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Vame individuals ve material, Comp	who will plete Supp	use or directly elements A and B	5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resu- me of training and experience as in Supplement A.)				
n, M. D.			Daryl R. Mel	vin, M. D.			
ATERIAL FOR	MEDIC	AL USE			1	24	
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INRMATION	REQUIRED	FOR ITEMS	7 THP	UGH 23
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For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8, Rev. 1 Date: 10-80

		15. GENERAL RULES FOR THE SAFE USE OF				
7. 6	MEDICAL ISOTOPES COMMITTEE	X	Appendix G Rules Followed; or			
	Names and Specialties Attached; and					
	Duties as in Appendix B; or (Check One)		Equivalent Rules Attached			
	Equivalent Duties Attached	16.	EMERGENCY PROCEDURES (Check One)			
B. T	RAINING AND EXPERIENCE	X	Appendix H Procedures Followed; or			
	Supplements A & B Attached for Each Individual User; and		Equivalent Procedures Attached			
	Supplement A Attached for RSO.	17.	AREA SURVEY PROCEDURES (Check One)			
9, 1	NSTRUMENTATION (Check One)	x	Appendix I Procedures Followed; or			
	Appendix C Form Attached; or		Equivalent Procedures Attached			
X	List by Name and Model Number	18.	WASTE DISPOSAL (Check One)			
10.	CALIBRATION OF INSTRUMENTS	1	Appendix J Form Attached; or			
X	Appendix D Procedures Followed for Survey	X	Equivalent Information Attached			
_	Equivalent Procedures Attached; and	19.	THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)			
X	Appendix D Procedures Followed for Dose		Appendix K Procedures Followed; or			
	Equivalent Procedures Attached (Check One)		Equivalent Procedures Attached			
1.	FACILITIES AND EQUIPMENT	20. THERAPEUTIC USE OF SEALED SOURCES				
X	Description and Diagram Attached		Detailed Information Attached; and			
12.	PERSONNEL TRAINING PROGRAM		Appendix L Procedures Followed; or (Check One)			
X	Description of Training Attached		Equivalent Procedures Attached			
3.	PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	21.	PROCEDURES AND PRECAUTIONS FOR USE OF RADIDACTIVE GASES (e.g., Xenon - 133)			
X	Detailed Information Attached		Detailed Information Attached			
	PROCEDURES FOR SAFELY OPENING PACKAGES	22.	PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS			
4.	CONTAINING RADIOACTIVE MATERIALS (Check One)	-	Detailed Information Attached			
	Appendix F Procedures Followed; or	23.	PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.6			
	Equivalent Procedures Attached	1	Detailed Information Attached			

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		24. PERSONNEL MONT		1
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NRC FORM 313M (9-81)

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401 WEST GREENLAWN, LANSING, MICHIGAN 48909 (517) 374-2261



JOHN C. SODERHOLM, MHA Executive Vice-President

August 19, 1982

Daryl R. Melvin, M.D. 405 W. Greenlawn, Suite 220 Lansing, Michigan 48910

Dear Dr. Melvin:

This is to advise that Mid-Michigan Medical Group, P.C. (405 W. Greenlawn, Suite 220, Lansing, Michigan) is hereby approved to admit patients to Ingham Medical Center (401 W. Greenlawn, Lansing, Michigan) who have been given parenteral radioactive materials.

In addition, be advised that while you will be responsible for radiation safety matters pertaining to patients admitted as described above, the Center's Radiation Safety Officer and Isotope Surveillance Committee will be available to assist you in your practice.

Sincerely,

INGHAM MEDICAL CENTER

Blue

John C. Soderholm Executive Vice-President

JCS/db

Mid-Michigan Medical Group, P.C.

OFFICES: 405 W. GREENLAWN - SUITE 220 LANSING, MICHIGAN 48910 (517) 374-2304

1201 W. OAKLAND AVE. - SUITE 341 LANSING, MICHIGAN 48915 (517) 374-2398 CARDIOVASCULAR SURGERY T. CALVIN BLAIR, M.D. SEONG H. CHI, M.D. ANTHONY B. FABAZ, D.O. JIA Y. JUNG, M.D.

CARDIOLOGY WALTER M. BAIRD, M.D. EDWARD T. HELBLE, D.O. MICHAEL J. JAMES, D.O. GEORGE E. KLEIBER, D.O. JAMES C. KLOEPFER, M.D. MARSHALL S. SPENCER, M.D. MARK VEENENDAAL, M.D. KARL F. YOSHONIS, M.D.

THORACIC & VASCULAR SURGERY JAMES E. McGILLICUDDY, M.D.

Ionizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentalities of medicine, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures. Thus, the safety rules which govern the use of radiation are concerned with preventing genetic damage as well as with protecting the health of the exposed individual.

The rules and procedures set forth here have one single, straightforward purpose: to protect the patients and employees, from unnecessary and potentially harmful radiation.

The existing radiation safety program has many facets designed to keep the levels of exposure to personnel at a minimum. This program has three main phases:

PHASE I

Achieve the objective of maintaining radiation exposure to "As Low As Reasonably Achievable" (ALARA) to employees, students, and patients who are not under medical supervision for the administration of radiation or radioactive materials for diagnostic or therapeutic purposes.

PHASE II

Control operational procedures by the user of radiation sources.

PHASE III

Evaluate the radiation safety program performed by the Radiation Safety Officer and health physics consultant.

We, the management of this facility, are committed to the program described herein for keeping exposures, individual and collective, to as low as reasonably achievable (ALARA).

All primary users of radiation sources are encouraged to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

Signature of Authorized Physician

I. INTRODUCTION

A. Purpose

This program sets forth the philosophy and general management policies that are established by this facility to achieve the objective of maintaining radiation exposure to "as low as reasonably achievable" (ALARA), for employees, visitors, etc., not under medical supervision for the administration of radiation or radioactive materials for diagnostic or therapeutic purposes.

B. Policy

In addition to complying with the limits set forth in pertinent regulations, guides, and standards, users and supervisors of radiation sources shall make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas to as low as reasonably achievable.

II. MANAGEMENT COMMITMENT

- A. The management and the entire staff of this facility are committed to the program described herein for keeping radiation exposures, individual and collective, to as low as reasonably achievable.
- B. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- C. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- D. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable 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.

E. The services of Health Physics Services, Inc. * has been contracted to assist in the program management to insure that all pertinent staff and employees receive appropriate briefings and training in radiation safety including ALARA concepts.

III. RADIATION SAFETY OFFICER

In addition to other responsibilities delineated in pertinent radiation control standards, the Radiation Safety Officer (RSO) shall:

- A. Determine whether current procedures are, in fact, maintaining radiation exposures to ALARA. The efforts of the health physics consultant, users, and supervisors of radiation sources will be reviewed periodically.
- B. When considering a new use of byproduct material, the RSO will review the efforts of the applicant to maintain exposure to ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
- C. Perform an annual audit of all aspects of the radiation safety program to insure that the overall philosophy and policies of the ALARA program are being accomplished.
- D. Thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and the uses for which he has applied, to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.
- E. 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 a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded.
 - 3. The RSO will evaluate the facility's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

*or an equally gualified consulting firm.

- IV. RADIATION SAFETY OFFICER AND CONSULTANT STAFF ARE RESPONSIBLE FOR THE FOLLOWING:
 - A. Annual and Quarterly Review
 - 1. Annual review of the Radiation Safety Program. The HPC will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
 - 2. Quarterly review of Occupational Exposures. The HPC will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraphVII of this program.
 - 3. Quarterly review of records of Radiation Level Surveys. The HPC will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous guarter.
 - B. Education Responsibilities for an ALARA Program
 - 1. The HPC will schedule briefings and educational sessions to inform workers of ALARA program efforts.
 - 2. The HPC will assure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in ALARA philosophy and informed that management, and the HPC are committed to implementing the ALARA concept.
 - C. Cooperative Efforts for Development of ALARA Procedures

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

- The HPC will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- The HPC will establish procedures for receiving and evaluating the suggestion of individual workers for improving health physics practices and encourage the use of those procedures.
- D. Reviewing Instances of Deviation from Good ALARA Practices

The HPC will investigate all known instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the HPC will suggest changes in the program to maintain exposures ALARA.

AUTHORIZED USERS

V.

- A. New Procedures Involving Potential Radiation Exposures
 - 1. The authorized user will consult with, and receive the approval of, the RSO during the planning stage before using radiation sources for a new procedure.
 - The authorized user will evaluate all procedures before using radiation sources to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.
- B. Responsibility of the Authorized User to Those He Supervises
 - The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.
 - 2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.
- VI. PERSONS WHO RECEIVE OCCUPATIONAL RADIATION EXPOSURE
 - A. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.
 - B. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job.
- VII. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This facility hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Officer or consultant staff. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

TABLE 1

Investigational Levels - (mrems per calendar quarter)

		LEVEL 1	LEVEL II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body*	750	2250

*Not normally applicable to medical facilities except those using significant quantities of beta emitting isotopes.

The RSO and/or HPC will review the results of personnel monitoring, film badge report, not less than once in any calendar guarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

A. Quarterly exposure of individuals to less than Investigational Level I.

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

- B. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II. The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. No specific action related to these exposures is required, but will be considered in comparison with the exposures of other personnel performing similar tasks.
- C. Exposure equal to or greater than Investigational Level II. The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's film badge record will be documented and maintained on file.
- D. Re-establishment of an individual occupational worker's Investigational Level II above that listed in Table 1.

In cases where a worker's or a group of workers' exposure needs to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Officer will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established

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Investigational Level II, those actions listed in paragraph C above will be followed.

VIII. SIGNATURE OF CERTIFYING OFFICIAL

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

Signature of Physician

elvin Name (Print or type)

FORM NR((6-78)	C-313M-SUPPLEMENT B			U. S. NUCLEAR REGULATORY COMMISSION
	PRECI	PTOR	STATEME	NT
Supplemer experience	nt B must be completed by the applicant phy , obtain a separate statement from each.	sician's p	preceptor, II	more than one preceptor is necessary to document
1. APPLICA	ANT PHYSICIAN'S NAME AND ADDRESS		1	KEY TO COLUMN C
FULLN	AME		PER	SONAL PARTICIPATION SHOULD CONSIST OF:
Dar	yl Richard Melvin, M.D.		radioisoto	ape diagnosis and/or treatment and recommendation for dosage.
STREET	ADDRESS		2-Collabora to the pat	tion in dose calibration and actual administration of dose tient including calculation of the radiation dose, related tents and plotting of data
CITY	STATE ZIP	CODE	- 3-Adequate patients a	period of training to enable physician to manage radioacti and follow patients through diagnosis and/or course of
Oke	mos MI 488	394	treatment	L.
	2. CLINICAL TRAINING AND	EXPER	IENCE OF A	ABOVE NAMED PHYSICIAN
ISOTOPE	CONDITIONS DIAGNOSED OR TREATED	CASES I PER PARTI	NVOLVING SONAL CIPATION	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.)
	DIAGNOSIS OF THYROID FUNCTION			
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME			
1-131	LIVER FUNCTION STUDIES			
1-125	FAT ABSORPTION STUDIES			
	KIDNEY FUNCTION STUDIES			
	IN VITRO STUDIES			
OTHER				
1-125	DETECTION OF THROMBOSIS			
1-131	THYROID IMAGING			
P-32	EYE TUMOR LOCALIZATION			
Se-75	PANCREAS IMAGING			
Yb-169	CISTERNOGRAPHY			
Xe-133	BLOOD FLOW STUDIES AND PULMCNARY FUNCTION STUDIES			
OTHER				
	BRAIN IMAGING			
	CARDIAC IMAGING	10)	
	THYROID IMAGING			
	SALIVARY GLAND IMAGING			
Tc-99m	BLOOD POOL IMAGING Lt. ventricul	ar 15	0	
	FLACENTALOCALIZATION function			
	LIVER AND SPLEEN IMAGING			
	LUNG IMAGING			
	BONE IMAGING			
OTHER				

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	2. CLINICAL TRAINING AND EXI	PERIENCE OF ABO	VE NAMED PHYSICIAN (Continued)
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P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA. LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
1.1.31	TREATMENT OF THY ROID CARCINOMA		
1-151	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		0
Co-60	INTERSTITIAL TREATMENT		
CF-137	INTRACAVITARY TREATMENT		
1-125 or 1r-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION	-	
Mo-99/ Tc-99m	GENERATOR	5	
Sn-113/ In-113m	GENERATOR	1	
Tc-99m	REAGENT KITS	5	
Other			
T1-201	Cardiac	25	
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C. MAIL	ING ADDRESS	Wm.	H. Beierwaltes, M.D.
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Ann	Arbor, MI 48109 ALSLICENSE NUMBER(S)	Aug	ust 13, 1982
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 RADIOPHARMACEUTICAL CHEMISTRY 		н	11				25
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RADIATION PHYSICS AND INSTRUMENTATION	Health Physics Potomac, Maryla	Health Physics Services, Inc. Potomac, Maryland, 7/82-8/82		
6 RADIATION PROTECTION	Health Physics Potomac, Maryla	Health Physics Services Potomac, Maryland, 7/82-8/82		
C. MATHEMATICS PERTAINING THE USE AND MEASUREMEN OF RADIOACTIVITY	Health Physics Potomac, Maryla	Services, Inc. nd, 7/82-8/82	20	
# RADIATION BIOLOGY	Health Physics Potomac, Maryla	Health Physics Services, Inc. Potomac, Maryland, 7/82-8/82		
. RADIOPHARMACEUTICAL CHEMISTRY	Health Physics Potomac, Maryla	Health Physics Services, Inc. Potomac, Maryland,7/82-8/82		
E EVOCOLENC	WITH PADIATION (Actual us	se of Radioisotopes or El	quivalent Experience	e)
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2	Plat Dat	on	Bully G. B Course Du Augh B.

COURSE ABSTRACT: RADIONUCLIDE USE FOR PHYSICIANS

This course is designed to provide the practicing physician with 200 hours of didactic instruction in the use of radionuclides. The course is highly intensified but broad enough in scope to provide the physician with the technical information necessary to safely use radionuclides in clinical practice. The course is also modular in design to allow presentation in logically structured segments to fit into a compact schedule. It can be given as a twenty-five week unit; as a twenty day, 10 hour per day unit; or, it can be given in any combination of four, eight, or ten hour segments as dictated by the student's schedule.

The course contains a review of mathematics, from simple algebraic expressions and equations, to differential calculus to include derivatives, infintesimals, average rate of change, velocity, acceleration and differentiation. Simple problems are presented and solved. Integral calculus is reviewed to provide the student with an appreciation of the value of integral functions in expressing the principles involved in radioactivity and its application to clinical medicine.

The Unites Systeme Internationale (SI Units) is presented in two parts. The first part includes the conventional physical units: MKS and cgs. The second part, dealing with the new radiation units, is presented after a section on particle physics and radiation measurement. Modern atomic structure is presented as it evolved from the early Thomson Model to the Bohr Model. Nuclear forces, binding energy, atomic number, atomic mass, and other concepts such as nuclear particle characteristics are presented in light of that model. Atomic energy states are explained in terms of electronic transitions and the formation of radiant electromagnetic energy which accompanies those transitions. Radioactivity, natural and artificial, is explained with a minimum of mathematical rigor, but with sufficient depth to provide the student with a working knowledge of all aspects of nuclear decay. Representative nuclear decay schemes are presented and explained.

The chemistry of radiopharmaceuticals and imaging agents is presented along with the physical and instrumental aspects of radionuclide imaging. Radiation detection and instrumentation from basic personnel monitors to highly sophisticated, computerized gamma cameras are presented and explained in detail. Applications of computers and statistics in nuclear medicine are reviewed. Other imaging systems such as CAT and NMR are reviewed, along with a brief presentation of basic electronics and medical instrumentation.

The principles and practices of radiation protection are presented from the standpoints of regulatory (NRC and FDA), physical, and biological factors. The requirements placed on the user by federal and state regulations are presented. The physics of radiation protection is presented in terms of shielding design, instrumentation, safe design of clinical protocols using radionuclides and basic radiation particle physics. Biological effects of ionizing radiation are reviewed from chronic low level conditions to acute high exposure rate situations. Cellular effects, organic effects, as well as systemic effects of radiation injury, are presented.

Nine, 2 hour exams are given on the major subdivisions of the course: mathematics, atomic structure and SI Unites, radioactivity and radiation physics, radiation protection, radiation biology, radiopharmaceutical chemistry, imaging physics and instruments, electronics and X-ray production, statistics and licensing.

RADIONUCLIDE USE SURSE FOR PHYSICIANS

SYLLABUS

Day

Subject

1

Introduction to Course Mathematics Review: Algebra Equations (Roots and Solutions) Radicals and Roots Exponents Logarithms Plane Geometry Trigonometry Vectors

2

Mathematics Review: Functions Differential Calculus Derivatives Infinitesimals Average Rate of Change Velocity Acceleration Differentiation Integral Calculus Integration Indefinite Integral Polynomial Integration Constant of Integration Area Summation

Mathematics Review: Derivatives Theorems Applications Differentiation Trig. Functions Log. Functions Exponentials Integration Trig. Functions Log. Functions Exponentials Approximate Integration Prismoidal Formula Simpson's Rule

Page 2 - Syllabus

Day

4

Subject



Introduction to Electronics Alternating current Generators Vectors Capacitance Inductance Transformers Power Supplies Amplifiers DC AC Operational Amplifiers Impedance Matching

Introduction to Electronics Measuring Devices Magnetism Basic Meter Movement D'Arsonval Meter Movement DC Ammeter DC Voltmeter Ohmmeter AC Measurements Wattmeter Cathode Ray Tube

6

Page 3- · Syllabus

Day

7

Subject

Radioactivity Radioactivity Decay Law Halflife Series Decay Secular Equilibrium Types of Radiation (Review) Alpha Beta Gamma Interaction of Radiation with Matter Exponential Absorption Attenuation Coefficients Absorption Components Photoelectric Compton Scattering Pair Production Half Value Levels Shielding Considerations Energy Loss by Charged Particles Excitation Ionization Inelastic Collision Bremsstrahlung Radiative energy loss Collision energy loss dE/dxLinear Energy Transfer (LET) Cerenkov Radiation Cluster Ionization Specific Ionization Bragg Ionization Surve Radiation Dosimetry Electron Range Alpha Range Photon Dosimetry Exposure dose (roentgen) Absorbed dose (rad) Standard Air Chamber Thimble Chambers Air Equivalence Tissue Dose

Radiation Measurement Integrating Devices Ion Chamber Electroscope Electro meter Condensor r-meter

8

Page 4 - Syllabus

Subject

Photographic emulsions

9 (cont'd)

Day

Chemical Systems TLD Theory Glow Curves Response/Sensitivity Energy Dependence of Instruments Survey Instruments Counting Devices Ion Chamber Proportional Counter GM Counter Scintillation Detectors Gamma Detection Compton Photoelectric Pair Production Type of Scintillators Solid NaI (TI), CsI (TI), LiI (Eu), Anthracene, Stilbene, Plastic Liquid Semiconductor Detectors Nuclear Instrumentation Detectors Amplifiers Discriminators Scalers Pulse Height Analysis Multichannel Analyzers Counting Principles Integral counting Differential counting Dead time Resolving time Coincidence counting Noise effects Counting efficiency Geometric Intrinsic Principles of Scintillation Counting Gamma and X-ray Photon Counting Construction techniques for solid crystals Crystal efficiencies Liquid Scintillation Counting Principles Applications

Page 5 - Syllabus

Day

11

Subject

Radioisotope Counting and Calibration Ionization Chambers for Beta and Gamma Calibration Well Counters (NaI) Differential spectra Integral spectra Flat face crystal counters Standards of Accuracy Standardized solutions Reference solutions Mock standards Certification of Standards Use of Standards Calibration of Laboratory Instruments Precautions Radionuclide assay - Beta Emitters Halflife Max Energy Measurement Chemical separation Carrier techniques Precipitation Distillation Liquid - liquid extraction Electrodeposition Ion exchange Radionuclide assay - Gamma Emitters Radionuclide applications

Fission and Fusion Production of Radiopharmaceuticals Nuclear Reactors Particle Accelerators X-ray production

Radiation Protection Units (conventional) Roentgen Rad, Rem, REP Absorption coefficients Units (New SI) Gray, Sievert, J/Kg Philosophy of Radiation Protection Radiation Shielding Sources of Radiation Exposure Natural, Artificial

Cellular Effects of Ionizing Radiation Survival Curves - in vitro, in vivo Critical Targets for Radiation Damage Radiosensitivity - Physical Modifications Chemical Aspects

12

13

Page 6 - Syllabus



Subject

<u>Day</u>

Radiation Biology Cellular Effects of Ionizing Radiation Radiosensitivity - Biological Aspects Oxygen Effect Radiation effects on tissue Whole Body Irradiation effects Late Effects of Radiation Exposure Radiation Genetics

16

Radiation Dosimetry Internal emitters (radionuclide combinations) Internal dose calculations NRC and FDA Licensing Regulations Requirements Procedures Responsibilities of licensee ALARA Duties of Radiation Safety Officer Duties of Health Physicist

Overview: Radiopharmaceuticals and Imaging Agents Isotope dilution technique Design criteria of effective radiopharmaceuticals Production of radiopharmaceuticals Radioisotope generators (cows)

- Radiopharmaceutical Chemistry Technetium chemistry Iodine chemistry Xenon chemistry Tha'llium chemistry
- Radiopharmaceutical Chemistry Physics of localization Biodistribution Tracer Kinetics
- Radiopharmaceutical Chemistry Quality Control of Radiopharmaceuticals Radiopharmacy layout and operation Storage and Stability of Radiopharmaceuticals Responsibilities of Nuclear Pharmacist

Overview: Physics of Radioisotope Scanning Detector Design -Performance Parameters Collimator Design -Performance Parameters Rectilinear Scanners Gamma Cameras (system design, physics)

17

19

18

20

Page 7 - Syllabus

Subject Day Imaging Systems (Physics, design, 22 operational characteristics) CAT scanner NMR scanner Whole body counters Introduction to Logic and Computer Systems Computer applications in Nuclear Medicine 23 Nuclear Medicine Computer Architecture A/D conversion Computer Instrument interface specifications Interactive vs. Dedicated Systems Performance Machine Language Programming Assemblers Compilers Linkers Loaders

> Introduction to Probability and Statistics Binomial Poisson and normal distributions Student-t and Chi-square distributions Computation of most used statistics (mean, st'd. dev., SEM, etc.) Hypothesis testing

Statistics in Nuclear Medicine Application of probability theory to radioactivity measurement Inefficient statistics Chi-square test Minimum detectable activity Instrument quality control and performance testing Radioactive waste management and diposal Laboratory design Course recap and review of selected topics Course Critique

25

INSTRUMENTATION

1. Survey Meters

Eberline Model E-120 with HP-190 detector probe, 0-50 mR/hr., or equivalent. Eberline Model E-130A, 0-1000 mR/hr., or the equivalent

2. Dose Calibrator

Capintec Model CRC-5, or the equivalent

Diagnostic Instrumentation
 Baird Atomic 77 gamma camera system, or the equivalent

ITEM 9. 8-82

CALIBRATION OF SURVEY METER INSTRUMENTATION

Survey meter calibrations will be conducted on a quarterly basis by Health Physics Services, Inc., Potomac, Maryland, using sealed Cesium-137 sources of approximately 500 mCi, authorized by the State of Maryland under license Number MD-31-035-01. The calibration procedures are on file with the NRC, under License No. 19-19791-01.

DOSE CALIBRATOR CALIBRATION AND LINEARITY PROCEDURES

- On a daily basis, the constancy of the dose calibrator will be determined with two sources: 200 uCi of Cesium-137, and greater than one millicurie of Cobalt-57. These sources are NBS traceable with an accuracy of 100+5%. Should the error of the constancy measurement be greater than +5%, appropriate adjustment or instrument repair will be affected.
- On a quarterly basis, Health Physics Services, Inc., Potomac, Maryland, will conduct the dose calibrator calibrations under Maryland License Number MD-31-035-01.

A Cobalt-57 source of approximately 10 millicuries will be used to insure the dose calibrator accuracy. Should the calibration deviate by greater than ±5%, appropriate adjustment or instrument repair will be conducted. This quarterly procedure will be repeated using a Cesium-137 and a Barium-133 source of approximately 0.2 millicuries each. The three calibration sources are NBS traceable with an accuracy of 100+5%

- 3. The linearity of the dose calibrator will be determined quarterly, by Health Physics Services, Inc., in accordance with the NRC Medical Licensing Guide, Appendix D, Section 2.E., over the full range of activities of Technetium used. Should the linearity (measured versus calculated) vary by greater than <u>+5%</u>, appropriate corrective action will be conducted.
- Test for geometrical variation will be conducted in accordance with Appendix D, Section 2, Item F., of the NRC Medical Licensing Guide, unless certified data is supplied by the dose calibrator manufacturer.

ITEM 10. 8-82

FACILITIES AND EQUIPMENT

Radiation Handling Equipment

To enable personnel to work safely with unsealed radioactive materials, the Nuclear Cardiology laboratory will have the proper radiation handling equipment. The following is a list of basic radiation handling equipment which is available in the Nuclear Medicine department.

Lead bricks

Lead vial and container shields

Laboratory coats or equivalent

Absorbent pads

Disposable gloves

Decontaminating agents

Signs and labels indicating the presence of radioactive material Syringe shields

A diagram of the facilities is also enclosed herewith.

Facility Diagram

Room Dimensions: Approx. 16' x 8'

(OUTSIDE - 2nd FLOOR)



(RECEPTION AREA)

ITEM 11. 8-82

PERSONNEL TRAINING PROGRAM

The personnel training program will be given to all personnel who work with or in the vicinity of radioactive materials. The training will be in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel receive proper instruction in the items specified in 19.12 of 10 CFR Part 19, to include:

- A. Areas where radioact a material are used or stored.
- B. Potential hazards associated with radioactive material
- C. Radiological safety procedures appropriate to their respective duties.
- D. Pertinent NRC regulations.
- E. Rules and regulations of the licensee.
- F. Pertinent terms of the license.
- G. Their obligation to report unsafe conditions.
- H. Appropriate response to emergencies or unsafe conditions.
- Their right to be informed of their radiation exposure and bioassay results.
- J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Personnel will be properly instructed as follows:

- A. Before assuming duties with or in the vicinity of rad.oactive materials.
- B. During annual refresher training.
- C. Whenever there is a significant change in duties, regulations, or the terms of the license.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- The Chief Nuclear Cardiology technologist or his designee will place all orders for radioactive material, and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
- During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
- 3. During off-duty hours, NO radioactive material shipments will be delivered to this facility.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

For safely opening packages containing radioactive material, the technologist will:

- 1. Put on gloves to prevent hand contamination.
- Visually inspect packages for any sign of damage (wetness, crushed, etc.) If damage is noted, the procedure will be stopped and the radiation safety officer notified.
- Measure exposure rate at 3 feet from package surface and record. If greater than 10 mR per hour, the procedure will be stopped and the radiation safety officer notified (see NOTE, below).
- Measure surface exposure rate and record. If greater than 200 mR per hour, the procedure will be stopped and the radiation safety officer notified (see NOTE, below).
- 5. Wipe test surface of outer container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/100cm², etc.). Check wipes with end window GM survey meter, and take precautions against spread of contamination as necessary. STOP PROCEDURE if 22,000 dpm per 100cm², or above*
- 6. Open the package with the following precautionary steps:
 - A. Open the outer package following manufacturer's instructions if supplied and remove packing slip.
 - B. Open inner package and verify contents agree with packing slip. Compare requisition, packing slip and label on bottle.
 - C. Check integrity of final source container, i.e., inspect for breakage of sales or vials, loss of liquid, and discoloration of packing material.
 - D. Check that shipment does not exceed possession limits.
- 7. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., dpm/ -², etc.) Check wipes with an end window GM survey meter and take precautions against spread of contamination as necessary.

ITEM 14. 8-82 PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING DIOACTIVE MATERIAL -2-

8. Monitor the packing material and package for contamination before discarding. If contaminated, treat as radioactive waste. If not contaminated, radiation labels will be obliterated before discarding in regular trash.

Records will be maintained of the results of checking each package (see following sample).

*If maximum permissible levels indicated above are exceeded at any point, STOP THE PROCEDURE AND IMMEDIATELY NOTIFY THE RADIATION SAFETY OFFICER AND/OR CHIEF TECHNOLOGIST for further instructions. The R.S.O. will notify the appropriate regulatory agency (NRC or Agreement State) the final delivery carrier, and the vendor.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1.	P.O. # (if applicable)	Survey Date Surveyor		Time
2.	CONDITION OF PACKAGE: 0.K.	_Punctured	Status	Wet
3.	Crushed RADIATION UNITS OF LABEL:	Other	Units (r	mRem/hr)
4.	MEASURED RADIATION LEVELS a. Package surface	: mRem/hr(S	TOP PROCEDURE	if 200mR/hr. or above)*
5.	DO PACKING SLIP AND VIAL	CONTENTS AGREE?	nikeni/ nr	10mR/hr., or above)*
	a. Radionuclidey b. Amounty c. Chem Formy	esno, esno,	difference _ difference _ difference _	
6.	WIPE RESULTS FROM: a. Outer eff = (DPM (<u>STOP</u> PRO	DCEDURE if 22,	,000 dpm/100cm ² , or above)*
	b. Final source container	cPM = eff = (DPM)	
7.	SURVEY RESULTS OF PACKING	MATERIAL AND CA	ARTONS	mRem/hr,
8.	DISPOSITION OF PACKAGE AF	TER INSPECTION		
9.	IF NRC/CARRIER NOTIFICATION NOTIFIED.	ON REQUIRED, GIV	/E TIME, DATE,	AND PERSONS

*NOTE:

If maximum permissible levels indicated above are exceeded at any point, STOP PROCEDURE. Immediately notify the Radiation Safety Officer, or Chief Technologist of the department for further instructions.

The Radiation Safety Officer will notify the appropriate regulatory agency (NRC or Agreement State), the final delivery carrier, and the vendor.

CONTROL NO. 06817

USE OF MOLY/TECH GENERATORS AND PREPARATION OF REAGENT KITS AND DOSE ADMINISTRATION

- In all cases, all instructions supplied by the manufacturers of the generators and radiopharmaceutical kits will be followed precisely, including procedures for elution, assay, kit preparation, radiation precautions and the use of special equipment such as syringe shields, and other accessories.
- Areas used for elution of Mo-99/Tc-99m generators, for preparation of radiopharmaceuticals from reagent kits, and for preparation of individual patient doses will be surveyed for contamination after each procedure or at the end of each work day.
- 3. Every elution of generators will be assayed by use of the dose calibrator for technetium-99m activity and molybdenum-99 breakthrough contamination. The eluates will not be used if there is more than one (1) microcurie of Moly-99 per millicurie of technetium-99m or more than five (5) microcuries of Moly-99 per administered dose of technetium-99m. NOTE: Molybdenum breakthrough tests will be performed in accordance with the instructions provided in the Operating/Instruction Manual for

the dose calibrator.

- 4. Individuals who elute Mo-99/Tc-99m generators, prepare radiopharmaceuticals from reagent kits, and all personnel who prepare patient doses or work in areas used for elution of generators, preparation of radiopharmaceuticals or preparation of individual patient doses will monitor their hands and clothing for contamination before leaving those areas.
- 5. The activity of all radionuclides or radiopharmaceutical doses to be administered to patients will first be determined by mathematical calculations. Once drawn, the total activity contained in the syringe will be double checked by use of the dose calibrator. Except for this determination, the syringe will be kept in the syringe shield and/or pig. All radiopharmaceuticals will be assayed just prior to administration to the patient.
- Patient dose information of administered technetium-99 and all other administered radioactive materials will be recorded in the patient dose log.

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

- Laboratory coats and other protective clothing will be worn at all times in areas where radioactive materials are used.
- Disposable gloves will be worn at all times while handling radioactive materials.
- 3. Hands and clothing will be monitored for contamination at the end of each working day.
- 4. Syringe shields for preparation of patient doses and administration to patients will be used except in circumstances such as pediatric cases when their use would compromise the patient's well-being.
- 5. There will be no eating, drinking, smoking, or application of cosmetics in any area where radioactive material is stored or used.
- 6. Each patient dose will be assayed in the dose calibrator just prior to administration. Any doses that differ from the prescribed dose by more than 10% will not be used.
- 7. Personnel monitoring devices (film badge or TLD) will be worn at all times while in areas where radioactive materials are used or stored.* These devices will be worn at chest or waist level.
- 8. TLD finger badges will be worn during elution of generator and preparation, assay, and injection of radiopharmaceuticals.
- Radioactive waste will be disposed of only in specially designated receptacles.
- 10. There will be no pipetting by mouth.
- Generator, kit preparation, and injection areas will be surveyed for contamination after each procedure or at the end of the day and will be decontaminated if necessary.
- 12. Radioactive solutions will be confined in covered containers, plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.
- Radioactive material will always be transported and maintained in shielded containers.
- 14. The laboratory will be locked when personnel are not present.
- Emergency notification home telephone numbers will be posted on the door.
- 16. There will be no storage of food, drink, or personal effects with radioactive material.
- *Personnel monitoring devices will be stored in a designated low background area when not being worn. 8-82

EMERGENCY PROCEDURES

Minor Spills

*

- 1. All persons in the area will be notified when a spill has occurred.
- 2. The spill will be covered with absorbent paper to prevent its spread.
- 3. Disposable gloves and remote handling tongs will be used to clean up the spill. The absorbent paper and pad will be carefully folded, inserted into a plastic bag and disposed of in the radioactive waste container. All other contaminated materials such as disposable gloves will also be inserted into the plastic bag.
- 4. The survey will be conducted using a low-range, thin-window G-M survey meter. The area around the spill, hands, and clothing will be checked for contamination.
- 5. The incident will be reported to the radiation safety officer.

Major Spills

- All persons not involved in the spill will be notified to vacate the room.
- The spill will be covered with absorbent pads, but no attempt to clean it up will be made. The movement of all personnel potentially contaminated will be confined to prevent the spread.
- If possible, the spill will be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
- 4. The room will be vacated, and the door(s) locked to prevent entry.
- 5. The radiation safety officer will be immediately notified.
- 6. Contaminated clothing will be removed and stored for further evaluation by the radiation safety officer. If the spill is on the skin, the area will be flushed thoroughly and washed with mild soap and lukewarm water.

RADIATION SAFE	ETY OFFICER:	Daryl R.	Melvin, M	M. D.	
OFFICE PHONE:	517-374-2304				
HOME PHONE:	517-349-4932				

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER: Marshall Spencer, M. D.

Offi	ce	:		5	1	7	-	3	7	4	-	2	3	04	
Home		5	1	7	-	3	5	1		0	8	1	3		

AREA SURVEY PROCEDURES

The following area survey procedures will be conducted by the Chief Technologist of the department or his designee, in each area where radioactive material is used or stored:

- All elution, preparation, and injection areas will be surveyed daily with an appropriately low range G-M survey meter and decontaminated if necessary.
- 2. All other laboratory areas will be surveyed weekly.
- 3. The weekly survey will consist of:
 - A. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mRem per hour.
 - B. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm per 100 cm² for the contamination involved.
- A permanent record will be kept of all survey results, including negative results. The record will include:
 - A. Location, date, and type of equipment used.
 - B. Name of person conducting the survey.
 - C. A drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
 - D. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).
 - E. Detected contamination levels, keyed to locations on drawing.
 - F. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
- The area will be cleaned if the contamination level exceeds 100 dpm per 100 cm².
- NOTE: For daily surveys where no abnormal exposures are found, only the date, identification of the person performing the survey and the survey results will be recorded.

Solid radioactive waste will be divided into two groups: Long lived and short lived.

Adequate lead or other suitable shielding will be provided as necessary to reduce the radiation exposure levels to the lowest reasonable level while radioactive waste is in temporary storage.

All solid radioactive waste (short and long-lived) will be held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. Once this has been achieved, all radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash. Appropriate documentation will be maintained.

Liquid radioactive waste will be disposed of in the sanitary sewerage system in accordance with Section 20.303 of 10 CFR 20.

Generators will be disposed of by either of the following methods:

- Returned to the manufacturer in accordance with applicable DOT, NRC and/or State regulations governing the transport of radioactive materials.
- Generators will be disassembled after a minimum of 10 half-lives from the original assay date. The Molybdenum core will be placed in the long-lived waste container for subsequent storage and monitoring as described above. The lead will be surveyed as above, and disposed of accordingly.
- NOTE: The radioactive waste area is located within the Nuclear Cardiology Lab, which is locked when staff personnel are not present. Radiation surveys are conducted at least weekly.

ITEM 18. 8-82

CONTROL NO. 06817