Charleston Area Medical Center

NUCLEAR PHARMACY

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MS-16

9/21/2011

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475 Allendale Road
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03009164

Re: Request for additional information (Amendment request License #47-15473-01)
Control No. 575696

Ms. Weidner,

Per your request please see the attached training outline for the required 80 hours provided by CorScan Plus. Included in this outline is an estimate of the clock hours for both self study and classroom training for each section as recalled by Dr. Mandapaka.

If there are any questions regarding this information please feel free to contact me at the telephone numbers provided below or you may e-mail your questions to me at kim.lowe@camc.org .

Sincerely,

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575696
NMSS/RGN1 MATERIALS-002

CorScan Plus
Authorized User Training Program
Outline

PHYSICS

24 hours SELF STUDY
4 hours INTERACTIVE

9/21/11

I. Structure of Matter

A. Atomic mass and energy units
   1. Electron Volt (eV)
   2. Atomic Mass Unit (amu)

B. Organization of the Atom
   1. Atomic Structure
   2. X-rays, Origins and Properties
   3. Auger Electrons, Internal Conversion Electrons
   4. Chart of the Nuclides
   5. Nuclear Nomenclature - Z, A, N

C. Structure of Nucleus
   1. Nuclear Particles (Nucleons),
      Neutrons, protons, neutrinos, positrons
   2. Quantum Energy Levels
   3. Neutron: Proton Nuclear Stability
   4. Isotopes, Isobars, Isotones, Isomers

II. Nuclear Reactions

A. Alpha Decay
B. Beta Decay
C. Positron Decay
D. Electron Capture
E. Gamma Emission
   1. Isomeric Transition
   2. Internal Conversion
F. Decay Schemes
G. Radioactive Decay
   1. Half-life
   2. Decay Constant
   3. Average Life Expectancy
H. Parent-Daughter Relationships
   1. Radioactive Series
   2. Secular Equilibrium
   3. Transient Equilibrium

I. Units of Activity
   1. Curie and Sub-multiples
   2. SI Units

III. Interaction With Matter

   A. Ionization and Excitation
      1. Specific Ionization
      2. Linear Energy Transfer
   B. Scatter
   C. Alpha Particles
      1. Interactions with Matter
      2. Path Characteristics
         a. Range
         b. Bragg Curve
   D. Beta Particles
      1. Interactions with Matter
      2. Path Characteristics
         a. Range
         b. Path Length
      3. Bremsstrahlung
      4. Annihilation
   E. Electromagnetic Radiation
      1. Electromagnetic Spectrum
      2. Interactions with Matter
         a. Coherent Scatter
         b. Photoelectric Effect
         c. Compton Effect
         d. Pair Production
         e. Triplet Production
      3. Mathematics of Attenuation and Absorption
         a. Attenuation and Absorption Coefficient
            1. Linear
            2. Mass
         b. Half-Value Layer

IV. Production of Nuclides

   A. Fission
   B. Fusion
   C. Neutron Activation
   D. Transmutation
   E. Linear Accelerators and Cyclotrons

INSTRUMENTATION

I. Gas Detectors

A. Theory of Gas Ionization

B. Types of Detectors
   1. Ionization
   2. Geiger-Mueller

C. Specific Examples in Nuclear Medicine
   1. Cutie Pie
   2. G-M
      a. Types of probes
      b. Low energy correction factor
      c. Check sources
   3. Dose Calibrators
   4. Pocket Dosimeters

D. Quality Control and Assurance

SELFSTUDY : 4hours (1,2,3)
INSTRUMENTATION: 8hours.

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INSTRUMENTATION II

I. Scintillation Detectors

- A. Theory of Light, Emission and Collection
  - 1. General Overview
- B. Scintillators
  - 1. Inorganic (NaI - Tl)
  - 2. Organic - Solid, Liquid
- C. Components
  - 1. Detector/Photomultiplier Tubes
  - 2. High Voltage Power Supply
  - 3. Preamplifier and Amplifiers/Gain
  - 4. Pulse Height Analysis - Single/Multiple Channel
  - 5. Read-out Devices - Uptake/Well Systems
    - a. scalers, timers, ratemeters

II. Qualitative and Quantitative Techniques

- A. Spectra
  - 1. Components
  - 2. Energy Resolution
  - 3. Dependence On:
    - a. detector
    - b. source configuration
    - c. scattering material
- B. Integral vs. Differential
- C. Assay of Radioactive Sources
  - 1. Standards
  - 2. Counter Efficiency
    - a. self absorption
    - b. scatter
    - c geometry
    - d. dead time (resolving time)
    - e. efficiency

INSTRUMENTATION III

I. Scintillation Camera

A. Basic Principles (Single Crystal Type)
1. Detector - Crystal, Light Pipe, PM Tubes
   General Overview
2. Electronics - Position Circuits, Ratio Circuits, Energy Discrimination
3. Collimator - Types, Performance Characteristics
4. Image Display - Digital, Multiformat
   a. CRT, persistence
   b. whole body
5. Performance Characteristics
   a. spatial resolution - FWHM, FWTM, LSF
   b. sensitivity
   c. dead time, pulse pile-up
   d. image contrast
   e. energy resolution
6. Quality Assurance
   a. uniformity
   b. resolution
   c. sensitivity
   d. linearity
   e. image artifacts
7. NEMA Standards
   Acceptance testing

B. Planar Imaging
1. Proper Intensity Setting
2. Flood Field Uniformity
   a. intrinsic - NEMA, other
   b. total system
3. Sensitivity
4. Spatial Resolution
   a. intrinsic - NEMA, other
   b. total system
5. Saturation - NEMA
6. Temporal Resolution - NEMA
7. Multiple Window Registration - NEMA
8. Spatial Linearity
   a. intrinsic - NEMA, other
   b. total system
9. Energy Resolution
10. Collimators
   a. parallel hole, pinhole, diverging, converging

b. high, medium, low energy
c. high resolution vs. high sensitivity
d. tomographic
e. resolution vs sensitivity, depth of field of view

II. Tomographic Imaging Techniques

A. SPECT
1. Basic Principles - Pulse Processing, Filters
2. Electronics
3. Performance Characteristics
a. uniformity
b. resolution - spatial
c. center of rotation
d. resolution - energy
e. linearity
4. NEMA Standards

B. Parameters of Performance
1. Center of Rotation
2. Single Slice Volume Sensitivity
3. Total Volume Sensitivity
4. Spatial Re-solution Using an Array of Various Sized Rods
5. Lesion Detectability Using Multi-Sized Spheres
6. Angular Variation of Flood Field Uniformity
7. Angular Variation of Sensitivity
8. Reconstructed System Spatial Resolution
9. Angular Variation of Spatial Position

C. Computers
1. Hardware
2. Software
3. Applications

D. PET
2. Scanners
3. Coincidence imaging cameras

RADIATION BIOLOGY

SELF STUDY: 24 hours
INTERACTIVE: 5 hours.

9/21/11

I. Radiation Chemistry

- A. Ionization
- B. Excitation
- C. Free Radical
- D. Interaction of Ionizing Radiation with Water (LET, RBE)
- E. Free Radical Reactions

II. Radiation Biochemistry

- A. DNA Damage
- B. DNA Repair
- C. Other Biomolecular Damage

III. Radiation Effects on Cells

- A. Alteration of Proliferative Ability
- B. Chromosome Aberration
- C. Interphase Death
- D. Membrane Damage
- E. Metabolic Change
- F. Cell Division Delay
- G. Survival Curves

IV. Repair of Radiation Injury

- A. Sublethal Damage Repair
- B. Potentially Lethal Damage Repair

V. Factors Affecting Radiation Injury

- A. Physical
  1. Dose
  2. Dose Rate
  3. Fractionation
  4. Linear Energy Transfer
     RBE, QF, dose equivalent
- B. Clinical
  1. Oxygen Effect, hyperbaric
  2. Chemical Sensitizers
  3. Chemical Protectors

C. Biological
   1. Mitotic Rate
   2. Degree of Differentiation
   3. Normal Tissue Tolerance
   4. Law of Bergonie and Tribondeau

VI. Early Nonstochastic Effects

A. Acute Effects on Organ Systems
B. Lethality (LD 50/30)
C. Acute Radiation Syndrome
   1. Immunological Suppression
   2. Hematopoietic Syndrome
   3. Gastrointestinal Syndrome
   4. Central Nervous System Syndrome
   5. Molecular Death
D. Radiation Effect on Reproductive Capacity
E. Radiation Effect on the Embryo and Fetus

VII. Genetic Effects

A. Immediate Effects on All
B. Effects on Tissues
C. Effects on Offspring

VIII. Delayed Somatic Effects

A. Leukemia
B. Other Cancers
C. Cataracts
D. Aging
E. Life Shortening

IX. Assessment of Low Dose/Low Dose Rate Effects on Human Health

X. Risk Assessment

A. Absolute Risk
B. Relative Risk

XI. Dosimetry

A. Principles
B. MIRD Equations
C. Dosimetry for Specific Radiopharmaceuticals

MATHEMATICS

SELF STUDY : 24 hours

INTERACTIVE: 3 hours

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I. Applied Mathematics

- A. Concentrations
  1. Concentration
  2. Dilution
- B. Inverse Square
  1. Inverse Square
  2. Gamma Constant
- C. Decay Rate
  1. Activity - Decay Rate Relations
  2. Decay Constant/Half-Life
  3. Decay Rate
  4. Units, Conversions
- D. Decay Equation
  1. Decay Equation
  2. Decay Factors
  3. Predecay
- E. Biological and Effective Half-Lives
  1. Biological Half-Life
  2. Effective Half-Life
  3. Mean Life
- F. Shielding Equation
  1. Shielding Equation
  2. Attenuation Coefficients
  3. Half-Value Layer

II. Statistics

- A. Counting Statistics
- B. Chi Square
- C. Imaging Statistics

RADIOPHARMACEUTICAL CHEMISTRY

SELF STUDY : 18 hours

INTERACTIVE : 2 hours

9/21/11

I. Introduction
   A. Definition of Radiopharmaceuticals
   B. Definition of Tags and Tracers
   C. Therapy Vs. Diagnostic Radiopharmaceuticals
   D. Information Obtained from Radiopharmaceuticals
      1. Functional Vs. Morphological

II. General Uses of Radiopharmaceuticals
   A. Dilution Studies
   B. Perfusion Studies
   C. Metabolic Studies
   D. Mechanisms of Localization and Kinetics
   E. Characteristics of an Ideal Radiopharmaceutical
   F. Radionuclide Vs. Radiochemical Purity

III. Quality Control
   A. Sterility and Tests
   B. Pyrogenicity and Tests
   C. Chromatography
   D. Determination of Alumina Content

IV. Preparation of Radiopharmaceuticals
   A. Inorganic Preparation
   B. Exchange Reaction
   C. Tracer Iodination
   D. Radiochemical Synthesis
   E. Biosynthesis

V. Generator Systems
   A. Mo/Tc Generator System
      1. Preparation of Mo-99 - Neutron Bombardment vs. Fission
      2. Column Preparation
      3. Charging the Column
      4. Decay of Mo-99
      5. Elution of Mo/Tc Generator
         a. Assay of eluate
         b. Alumina, pH
   B. Other generators

VI. Biorouting and Compounds
   A. Iodine
   B. Tc-99m
   C. Other Compounds Used in Nuclear Medicine

VII. Blood Labeling
   A. Special Handling Considerations

RADIATION SAFETY

SELF STUDY : 20hours
INTERACTIVE: 5hours

9/21/11

I. Sources of Regulations

A. NRC - Title 10 CFR, Regulatory Guide
B. State Regulations
C. NCRP (National Council on Radiation Protection)
D. ICRP (International Council on Radiation Protection)
E. DOT (Department of Transportation)
F. Other

II. Radiation Exposure Regulations

A. MPD (Maximum Permissible Dose)
B. ALI (Annual Limit on Intake)
C. DAC (Derived Air Concentration)
D. MPC (Maximum Permissible Concentration in Effluents)

III. Licensing for Human Use of Radioactive Material

A. Types
B. Fees
C. Conditions

IV. Principles of Radiation Protection

A. From External Hazards - Distance, Shielding, Time
B. From Internal Hazards - Entry, Contamination Control
C. Handling Radioactive Gases - Iodine, Xenon
D. Handling Radioactive Aerosols - DTPA
E. Background Radiation
F. Units, Special and S.I.
G. ALARA

V. Methods of Radiation Exposure Reduction

A. Facility Design
   1. Traffic Pattern
   2. Hot Lab Design
   3. Ventilation
   4. Equipment - Shields
   5. Restricted, unrestricted
   6. Storage, handling

B. Posting and Notices
   1. Caution Signs
   2. NRC-3 Maps
   3. Part 19 Posting
C. Receipt Procedures
   1. During and After Working Hours
   2. Package Surveys
D. Surveys
   1. Personnel Monitors - Film, TLD, Pocket
   2. Area Monitoring - Instruments
   3. Leak Testing of Sealed Sources
E. Radioactive Spill - Minor, Major
F. Disposal
   1. Storage for Decay
   2. Release to Sanitary Sewage
   3. Transfer to Commercial Disposal Service
   4. Release to Environment - Gases
G. Decontamination
H. Training of Occupational Personnel
I. Records
J. Transportation
K. Therapies and QMP