SYLLABUS FOR NUCLEAR PHARMACY TRAINING

Prologue

This syllabus is intended to provide guidance to pharmacy school educators and Nuclear Pharmacy preceptors who wish to be involved in the education and training of Nuclear Pharmacists. For those educators and preceptors not presently engaged in this activity, this document can be used as a tool to aid them in the development of curricular and/or experiential training programs. The information provided in this document lists those areas that, at minimum nuclear pharmacy students should be exposed to during their training program. The overall intent of this syllabus is to encourage consistency between nuclear pharmacy training programs. In this way it is expected that, regardless of which program is completed, each student will acquire a comparable level of "specialized" knowledge and skill needed to practice nuclear pharmacy in an independent and competent manner. It is also expected, therefore, that an individual who successfully matriculates through a program adhering to this syllabus will: 1) be qualified to seek authorization from the U.S. Nuclear Regulatory Commission (NRC) (and/or NRC Agreement State Agency) as a nuclear pharmacist and 2) be eligible for recognition and/or licensure as a nuclear pharmacist by most, if not all, State Boards of Pharmacy.

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PART I - DIDACTIC COMPONENT OF INSTRUCTION

(Suggested 250 Hours)

This section describes those areas of nuclear pharmacy education expected to be included in formal lecture and laboratory courses in training programs. The Intent here is to expand, in greater detail, those areas of training designated by the NRC. Additionally, a clinical applications component is included which, although not specified by the NRC, nonetheless is necessary for nuclear pharmacy practice. It is important to note that a nuclear pharmacist should have familiarity with as many different subject areas as possible, but not necessarily achieve mastery in all areas contained in this syllabus. The major emphasis here is one of good pharmacy practice relative to the safe handling and use of radioactive drugs, rather than any specific NRC expectation towards these agents. An asterisk (*) indicates subject matter to be covered in lecture and/or laboratory. An Item listed without an asterisk indicates subject matter best addressed by lecture presentation(s) only.

RADIATION PHYSICS AND INSTRUMENTATION
(Suggested 85 hours)

I. Structure and Properties of Atoms
   A. Atomic Models, Nomenclature
   B. Nuclides and Radionuclides
      1. Isotopes, isobars, isotones, Isomers
      2. Chart of the nuclides
   C. Orbital Energy Levels
      1. Energy units: eV, keV, and MeV
      2. Electron shell binding energy, excitation and de-excitation
      3. Characteristic X-rays, Auger electrons, visible radiation
   D. Nuclear Energy Levels
      1. Nuclear excitation and de-excitation processes
      2. Gamma rays
   E. Mass and Energy Intraconversion
   F. Nuclear Forces and Binding Energy
   G. Nuclear Fission and Fusion

II. Radiation and Radioactive Decay
   A. Radiation
      1. Defined
      2. Principal forms
   B. Nuclear Stability and Radioactive Decay
      1. Decay constant
      2. Half life
      3. Average lives
      4. Effective half-life
   C. Types of Decay
      1. Alpha
      2. Negatron (beta minus)
      3. Positron (beta plus)
      4. Electron capture decay
5. Isomeric transition
D. Considerations in Radioactive Decay Processes
   1. Disposition of decay energy
   2. Beta energy spectrum
   3. Neutrinos
   4. Beta only vs. beta-gamma emission
   5. Annihilation reaction
   6. Characteristic X-rays
   7. Auger electrons
   8. Isomeric transition
   9. Metastable states
  10. Internal conversion

III. Decay schemes of Radionuclides Load in Nuclear Medicine
   A. Trilinear Chart of the Nuclides
   B. Sequential Decay
   C. Growth of Radioactive Daughters
   D. Transient Equilibrium
   E. Secular Equilibrium

IV. Production of Radionuclides
   A. Nuclear Reactors - fission by-product or neutron activation
   B. Cyclotrons and Linear Accelerators
   C. Types of Nuclear Reaction
   D. Target preparation, Bombardment and Processing
   E. Isotope Activation Equations
   *F. Radionuclide Generators

V. Interactions of Radiation with Matter
   A. Excitation and Ionization
   B. Positive Particle Interactions
      1. Mechanism of excitation and ionization
      2. Alpha particle, positive and heavy ion Interactions
      3. LET, specific ionization
      4. Annihilation radiation
   *C. Electron Interactions
      1. Mechanism of excitation and Ionization
      2. Bremsstrahlung production
   D. Neutron Interactions
   *E. Photon Interactions
      1. Photoelectric effect
      2. Compton scattering
      3. Pair production

VI. Instruments for Radiation Detection and Measurement
   *A. Ion Collection Methods (i.e. Cutie Pie, Pocket Dosimeters, Proportional Counters, Dose Calibrators, and G-M detectors)
      1. Ionization chambers
      2. current-voltage relationships
         a. Simple ionization
b. Primary and secondary ionization
c. Proportional region
d. Geiger region
e. Pulse vs. current
f. Calibration

*B. Scintillation Detectors
  1. Principles of operation
  2. Calibration
  3. Use
  4. Quality control
  5. External solid crystals
  6. Internal liquid scintillation
  7. Pulse height analyzers
     a. Single channel
     b. Multichannel

*C. Film Emulsions
  1. Film badges
  2. Autoradiography

*D. Thermoluminescent Detectors

*E. Solid State Detectors

MATHEMATICS OF RADIOACTIVITY USE AND MEASUREMENT
(Suggested 20 hours)

I. Radioactivity
   A Radioactive Decay Law and Equations
   B. Units of Radioactivity
      1. Traditional
      2. SI
   C. Half-life and Decay Constant
   D. Decay Tables (construction and use)

II. Nuclear Counting Statistics and Measurement
    A Gaussian Distribution
    B. Poison Distribution
    C. Chi Square
    D. Percent Error

III. Health Physics Equations and Use
    A. Inverse Square Law
    B. Half Value Layers
    C. Linear Attenuation Coefficient
    D. Mass Attenuation Coefficient

IV. Radiopharmaceutical Preparation and Dispensing Calculations
    A. Activity
    B. Concentration
    C. Volume
    D. Pre-calibration post-calibration decay tables
    E. Particle number
    F. Expiration time
G. Specific activity

V. Generator operation and Use
   A. Calculations to determine parent activity over time
   B. Calculations using transient and secular equilibrium equations to determine:
      1. Daughter activity-time profiles following elution
      2. Theoretical yields
      3. Elution efficiency
      4. Parent-daughter-granddaughter nuclide cascade
      5. Mole fractions

VI. Calculations Involved with Radioactivity Measurement and Counting Statistics
   A. Accuracy, Precision and Percentage Error of Radiopharmaceutical Dosage
   B. Mean, Standard Deviation, Probable Error
   C. Background Correction
   D. Geometry Correction

VII. Quality Assurance Calculations
   A. Radionuclide, Radiochemical and Chemical Purity of Radiopharmaceuticals
   B. Dose Calibrator Accuracy, Constancy, Linearity and Geometry
   C. Scintillation Counter
      1. Efficiency
      2. Dead time
      3. Resolution
      4. Precision
      5. Minimum and maximum detectable activity
   D. Size Analysis of Particulate Radiopharmaceuticals

VIII. Calculations Associated with the Quantitative Assessment of Radiopharmaceutical Absorption, Distribution, Metabolism and Excretion
   In-vivo Function Studies
   In-vitro Studies
   Kinetic Studies

IX. Calculations Involved with Medical Decisions
   A. Sensitivity
   B. Specificity
   C. Accuracy
   D. Predictive Diagnostic Value

X. Radiation Dosimetry Calculations
   A. MIRD Equation
   B. Internal Dose Equivalents
   C. External Dose

RADIATION PROTECTION & REGULATIONS (Suggested 45 hours)

I. Interactions of Radiation with Matter
   A. Excitation, Ionization, Energy Deposition
   B. Specific Ionization-, Linear Energy Transfer (LET)
      1. Comparison of alpha, beta and gamma radiation
      2. Range in matter
      3. Relative hazard as external and internal sources
II. Units of Radiation Measurement
   A. Roentgen (R)
   B. Radiation Absorbed Dose (RAD)
   C. Gray (Gy)
   D. Radiation Biological Equivalents (RBE)
   E. Radiation Equivalent Man (REM)
   F. Seivert (Sv)
   G. Quality Factors (QF)
   H. Internal Dose Equivalents
      1. Committed Dose Equivalent (Hc,T)
      2. Committed Effective Dose Equivalent (HE,C)
      3. Stochastic Risk Weighing Factor (Wt)
   I. External Dose Equivalents
      1. Deep Dose Equivalent (Hd)
      2. Eye Dose Equivalent (He)
      3. Shallow Dose Equivalent (Hs)
   J. Internal + External Dose Equivalents
      1. Total Organ Dose Equivalent (TODE)
      2. Total Effective Does Equivalent (TEDE)
   K. Airborne Radiation Exposure Measurements
      1. Annual Limit on Intake (ALI)
      2. Derived Air Concentration (DAC)
      3. Effluent Concentration (Iodine-131, Xenon-1133, etc)

III. Occupational and Non-Occupational Exposure Radiation Protection Guides
   A. National Council on Radiation Protection & Measurements (NCRP)
   B. International Commission on Radiological Protection (ICRP)
   C. As Low As Reasonably Achievable (ALARA) Program
      1. Investigational Levels
      2. Radiation Safety Authority
   D. Occupational Safety & Health Administration (OSHA)
      1. Medical Safety Date Sheets (MSDS)
   E. Nuclear Regulatory Commission (NRC)
      1. 10 CFR Parts 2,19,20,30, and 35
   F. Environmental Protection Agency (EPA)
   G. State Radia0on Control Agency

*IV. Principles of Radiation Protection
   A. Time of Exposure
   B. Distance from Source (Inverse Square Law)
      1. Specific gamma ray dose constant
      2. Exposure dose calculations
   C. Shielding
      1. Half-value layer and attenuation coefficients
      2. Determination of shielding requirements
         a. Type of material
         b. Thickness needed
   D. Quantity/Amount of Radiation (i.e. Radiation Accidents)

V. Personnel Monitoring and Precautions
A. ALARA
   1. Concept, scope, and Implementation
   2. Exposure of embryo/fetus
   3. Exposure of the public
   4. Occupational exposure limits
B. Restricted, Controlled and Unrestricted Area
C. Effective Dose Equivalents
D. Monitoring Devices
   1. Film badges
   2. Ring badges
   3. Thermoluminescent dosimeters (TLD's)
   4. Pocket dosimeters
   5. Other types of dosimeters
E. Bioassays
F. Precautionary Warning (Caution) Signs
G. Reports and Notices
   1. NRC Form 4
   2. NRC Form 5

VI. Area Monitoring (Personnel and Work Environment)
   A. Surveys, wipe tests and monitoring intervals required in work areas Where:
      1. Radioactive material is stored or
      2. Compounded, dispensed or administered
      3. Unrestricted area
   B. Limits of radiation contamination and exposure
      1. In work area (restricted)
      2. Unrestricted area
   C. Air Monitoring (10 CFR 20)
      1. Airflow velocity measurements - hood & room
      2. Restricted and unrestricted areas

VII. Radioactive Packages and Sources
   A. Procedures for opening radioactive packages
   B. Requirements for shipment of radioactive material
      1. Packaging
      2. Labeling
      3. Transport Index
      4. Shipping papers
      5. Pleasing of vehicles
      6. Removable contamination survey
   C. Monitoring sealed sources (leak tests)

VIII. Radioactive & Biohazardous Waste Disposal Methods
   A. Decay in Storage
   B. Separation by Half Life
   C. Incineration
   D. Sewer or Atmosphere

*IX Radiation Safety
A. Laboratory techniques for handling radioactive material safely
B. Laboratory design
   1. Minimizes potential for radioactive contamination and radiation exposure
   2. Proper placement of hoods and sinks
   3. Location of storage, compounding, dispensing, quality control, and waste areas
C. Regulatory Agencies
   1. Nuclear Regulatory Commission (NRC)
   2. Foods and Drug Administration (FDA)
   3. State Radiation Control Agency
   4. Department of Transportation (DOT)
   5. Occupational Safety & Health Administration (OSHA)
   6. State Boards of Pharmacy
   7. Environmental Protection Agency (EPA)
D. Quality Management Plan
E. Radiation Safety Committee
F. Radiation Safety Officer

*X Radiation Accidents
A. Emergency Procedures
B. Major and Minor Spills
C. Decontamination Procedures
   1. Facility
   2. Personnel
D. Incident Reporting (10 CFR 30.50)

RADIATION BIOLOGY
(Suggested 20 hours)

I. Interaction of Ionizing Radiation with Matter
   A. Types of radiation
      1. Particulate
      2. Photons
   B. Interactions of Radiation with Emphasis on Biological Systems
      1. Direct and Indirect effects
      2. Energy distribution patterns
   C. Units of Energy Transfer
      1. Specific Ionization
      2. Roentgen (R)
      3. Rad
      4. Roentgen equivalent man (REM)
      5. Linear energy transfer (LET)
      6. SI units (sieverts, grays, etc)
   D. Initial Physical and Chemical Actions of Imparted Energy (including application to RBE and Quality Factors)

II. Radiation Chemistry
   A. General Concepts
   B. Aqueous Systems
1. Ionization, excitation and formation of free radicals
2. Initial reactions (including influence of LET, oxygen and various compounds on free radical forming reactions)

C. Factors Affecting Reactions
   1. Oxygen
   2. Concentration
   3. LET

D. Application to D031metry (including MIRD techniques)

E. Application to Basic Compounds and Macromolecules
   1. Types of molecules; enzymes, DNA, RNA
   2. Structural changes
   3. Influence of dose, dose rate, LET, and Oxygen

III. Cellular Response
   A. Effect on Cells
      1. Nucleus vs. cytoplasm
      2. DNA vs. RNA
   B. Sensitive Organelles
   C. Concept of Target(s) and Radiosensitivity
      1. Single hit vs. multiple hit concepts
      2. Multi-hit/multiple targets
   D. Response to Increasing Radiation Dose
      1. Expression and determination
      2. Relation to maximum permissible dose
   E. Factors Influencing Response
      1. Dose rate and dose fractionation
      2. LET
      3. Oxygen
      4. Cell type and call cycle

IV. Effects on Nucleic Acids
   A. Structural Changes
   B. Synthesis and Replication
   C. Mechanism(s) of Repair
   D. Influence on Cell Cycle

V. Radiation Genetics (Hereditary Effects)
   A. Gene Effects
   B. Chromosomal Effects
   C. Assessment of Risk

VI. Effects of Ionizing Radiation on the Embryo and Fetus
   A. Mechanism and Consequences
   B. Assessment of Risk (Teratogenic and delayed effects)

VII. Whole-Body Effects of Ionizing Radiation
   A. Overview of Radiation Exposure of Tissues and Organs
   B. Hematopoietic Tissue
   C. Gastrointestinal Tract
   D. Skin
E. Reproductive Organs
F. Nervous System
G. Respiratory System
H. Circulatory System
I. Urinary System
J. Musculoskeletal System
K. Endocrine Organs
L. Sensory Organs

VIII. Acute Effects of Ionizing Radiation
   A. Bone Marrow Syndrome
   B. Gastrointestinal Syndrome
   C. Cerebrovascular Syndrome
   D. Influencing Factors
      1. Type of radiation and area of exposure
      2. Dose, dose rate, and dose fractionation

IX. Delayed Effects of Ionizing Radiation
   A. Historical Overview (including BEIR Report)
   B. Occurrence, Risks and Types of Exposure
   C. Hereditary Effects (see also Radiation Genetics)
   D. Somatic Effects
      1. Cancer induction
      2. Life span shortening
      3. Organ fibrosis and degeneration

X. Low Level (Low Dose Exposure to Ionizing Radiation)
   A. Sources
      1. Medical
      2. Natural background
      3. Radon
   B. Significance
   C. Radiation Hormesis
   D. Recommendations

XI. Radiotherapy
   A. Types of Radiotherapy (An Overview)
   B. Basic Principles of Radiotherapy (the Four R's)
      1. Repair
      2. Deoxygenating
      3. Repopulation
      4. Redistribution
   C. Treatment Protocols
   D. Radiosensitive
   E. Hypothermia
RADIOPHARMACEUTICAL CHEMISTRY  
(Suggested 30 hours)  
I. Production of Radionuclides  
   A. Accelerator/Cyclotron Produced Radionuclides  
      1. Targeting  
      2. Kinetics  
   B. Reactor Produced Radionuclides  
      1. Targeting  
      2. Kinetics  
   C. Radionuclide Generators  
      1. Mathematical Principles  
      2. Use and advantages  
      3. Applications  
      4. Quality Assurance  

II. General Physicochemical Properties of Radioactive Compounds  
   A. Distinction between radionuclide, radiochemical and radiopharmaceuticals  
   B. Activity-mass relationship  
   C. Tracer concentration expressions  
      1. Specific activity  
      2. Concentration  
   D. Carrier concept/designations (carrier-free, carrier added, no carrier added)  
   E. Solution chemistry of tracer radionuclide metals  
      1. Hydrolysis  
      2. Reduction-oxidation  
      3. Complications reactions  
      4. Radiolytic decomposition  
   F. Diagnostic vs. therapeutic use  
   G. Types of labeling: isotopic vs. non-isotopic (foreign) labeling  
   H. Physical properties  
      1. Decay mode  
      2. Photon energy  
      3. Particulate energy and range  
      4. Half-life  
      5. Chemistry  
      6. In-vitro stability  

III. Properties of Radiopharmaceuticals  
   A. Physical properties  
      1. Decay mode  
      2. Photon energy  
      3. Particulate energy and range  
      4. Half-life,  
      5. Chemistry  
      6. In-vitro stability  
   B. Biological properties  
      1. Distribution  
      2. Metabolism  
      3. Excretion
4. Pharmacokinetics
   C. Metal-tagged Radiopharmaceuticals
      1. Proteins
      2. Colloids
      3. Cells
   D. Metal Essential Radiopharmaceuticals
   E. Substrate specific radiopharmaceutical localization
      1. Isotopically substituted
      2. Biochemical
      3. Metabolic trapping
      4. Enzyme Inhibitor
      5. Enzyme substrate
      6. Receptor-binding biochemical or drug
      7. Antibodies to tumor associated antigens
   F. Substrate nonspecific radiopharmaceutical localization
      1. Diffusion
      2. Compartmental space
      3. Capillary blockade
      4. Cell sequestration
      5. Phagocytes
      6. Chemisorptions
   G. Radiopharmaceutical Development
      1. Empirical approaches to design
      2. Rational approaches to design
   H. Structure / Distribution Relationship

*IV. Quality Control of Radiopharmaceuticals
   A. Radionuclidic Purity
      1. Gamma scintillation spectrometry
      2. Differential attenuation
   B. Radiochemical Purity (i.e. chromatographic and other separation methods)
   C. Chemical Purity (i.e. chromatographic methods)
   D. Visual Inspection (i.e. color, clarity, particle size and number of particles)
   E. pH measurement
   F. Sterility testing
   G. Endotoxin testing
   H. Cell viability
   I. Antigen-excess

*V. Technetium Radiopharmaceuticals
   A. Molybdenum Mo-Technetium Tc-99m generator
      1. Production schema
      2. Operation
      3. Quality control
      4. Generator physics
      5. Transient equilibrium
      6. Specific activity
      7. Wet vs. dry column
   B. Technetium chemistry
      1. Oxidation states
2. Reduction methods
3. Technetium tin-ligand reactions in aqueous solution
   a. Hydrolysis
   b. Re-oxidation
   c. Complexation
   d. Carrier effects
   e. Radiolytic decomposition
C. Technetium kits (i.e. proportion and composition)
D. Specific kits (i.e. methods for radiolabeling with Tc-99m)
E. Miscellaneous (i.e. monoclonal antibodies, peptides and molecular recognition limits)

VI. Iodine Radiopharmaceuticals
A. Solution chemistry of radiolodide (i.e. oxidation to volatile forms)
B. Radiolodination procedures (including preparation and quality control)
   1. radioiodinated albumin
   2. Ortho-iodohippurate
   3. Meta-iodobeziyguanidine (MIBG)
   4. Iodocholesterol
   5. Amphetamines
   6. Proteins
   7. Monoclonal antibodies
   8. Peptides
   9. Molecular recognition units (MRU's)
C. Dosage forms available
D. Safety techniques for handling radioiodine

*VII. Radiolabeled Blood Calls
A. Methods for blood cell separation prior to labeling
B. Tc-99m red blood cells (i.e. In-vitro, in-vivo and modified In-vivo methods of labeling for blood pool studies and detection of gastrointestinal bleeding)
C. Tc-99m red blood cells (heat damaged) for spleen specific imaging
D. In-111 white blood cells (i.e. methods of radiolabeling for abscess localization)
E. Cr-51 red blood cells (i.e. methods of radiolabeling for blood volume measurement)
F. In-111platelets (i.e. methods for radiolabeling)
G. Tc-99m white blood calls (i.e. methods for radiolabeling for abscess or Inflammation detection)

VIII. Prepared Radiopharmaceuticals (i.e. quality control, physicochemical and kinetic properties, and dosage forms, etc)
A. Gallium (Ga)
B. Indium (In)
C. Phosphorous (P)
D. Chromium (Cr)
E. Cobalt (Co)
F. Radioactive Gases (i.e. Xenon Xe-133, X9-127, "on Kr-81w)
G. Iron (Fe)
H. Thallium (TI)
I. Strontium (Sr)
J. Iodine (I)
K. Yttrium (Y)
L. Rhenium (Re)
M. Samarium (SM)
N. Miscellaneous

IX. Positron Emitting Nuclides (i.e. preparation, quality control, physicochemical and kinetic properties, and dosage forms, etc)
   A. Fluorine (F)
   B. Oxygen (O)
   C. Carbon (C)
   D. Nitrogen (N)
   E. Copper (Cu)
   F. Rubidium (Rb)
   G. Gallium (Ga)
   H. Miscellaneous

X. Receptor Specific Radiopharmaceuticals (i.e. preparation, quality control, physicochemical and kinetic properties, and dosage forms, etc)
   A. Antibodies, Polyclonal & Monoclonal
   B. Peptides
   C. Molecular Recognition Units
   D. Miscellaneous Investigational Agents
   E. Radionuclides
      1. Indium (In-111)
      2. Technetium (Tc-99m)
      3. Iodine (I-131)
      4. Rhenium (Re-186 & 188)
      5. Miscellaneous

THE CLINICAL USE OF RADIOPHARMACEUTICALS
(Suggested 50 hours)

I. In vivo kinetics of radiopharmaceuticals
   A. Absorption, distribution, metabolism, elimination
   B. Normal vs. abnormal kinetics
   C. Factors that affect/alter the kinetics of radiopharmaceuticals

II. Specific procedures that employ radiopharmaceuticals
   A. Indications for the procedure
   B. Criteria for the selection of the appropriate radiopharmaceutical
   C. Optimal imaging or therapeutic protocols
   D. Interventional techniques that enhance the procedure
   E. Interpretation of the procedure outcome and its effect on patient management
   F. Sensitivity, specificity, and predictive value of diagnostic procedures
   G. Expected benefits of therapeutic procedures.

III. Preparation and monitoring of patients who receive radiopharmaceuticals
   A. Patient education and preparation for procedure
   B. Precautions and considerations for *pedal patient populations
C. Dosage adjustment based on age, weight, body surface area, organ function, instrument sensitivity, etc
D. Clinical problems associated with the use of radiopharmaceuticals
   1. Adverse reactions / untoward effects
   2. Misadministrations / reportable events
   3. Unusual or unanticipated Images or therapeutic outcomes.
      a. Artifacts
      b. Altered radiopharmaceutical biodistribution due to interference from drug therapy or surgical Intervention; radiopharmaceutical formulation problems; improper administration techniques, etc.
      c. Variations in human anatomy
E. Correlation between the results of product quality control testing and clinical outcome of the procedure
F. Use of radiopharmaceuticals to monitor the safety and/or efficacy of specific drug therapy regimens
G. Drug information resources for nuclear medicine and nuclear pharmacy
H. The role of the nuclear pharmacist as consultant and provider of patient specific Information.
PART II: EXPERIENTIAL COMPONENT (Suggested 500 hours)

The experiential component of nuclear pharmacy education and training is intended to provide the student with hands-on experience handling radioactive material. The student will gain experience in all aspects of providing radiopharmaceutical services to departments of nuclear medicine at one or more Institutions. Although the specific services rendered by individual nuclear pharmacies will likely be different, the types of experiences described in this section are those that a nuclear pharmacist is expected to be familiar with in most practice situations: that is, they are fundamental to nuclear pharmacy practice.

I. Orientation to Nuclear Pharmacy Practice (Suggested 5 hours)
   A. The student will gain an overview of nuclear pharmacy practice by becoming familiar with daily routines and the functions performed by nuclear pharmacists namely, procurement, compounding, quality control, dispensing and distribution of radiopharmaceuticals, waste disposal and radiation safety procedures. Related to these routine functions are the development and testing of new drugs and formulations.
   B. The student should also participate in the transport and delivery of radiopharmaceuticals and visitation with the professional staff at nuclear medicine departments serviced by the nuclear pharmacy.

II. Procurement of Radiopharmaceuticals (Suggested 20 hours)
   A. Radioactive materials license - become familiar with the license and the types and limits of radionuclide material that can be ordered.
   B. Ordering radiopharmaceuticals - be able to order a radiopharmaceutical with consideration of purchase orders, suppliers, standing orders, on-demand orders, ordering schedules and times, precalibration times and record keeping, including familiarity with computer procedures.
   C. Receipt of radiopharmaceuticals - be able to conduct procedures for receiving and opening radiopharmaceuticals with consideration of delivery procedures, trace of delayed shipments, surveys, wipe tests, radioassay, packaging, disposal, storage requirements, and record keeping logs.

III. Compounding of Radiopharmaceuticals (Suggested 80 hours)
   A. Tc-99m generator operations - be able to conduct procedures for receipt and setup of the generator, elution, eluate assay (radioconcentration), quality control (moly breakthrough, Al ion test), establishing expiration time, assigning control numbers, labeling and record keeping.
   B. Tc-99m kits - be familiar with manufacturer’s package insert regarding Tc-99m label, procedures, storage, shelf-life, dosage, approved Uses, assignment of control numbers, labeling and record keeping. Be able to prepare such kits, including awareness for V is need of extemporaneous compounding.
   C. Work aims - be able to set up the compounding and dispensing areas with proper shielding barriers, absorbent coverings and materials (disposable glove3, syringe and vial shields, waste containers, syringes, noodles, diluents and labels).
   D. Laminar airflow hoods - become familiar with proper setup, opening, and maintenance of hood for radiopharmaceutical procedures.
   E. Aseptic and safety techniques - be familiar with aseptic techniques to prevent bacterial contamination of radiopharmaceuticals such as labeled proteins, blood cells and
specific chemical entities, and protecting self from infectious diseases (e.g., universal precautions).
F. Compounding procedures - is able to conduct procedures for preparing non-kit and specially-prepared radiopharmaceuticals such as labeled proteins, blood calls, monoclonal antibodies and specific chemical entities.
G. Radiation measurement - understand principles of operation and use of the following instruments:
   1. GM survey meter calibration and use
   2. Dose calibrator calibration and use with consideration of the factors (amount of activity and source geometry) that affect accuracy in measurement
   3. Scintillation well counter calibration and use with consideration of efficiency, minimum and maximum detectable activities, geometry and precision.
   4. Single vs. multichannel counters.

IV. Quality Control of Radiopharmaceuticals (Suggested 50 hours)
Performs routine analytical testing and determines the suitability for use by comparison of results with established professional, institutional or published methods.
   A. Radionuclidic purity - be able to quantitate purity using gamma scintillation spectrometry or shielding methods.
   B. Radiochemical purity - be able to determine amount of radiochemical impurities
      1. Thin layer chromatography
      2. Solvent extraction
      3. Column chromatography - low pressure and HPLC
      4. Precipitation with filtration or centrifugation
   C. Pharmaceutical purity
      1. pH: be knowledgeable of the acceptable range of pH values for each radiopharmaceutical and the significance of deviations from this range.
      2. Visual inspection: be familiar with the accepted norm for color clarity, particle size and number, where appropriate, for each radiopharmaceutical
      3. Chemical tests: be able to test radiopharmaceuticals using accepted procedures for chemical impurities when appropriate, e.g., AJ+3 Ion in Tc-99m eluate
      4. Cell viability (e.g., white blood cells)
      5. Antigen excess (monoclonal antibodies)
   D. Instrument tests
      1. Dose calibrator - accuracy, constancy, linearity and geometry effects
      2. Scintillation counter - efficiency, resolution, minimum detectable activity, Chi square statistics
      3. G-M meter - calibration
      4. Perform tests at appropriate intervals and record results
   E. Equipment Tests - familiarity with and ability to determine the proper operation of laminar airflow hoods, exhaust hoods, centrifuges and balances through standard in house or independent laboratory test methods.

V. Dispensing Radiopharmaceuticals (suggested 50 hours)
   A. Prescription order - receives and transcribes radiopharmaceutical orders from clients. Determines appropriateness of the prescription or institutional requisition concerning the type of radiopharmaceutical, the intended use, dosage, route of administration, patient name, age, identification number and prescriber.
   B. Dose preparation
      1. Selects appropriate preformulated radiopharmaceutical
2. Formulates the appropriate radiopharmaceutical kit with Tc-99m pertechnetate determining the appropriate activity and volume needed based on established stability studies and manufacturers recommendations. Performs appropriate quality control tests
3. Calculates the activity and volume of the dose required using appropriate decay factors and considering the amount of precalibration time before use
4. Dispenses the dose using aseptic and safety (shielding) techniques
5. Labels the dose appropriately to identify the patient's name, radiopharmaceutical, activity, volume, calibration time and date, expiration date and control number
6. Shields the dose appropriately
7. Completes record log to identify the radiopharmaceutical, control number, patient name, identification number or prescription number, activity, volume, time and date.

VI. Distribution of Radiopharmaceuticals (Suggested 50 hours)
A. Complies with all institutional, local, state and federal regulations concerning the labeling, packaging and transportation of radioactive materials
B. Consideration should be given to procedures for the following:
   1. Appropriate packaging
   2. Labeling
   3. Vehicle placarding
   4. Monitoring (surveys and wipe tests)
   5. Shipping papers
   6. Accident reporting.

VII. Waste Disposal of Radioactive Material (Suggested 25 hours)
A. Complies with all institutional, local, state and federal regulations regarding the disposal of radioactive material
B. Consideration should be given to the method of disposal and the limits of radioactivity that apply.

VIII. Radiation Safety Procedures (Suggested 50 hours)
A. Complies with all institutional, local, state and federal regulations regarding their use and protection from radiation.
B. Become familiar with nuclear pharmacy design that separates work area into gradations of radiation levels to minimize radiation exposure and contamination.
C. Complies with regulations regarding exhausting of radioactivity into the environment.
D. Complies with decontamination procedures for handling radioactive spills.
E. Complies with procedures for personnel monitoring concerning use, storage, exchange of radiation badges and the report of exposure levels
F. Complies with appropriate procedures for receiving and opening radioactive packages regarding surveys, wipe tests, contamination control and reporting
G. Complies with standards of practice to keep personal radiation exposure as low as reasonably achievable (ALARA) through appropriate consideration of time, distance and shielding and use of protective garments and disposable gloves
H. Maintains calibration of radiation detection equipment and assures proper operation
   1. Monitors work areas at appropriate intervals using surveys, wipe tests, and other techniques to assure that radiation levels and contamination are within acceptable limits for restricted and unrestricted areas
J. Complies with posting requirements to identify with appropriate signs: radiation areas, high radiation areas and areas where radioactive materials are stored. Additionally, is familiar with requirements to inform employees of their rights to information as radiation workers (NRC-FORM 3).

IX. Consultation and Educational Activities (Suggested 120 hours)

A. The nuclear pharmacy student should provide information to health care professionals about radiopharmaceuticals, including:
   1. The physicochemical, biological and kinetic properties of radiopharmaceuticals
   2. Deviations (departures) in radiopharmaceutical preparation from package insert instructions
   3. New indications for the use for radiopharmaceuticals
   4. Radiopharmaceutical usage in special/unique patient populations (e.g. pediatric, geriatric, pregnant, handicapped, etc.)
   5. Altered biorouting or performance of radiopharmaceuticals due to drug interactions, disease, physical trauma, interventional procedures (e.g., blood transfusions, dialysis, etc.), radiopharmaceutical formulation problems, inappropriate administration techniques, etc.
   6. The investigation, identification, treatment, and reporting of adverse reactions to radiopharmaceuticals.

B. The nuclear pharmacy student should provide information to patients and or family members of patients about radiopharmaceuticals and nuclear medicine, including:
   1. How to properly prepare for a nuclear medicine study in order to achieve optimal results
   2. Why the procedure is being performed (i.e. how the procedure affects patient care)
   3. What to expect during the procedure
   4. What effects the radiation will have on the patient
   5. Special radiation safety procedures the patient should follow after receiving a therapeutic radiopharmaceutical

X. Clinical Applications of Radiopharmaceuticals, Case reports: (Suggested 100 hours)

Nuclear pharmacy students should present several case reports that describe how nuclear medicine affected the medical management of selected patients.

Among other things, case reports may illustrate:
1. How a nuclear medicine diagnostic study led to an improved understanding of the patient's condition and/or helped with the process of formulating therapeutic objectives for the patient,
2. How a nuclear medicine therapeutic procedure improved the patient's condition,
3. How unusual imaging results may have caused diagnostic conclusions or led to the need for further diagnostic workup,
4. How nuclear medicine was useful for monitoring the safety and/or efficacy of a therapeutic drug regimen or surgical intervention.

The focus of the case reports should be patients who undergo any of the following nuclear medicine procedures:

A. Diagnostic Imaging Procedures
   1. Brain and cerebrospinal fluid
   2. Endocrine organs (thyroid, parathyroid, adrenal glands)
   3. Cardiovascular (including deep vein thrombosis)
4. Pulmonary (perfusion and ventilation studies)
5. RES (liver, spleen, bone marrow)
6. Hepatobiliary
7. Musculoskeletal
8. Genitourinary
9. Tumor/Abscess/Inflammatory processes
10. Gastrointestinal
11. Miscellaneous studies (e.g. lymphoscintigraphy)

B. In Vivo Function Studies
1. Thyroid uptake
3. Blood related parameters (e.g., RBC mass, plasma volume and RBC survival)
4. Glomerular filtration rate (GFR)
5. Effective renal plasma flow (ERPF)
6. Miscellaneous

C. Therapeutic Procedures
1. Hyperthyroidism and thyroid carcinoma
2. Polycythemia vera
3. Malignant effusions
4. Painful bone metastases
5. Radioimmunotherapy using radiolabeled monoclonal antibodies, peptides, or molecular recognition units
6. Miscellaneous