 and confirm that records of releases will be maintained.

6. Item 6 of your application states "Radioactive materials will be purchased as labeled proteins, nucleotides, or will be supplied by client contracting our services." Please explain what "or will be supplied by client contracting our services" means.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 123526. If you have any technical questions regarding this deficiency letter, please call Dr. Sattar Lodhi at (610) 337-5364. In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original Signed By:
Pamela J. Henderson

Pamela J. Henderson
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Docket No. 030-34216
Control No. 123526

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DOCUMENT NAME: R:\WPS\DLTR\L2030331.01

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	DNMS/RI	N	DNMS/RI	N				
NAME	SLodhi		JKinneman					
DATE	09/17/96		09/ /96		09/ /96		09/ /96	

OFFICIAL RECORD COPY

Charles River
PHARMSERVICES
Formerly East Acres Biologicals

LL 30331
030-34216
03620

July 30, 1996

Licensing Assistant Section
US Nuclear Regulatory Commission
Region 1
475 Allendale Rd.
King of Prussia, PA 19406-1415

Attention: Licensing Agent

Enclosed please find 2 copies of Charles River PharmServices application for a Nuclear Regulatory Commission License for research and development use of radioactive materials. We have planned some animal experiments for the end of the summer, so we request a expedited review of our application.

Also enclosed is a check in the amount of $1500, the current fee for a Category 3M license. Please contact Dr. Mary Ball if you require any additional information.

Thank you in advance for your timely help in this licensing matter.

Sincerely,

Robert F. Doolin
President/General Manager

OFFICIAL RECORD COPY ML 10

123526

AUG - 1 1996

P.O. Box 727, 236 Blackmer Road, Southbridge, MA 01550 (508) 765-9580 FAX (508) 765-1288
A Division of Charles River Laboratories

NRC FORM 313 (6-93) 10 CFR 30, 32, 33 34, 35, 36, 39 and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

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

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

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

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

LL 30331
030-34216
03620

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

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

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Charles River PharmServices
236 Blackmer Road
Southbridge, MA 01550

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

Charles River PharmServices
236 Blackmer Road
Southbridge, MA 01550

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dr. Mary Ball, DVM

TELEPHONE NUMBER
508 765-9580

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5.	RADIOACTIVE MATERIAL. a. Element and mass number; b. chemical and/or physical form; and c. 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 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 3M; AMOUNT ENCLOSED $ 1500.

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION 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.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Robert F Doolin, General Manager		7/1/96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		123526
APPROVED BY	OFFICIAL RECORD COPY		DATE	IL 10	AUG - 1 1996

NRC FORM 313 (6-93)

Continuation Sheet - NRC Form 313:

5. Radioactive Material:

a. Element & Mass #	b. Chemical/physical form	c. Possession limit
^{3}H	liquid/solid	50 millicuries
^{14}C	liquid/solid	25 millicuries
^{35}S	liquid/solid	50 millicuries
^{33}P	liquid/solid	20 millicuries
^{32}P	liquid/solid	50 millicuries
^{51}Cr	liquid	10 millicuries
^{99m}Tc	liquid	10 millicuries
^{125}I	liquid/protein bound	5 millicuries
^{177}Lu	liquid	10 millicuries

6. Purposes For Which Licensed Material Will Be Used:

Charles River PharmServices is a large animal research facility specializing in pharmacological/toxicological testing. The uses of the radioactive materials involve in vitro and in vivo studies. Radioactive materials will be purchased as labeled proteins, nucleotides, or will be supplied by client contracting our services. In vitro experiments follow standard biochemical procedures such as incubation, centrifugation, autoradiography, and liquid scintillation counting similar to those used daily in most biochemical and molecular biology laboratories. Most procedures involve the use of less than 1 millicurie of radioactivity (usually on the order of 100 - 200 microcuries per experiment). Only protein bound ^{125}I material will be purchased and used. No iodinations will be performed under this license.

In vivo animal experiments will follow standard animal handling procedures. We anticipate experiments requiring administration of radioactive labeled compounds to rabbits, sheep, and pigs. All radioactive animal studies will be isolated from other animal experiments. General handling procedures are outlined in our radiation safety manual.

The experiments involving licensed material do not involve the use of volatile radioactive materials and to the best of our knowledge do not produce volatile materials during the experimental process. As stated above, no protein iodination will be performed. Only protein bound ^{125}I will be purchased. Thus, we currently do not have any plans for specialty ventilation systems equipped with filter systems and do not anticipate the need for such.

7. Individual Responsible For The Radiation Safety Program

Dr. Mary Ball, a licensed veterinarian and Director of Clinical Services, will be the Radiation Safety Officer with the responsibility of implementing the Charles River PharmServices Radiation Safety Program as outlined in the attached documents. Please see Dr. Ball's attached curriculum vitae.

In addition to Dr. Ball, work with radioactive materials will be done by several technicians under her supervision. Craig Wallace and Nathan Hawkins will be work under Dr. Ball's supervision. The company is small and the use of radioactive materials will be limited to only a few people all under Dr. Ball's supervision.

Dr. Ball and the named technicians have not had training in the safe use of radioactive materials. We plan to hire Mitchell Galanek, a certified health physicist from MIT, to give us a formal training seminar prior to any work with radioactive materials. In addition, Mr. Galanek will provide some hands on training during our first use of licensed material.

8. Training For Individuals Working in Restricted Areas

All work performed in controlled areas will be under the supervision of Dr. Ball. As Radiation Safety Officer, Dr. Ball will be responsible for training persons in the safe handling of radioactive materials. See the attached outline of specific topics to be covered during training sessions. As mentioned above, our radiation safety consultant will provide the initial training of the radiation workers. Additional training seminars will be provided as necessary. Training for radiation workers is also outlined in the radiation safety program.

9. Facilities and Equipment

Facilities:

See the attached floor plan of the laboratory facilities located at 236 Blackmer Road, Southbridge, Massachusetts.

Hot Labs:

Radioactive material will be stored and used in primarily in Building 3 Room A. This is an animal procedures room and will will attempt to limit all work to this area. Rooms B, C, and D are also procedure rooms as will be used as needed. Room E is an animal holding area where dosed animal will be housed during the study.

Rad Waste Storage:

A lockable waste storage area will be located in Room E and used for storage of low level radioactive waste. Low level radioactive waste will be stored in steel 30 and 55 gallon drums. An inventory of the stored waste will be kept in the facility. The facility will be surveyed monthly.

Equipment:

Survey Instruments:

A minimum of two Ludlum Model 3 survey instruments equipped GM detectors for dose rate measurements and contamination monitoring. The range of these instruments is 0-200 mr/hr or 0-200K cpm. Also, one additional instrument will be equipped with a NaI scintillation detector for ^{125}I monitoring. Survey instruments will be calibrated at annual intervals by a licensed calibration facility (i.e. Bolton & Galanek, Inc., NRC License # 20-13302-01).

Liquid Scintillation Counter:

A liquid scintillation counter to be used for assay measurement and analysis of contamination control monitoring wipe tests. The range of this instrument is 0-999K cpm. The instrument will be calibrated on an annual frequency. (Packard Model 1800 or equivalent manufacturer and model # still to be determined).

10. Radiation Safety Program

The Charles River PharmServices Radiation Safety Program is attached.

11. Radioactive Waste Management

The following summarizes our low level radioactive waste management program for low level radioactive waste:

Decay-In-Storage Program:

All solid material contaminated with radioactive material with a half life of 65 days or less and waste contaminated with ^{35}S ($T_{1/2}$=88 days) will be stored "in house" for radioactive decay and subsequent disposal as non-radioactive waste. The following procedures will be used:

a. Contaminated solids will be put in the waste containers provided in each laboratory. A record of the isotope and amount being disposed will be maintained. When these containers are full, the waste will be transferred to steel drums and stored in our locked waste storage facility for radiological decay. No liquids are to be put in the solid waste containers.

b. Stored material will be held for a minimum of 10 half-lives prior to disposal.

c. The material will be stored in 55 gallon or 30 gallon steel drums. The drums will be labeled with the contents, the date the drum was full, and the date the waste has decayed through ten half lives and is ready to be surveyed.

d. 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.

e. All reference to radioactive materials (labels, tape, etc.) will be removed or completely obliterated prior to final disposal as normal trash.

f. A record of the date waste was put in storage, the date removed from storage, the date disposed as regular trash, the survey instrument used, and the name of the surveyor will be maintained for all decay in storage (DIS) waste.

Long Half Lived Solid Waste:

All solid waste contaminated with tritium or carbon-14 will be segregated from the short half-lived waste and stored in a 55 gallon steel drum. Final disposal will be through a licensed radioactive waste disposal contractor such as SEG in Oak Ridge, Tennessee.

Aqueous Liquid Waste:

Liquid radioactive waste will collected and disposed through a licensed disposal contractor such as SEG. There will be no sanitary sewerage system disposal of liquid waste because our facility has a private septic system.

Liquid Scintillation Vial Waste:

Liquid scintillation vial/fluid waste will be stored in 30 gallon drums and disposed of through a licensed waste disposal contractor such as Permafix Corporation in Gainsville, Florida.

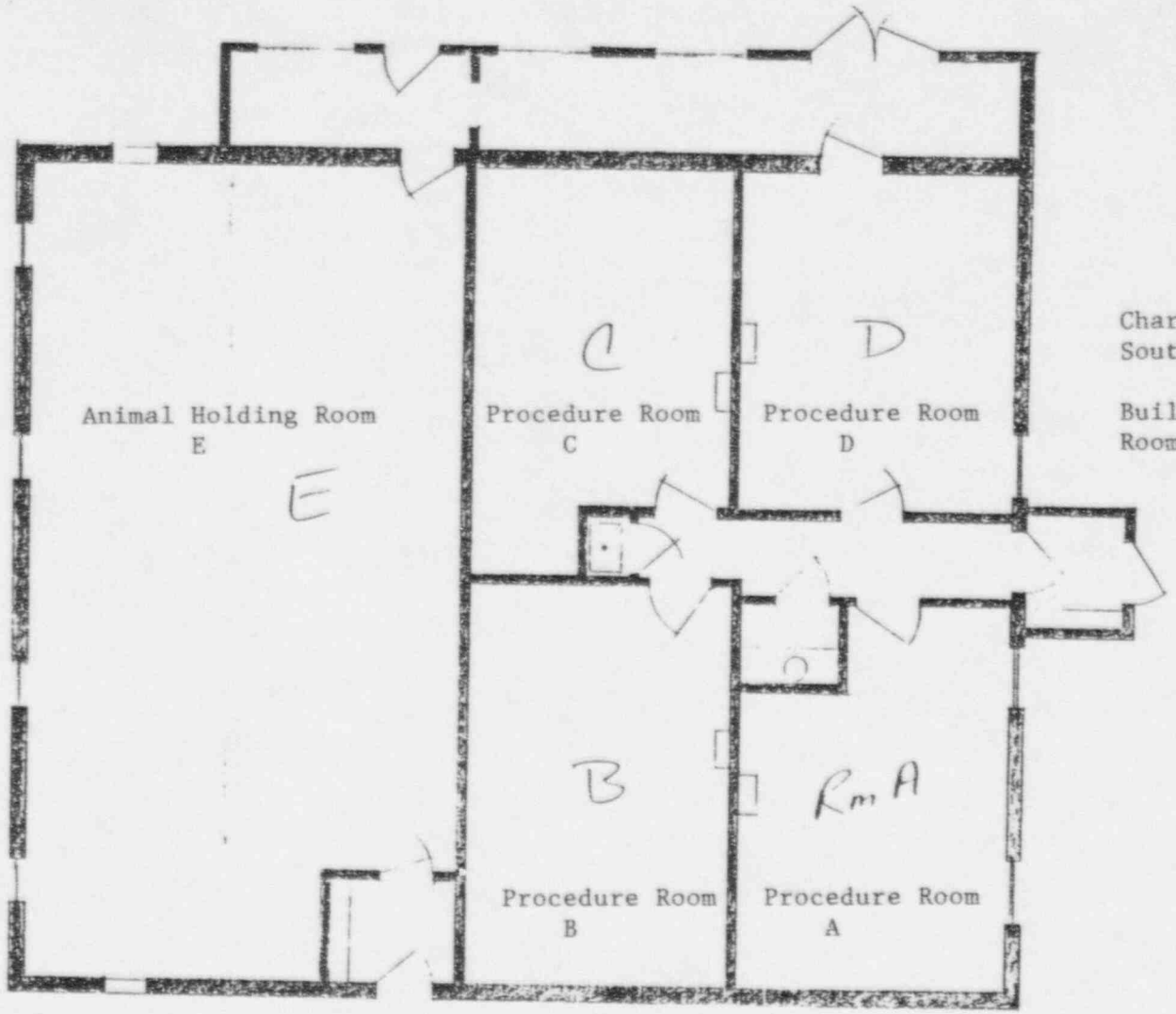
Animal Carcasses/Tissues:

Animal carcasses, tissues, and bedding will be collected and disposed as waste through a licensed waste disposal contractor such as SEG.

Storage Facility:

A locked waste disposal storage area in Room E (see attached floor plan) will be designated for storage of low level radioactive waste. Routine radiation and contamination surveys will be performed in this storage area.

BUILDING #3.



Charles River PharmServices
Southbridge, MA

Building 3: Animal Facility
Rooms A-E: Majority of work to be done in procedure room A.

MARY M. BALL, V.M.D., M.S.
90 English Neighborhood Road
Woodstock, CT 06281
(203) 928-3838
E-MAIL: 74232.1126@COMPUSERVE.COM

EXPERIENCE

Charles River PharmServices
Southbridge, MA 01550
1993-present - Director, Clinical Services
Acts as scientific liaison between clients and Charles River PharmServices. Responsible for all aspects of medical and surgical care for multiple species in a research setting. Performs all surgical procedures and treatments. Serves as study director for all GLP projects. Serves as IACUC Chair and Regulatory contact person. Assures internal compliance with quality assurance and continuing education. Acts as liaison between Charles River PharmServices and FDA, USDA and DEA.

Middleburg Equine Clinic, Middleburg, Virginia
1988-1993 - Veterinarian:
Private practitioner in all equine veterinary hospital. Responsible for all aspects of medical and surgical care for horses.
Additionally had my own small animal practice, part time, including surgical procedures on dogs and cats.

Virginia Polytechnic Institute, Marion duPont Scott Equine Medical Center, Leesburg, Virginia
1986-1988 - Residency
Primary responsibility for care and treatment of critically ill horses presented to the hospital. Responsible for fifty percent of the emergency surgery performed during the two year period. Taught senior students, through lectures and rounds. Presented continuing education lectures to the Maryland Veterinary Medical Association and Virginia 4-H Groups. Passed qualifying exam for board certification in Internal Medicine.

University of Minnesota, Minneapolis, Minnesota
1985-1986 - Internship in Large Animal Medicine and Surgery:
Primary responsibility for animal patients presented to the large animal hospital. Advanced surgical training in equine and ruminant species. Taught senior and junior veterinary students on clinical rotation. Assisted in teaching of junior surgery lab. Responsible for oral and written presentations to faculty and staff.

Walter Reed Army Institute of Research, Armed Forces Institute of Pathology, Division of Veterinary Medicine, Washington, D.C.

1985 U.S. Army Captain, Veterinary Corps. Chief, Surgery Section:
Responsible for all surgical procedures, post-experimental rehabilitation, and medical treatments. Directly supervised three animal care technicians. Coordinated needs and acted as Veterinary Surgeon on mission research protocols. Primary protocols involved myocardial ischemia models in rabbits.

1984 - Veterinary Microbiologist:
Complete administration and technical management of two microbiology laboratories. Supervised six military and four civilian employees, fiscal management, supply and equipment management, various training duties in areas such as safety, technical laboratory skills and veterinary technical skills. Technical supervision of quality control and microbiological testing of animals used in research. Pathological support duties included necropsy duty, detail histopathological determination of cases and rendering pathological assistance in protocols.

Yongsan Veterinary Hospital, U.S. Army Base, Seoul, Korea
1984 - Officer in Charge:
Provided complete veterinary care to military working dogs as well as dogs and cats owned by military personnel. Acted as referral surgical site for four outlying clinics. Supervised six military and one civilian personnel. Performed sanitary inspections of government animal facilities. Taught veterinary medicine and first aid to military dog handlers.

CRAIG D. WALLACE
CHARLES RIVER PHARMSERVICES
236 BLACKMER ROAD
P.O. BOX 727
SOUTHBRIDGE, MA 01550

EDUCATION:

6/1992 - PRESENT	Worcester State College, Biology Program ALAT Training and Certification
6/1986	Graduated Clinton High School

MILITARY TRAINING AND EDUCATION:

6/1992	Completed 3M PQS for NSSF, Groton, CT
6/1991	Completed 3M PAS for SIMA, Newport, RI
6/1990	Completed 3M PQS for U.S.S. Valdez, Newport, RI Completed Basic Damage Control PQS for U.S.S. Valdez, Newport, RI
1/1988	Completed 3M P.Q.S. for U.S.S. Fletcher Completed Basic Damage Control P.Q.S. for U.S.S. Fletcher Completed Security Force P.Q.S. for U.S.S. Fletcher
3/1987 - 9/1987	Fire Control "A" School N.T.C., Great Lakes, IL
1/1987 - 3/1987	Basic Electricity & Electronics NTC, San Diego, CA
10/1986 - 12/1986	Basic Training NTC/RTC, San Diego, CA

WORK EXPERIENCE:

11/1989 - PRESENT	**Charles River PharmServices, Southbridge, MA 01550** Senior Large Animal Technician: Duties include phlebotomy of large and small animals; laboratory preparation of blood products; routine health and maintenance of large animals; surgical assistant; surgery preparation; anesthesia technician.
12/1991 - 9/1992	U.S. Naval Reserve - assigned to N.S.S.F. Det. 301 Provided technical support to submarines
12/1990 - 12/1991	U.S. Naval Reserve - assigned to S.I.M.A. , Newport , R.I. Provided technical support to ships.
12/1989 - 12/1990	U. S. Naval Reserve - assigned to U.S.S. Valdez - Routine maintenance of 3 inch gun system.
9/1987 - 10/1989	U.S. Navy - assigned to U.S.S. Fletcher DD-992 CSF Div. - Duties included: routine maintenance of Sea Sparrow missile system, Harpoon Missile System; Ammunition handling for C.I.W. S. gun system

NATHAN E. HAWKINS
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EDUCATION:

Western State College, Gunnison, Colorado. Completed two years Liberal Arts studies. Sept. 1986 - May 1988.
Eastern Connecticut State University, Willimantic, CT. Completed one year of Liberal Arts studies. Sept. 1988 - May 1989.
University of Connecticut, Storrs, CT. Currently working toward degree in Natural Resource Management.

WORK EXPERIENCE:

1/93 - Present	*Veterinary Technician,* **Charles River PharmServices, Southbridge, MA.** Laboratory Animal Technician, Surgical Technician, Anesthesiologist, Large Animal Phlebotomist, Involved with Medical Device Testing and Polyclonal Antibody Production.
6/92 - 12/92	*Veterinary Technician,* **Everett Street Veterinary Hospital Southbridge, MA** Played a major role in opening new practice. Tasks include reception, filing system development, lab work, surgical prep, autoclaving, and placing orders for hospital equipment and pharmaceuticals. In addition, act as liaison between veterinary hospital and suppliers' representatives.
1/90 - 5/92	*Veterinary Technician,* **Marlborough Animal Hospital, Marlborough, CT.** Responsible for lab and microscope work, cleaning and autoclaving instruments and gowns, developing x-rays, and the medicating, treatment, feeding and care of animals. Other duties include intake, appointment scheduling and preparation, telephone communication, cash-out, and handyman and basic maintenance work.
9/89 - 1/90	*Office Furniture Installer,* **B.K.M. Total Office, E. Hartford, CT.** Tasks included transportation, installation and inspection of office cubicles and electrical wiring. Duties required self-supervision.
9/88 - 5/89	*Sales Representative/Customer Relations,* **Lebanon Sports Center, Lebanon, CT.** Responsible for customer relations and the sales of a wide variety of sporting equipment. Other duties included acting as archery technician, cash management, inventory control and completion of detailed paperwork required for the sale of firearms.
Summers 1985 - Present	*Landscaper/Carpenter's Assistant,* **Ken Gaumond Landscaping, Auburn, MA.** Building duties include the design and construction of brick sidewalks, retaining walls, stairs and patios. Other work includes grading, seeding and sodding lawns, planting trees and excavation while maintaining the balance of the natural landscape. In addition, assist carpenter with variety of construction work.

RADIATION PROTECTION TRAINING PROGRAM

Outline of Subject Material

1. **Concepts of Ionizing Radiation**

2. **Units of Radioactivity and Radiation**

   A. Radioactivity
   B. Activity (Curie, Becquerel)
   C. Exposure (Roentgen)
   D. Absorbed Dose (Rad, Gray)
   E. Dose Equivalent (Rem, Seivert)
   F. Dose Rate
   G. Half Life
   H. Radioactive Decay Process
      - Alpha, Beta, Gamma ray, X-ray

3. **Biological Effects of Radiation:**

   A. History of Radiation Exposure

   B. Acute vs. Chronic Exposure

   C. Threshold vs. Linear Relation Between Dose and Effect

   D. Balancing Risk vs. Benefit

   E. Regulatory Guide 8.29

4. **Maximum Permissible Exposures:**

   A. Current MPE Values
      - External and Internal Exposures

   B. Concept of ALARA

   C. Natural Background Radiation Exposures.

   D. Occupational Exposures

   E. Regulatory Guide 8.13

5. **Measurement and Control of Radiation Exposures:**

   A. External Exposures
      - Time
      - Distance
      - Shielding

   B. Internal Exposures
      - Ventilation
      - Engineering controls
      - Glove Boxes
      - Iodination Hoods

   C. Dosimeters
      - Film badges
      - TLD Ring Dosimeters

   D. In Vivo Measurements
      - Whole Body Burden Measurements
      - Thyroid Burden Measurements

6. **Radiation Survey Techniques:**

   A. Wipe Tests

   B. Radiation Survey Instruments
      - Geiger Mueller detectors
      - NaI Scintillation detectors

   C. Radioactivity Analysis
      - Liquid Scintillation Counting
      - Gamma Counting

   D. Environmental Monitoring
      - Environmental Air Sampling
      - Breathing Zone Sampling

7. **Handling Radiation Emergencies**

   A. Emergency Procedures

   B. Decontamination Techniques

8. Waste Disposal Techniques

- Segregation by Radiological Half Life
- Sanitary Sewerage Disposal Rules
- Liquid Scintillation Vial Disposal
- Animal Carcass Disposal
- Mixed Waste Disposal

9. Safe Handling Techniques

- General Radiation Laboratory Rules
- Specific Radiation Laboratory Rules
  - Phosphorus 32
  - Iodine 125
- Animal Handling Guidelines

10. Compliance with Regulations:

A. NRC license Conditions of Approval

B. Title 10 CRF Parts 19 & 20

C. Massachusetts Department of Radiation Control

D. DOT Regulations: Title 49 CFR

Appropriate reference material will be distributed at the time of the training lectures to further reinforce the above concepts.

Charles River PharmServices

RADIATION SAFETY PROGRAM

JUNE 1996

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Charles River PharmServices

Radiation Safety Program

Introduction

I. Purpose

It is the policy of Charles River PharmServices to provide the necessary training, facilities, equipment, and personnel to maintain levels of radiation exposure to its employees, the general public and the environment as low as reasonably achievable. Charles River PharmServices is committed to ensuring that radioactive materials are possessed, used, transported, and disposed in accordance with the following:

- N.R.C. License Conditions of Approval
- U.S.N.R.C. Rules and Regulations, Title 10, Code of Federal Regulations
- Department of Transportation, Title 49, Code of Federal Regulations
- Environmental Protection Agency, Title 40, Code of Federal Regulations
- Commonwealth of Massachusetts, Department of Public Health, Radiation Control Section

All Charles River PharmServices employees who work with and around sources of radioactivity or frequent areas where radiation sources are used or stored will be given a copy of this document.

II. Radiation Safety Officer Responsibilities

The responsibilities of the Radiation Safety Officer include:

1. The maintenance and continual review of an adequate Radiation Safety Program.

2. Compliance with radiation protection regulations established by the Nuclear Regulatory Commission (NRC).

3. Reviewing proposed uses of radioactive materials and implementing necessary controls to keep radiation worker exposures, general population exposures, and releases to the environment as low as reasonably achievable (ALARA).

4. Providing new and current employees with the proper training and information regarding radiation health and safety.

5. Reviewing reports of infractions or noncompliance with any rules or regulations, and implementing corrective actions.

6. Supervising any radiation emergencies or special decontamination procedures.

7. Maintaining all records as required by the Charles River PharmServices Radiation Safety Program and the Nuclear Regulatory Commission.

8. Supplying reports, if necessary, to the NRC or to employees as required by 10 CFR Parts 19 and 20.

9. Maintaining records of all radioactive material shipped from Charles River PharmServices.

10. Conduct and document an annual audit of the Charles River PharmServices radiation safety program.

III. Training/Instruction of Radiation Workers

The following requirements apply to all Charles River PharmServices employees who will work with unsealed sources of radioactive materials or frequent areas where radioactive materials are stored or used:

1. Employees are given a lecture and hand-out material on the mechanics of radioactivity and radiation protection practices. Periodic retraining sessions will be held as needed with a minimum of one annual retraining seminar.

2. Employees are provided with a copy of the Charles River PharmServices Radiation Safety Program as accepted by the Nuclear Regulatory Commission (NRC). The content of the radiation safety program is reviewed during radiation worker training seminars.

3. Informed that compliance with rules and regulations as outlined is mandatory. Failure to comply with established radiation safety procedures may result in disciplinary action.

4. Informed of relevant portions of NRC regulations contained within 10 CFR Parts 19 and 20, contents of Regulatory Guide 8.13, Regulatory Guide 8.29, and the conditions of approval in the NRC license. Copies of these documents shall be maintained by the RSO for review by employees upon request.

5. Required to sign the statement of training found in Appendix A confirming that the information contained in this section has been conveyed and that the opportunity to ask questions has been afforded.

6. Training shall be provided for ancillary personnel such as glasswashers, facilities maintenance personnel, or others who may frequent areas where radioactive materials are stored and used. These persons would attend the same training seminars as the radiation workers and will attend annual retraining seminars. Other ancillary personnel such as security or janitorial will be given written information concerning the storage and use of radioactive materials in the Charles River PharmServices facilities, as necessary.

IV. Control of Radiation Exposure

1. External and internal exposure to ionizing radiation shall be kept as low as reasonably achievable (ALARA).

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

TABLE 1

OCCUPATIONAL DOSE VALUES

AREA EXPOSED	ANNUAL LIMIT
Total effective whole body dose equivalent (External and Internal)	5.0 Rems
Skin of whole body, lens of the eye, and extremities	50.0 Rems

3. The maximum permissible dose equivalent for minors is 500 mrem per year.

4. The maximum permissible dose equivalent for the declared pregnant women is 500 mrem for the entire term of the pregnancy. The Radiation Safety Officer instructs all pregnant women to follow those N.R.C. guidelines established in Regulatory Guide 8.13 concerning prenatal radiation exposure. A copy of this guide is located at the end of this document. In addition, the declared pregnant woman will be required to complete the declaration form found in Appendix B.

5. The RSO will formally investigate any exposures in excess of 10% of the maximum permissible exposure limits. The exposed worker will not be allowed to handle radioactive sources until the investigation is completed. Engineering controls and/or improved handling procedures will be implemented to limit future doses to the worker. Any worker receiving a dose in excess of 10% of the applicable limits will be required to attend a radiation safety seminar prior to resuming work with radioactive sources. The Charles River PharmServices ALARA program is outlined in Appendix C.

. Personnel Monitoring of Internal and External Exposure

I. Internal Exposures

A. Urinanalysis

Radiation workers who handle tritium in quantities of 5 millicuries or greater will be required to submit a urine specimen to the RSO within 24-48 hours after handling the radioisotope. Specimens will be analyzed by liquid scintillation counting in an appropriately calibrated analyzer. Action levels as well as corrective actions taken will be those outlined in Item 5, Regulatory Guide 8.32.

Bioassays may be performed on designated individuals at the discretion of the RSO in cases of accidental widespread contamination. Records of bioassay results will be maintained as required by 10CFR 20.2106.

B. Thyroid Monitoring

There will be no formal requirement for radiation workers handling unsealed quantities of protein bound radioiodine. In the event of personnel contamination or unexpected significant contamination levels detected in the laboratory, thyroid monitoring may be performed on designated individuals at the discretion of the RSO. Records of all thyroid burden measurements will be maintained as required by 10CFR 20.2106.

II. External Exposures

A. Whole Body Dosimeters

Radiation workers who handle radioisotopes ^{32}P, ^{51}Cr, and ^{125}I or are routinely present in areas where isotopes are used or stored will be required to wear a whole body film badge dosimeter. This will include the scientific and research staff. Ancillary personnel such as glasswashers and maintenance persons or employees who do not frequent the radiation laboratories such as secretarial help will not be issued a film badge unless they personally request one.

V. Personnel Monitoring of Internal and External Exposure

II. External Exposures

B. Extremity Dosimeters

Persons who handle millicurie quantities of hard beta and/or gamma ray emitting radioisotopes (^{32}P, ^{51}Cr and ^{125}I) will be required to wear finger ring dosimeters as well as whole body badges.

Dosimeters will be supplied by R.S. Landauer and will have a quarterly replacement frequency. Records of personnel exposures will be maintained by the Radiation Safety Officer.

VI. Radiation Surveys of Radiation Laboratories

1. All laboratories in which greater than 100 microcuries of radioactivity is handled on a routine basis will be surveyed weekly. All other laboratories will be surveyed on a monthly basis. These surveys will consist of radiation dose rate measurements at specified locations accompanied by wipe testing for removable contamination. A map indicating the survey locations will be kept with the results.

2. Wipe tests consist of wiping a 1-inch dry filter disc over an area of approximately 100 cm^2. Any results greater than 100 dpm/100cm^2 for ^{125}I and 200 dpm/100cm^2 for all other licensed radioisotopes will be decontaminated and resurveyed. Wipe test samples will be analyzed in a liquid scintillation counter or gamma counter as appropriate. Results of contamination surveys will be kept in units of disintegrations per minute (dpm) per 100 cm^2.

3. Radiation surveys will be performed using a calibrated survey instrument equipped with an end window Geiger Mueller (GM) detector. Results of radiation surveys will be kept in milliroentgen per hour (mr/hr).

   Our action limit for radiation dose rate surveys in our radiation laboratories will be 0.5 millrem/hour. If the action limit is exceeded, the RSO will be notified and steps will be taken to reduce the levels to as close to natural background levels as possible.

Note: Our laboratories will be controlled areas.

VI. Radiation Surveys of Radiation Laboratories

The types of surveys to be performed will be for fixed and/or removable contamination. The worker will survey the lab bench, equipment, floor, and other articles/tools in the immediate work area to determine contamination levels. The worker will decontaminate/dispose of any articles found to be contaminated during the survey.

We do not anticipate elevated radiation dose rate levels from the amounts and types of licensed material to be routinely handled. We do anticipate some localized radioactive contamination of bench paper, lab apparatus, handling tools, etc. The radiation surveys will be done to detect any contamination (fixed or removable) so appropriate actions (decontamination, shielding, etc.) may be implemented. In effect, the contamination survey will detect elevated radiation dose rate levels and again appropriate actions would be implemented.

The following instructions will be given to radiation workers with regards to radiation surveys:

1. Perform a radiation survey of yourself, your work area, and any equipment used with licensed material after any use of radioactive material.

2. For the low energy beta emitters, ^{14}C, ^{35}S, and ^{33}P, use the Ludlum survey instrument equipped with the Model 44-9 or 44-88 pancake GM detector. The red protective covering or any Parafilm covering of the detector surface must be removed prior to this survey. The detector should be positioned approximately 1-2 centimeters from the surface to be monitored and the detector moved at a slow speed over the surface being monitored. The audio switch should be in the on position.

   For the high energy beta emitter ^{32}P, use the Ludlum survey instrument equipped with the Model 44-9 or 44-88 pancake GM detector. The red cover protecting the detector surface must be removed prior to this survey. The detector should be positioned approximately several (5-10) centimeters from the surface to be monitored and the detector moved at a slow speed over the surface being monitored. The audio switch should be in the on position.

   For the low energy x and gamma ray emitter ^{125}I, use the Ludlum survey instrument equipped with the Model 44-3 thin crystal scintillation detector. The red cover protecting the detector surface should be removed prior to this survey. The detector should be positioned approximately several (3-5) centimeters from the surface to be monitored and the detector moved at a slow speed over the surface being monitored. The audio switch should be in the on position.

VII. Radioactive Material Security and Inventory

1. Our radiation laboratories are classified as controlled areas. The doors to these laboratories remain locked at all times when radioactive material is present.

2. In addition to the locked laboratory doors, all stock vials containing radioactive material will be stored in a locked refrigerator/freezer or a locked storage container within the refrigerator/freezer.

3. An up-to-date inventory will be kept at the stock material locked storage containers. The inventory records will also have a use log. Radiation workers will log all removals of stock material on the inventory/use log. When orders for additional radioactive material are placed, the RSO will confirm that the license possession limits will not be exceeded by comparing the amount to be ordered and the current inventory against the licensed possession limits.

4. Experiments in progress will be labeled as required by 10 CFR Part 20 and the quantities in Appendix C.

VII. Procurement and Monitoring of Radioactive Packages

1. All orders for radioactive material must be approved by the Radiation Safety Officer or her designate prior to ordering. In addition, the Radiation Safety Officer or designate must sign the purchase order.

2. The Radiation Safety Officer or designate will sign the purchase order after verifying that the material to be ordered is covered by the NRC license and that the possession limits for the license are not exceeded.

3. Incoming shipments of radioactive material are delivered to the laboratory and the Radiation Safety Officer or her designate is notified. The package will then be logged in and surveyed for radiation dose rates and external contamination within 3 hours of receipt of delivery.

4. Radioactive shipments will be received only during normal working hours. These hours are 8:00am to 5:00pm, excluding weekends.

5. All packages of radioactive material will be subject to the following check-in procedures:

a. Using a survey instrument equipped with a GM detector, make dose rate measurements at one meter from the surface of the package and on the surface. If dose rates exceed 50 mr/hr at the package surface or 1.0 mr/hr at one meter, the package will be isolated and the RSO contacted immediately.

b. Wipe test the outside surface of the package to check for removable contamination. The wipe test will consist of rubbing a filter disk over the entire outside surface of the package. If removable contamination is detected above a level of 2000 dpm/100cm^2, the package will be placed in a plastic bag, isolated, and the RPO will be notified immediately.

c. The outside surface of the primary container should be wipe tested by the radiation worker prior to initial use to check for removable contamination. If removable contamination is detected, the container will be decontaminated before use to prevent spread of the contamination.

VIII. Procedures for Opening Radioactive Material Shipments

1. Packages of radioactive material are to be opened only in the designated radioisotope laboratories. If radioactive sample is believed to be in a volatile form, the package will be opened in a designated fume hood.

2. Wearing protective gloves, open the outer package. Remove the packing slip and inspect it to verify that the shipment is in agreement with what was ordered. If special instructions for opening the isotope container are enclosed, these instructions are to be followed.

3. Monitor the inner container with a GM survey instrument. Check the inner packing material for contamination.

4. Remove the inner container and place behind appropriate shielding, as necessary.

5. Open the inner container. Monitor and inspect the primary container for leakage (loss of volume, discoloration of the absorbing material, etc.). Monitor the lead pig for any leakage from the primary container.

6. Notify the Radiation Safety Officer if:

   a. Contamination or leakage is detected.
   b. If readings in excess of expected values are obtained on the survey meter.
   c. There is a discrepancy between the material received and that ordered.

7. Obliterate all references to radioactive material prior to disposing of the packaging material in the normal trash.

IX. Calibration of Radiation Survey Instruments

All radiation survey instruments will be calibrated by our radiation protection consultants on a six month basis. If the instruments are repaired, they will be recalibrated after the completion of the repair.

Radiation survey instruments are calibrated as described in the application for NRC license # 20-13302-01. Calibrations are performed by Mitchell S. Galanek. A calibration record with applicable information is attached to each calibrated instrument. Calibration certificates are maintained by the Radiation Safety Officer.

A minimum of two Ludlum Model 3 survey instruments equipped GM detectors (Model 44-9, 44-88, or equivalent) for dose rate measurements and contamination monitoring. The range of these instruments is 0-200 mr/hr or 0-200K cpm. Also, one additional instrument will be equipped with a NaI scintillation detector(Model 44-3) for ^{125}I monitoring. An instrument will be available in the laboratory while others are sent for calibration.

X. Radioactive Waste Disposal

1. All solid material contaminated with radioactive material with a half life of 65 days or less and waste contaminated with ^{35}S ($T_{1/2}$=88 days) will be stored "in house" for radioactive decay and subsequent disposal as non-radioactive waste. The following procedures will be used:

a. Contaminated solids will be put in the waste containers provided in each laboratory. A record of the isotope and amount being disposed will be maintained. When these containers are full, the waste will be transferred to 55 gallon drums and stored for decay. No liquids are to be put in the solid waste containers.

b. Stored material will be held for a minimum of 10 half-lives prior to disposal.

c. The material will be stored in 55 gallon or 30 gallon steel drums.

d. The material will be surveyed with an appropriate survey instrument prior to disposal. Survey results must be background before any material is disposed of as normal trash.

e. All reference to radioactive materials (labels, tape, etc.) must be removed or completely obliterated prior to final disposal.

X. Radioactive Waste Disposal

f. A record of the date waste was put in storage, the date removed from storage, the date disposed as regular trash, the survey instrument used, and the name of the surveyor will be maintained for all decay in storage (DIS) waste.

2 All solid waste contaminated with tritium or carbon-14 will be segregated from the waste in #1 above and stored in a 55 gallon steel drum. Final disposal will be through a licensed radioactive waste disposal contractor.

3. Liquid radioactive waste will be disposed of via the sanitary sewage system in accordance with 10 CFR20.2003 and the applicable concentrations in Appendix B, Table 3. Any liquids that cannot meet these requirements will be absorbed and disposed of as low level radioactive waste. A record of the solubility of aqueous waste will be maintained.

4. Liquid scintillation vial waste will be stored in 30 gallon drums and disposed of through a licensed waste disposal contractor.

XI. Radiation Emergencies

In the event of a major spill or accident involving radioactive material, the following procedures should be used:

1. The area is quarantined immediately.

2. If volatile material is involved, activate the hood if necessary and evacuate personnel from the immediate work area.

3. Survey persons involved in the accident. If clothing is contaminated, remove and place in a plastic bag.

4. If skin is contaminated, begin decontamination procedures and continue until levels are as close to background as possible.

5. Decontaminate the work area. Continue with decontamination and resurvey procedures until removable contamination and dose rates are within permissible limits.

6. Notify the Radiation Safety Officer. The home phone number of the Radiation Safety Officer will be posted in laboratories for use as needed in an emergency.

XI. Radiation Emergencies

A copy of the emergency procedures is posted in all radiation laboratories. Responsibility for any decontamination procedures rests with the Radiation Safety Officer and the laboratory supervisor. Under no circumstances are these procedures to be performed by members of the maintenance or housekeeping staff. The R.S.O. will perform a thorough survey of the affected areas to determine if additional action is necessary. The R.S.O. will establish and maintain a log of radiation accident reports and corrective actions taken. Our consultants will be used as needed by the R.S.O.

In the event that the accident occurs after hours or on a weekend, the following steps shall be taken:

1. Do not attempt to clean up the spill. Quarantine the area as much as possible.

2. Notify the R.S.O. or the Facility Supervisor for specific instructions as to the course of action to be followed.

3. Survey yourself for radioactive contamination. If you are contaminated, begin decontamination procedures and await help from the R.S.O. as above.

XII. General Laboratory Rules

1. Lab coats, safety glasses, and other designated protective clothing must be worn at all times when working with unsealed radioactive materials.

2. Mouth pipetting of radioactive solutions is prohibited.

3. There will be no eating, drinking, smoking, storage of food, or application of cosmetics in areas where radioactive materials are stored or used.

4. Personnel will wear protective gloves when handling unsealed quantities of radioactive material. Gloves are to be removed and disposed of before leaving the work area.

5. Dosimeters (film badges and finger rings), as assigned by the RSO, must be worn when in the areas where radioactive materials are stored or used. In addition, personnel must submit bioassay samples or have thyroid burden measurements as requested by the Radiation Safety Program.

6. After-hours or weekend work must have the specific approval of the RSO.

XII. General Laboratory Rules

7. All equipment and instrumentation containing radioactive material must be properly labeled.

8. All radioactive materials not in use will be stored in a safe and approved manner that will prevent their unauthorized removal from the laboratory.

9. All areas where radioactive materials are stored or used must be properly posted.

10. Work performed on an open bench must be done in a manner such that any spills are contained and the spread of contamination is controlled (i.e. use of trays, absorbent bench paper, etc.)

11. Any radiation survey instruments found to be defective or suspected to be malfunctioning will be brought to the attention of the RSO immediately.

12. "Close-down" procedures will be established in all areas in which radioactive materials are used. After each day that radioactive materials are used, a radiation survey will be conducted to ensure that:

a. Radiation sources are properly labeled, stored and secured.
b. Survey meter measurements have established that radiation and contamination levels are within permissible limits and as low as reasonably achievable.
c. Each laboratory is secured against unauthorized access.

14. All persons who work with radioactive materials will thoroughly survey their hands and clothing for contamination before leaving the laboratory.

XIII. Specific Rules for ^{32}P :

a. Persons handling millicurie quantities of ^{32}P will use low density shielding (plexiglas) to minimize bremstrahlung radiation production.

b. Wear safety glasses or similar protective devices when handling millicurie quantities of ^{32}P to keep beta exposures to the lens of the eye to a minimum.

c. Thoroughly survey the work area after each use of ^{32}P.

d. Use the GM detector when surveying for ^{32}P contamination.

e. Perform a dry run prior to any new procedures to preclude unexpected complications.

f. Wear whole body film badges and finger ring badges when handling millicurie quantities.

XIV. Specific Rules for ^{125}I

a. Persons working with ^{125}I will use appropriate lead shielding and/or leaded acrylic shielding to minimize external exposures as necessary.

b. Perform a dry run prior to any new procedures to preclude unexpected complications.

c. Wear whole body and ring badge dosimeters when handling millicurie quantities of ^{125}I.

d. Thoroughly survey the work area after each use of ^{125}I.

e. Use the NaI scintillation detector when monitoring for ^{125}I contamination.

XV. In Vivo Animal Experiment Guidelines

1. Animals shall be injected with radioactive material and housed or sacrificed only in a room that is specifically approved for such purpose by the Radiation Safety Officer.

2. Injection of animals shall be done in a manner that will confine any accidental spill of radioactive solution. (For example, perform injections on a tray or other surface that is covered with plastic-backed absorbing paper.)

3. Cages or pens housing "radioactive" animals shall be clearly identified with a (magenta on yellow) "Caution Radioactive Material" label or sign on which is specified the following information:

   Radionuclide
   Amount of radionuclide, and date
   Name of person responsible for animal(s)

4. Cages or pens housing "radioactive" animals shall be equipped with appropriate containment (such as filter covers, etc.) which will prevent displacement from the cages of contaminated excreta, bedding, or nutrients.

5. Should there be a possibility of the release of airborne radioactive contamination

during animal injection, housing or sacrifice, an approved hood or exhaust-ventilated enclosure shall be used. The procedures for airborne contamination control must be approved by the Radiation Safety Officer prior to conduct of the proposed work.

6. All radioactive solid and liquid waste shall be put into appropriate containers. A record of the nuclide, amount, etc., shall be maintained.

7. Animals shall be sacrificed such that all potentially radioactive tissues and body fluids are collected and stored as radioactive materials for further analysis or disposed of as radioactive waste. If they are to be disposed of, carcasses and tissues shall be packaged in accordance with current waste disposal site requirements.

8. Animal carcasses containing 0.05 microcuries or less of tritium or carbon-14 per gram of tissue averaged over the weight of the entire animal may be disposed of without regard to their radioactivity. This waste shall be disposed of with other non-radioactive animal waste (incineration). A record of all such disposal will be maintained.

9. The cleaning of cages/pens used to house animals containing radioactive material shall be done by the principal investigator as follows: Place the radioactive waste collection container (30 or 55 gallons drum) in front of a hood when appropriate. Empty the potentially contaminated bedding into the collection container. Potentially contaminated cages will be surveyed for residual contamination, decontaminated as necessary, before being washed in the cage washer.

10. Any radioactive waste that contains potentially bio-hazardous or carcinogenic material shall be treated to make the material harmless prior to its disposal into a radioactive waste collection container.

11. Laboratories where radioactive animals are housed will be surveyed routinely. For experiments of short duration (less than a few days), the laboratory will be wipe test surveyed at the completion of the experiment.

Charles River PharmServices

RADIATION PROTECTION TRAINING PROGRAM

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   D. Absorbed Dose (Rad, Gray)
   E. Dose Equivalent (Rem, Seivert)
   F. Dose Rate
   G. Half Life
   H. Radioactive Decay Process

      - Alpha, Beta, Gamma ray, X-ray

3. **Biological Effects of Radiation:**

   A. History of Radiation Exposure
   B. Acute vs. Chronic Exposure
   C. Threshold vs. Linear Relation Between Dose and Effect
   D. Balancing Risk vs. Benefit
   E. Regulatory Guide 8.29

4. **Maximum Permissible Exposures:**

   A. Total Effective Dose Equivalent Values

      - External and Internal Exposures
      - Occupational Limits
      - Pregnant Worker Limits
      - General Public Limits

   B. Concept of ALARA
   C. Natural Background Radiation Exposures.
   D. Occupational Exposures
   E. Regulatory Guide 8.13

5. **Measurement and Control of Radiation Exposures:**

A. External Exposures
- Time
- Distance
- Shielding

B. Internal Exposures
- Ventilation
- Engineering controls
- Glove Boxes
- Iodination Hoods

C. Dosimeters
- Film badges
- TLD Ring Dosimeters

D. In Vivo and In Vitro Measurements
- Whole Body Burden Measurements
- Thyroid Burden Measurements
- Urinanalysis Bioassay

6. **Radiation Survey Techniques:**

A. Wipe Tests
- Procedures
- Recordkeeping

B. Radiation Survey Instruments
- Geiger Mueller detectors
- Nal Scintillation detectors

C. Radioactivity Analysis
- Liquid Scintillation Counting
- Gamma Counting

D. Environmental Monitoring
- Environmental Air Sampling
- Breathing Zone Sampling

7. **Handling Radiation Emergencies**

A. Emergency Procedures

B. Decontamination Techniques

8. Waste Disposal Techniques

- Segregation by Radiological Half Life
- Sanitary Sewerage Disposal Rules
- Liquid Scintillation Vial Disposal
- Mixed Waste Disposal
- Waste Avoidance

9. Safe Handling Techniques

- General Radiation Laboratory Rules
- Specific Radiation Laboratory Rules
- Phosphorus 32
- Iodine 125

10. Packaging and Transportation

11. Compliance with Regulations:

A. NRC license Conditions of Approval
B. Title 10 CRF Parts 19 & 20
C. Massachusetts Department of Radiation Control
D. DOT Regulations: Title 49 CFR

Appropriate reference material will be distributed at the time of the training lectures to further reinforce the above concepts.

U.S. NUCLEAR REGULATORY COMMISSION

Revision 2
December 1987

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.13
(Task OP 031-4)

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12, "Instructions to Workers," of 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections," requires that all individuals working in or frequenting any portion of a restricted area[1] be instructed in the health protection problems associated with exposure to radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the regulations that they are expected to observe. The present 10 CFR Part 20, "Standards for Protection Against Radiation," has no special limit for exposure of the embryo/fetus.[2] This guide describes the instructions an employer should provide to workers and supervisors concerning biological risks to the embryo/fetus exposed to radiation, a dose limit for the embryo/fetus that is under consideration, and suggestions for reducing radiation exposure.

This regulatory guide takes into consideration a proposed revision to 10 CFR Part 20, which incorporates the radiation protection guidance for the embryo/fetus approved by the President in January 1987 (Ref. 1). This revision to Part 20 was issued in January 1986 for comment as a proposed rule. Comments on the guide as it pertains to the proposed Part 20 are encouraged. If the new Part 20 is codified, this regulatory guide will be revised to conform to the new regulation and will incorporate appropriate public comments.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Parts 19 or 20, which provide the regulatory basis for this guide. The information collection requirements in 10 CFR Parts 19 and 20 have been cleared under OMB Clearance Nos. 3150-0044 and 3150-0014, respectively.

B. DISCUSSION

It has been known since 1906 that cells that are dividing very rapidly and are undifferentiated in their structure and function are generally more sensitive to radiation. In the embryo stage, cells meet both these criteria and thus would be expected to be highly sensitive to radiation. Furthermore, there is direct evidence that the embryo/fetus is radiosensitive. There is also evidence that it is especially sensitive to certain radiation effects during certain periods after conception, particularly during the first 2 to 3 months after conception when a woman may not be aware that she is pregnant.

Section 20.104 of 10 CFR Part 20 places different radiation dose limits on workers who are minors than on adult workers. Workers under the age of 18 are limited to one-tenth of the adult radiation dose limits. However, the present NRC regulations do not establish dose limits specifically for the embryo/fetus.

The NRC's present limit on the radiation dose that can be received on the job is 1,250 millirems per quarter (3 months).[3] Working minors (those under 18) are limited to a dose equal to one-tenth that of adults, 125 millirems per quarter. (See § 20.101 of 10 CFR Part 20.)

Because of the sensitivity of the unborn child, the National Council on Radiation Protection and Measurements (NCRP) has recommended that the dose equivalent

[1] Restricted area means any area that has controlled access to protect individuals from being exposed to radiation and radioactive materials.

[2] In conformity with the proposed revision to 10 CFR Part 20, the term "embryo/fetus" is used throughout this document to represent all stages of pregnancy.

[3] The limit is 3,000 millirems per quarter if the worker's occupational dose history is known and the average dose does not exceed 5,000 millirems per year.

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This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

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to the unborn child from occupational exposure of the expectant mother be limited to 500 millirems for the entire pregnancy (Ref. 2). The 1987 Presidential guidance (Ref. 1) specifies an effective dose equivalent limit of 500 millirems to the unborn child if the pregnancy has been declared by the mother; the guidance also recommends that substantial variations in the rate of exposure be avoided. The NRC (in § 20.208 of its proposed revision to Part 20) has proposed adoption of the above limits on dose and rate of exposure.

In 1971, the NCRP commented on the occupational exposure of fertile women (Ref. 2) and suggested that fertile women should be employed only where the annual dose would be unlikely to exceed 2 or 3 rems and would be accumulated at a more or less steady rate. In 1977, the ICRP recommended that, when pregnancy has been diagnosed, the woman work only where it is unlikely that the annual dose would exceed 0.30 of the dose-equivalent limit of 5 rems (Ref. 3). In other words, the ICRP has recommended that pregnant women not work where the annual dose might exceed 1.5 rem.

C. REGULATORY POSITION

Instructions on radiation risks should be provided to workers, including supervisors, in accordance with § 19.12 of 10 CFR Part 19 before they are allowed to work in a restricted area. In providing instructions on radiation risks, employers should include specific instructions about the risks of radiation exposure to the embryo/fetus.

The instructions should be presented both orally and in printed form, and the instructions should include, as a minimum, the information provided in Appendix A (Instructor's Guide) to this guide. Individuals should be given the opportunity to ask questions and in turn should be questioned to determine whether they understand the instructions. An acceptable method of ensuring that the information is understood is to give a simple written test covering the material included in Appendix B (Pregnant Worker's Guide). This approach should highlight for instructors those parts of the instructions that cause difficulties and thereby lead to appropriate modifications in the instructional curriculum.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the NRC will use the material described in this guide to evaluate the instructional program presented to individuals, including supervisors, working in or frequenting any portion of a restricted area.

APPENDIX A

INSTRUCTOR'S GUIDE

EFFECTS ON THE EMBRYO/FETUS OF EXPOSURE TO RADIATION AND OTHER ENVIRONMENTAL HAZARDS

In order to decide whether to continue working while exposed to ionizing radiation during her pregnancy, a woman should understand the potential effects on an embryo/fetus, including those that may be produced by various environmental risks such as smoking and drinking. This will allow her to compare these risks with those produced by exposure to ionizing radiation.

Table 1 provides information on the potential effects resulting from exposure of an embryo/fetus to radiation and nonradiation risks. The second column gives the rate at which the effect is produced by natural causes in terms of the number per thousand cases. The fourth column gives the number of additional effects per thousand cases believed to be produced by exposure to the specified amount of the risk factor.

The following section discusses the studies from which the information in Table 1 was derived. The results of exposure of the embryo/fetus to the risk factors and the dependence on the amount of the exposure are explained.

1. RADIATION RISKS

1.1 Childhood Cancer

Numerous studies of radiation-induced childhood cancer have been performed, but a number of them are controversial. The National Academy of Science (NAS) BEIR report reevaluated the data from these studies and even reanalyzed the results. Some of the strongest support for a causal relationship is provided by twin data from the Oxford survey (Ref. 4). For maternal radiation doses of 1,000 millirems, the excess number of deaths (above those occurring from natural causes) was found to be 0.6 death per thousand children (Ref. 4).

1.2 Mental Retardation and Abnormal Smallness of the Head (Microcephaly)

Studies of Japanese children who were exposed while in the womb to the atomic bomb radiation at Hiroshima and Nagasaki have shown evidence of both small head size and mental retardation. Most of the children were exposed to radiation doses in the range of 1 to 50 rads. The importance of the most recent study lies in the fact that investigators were able to show that the gestational age (age of the embryo/fetus after conception) at the time the children were exposed was a critical factor (Ref. 7). The approximate risk of small head size as a function of gestational age is shown in Table 1. For a radiation dose of 1,000 millirems at 4 to 7 weeks after conception, the excess cases of small head size was 5 per thousand; at 8 to 11 weeks, it was 9 per thousand (Ref. 7).

In another study, the highest risk of mental retardation occurred during the 8 to 15 week period after conception (Ref. 8). A recent EPA study (Ref. 16) has calculated that excess cases of mental retardation per live birth lie between 0.5 and 4 per thousand per rad.

1.3 Genetic Effects

Radiation-induced genetic effects have not been observed to date in humans. The largest source of material for genetic studies involves the survivors of Hiroshima and Nagasaki, but the 77,000 births that occurred among the survivors showed no evidence of genetic effects. For doses received by the pregnant worker in the course of employment considered in this guide, the dose received by the embryo/fetus apparently would have a negligible effect on descendants (Refs. 17 and 18).

2. NONRADIATION RISKS

2.1 Occupation

A recent study (Ref. 9) involving the birth records of 130,000 children in the State of Washington indicates that the risk of death to the unborn child is related to the occupation of the mother. Workers in the metal industry, the chemical industry, medical technology, the wood industry, the textile industry, and farms exhibited stillbirths or spontaneous abortions at a rate of 90 per thousand above that of workers in the control group, which consisted of workers in several other industries.

2.2 Alcohol

It has been recognized since ancient times that alcohol consumption had an effect on the unborn child. Carthaginian law forbade the consumption of wine on the wedding night so that a defective child might not be conceived. Recent studies have indicated that small amounts of alcohol consumption have only the minor effect of reducing the birth weight slightly, but when consumption increases to 2 to 4 drinks per day, a pattern of abnormalities called the fetal alcohol syndrome (FAS) begins to appear (Ref. 11). This syndrome consists of reduced growth in the unborn child, faulty brain function, and abnormal facial features. There is a syndrome that has the same symptoms as full-blown FAS that occurs in children born to mothers who have not consumed alcohol. This naturally occurring syndrome occurs in about 1 to 2 cases per thousand (Ref. 10).

TABLE 1

EFFECTS OF RISK FACTORS ON PREGNANCY OUTCOME

Effect	Number Occurring from Natural Causes	Risk Factor	Excess Occurrences from Risk Factor
		RADIATION RISKS	
		Childhood Cancer	
Cancer death in children	1.4 per thousand (Ref. 5)	Radiation dose of 1000 millirems received before birth	0.6 per thousand (Ref. 4)
		Abnormalities	
		Radiation dose of 1000 millirads received during specific periods after conception:	
Small head size	40 per thousand (Ref. 6)	4-7 weeks after conception	5 per thousand (Ref. 7)
Small head size	40 per thousand (Ref. 6)	8-11 weeks after conception	9 per thousand (Ref. 7)
Mental retardation	4 per thousand (Ref. 8)	Radiation dose of 1000 millirads received 8 to 15 weeks after conception	4 per thousand (Ref. 8)
		NONRADIATION RISKS	
		Occupation	
Stillbirth or spontaneous abortion	200 per thousand (Ref. 9)	Work in high-risk occupations (see text)	90 per thousand (Ref. 9)
		Alcohol Consumption (see text)	
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	2-4 drinks per day	100 per thousand (Ref. 11)
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	More than 4 drinks per day	200 per thousand (Ref. 11)
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	Chronic alcoholic (more than 10 drinks per day)	350 per thousand (Ref. 12)
Perinatal infant death (around the time of birth)	23 per thousand (Refs. 13, 14)	Chronic alcoholic (more than 10 drinks per day)	170 per thousand (Ref. 15)
		Smoking	
Perinatal infant death	23 per thousand (Refs. 13, 14)	Less than 1 pack per day	5 per thousand (Ref. 13)
Perinatal infant death	23 per thousand (Refs. 13, 14)	One pack or more per day	10 per thousand (Ref. 13)

For mothers who consume 2 to 4 drinks per day, the excess occurrences number about 100 per thousand; and for those who consume more than 4 drinks per day, excess occurrences number 200 per thousand. The most sensitive period for this effect of alcohol appears to be the first few weeks after conception, before the mother-to-be realizes she is pregnant (Refs. 10 and 11). Also, 17% or 170 per thousand of the embryo/fetuses of chronic alcoholics develop FAS and die before birth (Ref. 15). FAS was first identified in 1973 in the United States where less than full-blown effects of the syndrome are now referred to as fetal alcohol effects (FAE) (Ref. 12).

2.3 Smoking

Smoking during pregnancy causes reduced birth weights in babies amounting to 5 to 9 ounces on the average. In addition, there is an increased risk of 5 infant deaths per thousand for mothers who smoke less than one pack per day and 10 infant deaths per thousand for mothers who smoke one or more packs per day (Ref. 13).

2.4 Miscellaneous

Numerous other risks affect the embryo/fetus, only a few of which are touched upon here. Most people are familiar with the drug thalidomide (a sedative given to some pregnant women), which causes children to be born with missing limbs, and the more recent use of the drug diethylstilbestrol (DES), a synthetic estrogen given to some women to treat menstrual disorders, which produced vaginal cancers in the daughters born to women who took the drug. Living at high altitudes also gives rise to an increase in the number of low-birth-weight children born, while an increase in Down's Syndrome (mongolism) occurs in children born to mothers who are over 35 years of age. The rapid growth in the use of ultrasound in recent years has sparked an ongoing investigation into the risks of using ultrasound for diagnostic procedures (Ref. 19).

APPENDIX B

PREGNANT WORKER'S GUIDE

POSSIBLE HEALTH RISKS TO CHILDREN OF WOMEN WHO ARE EXPOSED TO RADIATION DURING PREGNANCY

During pregnancy, you should be aware of things in your surroundings or in your style of life that could affect your unborn child. For those of you who work in or visit areas designated as Restricted Areas (where access is controlled to protect individuals from being exposed to radiation and radioactive materials), it is desirable that you understand the biological risks of radiation to your unborn child.

Everyone is exposed daily to various kinds of radiation: heat, light, ultraviolet, microwave, ionizing, and so on. For the purposes of this guide, only ionizing radiation (such as x-rays, gamma rays, neutrons, and other high-speed atomic particles) is considered. Actually, everything is radioactive and all human activities involve exposure to radiation. People are exposed to different amounts of natural "background" ionizing radiation depending on where they live. Radon gas in homes is a problem of growing concern. Background radiation comes from three sources:

	Average Annual Dose
Terrestrial - radiation from soil and rocks	50 millirem
Cosmic - radiation from outer space	50 millirem
Radioactivity normally found within the human body	25 millirem
	125 millirem*
Dosage range (geographic and other factors)	75 to 5,000 millirem

The first two of these sources expose the body from the outside, and the last one exposes it from the inside. The average person is thus exposed to a total dose of about 125 millirems per year from natural background radiation.

In addition to exposure from normal background radiation, medical procedures may contribute to the dose people receive. The following table lists the average doses received by the bone marrow (the blood-forming cells) from different medical applications.

X-Ray Procedure	Average Dose*
Normal chest examination	10 millirem
Normal dental examination	10 millirem
Rib cage examination	140 millirem
Gall bladder examination	170 millirem
Barium enema examination	500 millirem
Pelvic examination	600 millirem

*Variations by a factor of 2 (above and below) are not unusual.

*Radiation doses in this document are described in two different units. The rad is a measure of the amount of energy absorbed in a certain amount of material (100 ergs per gram). Equal amounts of energy absorbed from different types of radiation may lead to different biological effects. The rem is a unit that reflects the biological damage done to the body. The millirad and millirem refer to 1/1000 of a rad and a rem, respectively.

NRC POSITION

NRC regulations and guidance are based on the conservative assumption that any amount of radiation, no matter how small, can have a harmful effect on an adult, child, or unborn child. This assumption is said to be conservative because there are no data showing ill effects from small doses; the National Academy of Sciences recently expressed "uncertainty as to whether a dose of, say, 1 rad would have any effect at all." Although it is known that the unborn child is more sensitive to radiation than adults, particularly during certain stages of development, the NRC has not established a special dose limit for protection of the unborn child. Such a limit could result in job discrimination for women of child-bearing age and perhaps in the invasion of privacy (if pregnancy tests were required) if a separate regulatory dose limit were specified for the unborn child. Therefore, the NRC has taken the position that special protection of the unborn child should be *voluntary* and should be based on decisions made by workers and employers who are well informed about the risks involved.

For the NRC position to be effective, it is important that both the employee and the employer understand the risk to the unborn child from radiation received as a result of the occupational exposure of the mother. This document tries to explain the risk as clearly as possible and to compare it with other risks to the unborn child during pregnancy. It is hoped this will help pregnant employees balance the risk to the unborn child against the benefits of employment to decide if the risk is worth taking. This document also discusses methods of keeping the dose, and therefore the risk, to the unborn child as low as is reasonably achievable.

RADIATION DOSE LIMITS

The NRC's present limit on the radiation dose that can be received on the job is 1,250 millirems per quarter (3 months).* Working minors (those under 18) are limited to a dose equal to one-tenth that of adults, 125 millirems per quarter. (See § 20.101 of 10 CFR Part 20.)

Because of the sensitivity of the unborn child, the National Council on Radiation Protection and Measurements (NCRP) has recommended that the dose equivalent to the unborn child from occupational exposure of the expectant mother be limited to 500 millirems for the entire pregnancy (Ref. 2). The 1987 Presidential guidance (Ref. 1) specifies an effective dose equivalent limit of 500 millirems to the unborn child if the pregnancy has been declared by the mother; the guidance also recommends that substantial variations in the rate of exposure be avoided. The NRC (in § 20.208 of its proposed revision to Part 20) has proposed adoption of the above limits on dose and rate of exposure.

ADVICE FOR EMPLOYEE AND EMPLOYER

Although the risks to the unborn child are small under normal working conditions, it is still advisable to limit the radiation dose from occupational exposure to no more than 500 millirems for the total pregnancy. Employee and employer should work together to decide the best method for accomplishing this goal. Some methods that might be used include reducing the time spent in radiation areas, wearing some shielding over the abdominal area, and keeping an extra distance from radiation sources when possible. The employer or health physicist will be able to estimate the probable dose to the unborn child during the normal nine-month pregnancy period and to inform the employee of the amount. If the predicted dose exceeds 500 millirems, the employee and employer should work out schedules or procedures to limit the dose to the 500-millirem recommended limit.

It is important that the employee inform the employer of her condition as soon as she realizes she is pregnant if the dose to the unborn child is to be minimized.

INTERNAL HAZARDS

This document has been directed primarily toward a discussion of radiation doses received from sources outside the body. Workers should also be aware that there is a risk of radioactive material entering the body in workplaces where unsealed radioactive material is used. Nuclear medicine clinics, laboratories, and certain manufacturers use radioactive material in bulk form, often as a liquid or a gas. A list of the commonly used materials and safety precautions for each is beyond the scope of this document, but certain general precautions might include the following:

1. Do not smoke, eat, drink, or apply cosmetics around radioactive material.
2. Do not pipette solutions by mouth.
3. Use disposable gloves while handling radioactive material when feasible.
4. Wash hands after working around radioactive material.
5. Wear lab coats or other protective clothing whenever there is a possibility of spills.

Remember that the employer is required to have demonstrated that it will have safe procedures and practices before the NRC issues it a license to use radioactive material. Workers are urged to follow established procedures and consult the employer's radiation safety officer or health physicist whenever problems or questions arise.

*The limit is 3,000 millirems per quarter if the worker's occupational dose history is known and the average dose does not exceed 5,000 millirems per year.

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VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the proposed Revision 2 to Regulatory Guide 8.13 (Task OP 031-4) when the draft guide was published for public comment in August 1981. No changes were necessary, so a separate value/impact statement for the final guide has not been prepared. A copy of the draft value/impact statement is available for inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC, under Task OP 031-4.

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U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
February 1996

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.29

(Draft was issued as DG-8012)

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12 of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," requires that all individuals who in the course of their employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) be instructed in the health protection issues associated with exposure to radioactive materials or radiation. Section 20.1206 of 10 CFR Part 20, "Standards for Protection Against Radiation," requires that before a planned special exposure occurs the individuals involved are, among other things, to be informed of the estimated doses and associated risks.

This regulatory guide describes the information that should be provided to workers by licensees about health risks from occupational exposure. This revision conforms to the revision of 10 CFR Part 20 that became effective on June 20, 1991, to be implemented by licensees no later than January 1, 1994. The revision of 10 CFR Part 20 establishes new dose limits based on the effective dose equivalent (EDE), requires the summing of internal and external dose, establishes a requirement that licensees use procedures and engineering controls to the extent practicable to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA), provides for planned special exposures, establishes a dose limit for the embryo/fetus of an occupationally exposed declared pregnant woman, and explicitly states that Part 20 is not to be construed as limiting action that may be necessary to protect health and safety during emergencies.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 19 or 10 CFR Part 20. These regulations provide the regulatory bases for this guide. The information collection requirements in 10 CFR Parts 19 and 20 have been cleared under OMB Clearance Nos. 3150-0044 and 3150-0014, respectively.

B. DISCUSSION

It is important to qualify the material presented in this guide with the following considerations.

The coefficient used in this guide for occupational radiation risk estimates, 4×10^{-4} health effects per rem, is based on data obtained at much higher doses and dose rates than those encountered by workers. The risk coefficient obtained at high doses and dose rates was reduced to account for the reduced effectiveness of lower doses and dose rates in producing the stochastic effects observed in studies of exposed humans.

The assumption of a linear extrapolation from the lowest doses at which effects are observable down to

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the occupational range has considerable uncertainty. The report of the Committee on the Biological Effects of Ionizing Radiation (Ref. 1) states that

> "... departure from linearity cannot be excluded at low doses below the range of observation. Such departures could be in the direction of either an increased or decreased risk. Moreover, epidemiologic data cannot rigorously exclude the existence of a threshold in the 100 mrem dose range. Thus, the possibility that there may be no risk from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero."

The issue of beneficial effects from low doses, or hormesis, in cellular systems is addressed by the United Nations Scientific Committee on the Effects of Atomic Radiation (Ref. 2). UNSCEAR states that "... it would be premature to conclude that cellular adaptive responses could convey possible beneficial effects to the organism that would outweigh the detrimental effects of exposures to low doses of low-LET radiation."

In the absence of scientific certainty regarding the relationship between low doses and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation can cause biological effects that may be harmful to the exposed person and that the magnitude or probability of these effects is directly proportional to the dose. These effects may be classified into three categories:

Somatic Effects: Physical effects occurring in the exposed person. These effects may be observable after a large or acute dose (e.g., 100 rems[1] (1 Sv) or more to the whole body in a few hours); or they may be effects such as cancer that may occur years after exposure to radiation.

Genetic Effects: Abnormalities that may occur in the future children of exposed individuals and in subsequent generations (genetic effects exceeding normal incidence have not been observed in any of the studies of human populations).

Teratogenic Effects: Effects such as cancer or congenital malformation that may be observed in children who were exposed during the fetal and embryonic stages of development (these effects have been observed from high, i.e., above 20 rems (0.2 Sv), acute exposures).

The normal incidence of effects from natural and manmade causes is significant. For example, approximately 20% of people die from various forms of cancer whether or not they ever receive occupational exposure to radiation. To avoid increasing the incidence of such biological effects, regulatory controls are imposed on occupational doses to adults and minors and on doses to the embryo/fetus from occupational exposures of declared pregnant women.

Radiation protection training for workers who are occupationally exposed to ionizing radiation is an essential component of any program designed to ensure compliance with NRC regulations. A clear understanding of what is presently known about the biological risks associated with exposure to radiation will result in more effective radiation protection training and should generate more interest on the part of the workers in complying with radiation protection standards. In addition, pregnant women and other occupationally exposed workers should have available to them relevant information on radiation risks to enable them to make informed decisions regarding the acceptance of these risks. It is intended that workers who receive this instruction will develop respect for the risks involved, rather than excessive fear or indifference.

C. REGULATORY POSITION

Instruction to workers performed in compliance with 10 CFR 19.12 should be given prior to occupational exposure and periodically thereafter. The frequency of retraining might range from annually for licensees with complex operations such as nuclear power plants, to every three years for licensees who possess, for example, only low-activity sealed sources. If a worker is to participate in a planned special exposure, the worker should be informed of the associated risks in compliance with 10 CFR 20.1206.

In providing instruction concerning health protection problems associated with exposure to radiation, all occupationally exposed workers and their supervisors should be given specific instruction on the risk of biological effects resulting from exposure to radiation. The extent of these instructions should be commensurate with the radiological risks present in the workplace.

The instruction should be presented orally, in printed form, or in any other effective communication media to workers and supervisors. The appendix to this guide provides useful information for demonstrating compliance with the training requirements in 10 CFR Parts 19 and 20. Individuals should be given an opportunity to discuss the information and to ask questions. Testing is recommended, and each trainee should be asked to acknowledge in writing that the instruction has been received and understood.

[1] In the International System of Units (SI), the rem is replaced by the sievert; 100 rems is equal to 1 sievert (Sv).

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant or licensee proposes acceptable alternative methods for complying with specified portions of the Commission's regulations, the guidance and instructional materials in this guide will be used in the evaluation of applications for new licenses, license renewals, and license amendments and for evaluating compliance with 10 CFR 19.12 and 10 CFR Part 20.

REFERENCES

1. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation*, Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.

2. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.

APPENDIX

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

This instructional material is intended to provide the user with the best available information about the health risks from occupational exposure to ionizing radiation. Ionizing radiation consists of energy or small particles, such as gamma rays and beta and alpha particles, emitted from radioactive materials, which can cause chemical or physical damage when they deposit energy in living tissue. A question and answer format is used. Many of the questions or subjects were developed by the NRC staff in consultation with workers, union representatives, and licensee representatives experienced in radiation protection training.

This Revision 1 to Regulatory Guide 8.29 updates the material in the original guide on biological effects and risks and on typical occupational exposure. Additionally, it conforms to the revised 10 CFR Part 20, "Standards for Protection Against Radiation," which was required to be implemented by licensees no later than January 1, 1994. The information in this appendix is intended to help develop respect by workers for the risks associated with radiation, rather than unjustified fear or lack of concern. Additional guidance concerning other topics in radiation protection training is provided in other NRC regulatory guides.

1. What is meant by health risk?

A health risk is generally thought of as something that may endanger health. Scientists consider health risk to be the statistical probability or mathematical chance that personal injury, illness, or death may result from some action. Most people do not think about health risks in terms of mathematics. Instead, most of us consider the health risk of a particular action in terms of whether we believe that particular action will, or will not, cause us some harm. The intent of this appendix is to provide estimates of, and explain the bases for, the risk of injury, illness, or death from occupational radiation exposure. Risk can be quantified in terms of the probability of a health effect per unit of dose received.

When x-rays, gamma rays, and ionizing particles interact with living materials such as our bodies, they may deposit enough energy to cause biological damage. Radiation can cause several different types of events such as the very small physical displacement of molecules, changing a molecule to a different form, or ionization, which is the removal of electrons from atoms and molecules. When the quantity of radiation energy deposited in living tissue is high enough, biological damage can occur as a result of chemical bonds being broken and cells being damaged or killed. These effects can result in observable clinical symptoms.

The basic unit for measuring absorbed radiation is the rad. One rad (0.01 gray in the International System of units) equals the absorption of 100 ergs (a small but measurable amount of energy) in a gram of material such as tissue exposed to radiation. To reflect biological risk, rads must be converted to rems. The new international unit is the sievert (100 rems = 1 Sv). This conversion accounts for the differences in the effectiveness of different types of radiation in causing damage. The rem is used to estimate biological risk. For beta and gamma radiation, a rem is considered equal to a rad.

2. What are the possible health effects of exposure to radiation?

Health effects from exposure to radiation range from no effect at all to death, including diseases such as leukemia or bone, breast, and lung cancer. Very high (100s of rads), short-term doses of radiation have been known to cause prompt (or early) effects, such as vomiting and diarrhea,[1] skin burns, cataracts, and even death. It is suspected that radiation exposure may be linked to the potential for genetic effects in the children of exposed parents. Also, children who were exposed to high doses (20 or more rads) of radiation prior to birth (as an embryo/fetus) have shown an increased risk of mental retardation and other congenital malformations. These effects (with the exception of genetic effects) have been observed in various studies of medical radiologists, uranium miners, radium workers, radiotherapy patients, and the people exposed to radiation from atomic bombs dropped on Japan. In addition, radiation effects studies with laboratory animals, in which the animals were given relatively high doses, have provided extensive data on radiation-induced health effects, including genetic effects.

It is important to note that these kinds of health effects result from high doses, compared to occupational levels, delivered over a relatively short period of time.

Although studies have not shown a consistent cause-and-effect relationship between current levels of occupational radiation exposure and biological effects, it is prudent from a worker protection perspective to assume that some effects may occur.

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[1] These symptoms are early indicators of what is referred to as the acute radiation syndrome, caused by high doses delivered over a short time period, which includes damage to the blood-forming organs such as bone marrow, damage to the gastrointestinal system, and, at very high doses, can include damage to the central nervous system.

3. What is meant by early effects and delayed or late effects?

EARLY EFFECTS

Early effects, which are also called immediate or prompt effects, are those that occur shortly after a large exposure that is delivered within hours to a few days. They are observable after receiving a very large dose in a short period of time, for example, 300 rads (3 Gy) received within a few minutes to a few days. Early effects are not caused at the levels of radiation exposure allowed under the NRC's occupational limits.

Early effects occur when the radiation dose is large enough to cause extensive biological damage to cells so that large numbers of cells are killed. For early effects to occur, this radiation dose must be received within a short time period. This type of dose is called an acute dose or acute exposure. The same dose received over a long time period would not cause the same effect. Our body's natural biological processes are constantly repairing damaged cells and replacing dead cells; if the cell damage is spread over time, our body is capable of repairing or replacing some of the damaged cells, reducing the observable adverse conditions.

For example, a dose to the whole body of about 300–500 rads (3–5 Gy), more than 60 times the annual occupational dose limit, if received within a short time period (e.g., a few hours) will cause vomiting and diarrhea within a few hours; loss of hair, fever, and weight loss within a few weeks; and about a 50 percent chance of death if medical treatment is not provided. These effects would not occur if the same dose were accumulated gradually over many weeks or months (Refs. 1 and 2). Thus, one of the justifications for establishing annual dose limits is to ensure that occupational dose is spread out in time.

It is important to distinguish between whole body and partial body exposure. A localized dose to a small volume of the body would not produce the same effect as a whole body dose of the same magnitude. For example, if only the hand were exposed, the effect would mainly be limited to the skin and underlying tissue of the hand. An acute dose of 400 to 600 rads (4–6 Gy) to the hand would cause skin reddening; recovery would occur over the following months and no long-term damage would be expected. An acute dose of this magnitude to the whole body could cause death within a short time without medical treatment. Medical treatment would lessen the magnitude of the effects and the chance of death; however, it would not totally eliminate the effects or the chance of death.

DELAYED EFFECTS

Delayed effects may occur years after exposure. These effects are caused indirectly when the radiation changes parts of the cells in the body, which causes the normal function of the cell to change, for example, normal healthy cells turn into cancer cells. The potential for these delayed health effects is one of the main concerns addressed when setting limits on occupational doses.

A delayed effect of special interest is genetic effects. Genetic effects may occur if there is radiation damage to the cells of the gonads (sperm or eggs). These effects may show up as genetic defects in the children of the exposed individual and succeeding generations. However, if any genetic effects (i.e., effects in addition to the normal expected number) have been caused by radiation, the numbers are too small to have been observed in human populations exposed to radiation. For example, the atomic bomb survivors (from Hiroshima and Nagasaki) have not shown any significant radiation-related increases in genetic defects (Ref. 3). Effects have been observed in animal studies conducted at very high levels of exposure and it is known that radiation can cause changes in the genes in cells of the human body. However, it is believed that by maintaining worker exposures below the NRC limits and consistent with ALARA, a margin of safety is provided such that the risk of genetic effects is almost eliminated.

4. What is the difference between acute and chronic radiation dose?

Acute radiation dose usually refers to a large dose of radiation received in a short period of time. Chronic dose refers to the sum of small doses received repeatedly over long time periods, for example, 20 mrem (or millirem, which is 1-thousandth of a rem) (0.2 mSv) per week every week for several years. It is assumed for radiation protection purposes that any radiation dose, either acute or chronic, may cause delayed effects. However, only large acute doses cause early effects; chronic doses within the occupational dose limits do not cause early effects. Since the NRC limits do not permit large acute doses, concern with occupational radiation risk is primarily focused on controlling chronic exposure for which possible delayed effects, such as cancer, are of concern.

The difference between acute and chronic radiation exposure can be shown by using exposure to the sun's rays as an example. An intense exposure to the sun can result in painful burning, peeling, and growing of new skin. However, repeated short exposures provide time for the skin to be repaired between exposures. Whether exposure to the sun's rays is long term or spread over short periods, some of the injury may not be repaired and may eventually result in skin cancer.

Cataracts are an interesting case because they can be caused by both acute and chronic radiation. A certain threshold level of dose to the lens of the eye is required before there is any observable visual impairment, and the impairment remains after the exposure is stopped. The threshold for cataract development

from acute exposure is an acute dose on the order of 100 rads (1 Gy). Further, a cumulative dose of 800 rads (8 Gy) from protracted exposures over many years to the lens of the eye has been linked to some level of visual impairment (Refs. 1 and 4). These doses exceed the amount that may be accumulated by the lens from normal occupational exposure under the current regulations.

5. What is meant by external and internal exposure?

A worker's occupational dose may be caused by exposure to radiation that originates outside the body, called "external exposure," or by exposure to radiation from radioactive material that has been taken into the body, called "internal exposure." Most NRC-licensed activities involve little, if any, internal exposure. It is the current scientific consensus that a rem of radiation dose has the same biological risk regardless of whether it is from an external or an internal source. The NRC requires that dose from external exposure and dose from internal exposure be added together, if each exceeds 10% of the annual limit, and that the total be within occupational limits. The sum of external and internal dose is called the total effective dose equivalent (TEDE) and is expressed in units of rems (Sv).

Although unlikely, radioactive materials may enter the body through breathing, eating, drinking, or open wounds, or they may be absorbed through the skin. The intake of radioactive materials by workers is generally due to breathing contaminated air. Radioactive materials may be present as fine dust or gases in the workplace atmosphere. The surfaces of equipment and workbenches may be contaminated, and these materials can be resuspended in air during work activities.

If any radioactive material enters the body, the material goes to various organs or is excreted, depending on the biochemistry of the material. Most radioisotopes are excreted from the body in a few days. For example, a fraction of any uranium taken into the body will deposit in the bones, where it remains for a longer time. Uranium is slowly eliminated from the body, mostly by way of the kidneys. Most workers are not exposed to uranium. Radioactive iodine is preferentially deposited in the thyroid gland, which is located in the neck.

To limit risk to specific organs and the total body, an annual limit on intake (ALI) has been established for each radionuclide. When more than one radionuclide is involved, the intake amount of each radionuclide is reduced proportionally. NRC regulations specify the concentrations of radioactive material in the air to which a worker may be exposed for 2,000 working hours in a year. These concentrations are termed the derived air concentrations (DACs). These limits are the total amounts allowed if no external radiation is received. The resulting dose from the internal radiation sources (from breathing air at 1 DAC) is the maximum allowed to an organ or to the worker's whole body.

6. How does radiation cause cancer?

The mechanisms of radiation-induced cancer are not completely understood. When radiation interacts with the cells of our bodies, a number of events can occur. The damaged cells can repair themselves and permanent damage is not caused. The cells can die, much like the large numbers of cells that die every day in our bodies, and be replaced through the normal biological processes. Or a change can occur in the cell's reproductive structure, the cells can mutate and subsequently be repaired without effect, or they can form precancerous cells, which may become cancerous. Radiation is only one of many agents with the potential for causing cancer, and cancer caused by radiation cannot be distinguished from cancer attributable to any other cause.

Radiobiologists have studied the relationship between large doses of radiation and cancer (Refs. 5 and 6). These studies indicate that damage or change to genes in the cell nucleus is the main cause of radiation-induced cancer. This damage may occur directly through the interaction of the ionizing radiation in the cell or indirectly through the actions of chemical products produced by radiation interactions within cells. Cells are able to repair most damage within hours; however, some cells may not be repaired properly. Such misrepaired damage is thought to be the origin of cancer, but misrepair does not always cause cancer. Some cell changes are benign or the cell may die; these changes do not lead to cancer.

Many factors such as age, general health, inherited traits, sex, as well as exposure to other cancer-causing agents such as cigarette smoke can affect susceptibility to the cancer-causing effects of radiation. Many diseases are caused by the interaction of several factors, and these interactions appear to increase the susceptibility to cancer.

7. Who developed radiation risk estimates?

Radiation risk estimates were developed by several national and international scientific organizations over the last 40 years. These organizations include the National Academy of Sciences (which has issued several reports from the Committee on the Biological Effects of Ionizing Radiations, BEIR), the National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). Each of these organizations continues to review new research findings on radiation health risks.

Several reports from these organizations present new findings on radiation risks based upon revised estimates of radiation dose to survivors of the atomic bombing at Hiroshima and Nagasaki. For example, UNSCEAR published risk estimates in 1988 and 1993 (Refs. 5 and 6). The NCRP also published a report in 1988, "New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates" (Ref. 7). In January 1990, the National Academy of Sciences released the fifth report of the BEIR Committee, "Health Effects of Exposure to Low Levels of Ionizing Radiation" (Ref. 4). Each of these publications also provides extensive bibliographies on other published studies concerning radiation health effects for those who may wish to read further on this subject.

8. What are the estimates of the risk of fatal cancer from radiation exposure?

We don't know exactly what the chances are of getting cancer from a low-level radiation dose, primarily because the few effects that may occur cannot be distinguished from normally occurring cancers. However, we can make estimates based on extrapolation from extensive knowledge from scientific research on high dose effects. The estimates of radiation effects at high doses are better known than are those of most chemical carcinogens (Ref. 8).

From currently available data, the NRC has adopted a risk value for an occupational dose of 1 rem (0.01 Sv) Total Effective Dose Equivalent (TEDE) of 4 in 10,000 of developing a fatal cancer, or approximately 1 chance in 2,500 of fatal cancer per rem of TEDE received. The uncertainty associated with this risk estimate does not rule out the possibility of higher risk, or the possibility that the risk may even be zero at low occupational doses and dose rates.

The radiation risk incurred by a worker depends on the amount of dose received. Under the linear model explained above, a worker who receives 5 rems (0.05 Sv) in a year incurs 10 times as much risk as another worker who receives only 0.5 rem (0.005 Sv). Only a very few workers receive doses near 5 rems (0.05 Sv) per year (Ref. 9).

According to the BEIR V report (Ref. 4), approximately one in five adults normally will die from cancer from all possible causes such as smoking, food, alcohol, drugs, air pollutants, natural background radiation, and inherited traits. Thus, in any group of 10,000 workers, we can estimate that about 2,000 (20%) will die from cancer without any occupational radiation exposure.

To explain the significance of these estimates, we will use as an example a group of 10,000 people, each exposed to 1 rem (0.01 Sv) of ionizing radiation. Using the risk factor of 4 effects per 10,000 rem of dose, we estimate that 4 of the 10,000 people might die from delayed cancer because of that 1-rem dose (although the actual number could be more or less than 4) in addition to the 2,000 normal cancer fatalities expected to occur in that group from all other causes. This means that a 1-rem (0.01 Sv) dose may increase an individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 10 rems, we could raise the estimate to 20.4 percent. A lifetime dose of 100 rems may increase chances of dying from cancer from 20 to 24 percent. The average measurable dose for radiation workers reported to the NRC was 0.31 rem (0.0031 Sv) for 1993 (Ref. 9). Today, very few workers ever accumulate 100 rems (1 Sv) in a working lifetime, and the average career dose of workers at NRC-licensed facilities is 1.5 rems (0.015 Sv), which represents an estimated increase from 20 to about 20.06 percent in the risk of dying from cancer.

It is important to understand the probability factors here. A similar question would be, "If you select one card from a full deck of cards, will you get the ace of spades?" This question cannot be answered with a simple yes or no. The best answer is that your chance is 1 in 52. However, if 1000 people each select one card from full decks, we can predict that about 20 of them will get an ace of spades. Each person will have 1 chance in 52 of drawing the ace of spades, but there is no way we can predict which persons will get that card. The issue is further complicated by the fact that in a drawing by 1000 people, we might get only 15 successes, and in another, perhaps 25 correct cards in 1000 draws. We can say that if you receive a radiation dose, you will have increased your chances of eventually developing cancer. It is assumed that the more radiation exposure you get, the more you increase your chances of cancer.

The normal chance of dying from cancer is about one in five for persons who have not received any occupational radiation dose. The additional chance of developing fatal cancer from an occupational exposure of 1 rem (0.01 Sv) is about the same as the chance of drawing any ace from a full deck of cards three times in a row. The additional chance of dying from cancer from an occupational exposure of 10 rem (0.1 Sv) is about equal to your chance of drawing two aces successively on the first two draws from a full deck of cards.

It is important to realize that these risk numbers are only estimates based on data for people and research animals exposed to high levels of radiation in short periods of time. There is still uncertainty with regard to estimates of radiation risk from low levels of exposure. Many difficulties are involved in designing research studies that can accurately measure the projected small increases in cancer cases that might be caused by low exposures to radiation as compared to the normal rate of cancer.

These estimates are considered by the NRC staff to be the best available for the worker to use to make an informed decision concerning acceptance of the risks associated with exposure to radiation. A worker who decides to accept this risk should try to keep exposure to radiation as low as is reasonably achievable (ALARA) to avoid unnecessary risk.

9. If I receive a radiation dose that is within occupational limits, will it cause me to get cancer?

Probably not. Based on the risk estimates previously discussed, the risk of cancer from doses below the occupational limits is believed to be small. Assessment of the cancer risks that may be associated with low doses of radiation are projected from data available at doses larger than 10 rems (0.1 Sv) (Ref. 3). For radiation protection purposes, these estimates are made using the straight line portion of the linear quadratic model (Curve 2 in Figure 1). We have data on cancer probabilities only for high doses, as shown by the solid line in Figure 1. Only in studies involving radiation doses above occupational limits are there dependable determinations of the risk of cancer, primarily because below the limits the effect is small compared to differences in the normal cancer incidence from year to year and place to place. The ICRP, NCRP, and other standards-setting organizations assume for radiation protection purposes that there is some risk, no matter how small the dose (Curves 1 and 2). Some scientists believe that the risk drops off to zero at some low dose (Curve 3), the threshold effect. The ICRP and NCRP endorse the linear quadratic model as a conservative means of assuring safety (Curve 2).

For regulatory purposes, the NRC uses the straight line portion of Curve 2, which shows the number of effects decreasing linearly as the dose decreases. Because the scientific evidence does not conclusively demonstrate whether there is or is not an effect at low doses, the NRC assumes for radiation protection purposes, that even small doses have some chance of causing cancer. Thus, a principle of radiation protection is to do more than merely meet the allowed regulatory limits; doses should be kept as low as is reasonably achievable (ALARA). This is as true for natural carcinogens such as sunlight and natural radiation as it is for those that are manmade, such as cigarette smoke, smog, and x-rays.

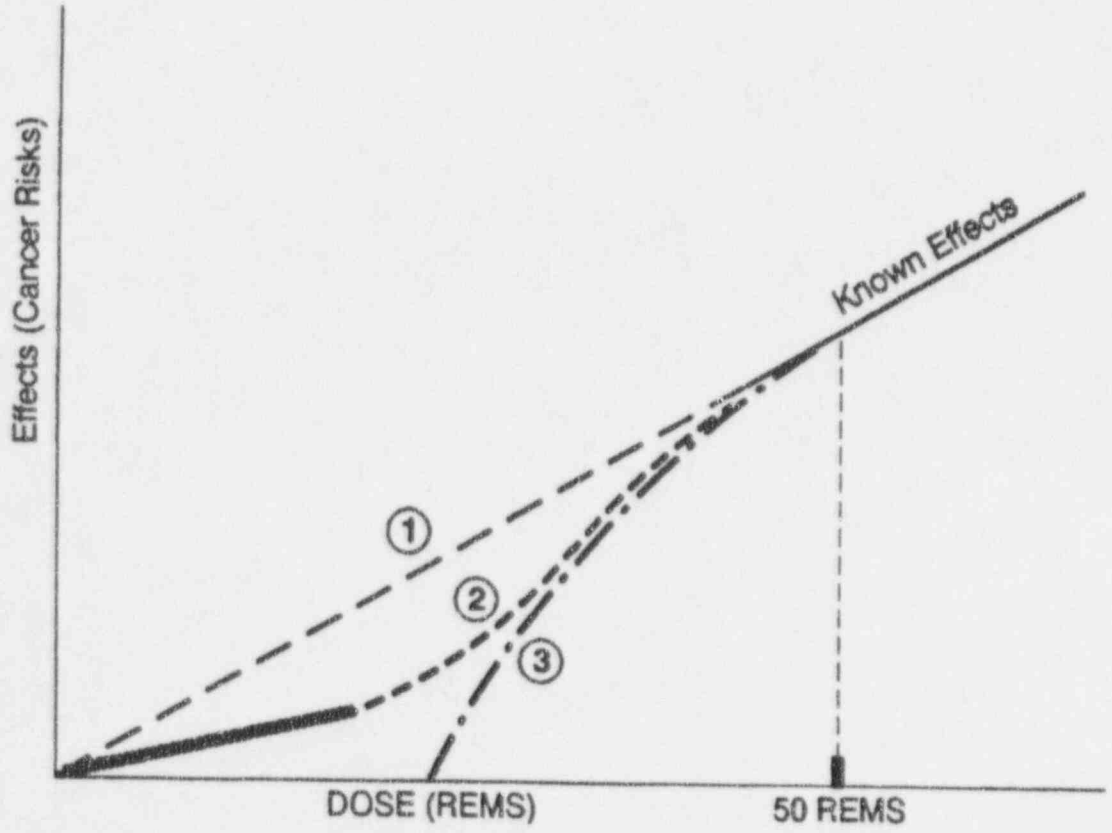

Figure 1. Some Proposed Models for How the Effects of Radiation Vary With Doses at Low Levels

10. How can we compare the risk of cancer from radiation to other kinds of health risks?

One way to make these comparisons is to compare the average number of days of life expectancy lost because of the effects associated with each particular health risk. Estimates are calculated by looking at a large number of persons, recording the age when death occurs from specific causes, and estimating the average number of days of life lost as a result of these early deaths. The total number of days of life lost is then averaged over the total observed group.

Several studies have compared the average days of life lost from exposure to radiation with the number of days lost as a result of being exposed to other health risks. The word "average" is important because an individual who gets cancer loses about 15 years of life expectancy, while his or her coworkers do not suffer any loss.

Some representative numbers are presented in Table 1. For categories of NRC-regulated industries with larger doses, the average measurable occupational dose in 1993 was 0.31 rem (0.0031 Sv). A simple calculation based on the article by Cohen and Lee (Ref. 10) shows that 0.3 rem (0.003 Sv) per year from age 18 to 65 results in an average loss of 15 days. These estimates indicate that the health risks from occupational radiation exposure are smaller than the risks associated with many other events or activities we encounter and accept in normal day-to-day activities.

It is also useful to compare the estimated average number of days of life lost from occupational exposure to radiation with the number of days lost as a result of working in several types of industries. Table 2 shows average days of life expectancy lost as a result of fatal work-related accidents. Table 2 does not include non-accident types of occupational risks such as occupational disease and stress because the data are not available.

These comparisons are not ideal because we are comparing the possible effects of chronic exposure to radiation to different kinds of risk such as accidental death, in which death is inevitable if the event occurs. This is the best we can do because good data are not available on chronic exposure to other workplace carcinogens. Also, the estimates of loss of life expectancy for workers from radiation-induced cancer do not take into consideration the competing effect on the life expectancy of the workers from industrial accidents.

11. What are the health risks from radiation exposure to the embryo/fetus?

During certain stages of development, the embryo/fetus is believed to be more sensitive to radiation damage than adults. Studies of atomic bomb survivors exposed to acute radiation doses exceeding 20 rads (0.2 Gy) during pregnancy show that children born after receiving these doses have a higher risk of mental retardation. Other studies suggest that an association exists between exposure to diagnostic x-rays before birth and carcinogenic effects in childhood and in adult life. Scientists are uncertain about the magnitude of the risk. Some studies show the embryo/fetus to be more sensitive to radiation-induced cancer than adults, but other studies do not. In recognition of the possibility of increased radiation sensitivity, and because dose to the

Table 1 Estimated Loss of Life Expectancy from Health Risks[a]

Health Risk		*Estimate of Life Expectancy Lost (average)*
Smoking 20 cigarettes a day		6 years
Overweight (by 15%)		2 years
Alcohol consumption (U.S. average)		1 year
All accidents combined		1 year
Motor vehicle accidents	207 days	
Home accidents	74 days	
Drowning	24 days	
All natural hazards (earthquake, lightning, flood, etc.)		7 days
Medical radiation		6 days
Occupational Exposure		
0.3 rem/y from age 18 to 65	15 days	
1 rem/y from age 18 to 65	51 days	

[a]Adapted from Reference 10.

Table 2 Estimated Loss of Life Expectancy from Industrial Accidents[a]

Industry Type	*Estimated Days of Life Expectancy Lost (Average)*
All industries	60
Agriculture	320
Construction	227
Mining and Quarrying	167
Transportation and Public Utilities	160
Government	60
Manufacturing	40
Trade	27
Services	27

[a]Adapted from Reference 10.

embryo/fetus is involuntary on the part of the embryo/fetus, a more restrictive dose limit has been established for the embryo/fetus of a declared pregnant radiation worker. See Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure."

If an occupationally exposed woman declares her pregnancy in writing, she is subject to the more restrictive dose limits for the embryo/fetus during the remainder of the pregnancy. The dose limit of 500 mrems (5 mSv) for the total gestation period applies to the embryo/fetus and is controlled by restricting the exposure to the declared pregnant woman. Restricting the woman's occupational exposure, if she declares her pregnancy, raises questions about individual privacy rights, equal employment opportunities, and the possible loss of income. Because of these concerns, the declaration of pregnancy by a female radiation worker is voluntary. Also, the declaration of pregnancy can be withdrawn for any reason, for example, if the woman believes that her benefits from receiving the occupational exposure would outweigh the risk to her embryo/fetus from the radiation exposure.

12. Can a worker become sterile or impotent from normal occupational radiation exposure?

No. Temporary or permanent sterility cannot be caused by radiation at the levels allowed under NRC's occupational limits. There is a threshold below which these effects do not occur. Acute doses on the order of 10 rems (0.1 Sv) to the testes can result in a measurable but temporary reduction in sperm count. Temporary sterility (suppression of ovulation) has been observed in women who have received acute doses of 150 rads (1.5 Gy). The estimated threshold (acute) radiation dose for induction of permanent sterility is about 200 rads (2 Gy) for men and about 350 rads (3.5 Gy) for women (Refs. 1 and 9). These doses are far greater than the NRC s occupational dose limits for workers.

Although acute doses can affect fertility by reducing sperm count or suppressing ovulation, they do not have any direct effect on one's ability to function sexually. No evidence exists to suggest that exposures within the NRC's occupational limits have any effect on the ability to function sexually.

13. What are the NRC occupational dose limits?

For adults, an annual limit that does not exceed:

- 5 rems (0.05 Sv) for the total effective dose equivalent (TEDE), which is the sum of the deep dose equivalent (DDE) from external exposure to the whole body and the committed effective dose equivalent (CEDE) from intakes of radioactive material.
- 50 rems (0.5 Sv) for the total organ dose equivalent (TODE), which is the sum of the DDE from external exposure to the whole body and the committed dose equivalent (CDE) from intakes of radioactive material to any individual organ or tissue, other than the lens of the eye.
- 15 rems (0.15 Sv) for the lens dose equivalent (LDE), which is the external dose to the lens of the eye.
- 50 rems (0.5 Sv) for the shallow dose equivalent (SDE), which is the external dose to the skin or to any extremity.

For minor workers, the annual occupational dose limits are 10 percent of the dose limits for adult workers.

For protection of the embryo/fetus of a declared pregnant woman, the dose limit is 0.5 rem (5 mSv) during the entire pregnancy.

The occupational dose limit for adult workers of 5 rems (0.05 Sv) TEDE is based on consideration of the potential for delayed biological effects. The 5-rem (0.05 Sv) limit, together with application of the concept of keeping occupational doses ALARA, provides a level of risk of delayed effects considered acceptable by the NRC. The limits for individual organs are below the dose levels at which early biological effects are observed in the individual organs.

The dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of the possibility of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure.

14. What is meant by ALARA?

ALARA means "as low as is reasonably achievable." In addition to providing an upper limit on an individual's permissible radiation dose, the NRC requires that its licensees establish radiation protection

programs and use procedures and engineering controls to achieve occupational doses, and doses to the public, as far below the limits as is reasonably achievable. "Reasonably achievable" also means "to the extent practicable." What is practicable depends on the purpose of the job, the state of technology, the costs for averting doses, and the benefits. Although implementation of the ALARA principle is a required integral part of each licensee's radiation protection program, it does not mean that each radiation exposure must be kept to an absolute minimum, but rather that "reasonable" efforts must be made to avert dose. In practice, ALARA includes planning tasks involving radiation exposure so as to reduce dose to individual workers and the work group.

There are several ways to control radiation doses, e.g., limiting the time in radiation areas, maintaining distance from sources of radiation, and providing shielding of radiation sources to reduce dose. The use of engineering controls, from the design of facilities and equipment to the actual set-up and conduct of work activities, is also an important element of the ALARA concept.

An ALARA analysis should be used in determining whether the use of respiratory protection is advisable. In evaluating whether or not to use respirators, the goal should be to achieve the optimal sum of external and internal doses. For example, the use of respirators can lead to increased work time within radiation areas, which increases external dose. The advantage of using respirators to reduce internal exposure must be evaluated against the increased external exposure and related stresses caused by the use of respirators. Heat stress, reduced visibility, and reduced communication associated with the use of respirators could expose a worker to far greater risks than are associated with the internal dose avoided by use of the respirator. To the extent practical, engineering controls, such as containments and ventilation systems, should be used to reduce workplace airborne radioactive materials.

15. What are background radiation exposures?

The average person is constantly exposed to ionizing radiation from several sources. Our environment and even the human body contain naturally occurring radioactive materials (e.g., potassium-40) that contribute to the radiation dose that we receive. The largest source of natural background radiation exposure is terrestrial radon, a colorless, odorless, chemically inert gas, which causes about 55 percent of our average, nonoccupational exposure. Cosmic radiation originating in space contributes additional exposure. The use of x-rays and radioactive materials in medicine and dentistry adds to our population exposure. As shown below in Table 3, the average person receives an annual radiation dose of about 0.36 rem (3.6 mSv). By age 20, the average person will accumulate over 7 rems (70 mSv) of dose. By age 50, the total dose is up to 18 rems (180 mSv). After 70 years of exposure this dose is up to 25 rems (250 mSv).

Table 3 Average Annual Effective Dose Equivalent to Individuals in the U.S.[a]

Source	*Effective Dose Equivalent (mrems)*	
Natural		
Radon	200	
Other than Radon	100	
Total		300
Nuclear Fuel Cycle		0.05
Consumer Products[b]		9
Medical		
Diagnostic X-rays	39	
Nuclear Medicine	14	
Total		53
Total		about 360 mrems/year

[a]Adapted from Table 8.1, NCRP 93 (Ref. 11).

[b]Includes building material, television receivers, luminous watches, smoke detectors, etc. (from Table 5.1, NCRP 93, Ref. 11).

16. What are the typical radiation doses received by workers?

For 1993, the NRC received reports on about a quarter of a million people who were monitored for occupational exposure to radiation. Almost half of those monitored had no measurable doses. The other half had an average dose of about 310 mrem (3.1 mSv) for the year. Of these, 93 percent received an annual dose of less than 1 rem (10 mSv); 98.7 percent received less than 2 rems (20 mSv); and the highest reported dose was for two individuals who each received between 5 and 6 rems (50 and 60 mSv).

Table 4 lists average occupational doses for workers (persons who had measurable doses) in various occupations based on 1993 data. It is important to note that beginning in 1994, licensees have been required to sum external and internal doses and certain licensees are required to submit annual reports. Certain types of licensees such as nuclear fuel fabricators may report a significant increase in worker doses because of the exposure to long-lived airborne radionuclides and the requirement to add the resultant internal dose to the calculation of occupational doses.

Table 4 Reported Occupational Doses for 1993[a]

Occupational Subgroup	Average Measurable Dose per Worker (millirems)
Industrial Radiography	540
Commercial Nuclear Power Reactors	310
Manufacturing and Distribution of Radioactive Materials	300
Low-Level Radioactive Waste Disposal	270
Independent Spent Nuclear Fuel Storage	260
Nuclear Fuel Fabrication	130

[a]From Table 3.1 in NUREG-0713 (Ref. 9).

17. How do I know how much my occupational dose (exposure) is?

If you are likely to receive more than 10 percent of the annual dose limits, the NRC requires your employer, the NRC licensee, to monitor your dose, to maintain records of your dose, and, at least on an annual basis for the types of licensees listed in 10 CFR 20.2206, "Reports of Individual Monitoring," to inform both you and the NRC of your dose. The purpose of this monitoring and reporting is so that the NRC can be sure that licensees are complying with the occupational dose limits and the ALARA principle.

External exposures are monitored by using individual monitoring devices. These devices are required to be used if it appears likely that external exposure will exceed 10 percent of the allowed annual dose, i.e., 0.5 rem (5 mSv). The most commonly used monitoring devices are film badges, thermoluminescence dosimeters (TLDs), electronic dosimeters, and direct reading pocket dosimeters.

With respect to internal exposure, your employer is required to monitor your occupational intake of radioactive material and assess the resulting dose if it appears likely that you will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in 1 year. Internal exposure can be estimated by measuring the radiation emitted from the body (for example, with a "whole body counter") or by measuring the radioactive materials contained in biological samples such as urine or feces. Dose estimates can also be made if one knows how much radioactive material was in the air and the length of time during which the air was breathed.

18. What happens if a worker exceeds the annual dose limit?

If a worker receives a dose in excess of any of the annual dose limits, the regulations prohibit any occupational exposure during the remainder of the year in which the limit is exceeded. The licensee is also required to file an overexposure report with the NRC and provide a copy to the individual who received the dose. The licensee may be subject to NRC enforcement action such as a fine (civil penalty), just as individuals are subject to a traffic fine for exceeding a speed limit. The fines and, in some serious or repetitive cases, suspension of a license are intended to encourage licensees to comply with the regulations.

Radiation protection limits do not define safe or unsafe levels of radiation exposure. Exceeding a limit does not mean that you will get cancer. For radiation protection purposes, it is assumed that risks are related to the size of the radiation dose. Therefore, when your dose is higher your risk is also considered to be higher. These limits are similar to highway speed limits. If you drive at 70 mph, your risk is higher than at 55 mph, even though you may not actually have an accident. Those who set speed limits have determined that the risks of driving in excess of the speed limit are not acceptable. In the same way, the revised 10 CFR Part 20 establishes a limit for normal occupational exposure of 5 rems (0.05 Sv) a year. Although you will not necessarily get cancer or some other radiation effect at doses above the limit, it does mean that the licensee's safety program has failed in some way. Investigation is warranted to determine the cause and correct the conditions leading to the dose in excess of the limit.

19. What is meant by a "planned special exposure"?

A "planned special exposure" (PSE) is an infrequent exposure to radiation, separate from and in addition to the radiation received under the annual occupational limits. The licensee can authorize additional dose in any one year that is equal to the annual occupational dose limit as long as the individual's total dose from PSEs does not exceed five times the annual dose limit during the individual's lifetime. For example, licensees may authorize PSEs for an adult radiation worker to receive doses up to an additional 5 rems (0.05 Sv) in a year above the 5-rem (0.05-Sv) annual TEDE occupational dose limit. Each worker is limited to no more than 25 rems (0.25 Sv) from planned special exposures in his or her lifetime. Such exposures are only allowed in exceptional situations when alternatives for avoiding the additional exposure are not available or are impractical.

Before the licensee authorizes a PSE, the licensee must ensure that the worker is informed of the purpose and circumstances of the planned operation, the estimated doses expected, and the procedures to keep the doses ALARA while considering other risks that may

be present. (See Regulatory Guide 8.35, "Planned Special Exposures.")

20. Why do some facilities establish administrative control levels that are below the NRC limits?

There are two reasons. First, the NRC regulations state that licensees must take steps to keep exposures to radiation ALARA. Specific approval from the licensee for workers to receive doses in excess of administrative limits usually results in more critical risk-benefit analyses as each additional increment of dose is approved for a worker. Secondly, an administrative control level that is set lower than the NRC limit provides a safety margin designed to help the licensee avoid doses to workers in excess of the limit.

21. Why aren't medical exposures considered as part of a worker's allowed dose?

NRC rules exempt medical exposure, but equal doses of medical and occupational radiation have equal risks. Medical exposure to radiation is justified for reasons that are quite different from the reasons for occupational exposure. A physician prescribing an x-ray, for example, makes a medical judgment that the benefit to the patient from the resulting medical information justifies the risk associated with the radiation. This judgment may or may not be accepted by the patient. Similarly, each worker must decide on the benefits and acceptability of occupational radiation risk, just as each worker must decide on the acceptability of any other occupational hazard.

Consider a worker who receives a dose of 3 rems (0.03 Sv) from a series of x-rays in connection with an injury or illness. This dose and any associated risk must be justified on medical grounds. If the worker had also received 2 rems (0.02 Sv) on the job, the combined dose of 5 rems (0.05 Sv) would in no way incapacitate the worker. Restricting the worker from additional job exposure during the remainder of the year would not have any effect on the risk from the 3 rems (0.03 Sv) already received from the medical exposure. If the individual worker accepts the risks associated with the x-rays on the basis of the medical benefits and accepts the risks associated with job-related exposure on the basis of employment benefits, it would be unreasonable to restrict the worker from employment involving exposure to radiation for the remainder of the year.

22. How should radiation risks be considered in an emergency?

Emergencies are "unplanned" events in which actions to save lives or property may warrant additional doses for which no particular limit applies. The revised 10 CFR Part 20 does not set any dose limits for emergency or lifesaving activities and states that nothing in Part 20 "shall be construed as limiting actions that may be necessary to protect health and safety."

Rare situations may occur in which a dose in excess of occupational limits would be unavoidable in order to carry out a lifesaving operation or to avoid a large dose to large populations. However, persons called upon to undertake any emergency operation should do so only on a voluntary basis and with full awareness of the risks involved.

For perspective, the Environmental Protection Agency (EPA) has published emergency dose guidelines (Ref. 2). These guidelines state that doses to all workers during emergencies should, to the extent practicable, be limited to 5 rems (0.05 Sv). The EPA further states that there are some emergency situations for which higher limits may be justified. The dose resulting from such emergency exposures should be limited to 10 rems (0.1 Sv) for protecting valuable property, and to 25 rems (0.25 Sv) for lifesaving activities and the protection of large populations. In the context of this guidance, the dose to workers that is incurred for the protection of large populations might be considered justified for situations in which the collective dose to others that is avoided as a result of the emergency operation is significantly larger than that incurred by the workers involved.

Table 5 presents the estimates of the fatal cancer risk for a group of 1,000 workers of various ages, assuming that each worker received an acute dose of 25 rems (0.25 Sv) in the course of assisting in an emergency. The estimates show that a 25-rem emergency dose might increase an individual's chances of developing fatal cancer from about 20% to about 21%.

Table 5
Risk of Premature Death from Exposure to 25-Rems (0.25-Sv) Acute Dose

Age at Exposure (years)	*Estimated Risk of Premature Death (Deaths per 1,000 Persons Exposed)*
20–30	9.1
30–40	7.2
40–50	5.3
50–60	3.5

Source: EPA-400-R-92-001 (Ref. 2).

23. How were radiation dose limits established?

The NRC radiation dose limits in 10 CFR Part 20 were established by the NRC based on the recommendations of the ICRP and NCRP as endorsed in Federal radiation protection guidance developed by the EPA

(Ref. 12). The limits were recommended by the ICRP and NCRP with the objective of ensuring that working in a radiation-related industry was as safe as working in other comparable industries. The dose limits and the principle of ALARA should ensure that risks to workers are maintained indistinguishable from risks from background radiation.

24. Several scientific reports have recommended that the NRC establish lower dose limits. Does the NRC plan to reduce the regulatory limits?

Since publication of the NRC's proposed rule in 1986, the ICRP in 1990 revised its recommendations for radiation protection based on newer studies of radiation risks (Ref. 13), and the NCRP followed with a revision to its recommendations in 1993. The ICRP recommended a limit of 10 rems (0.1 Sv) effective dose equivalent (from internal and external sources), over a 5-year period with no more than 5 rems (0.05 Sv) in 1 year (Ref. 13). The NCRP recommended a cumulative limit in rems, not to exceed the individual's age in years, with no more than 5 rems (0.05 Sv) in any year (Ref. 14).

The NRC does not believe that additional reductions in the dose limits are required at this time. Because of the practice of maintaining radiation exposures ALARA (as low as is reasonably achievable), the average radiation dose to occupationally exposed persons is well below the limits in the current Part 20 that became mandatory January 1, 1994, and the average doses to radiation workers are below the new limits recommended by the ICRP and the NCRP.

25. What are the options if a worker decides that the risks associated with occupational radiation exposure are too high?

If the risks from exposure to occupational radiation are unacceptable to a worker, he or she can request a transfer to a job that does not involve exposure to radiation. However, the risks associated with the exposure to radiation that workers, on the average, actually receive are comparable to risks in other industries and are considered acceptable by the scientific groups that have studied them. An employer is not obligated to guarantee a transfer if a worker decides not to accept an assignment that requires exposure to radiation.

Any worker has the option of seeking other employment in a nonradiation occupation. However, the studies that have compared occupational risks in the nuclear industry to those in other job areas indicate that nuclear work is relatively safe. Thus, a worker may find different kinds of risk but will not necessarily find significantly lower risks in another job.

26. Where can one get additional information on radiation risk?

The following list suggests sources of useful information on radiation risk:

- The employer—the radiation protection or health physics office where a worker is employed.
- Nuclear Regulatory Commission Regional Offices:

King of Prussia, Pennsylvania	(610) 337-5000
Atlanta, Georgia	(404) 331-4503
Lisle, Illinois	(708) 829-9500
Arlington, Texas	(817) 860-8100

- U.S. Nuclear Regulatory Commission
  Headquarters
  Radiation Protection & Health Effects Branch
  Office of Nuclear Regulatory Research
  Washington, DC 20555
  Telephone: (301) 415-6187
- Department of Health and Human Services
  Center for Devices and Radiological Health
  1390 Piccard Drive, MS HFZ-1
  Rockville, MD 20850
  Telephone: (301) 443-4690
- U.S. Environmental Protection Agency
  Office of Radiation and Indoor Air
  Criteria and Standards Division
  401 M Street NW.
  Washington, DC 20460
  Telephone: (202) 233-9290

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10. B.L. Cohen and I.S. Lee, "Catalog of Risks Extended and Updated," *Health Physics*, Vol. 61, September 1991.

11. National Council on Radiation Protection and Measurements, *Ionizing Radiation Exposure of the Population of the United States*, NCRP Report No. 93, September 1987.

12. U.S. Environmental Protection Agency, "Radiation Protection Guidance to Federal Agencies for Occupational Exposure," *Federal Register*, Vol. 52, No. 17, January 27, 1987.

13. International Commission on Radiological Protection, *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, Pergamon Press, Oxford, UK, 1991.

14. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, March 1993.

*Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202) 634-3273; fax (202) 634-3343. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this Revision 1 to Regulatory Guide 8.29. A value/impact statement, which evaluated essentially the same subjects as are discussed in a regulatory analysis, accompanied Regulatory Guide 8.29 when it was issued in July 1981.

This Revision 1 to Regulatory Guide 8.29 is needed to conform with the Revised 10 CFR Part 20, "Standards for Protection Against Radiation," as published May 21, 1991 (56 FR 23360). The regulatory analysis prepared for 10 CFR Part 20 provides the regulatory basis for this Revision 1 of Regulatory Guide 8.29, and it examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL-6712, November 1988), is available for inspection and copying for a fee in the NRC's Public Document Room at 2120 L Street NW., Washington, DC 20555-0001.

PART 19

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

59 FR 48944

Authority: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282, 2297f); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

55 FR 243

§ 19.1 Purpose.

The regulations in this part establish requirements for notices, instructions, and reports by licensees to individuals participating in licensed activities and options available to these individuals in connection with Commission inspections of licensees to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, Title II of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder regarding radiological working conditions. The regulations in this part also establish the rights and responsibilities of the Commission and individuals during interviews compelled by subpoena as part of agency inspections or investigations pursuant to section 161c of the Atomic Energy Act of 1954, as amended, on any matter within the Commission's jurisdiction.

61 FR 9901

§ 19.2 Scope.

The regulations in this part apply to all persons who receive, possess, use, or transfer material licensed by the Nuclear Regulatory Commission pursuant to the regulations in parts 30 through 36, 39, 40, 60, 61, 70, or part 72 of this chapter, including persons licensed to operate a production or utilization facility pursuant to part 50 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The regulations regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the Nuclear Regulatory Commission other than those involving NRC employees or NRC contractors. The regulations in this part do not apply to subpoenas issued pursuant to 10 CFR 2.720.

55 FR 243

§ 19.3 Definitions.

As used in this part:

"Act" means the Atomic Energy Act of 1954, (68 Stat. 919) including any amendments thereto.

"Commission" means the United States Nuclear Regulatory Commission.

57 FR 61780

Exclusion means the removal of counsel representing multiple interests from an interview whenever the NRC official conducting the interview has concrete evidence that the presence of the counsel would obstruct and impede the particular investigation or inspection.

58 FR 7715

"License" means a license issued under the regulations in Parts 30 through 36, 39, 40, 60, 61, 70, or 72 of this chapter, including licenses to operate a production or utilization facility pursuant to Part 50 of this chapter. "Licensee" means the holder of such a license.

56 FR 23360

Restricted area means 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. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

55 FR 243

"Sequestration" means the separation or isolation of witnesses and their attorneys from other witnesses and their attorneys during an interview conducted as part of an investigation, inspection, or other inquiry.

"Worker" means an individual engaged in activities licensed by the Commission and controlled by a licensee, but does not include the licensee.

38 FR 22217

§ 19.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

53 FR 43419

§ 19.5 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D of Part 20 of this chapter. Communications, reports, and applications may be delivered in person at the Commission's offices at 2120 L Street, NW., Washington, DC, or at 11555 Rockville Pike, Rockville, Maryland.

49 FR 19623

§ 19.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0044.

(b) The approved information collection requirements contained in this part appear in § 19.13.

38 FR 22217

§ 19.11 Posting of notices to workers.

(a) Each licensee shall post current copies of the following documents:

(1) The regulations in this part and Part 20 of this chapter;

(2) The license, license conditions, or documents incorporated into a license by reference, and amendments thereto;

(3) The operating procedures applicable to licensed activities;

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Subpart B of Part 2 of this chapter, and any response from the licensee.

(b) If posting of a document specified in paragraph (a) (1), (2) or (3) of this section is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

61 FR 6762

➢ (c)(1) Each licensee and each applicant for a specific license shall prominently post NRC Form 3 (Revision dated January 1996), "Notice to Employees."

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D to Part 20 of this chapter or by calling the NRC Information and Records Management Branch at (301) 415-7230.

38 FR 22217

(d) Documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(e) Commission documents posted pursuant to paragraph (a)(4) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's response, if any, shall be posted within 2 working days after dispatch by the licensee. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

60 FR 35038

§ 19.12 Instruction to workers.

(a) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be—

(1) Kept informed of the storage, transfer, or use of radiation and/or radioactive material;

(2) Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material;

(4) Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material;

(5) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and

(6) Advised as to the radiation exposure reports which workers may request pursuant to § 19.13.

(b) In determining those individuals subject to the requirements of paragraph (a) of this section, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place.

36 FR 22217

§ 19.13 Notifications and reports to individuals.

(a) Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Commission regulations, orders or license conditions, as shown in records maintained by the licensee pursuant to Commission regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement:

This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR Part 19. You should preserve this report for further reference.

58 FR 67657

(b) Each licensee shall advise each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to the provisions of § 20.2106 of 10 CFR part 20.

59 FR 41641

(c)(1) At the request of a worker formerly engaged in licensed activities controlled by the licensee, each licensee shall furnish to the worker a report of the worker's exposure to radiation and/or to radioactive material:

(i) As shown in records maintained by the licensee pursuant to § 20.2106 for each year the worker was required to be monitored under the provisions of § 20.1502; and

(ii) For each year the worker was required to be monitored under the monitoring requirements in effect prior to January 1, 1994.

(2) This report must be furnished within 30 days from the time the request is made or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later. This report must cover the period of time that the worker's activities involved exposure to radiation from radioactive material licensed by the Commission and must include the dates and locations of licensed activities in which the worker participated during this period.

58 FR 67657

(d) When a licensee is required pursuant to §§ 20.2202, 20.2203, 20.2204, or 20.2206 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material the licensee shall also provide the individual a report on his or her exposure data included therein. This report must be transmitted at a time not later than the transmittal to the Commission.

(e) At the request of a worker who is terminating employment with the licensee that involved exposure to radiation or radioactive materials, during the current calendar quarter or the current year, each licensee shall provide at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

58 FR 67657

§ 19.14 Presence of representatives of licensees and workers during inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records pursuant to the regulations in this chapter.

(b) During an inspection, Commission inspectors may consult privately with workers as specified in § 19.15. The licensee or licensee's representative may accompany Commission inspectors during other phrases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Commission inspections, the licensee shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

38 FR 22217

(d) Each workers' representative shall be routinely engaged in licensed activities under control of the licensee and shall have received instructions as specified in § 19.12.

(e) Different representatives of licensees and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee and the workers' representative an individual who is not routinely engaged in licensed activities under control of the license, for example, a consultant to the licensee or to the workers' representative, shall be afforded the opportunity to accompany Commission inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, Commission inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee to enter that area.

§ 19.15 Consultation with workers during inspections.

(a) Commission inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Commission regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

38 FR 22217

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the act, the regulations in this chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control. Any such notice in writing shall comply with the requirements of § 19.16(a).

(c) The provisions of paragraph (b) of this section shall not be interpreted as authorization to disregard instructions pursuant to § 19.12.

§ 19.16 Requests by workers for inspections.

(a) Any worker or representative of workers who believes that a violation of the Act, the regulations in this chapter, or license conditions exists or has occurred in license activities with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Administrator of the appropriate Commission Regional Office, or to Commission inspectors. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of workers. A copy shall be provided the licensee by the Regional Office Administrator, or the inspector no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released or made available by the Commission, except for good cause shown.

52 FR 31601

(b) If, upon receipt of such notice, the Regional Office Administrator determines that the complaint meets the requirements set forth in paragraph (a) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

§ 19.17 Inspections not warranted; informal review.

(a) If the Administrator of the appropriate Regional Office determines, with respect to a complaint under § 19.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Executive Director for Operation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, who will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position with the Executive Director for Operations who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Executive Director for Operations or his designee may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Executive Director for Operations shall affirm, modifying, or reverse the determination of the Administrator of the appropriate Regional Office and furnish the complainant and the licensee a written notification of his decision and the reason therefor.

52 FR 31601

(b) If the Administrator of the appropriate Regional Office determines that an inspection is not warranted because the requirements of § 19.16(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of § 19.16(a).

55 FR 243

§ 19.18 Sequestration of witnesses and exclusion of counsel in interviews conducted under subpoena.

(a) All witnesses compelled by subpoena to submit to agency interviews shall be sequestered unless the official conducting the interviews permits otherwise.

57 FR 61780

(b) Any witness compelled by subpoena to appear at an interview during an agency inquiry may be accompanied, represented, and advised by counsel of his or her choice. However when the agency official conducting the inquiry determines, after consultation with the Office of the General Counsel, that the agency has concrete evidence that the presence of an attorney representing multiple interests would obstruct and impede the investigation or inspection, the agency official may prohibit that counsel from being present during the interview.

(c) The interviewing official is to provide a witness whose counsel has been excluded under paragraph (b) of this section and the witness's counsel a written statement of the reasons supporting the decision to exclude. This statement, which must be provided no later than five working days after exclusion, must explain the basis for the counsel's exclusion. This statement must also advise the witness of the witness' right to appeal the exclusion decision and obtain an automatic stay of the effectiveness of the subpoena by filing a motion to quash the subpoena with the Commission within five days of receipt of this written statement.

(d) Within five days after receipt of the written notification required in paragraph (c) of this section, a witness whose counsel has been excluded may appeal the exclusion decision by filing a motion to quash the subpoena with the Commission. The filing of the motion to quash will stay the effectiveness of the subpoena pending the Commission's decision on the motion.

(e) If a witness' counsel is excluded under paragraph (b) of this section, the interview may, at the witness' request, either proceed without counsel or be delayed for a reasonable period of time to permit the retention of new counsel. The interview may also be rescheduled to a subsequent date established by the NRC, although the interview shall not be rescheduled by the NRC to a date that precedes the expiration of the time provided under § 19.18(d) for appeal of the exclusion of counsel, unless the witness consents to an earlier date.

61 FR 6762

§ 19.20 Employee protection.

Employment discrimination by a licensee (or a holder of a certificate of compliance issued pursuant to Part 76) or a contractor or subcontractor of a licensee (or a holder of a certificate of compliance issued pursuant to Part 76) against an employee for engaging in protected activities under this part or Parts 30, 40, 50, 60, 61, 70, 72, 76, or 150 of this chapter is prohibited.

57 FR 55062

§ 19.30 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

38 FR 22217

§ 19.31 Application for exemptions.

The Commission may upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

40 FR 8774

§ 19.32 Discrimination prohibited.

No person shall on the ground of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity licensed by the Nuclear Regulatory Commission. This provision will be enforced through agency provisions and rules similar to those already established, with respect to racial and other discrimination, under Title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

57 FR 55062

§ 19.40 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 19 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 19 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 19.1, 19.2, 19.3, 19.4, 19.5, 19.8, 19.16, 19.17, 19.18, 19.30, 19.31, and 19.40.

Appendix A: Radiation Worker Training Certificate

The following statement is to be signed by all Charles River PharmServices employees who work with or around radiation sources:

Charles River PharmServices
Statement of Training in Radiation Safety

" I have been provided with a copy of the Charles River PharmServices Radiation Safety Program as well as any additional material and information necessary to understand the radiation protection practices that are outlined in the program. I have been afforded the opportunity to ask questions concerning radiation safety and the safe use of radioactive material. I am aware of the NRC regulations in 10 CFR Part 19 & Part 20 pertaining to radiation safety and I understand my responsibility to comply with the applicable regulations."

Signature_____

Date _____

APPENDIX B:

Charles River PharmServices
DECLARATION OF PREGNANCY FOR RADIATION WORKERS

I. DECLARATION OF PREGNANCY

Name of Individual	
Social Security Number	
Date of Conception (Mo/Yr)	
By providing this information to my immediate supervisor, in writing, I am declaring myself to be pregnant as of the date shown above. Under the provisions of 10 CFR Part 20.1208 I understand that my exposure will not be allowed to exceed 5 mSv (500 mrem) during my pregnancy, from occupational exposure to radiation. I understand that this limit includes exposure I have already received. If my estimated exposure since the above date of conception has already exceeded 5 mSv (500 mrem), I understand that I will be limited to no more than 0.5 mSv (50 mrem for the remainder of my pregnancy. If I should find out that I am not pregnant, or if my pregnancy is terminated, I will inform my supervisor as soon as practical.	
Signature of Individual	
Date Signed	

II. DESCRIPTION OF CURRENT WORK WITH IONIZING RADIATION

Note principal radioactive materials used & include maximum amount used/use per experiment: Signature of RSO _____ Training Date_____

III. RECEIPT OF DECLARATION OF PREGNANCY

Name of Supervisor	
I have received notification from the above named woman that she is pregnant. I have explained to her the potential risks from exposure to radiation as provided in Regulatory Guide 8.13, Revision 3. I have evaluated her prior exposure and established appropriate limits to control the dose to the developing embryo/fetus in accordance with limits in 10 CFR part 20.1208. I have explained to her options for reducing her exposure to as low as reasonably achievable (ALARA).	
Signature of Supervisor	
Date Signed	

APPENDIX C

ALARA PROGRAM

Charles River PharmServices
MAY 1996

1. Management Commitment

   a. The management of this research and development facility are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (**ALARA**). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our facility. Organizationally, the Radiation Safety Officer (RSO) will be the lead person in our ALARA efforts backed by full management support.

   b. The RSO will perform or have performed a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to standard operating and maintenance procedures, experimental procedures, and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgement, is considered to be unjustified.

   d. In addition to maintaining doses to individuals as far below as reasonably achievable, the sum of doses received by all exposed individuals will also be maintained at an as low as reasonably achievable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Officer

   a. Review of Proposed Users and Uses

   (1) The RSO will thoroughly review all proposed uses of radioactive material with respect to the types and quantities of materials and methods of use to ensure that the proposed user will be able to take appropriate measures to maintain exposure ALARA.

   (2) When considering a new use of byproduct material, the RSO will review the efforts of the user to maintain exposure ALARA.

   (3) The RSO will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

   b. Delegation of Authority

   (1) The management at Charles River PharmServices will delegate the authority to the RSO for enforcement of the ALARA concept.

(2) The management will support the RSO when it is necessary for the RSO to assert authority.

c. Review of ALARA Program

(1) The RSO will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSO will perform monthly reviews of our occupational radiation exposures with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to initiate the appropriate action warranted when investigational levels are exceeded.

TABLE 1

Investigational Levels
(mRems per calendar quarter)

		Level I	Level II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	500	1500
2.	Hands and forearms; feet and ankles, skin of the whole body	5000	15000

(3) The RSO will evaluate our facilities's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and radiation workers as well as those of management.

d. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Monthly review of occupational exposures. The RSO will review at least monthly the external radiation doses of authorized users and workers to determine that their doses are ALARA.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in uncontrolled and controlled areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter.

e. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that radiation workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.

f. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

g. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all know instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

3. Authorized Users/Radiation Workers

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user/radiation worker will consult with the RSO during the planning stages before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

(3) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(4) The authorized user will ensure that supervised individuals who are subject to occupation radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in resources available if they feel that ALARA is not being promoted on the job.

Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This licensee hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The following actions will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigation Level I.

b. Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I. The exposed worker will be restricted from working with radioactive materials until the RSO completes an investigation and additional controls are instituted to keep future exposures ALARA. The RSO will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will immediately investigate the cause of all personnel doses equaling or exceeding Investigational Level II will take action. The affected worker will not be allowed to handle any additional radioactive materials until a qualified expert has been consulted to review the underlying causes for the exposure and recommend engineering controls or revised handling procedures to maintain future exposures to ALARA levels. A report of the investigation, any actions taken, and a copy of the individual's form NRC-5 or its equivalent will be kept in the workers registration file. The radiation worker will not be reinstated until the investigation is completed.

7. Signature of Certifying Official

I hereby certify that this research facility has implemented the ALARA Program set forth above.

_____
(Signature)

_____
Name (print or type)

_____
Title

APPENDIX D

INSTRUCTIONS FOR PROPER SEGREGATION AND DISPOSAL OF LOW LEVEL RADIOACTIVE WASTES

The Charles River PharmServices Nuclear Regulatory Commission (NRC) license allows for the decay-in-house storage of radioactive waste contaminated with radionuclides with a half-life ($T_{1/2}$) of less than or equal to 65 days and ^{35}S ($T_{1/2}$=88 days) The following conditions of approval in our NRC license apply to our waste management program:

1. The waste will be stored for a minimum of 10 half lives.

2. The waste will be thoroughly surveyed with an appropriate radiation survey instrument and disposed as "normal trash" only if the radiation levels detected are not different from background levels.

3. All references to radioactive material (labels, tape, signs) must be obliterated prior to disposal as "normal trash".

4. A record of all such disposal including information about the length of storage time, the radionuclide, the amount stored, the date put in storage, the date surveyed, survey results, and the date disposed must be maintained for NRC inspection.

All persons registered as radiation workers and trained in the safe handling of radioactive materials at Charles River PharmServices will be given this hand-out specifically describing our low level radioactive waste management program. The success of our program, including our continued use of radionuclides in research, depends upon each individual's ability to follow simple instructions. Compliance with the following instructions is mandatory for all Charles River PharmServices radiation workers:

- Discuss with your radiation safety officer which radionuclides your laboratory will be using.

- The following radionuclides qualify for our decay-in-storage management program:

Radionuclide	Half-life ($T_{1/2}$)
Phosphorus-32 (^{32}P)	14 days
Phosphorus-33 (^{33}P)	28 days
Iodine-125 (^{125}I)	60 days
Sulphur-35 (^{35}S)	88 days

- Separate waste containers will be provided in each laboratory for the segregation of each of the various radionuclides.

- Whenever waste is deposited in the container the worker must enter the radionuclide and amount on the waste log located on each container.

- When the container is full, the Radiation Safety Officer or her designate will remove the waste from the laboratory and transfer the waste to storage drums located in the low level radioactive waste storage facility in the basement of the building. The RSO or designate is responsible for the transfer of the radionuclide waste log information form the laboratory to the storage drum.

- Due to the large difference in the amount of time each radionuclide must be held in decay storage, it is imperative that workers follow these instructions and not mix wastes contaminated with different radionuclides.

- The following two licensed radionuclides do not qualify for the decay-in-storage program:

Radionuclide	Half-life ($T_{1/2}$)
Hydrogen-3 (^{3}H)	12.6 years
Carbon-14 (^{14}C)	5730 years

Separate waste collection containers will be provided for waste contaminated with these two radionuclides. **WASTE CONTAMINATED WITH 3H AND/OR 14C CANNOT BE MIXED WITH THE SHORT HALF LIFE WASTE.**

As stated above, the success of the Charles River PharmServices radioactive waste management program is dependent on each individual worker. Please contact the Radiation Safety Officer if you have any questions concerning the segregation and decay-in-storage program.

OFFICIAL RECORD COPY ML 10 123526

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 3
FEE CATEGORY: _____
EXP. DATE: 0
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: _

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: CHARLES RIVER PHARMSERVICES
RECEIVED DATE: 960801
DOCKET NO: 3034216
CONTROL NO.: 123526
LICENSE NO.:
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED
AMOUNT: $1500.00
CHECK NO.: 1792

3. COMMENTS

SIGNED M. A. Parkin
DATE 8/7/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /√/)

1. FEE CATEGORY AND AMOUNT: 3M $1,500

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE /

3. OTHER _____
_____

SIGNED _____
DATE _____

1996 AUG -7 AM 11:0

Log: Aug 8 '96
Remitter: EAST ACCESS BIOLOGICALS
Check No.: 1792
Amount: $1,500
Fee Category: 3M
Type of Fee: APP
Date Check Rec'd: 8/8/96
Date Completed: 8/8/96
By: BB