

# PUBLIC SUBMISSION

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**Docket:** NRC-2018-0230

Training and Experience Requirements for Different Categories of Radiopharmaceuticals

**Comment On:** NRC-2018-0230-0001

Training and Experience Requirements for Different Categories of Radiopharmaceuticals

**Document:** NRC-2018-0230-DRAFT-0023

Comment on FR Doc # 2018-23521

## Submitter Information

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## General Comment

My name is Richard Siska, I am a Nuclear Medicine Advanced Associate and Radiation Safety Officer. I am making this comment as an individual. I am arguing to keep the T & E the same but adding the NMAA (a non-physician mid level provider) as an AU. The NMAA is advanced practice, not a Nuclear Medicine Technologist, however; prior to applying the NMAA program one must have prior board certification and experience as a Nuclear Medicine Technologist.

Nuclear Medicine Advanced Associates (NMAAs) are physician extenders currently working under the supervision of nuclear medicine physicians and radiologists. NMAAs have a high level of training in radiation safety, radiation biology, radiation physics, instrumentation and radiation protection as required by the NRC. NMAAs operate under medical supervision and collaboration much like a Nurse Practitioner or Physician Assistant operates under their supervising physician. Thus, allowing NMAAs to become authorized users will improve patient access, operational efficiency, and throughput (which seems to be the main argument) without jeopardizing quality and safety.

The NMAA is trained comparable to conventional physician extenders, and are required to complete a graduate level program encompassing a didactic curriculum modeled after conventional physician extender programs, culminating in a Masters of Imaging Science Degree. The NMAA is also required to complete a 24 month clinical internship (this is in addition to didactic training). Based on nuclear medicine residency training, the NMAA must read required literature including teaching files and research, complete

competencies, perform and participate in research, participate in hospital rounds and tumor boards, work closely with a physician preceptor who is an AU ( much like a doctorate or fellowship program), and perform and manage case studies. The NMAA must establish knowledge regarding normal radiotracer distribution patterns, including the appearance of disease processes, radiologic-pathologic correlation, and the associated differential diagnosis. The NMAA must calculate a minimum number of therapeutic doses and subsequent administrations depending on institutional availability. Via this training, the NMAA has met the qualifications required under 10 CFR 35.390 to become authorized users. By comparison, nuclear radiologists complete 24-28 months of specific nuclear medicine training, including radiology residency and nuclear medicine fellowship. Alternatively, diagnostic radiology residency requires 16 18 weeks of nuclear medicine training, which also fulfills the minimum requirements for authorized user. In addition,

The Nuclear Medicine Technology Certification Board provides post graduate certification for the NMAA. I am including the content outline for the NMAA board certification exam and the NMAA scope of practice to offer perspective as to why this board exam could be added to a list of approved certifying exams for limited AU, it is also important to reiterate that this is in addition to the nuclear medicine technologist technical training and experience which is required prior to applying to an NMAA program. I am also attaching the basic nuclear medicine technologist components of preparedness which denotes what they face for board certification.

In summary, NRC should consider NMAAs as candidates for authorized user designation for radioactive byproduct use encompassing, uptake, dilution, excretion, imaging and localization, and therapy.

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## **Attachments**

NMAAContentOutline

NMTCB CNMT\_COPS\_2017

NMAA\_Scope\_of\_Practice\_2010

## NMAA Exam Content Outline

- I. Patient Care (Assessment, Management and Education)
  - a. Patient Based Decision Making
    - i. Patient and family education
    - ii. Patient history and physical examination
    - iii. Evaluation of Diagnostic and Laboratory Results
      1. Cardiac function and myocardial injury
      2. Hepatic function
      3. Pulmonary function
      4. Renal function and electrolytes
      5. Thyroid function
      6. Parathyroid function
      7. Complete Blood Count (CBC)
      8. Blood glucose
      9. Pregnancy tests (HCG)
    - iv. Identify and implement a plan of care
      1. Order and administer sedation
      2. Alternative options
    - v. Administration into existing catheters or routes
      - a. VP shunts
      - b. Central lines
      - c. Intra thecal
      - d. Intra arterial
    - vi. Establish additional routes of administration
      - a. Urinary catheter
      - b. Feeding tube
      - c. Rectal
      - d. Subcutaneous port
      - e. Intradermal
    - vii. Monitor vital signs and physiologic parameters
    - viii. Evaluate the need for contrast media
  - b. Systems Based Practice
    - i. Medical/Legal/Professional/Government/Regulatory
      1. Standards for Informed Consent
      2. Elements of written directives
      3. HIPAA
      4. Medical events and incidents
    - ii. Quality Assurance and Management
      1. Patient safety
  - c. Patient Emergency Management
    - i. Provide supportive medical management
      1. Advanced life support
      2. Blood glucose management
      3. contrast media reactions
      4. allergic response
      5. adverse response
- II. Clinical Procedures
  - a. Cross sectional imaging anatomy
  - b. Pathophysiology
  - c. Patterns of biodistribution for radiopharmaceuticals
  - d. Identify and/or assess for each diagnostic procedure:
    - i. Indications and Contraindications
    - ii. Patient preparation
    - iii. Existing correlative examinations

- iv. Complications
- v. Limitations
- vi. Appropriate Radiopharmaceutical
- vii. Radiopharmaceutical dose range
  - 1. Adjustment for patient size and age
- viii. Route of administration
- ix. Imaging technique
- x. Image quality and need for additional imaging
- xi. Quantitative data analysis
- xii. Need for pharmacological interventions in nuclear medicine procedures (Appendix B-  
Adjunctive Drugs)
- xiii. Need for complementary/correlative diagnostic imaging procedures
- e. Analyze Results
  - i. Assess image quality and other associated data
    - 1. Adequacy
    - 2. Artifact
    - 3. Incidental findings
- f. Therapy
  - i. Identify and/or assess for each therapeutic procedure:
    - 1. Indications and Contraindications
    - 2. Patient preparation and informed consent
    - 3. Existing correlative examinations
    - 4. Complications
    - 5. Limitations
    - 6. Appropriate Radiopharmaceutical
    - 7. Radiopharmaceutical dose range
    - 8. Route of administration
    - 9. Dosimetry and dosimetric consequences
    - 10. Patient release requirements
    - 11. Need for complementary/correlative diagnostic imaging procedures
- g. Nuclear Cardiology Stress Testing
  - i. Indications and Contraindications to stress testing
  - ii. Physiologic measures of stress capacity/performance
  - iii. Treadmill operation
  - iv. Patient assessment and monitoring
  - v. Isometric exercise protocols
  - vi. Pharmacologic stress protocols
  - vii. ECG
  - viii. Acquisition
  - ix. Rate calculation
  - x. Normal and abnormal rhythms
  - xi. Heart blocks
  - xii. Indicators of ischemia and infarction
  - xiii. Identification of significant cardiac events during stress test
  - xiv. Interpretation
  - xv. Interventions
  - xvi. Endpoints

*Appendix A Procedures- Diagnostic & Therapy*

III. Diagnostic and Therapeutic Pharmaceuticals

- a. Knowledge of drug characteristics:
  - i. Mechanism of action
  - ii. Indications of use
  - iii. Contraindications
  - iv. Appropriate management of adverse events and/or side effects

- v. Appropriate follow-up and monitoring of pharmacologic effects
- vi. Drug toxicity
- vii. Cross reactivity of similar medications
- b. Special considerations for contrast media agents:
  - i. Premedication
  - ii. Hydration status
  - iii. Renal status
  - iv. Diseases of concern
  - v. Incompatible medications
  - vi. Allergies
  - vii. Appropriate management of adverse events and/or side effects
  - viii. Conflicts with other procedures (e.g. another contrast procedure)
- c. Methods to reduce medication errors
- d. Evaluating and reporting adverse drug events
- e. Pharmacology

*Appendix B- Adjunctive Drugs*

*Appendix C- Radiopharmaceuticals*

*Appendix D- Contrast Agents*

#### IV. Radiation Safety and Radiobiology in Clinical Practice

- a. Radiation Safety
  - i. Understanding of absorbed dose principles
    - 1. Knowledge of critical organ versus total body effective dose equivalent
    - 2. Typical values from routine nuclear medicine procedures
    - 3. Typical values from CT
      - a. Diagnostic versus attenuation correction
      - b. Pediatric versus adult
      - c. Dose units
  - ii. Methods to reduce patient exposure
  - iii. Methods to reduce occupational exposure
- b. Radiobiology
  - i. Cell Growth and Division
  - ii. Radiosensitivity of cells
  - iii. Effects of radiation
    - 1. Deterministic effects versus stochastic effects
    - 2. Background radiation
    - 3. Dose-response relationships
    - 4. Skin effects
    - 5. Acute radiation syndrome
    - 6. Local tissue damage
    - 7. Hematological effects
    - 8. Carcinogenesis
    - 9. Fetal effects
    - 10. Genetic effects
    - 11. Fertility effects
  - iv. Dosimetry calculations
    - 1. Fetal calculations
    - 2. Organ calculations
    - 3. Whole body calculations



## Components of Preparedness

**Domain I:** Radiation Physics & Detection – 7%

**Domain II:** Radiation Safety & Regulations – 13%

**Domain III:** Pharmaceutical & Radiopharmaceutical Agents – 25%

**Domain IV:** Instrument Operations & Quality Control – 15%

**Domain V:** Clinical Procedures – 40%

The ***NMTCB Components of Preparedness*** provide a description of the concepts, tasks, knowledge, and skills an individual needs to successfully understand and perform the necessary duties for an entry-level nuclear medicine technologist. Components of preparedness statements are published by NMTCB to assist students, program directors, and item writers. Each task is keyed to the 2017 Job Task Analysis Survey published by the NMTCB, which is the basis for the NMTCB nuclear medicine exam.

The ***NMTCB Components of Preparedness*** document was updated by NMT subject matter experts through a rigorous job practice analysis study and validated by NMT professionals working in the field through an extensive survey instrument. The entry level NMT tasks and the knowledge needed to perform such tasks are extensively researched and grouped into the following functional content areas:

### Domain I: Radiation Physics and Detection

#### A Physical properties

- 1 Radioactive materials
  - a. Modes of decay
    - i. Gamma emitters
    - ii. Beta emitters
    - iii. Alpha emitters
    - iv. Positron emitters
  - 2 X-ray production
    - a. Bremsstrahlung
    - b. Characteristic x-ray

#### B Measurement of radioactivity and decay calculations

#### C Interactions of radiation with matter

#### D Radiation detector types and basic principles

#### E Counting statistics

**Domain II: Radiation Safety and Regulations**

- A Biological effects of radiation exposure**
- B Protection techniques and calculations**
  - 1 Time
  - 2 Distance (inverse square law)
  - 3 Shielding (shielding equations)
- C Monitoring protocols and requirements (e.g., timing and frequency)**
  - 1 Radiation surveys (area monitoring) including:
    - a. Survey meters and well counters
    - b. Choice of radiation detection devices (e.g., Geiger Counters, sodium iodide detectors)
    - c. Frequency and limits of wipe surveys
  - 2 Personal monitoring devices
  - 3 Personal protective equipment (e.g., lab coat, gloves, syringe shields)
  - 4 Effective dose equivalent limits for:
    - a. Radiation workers
    - b. Pregnant radiation workers
    - c. General public
- D Practice and adhere to ALARA**
- E Nuclear Regulatory Commission (NRC)**
  - 1 Posting warning and informational signs delineating restricted and unrestricted areas
  - 2 Surveying, inspecting and inventorying radioactive materials
  - 3 Responding to adverse events
    - a. Trigger levels and monitoring methods
    - b. Radiation exposure
    - c. Radiation spills
    - d. Protection during adverse events
    - e. Personnel, patient and/or public decontamination
    - f. Area/equipment decontamination
  - 4 Adhere to radioactive waste storage requirements
  - 5 Dispose of radioactive materials (e.g., liquids, solids, gasses, contaminated materials)
  - 6 Identify recordable and reportable events
  - 7 Maintain records as required for:
    - a. Receipt, storage and disposal of radioactive materials
    - b. Radiation monitoring and reporting
    - c. Equipment calibration and maintenance
    - d. Staff, patient, occupational and public exposure
    - e. Nuclear medicine diagnostic and therapeutic procedures
- F Department of Transportation (DOT) - radiopharmaceutical transport**
  - 1 Use of shielding containers
  - 2 Labeling requirements (e.g., transportation index, name, concentration, expiration date/time, total activity, assay date/time)

- 3 Package monitoring/receiving/returning
- G Environmental Protection Agency (EPA)**
- H Occupational Safety and Health Administration (OSHA)**
- I Health and Human Services (HHS)/Health Insurance Portability and Accountability Act (HIPAA)**
  - 1 Protecting patient rights and privacy
  - 2 Maintaining patient records
  - 3 Releasing information to authorized parties
- J Knowledge of institutional and departmental accreditation organizations**

### Domain III: Pharmaceutical and Radiopharmaceutical Agents

- A Elute radionuclide generator, perform and evaluate quality control tests**
  - 1 Types of generators (e.g.,  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ ,  $^{82}\text{Sr}/^{82}\text{Rb}$ , etc.,)
    - a. Elution
    - b. Generator yield – volume and activity
    - c. Quality control procedures
      - i.  $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$  ( $^{99}\text{Mo}$  breakthrough and Al +3 content)
      - ii.  $^{82}\text{Sr}/^{82}\text{Rb}$  (measured activity and levels of  $^{82}\text{Sr}$  &  $^{85}\text{Sr}$ )
  - 2 Dose calibrator operation / units of radioactivity
- B Prepare radiopharmaceutical kits , perform quality control, and evaluate results**
  - 1 Radiopharmaceutical kits
    - a. Preparation techniques including particle size and number
    - b. Activity and volume limitations
    - c. Activity calculations
  - 2 Radiopharmaceutical quality control
    - a. Visual inspection - color and clarity
    - b. Radiochemical purity
  - 3 Labeling kits
  - 4 Storage of kits before and after reconstitution
- C Understand the characteristics (i.e., mechanism of localization), indications, contraindications and administration of diagnostic radiopharmaceuticals**
  - 1 Tc99m labeled radiopharmaceuticals
    - a. Tc99m sodium pertechnetate
    - b. Tc99m oxidronate/HDP
    - c. Tc99m medronate/MDP
    - d. Tc99m pentetate/DTPA
    - e. Tc99m macroaggregated albumin/MAA
    - f. Tc99m sulfur colloid
    - g. Tc99m disofenin/mebrofenin (Choletec®)
    - h. Tc99m mertiatide/MAG3
    - i. Tc99m pyrophosphate/PYP
    - j. Tc99m sestamibi/MIBI (Cardiolite®)



- k. Tc99m tetrofosmin (Myoview®)
  - l. Tc99m succimer/DMSA
  - m. Tc99m exametazime/HMPAO (Ceretek®)
  - n. Tc99m bicisate/ECD (Neurolite®)
  - o. Tc99m labeled RBCs
  - p. Tc99m HMPAO tagged WBCs
  - q. Tc99m tilmanocept (Lymphoseek®)
- 2 Iodine labeled radiopharmaceuticals
- a. I-123 sodium iodide
  - b. I-131 sodium iodide
  - c. I-123 MIBG
  - d. I-131 MIBG
  - e. I-123 loflupane (DaTscan®)
- 3 Indium labeled radiopharmaceuticals
- a. In-111 Pentetate (DTPA)
  - b. In-111 chloride
  - c. In-111 oxine labeled WBCs
  - d. In-111 pentetretotide (Octreoscan®)
- 4 Miscellaneous diagnostic radiopharmaceuticals
- a. Tl201 thallos chloride
  - b. Ga67 gallium citrate
  - c. Xe133 gas
- 5 Positron Emission Tomography
- a. F-18 FDG
  - b. F-18 Florbetaben (Neuraceq®)
  - c. F-18 Florbetapir (Amyvid®)
  - d. F-18 Flutemetamol (Vizamyl®)
  - e. F-18 Sodium Fluoride (NaF)
  - f. Rb82 chloride
  - g. N13 ammonia
  - h. Ga-68 Dotatate
- D Understand the characteristics (i.e., mechanism of localization), indications, contraindications and administration of therapeutic radiopharmaceuticals**
- 1 Sr89 chloride (Metastron®)
  - 2 Sm153 EDTMP lexidronam (Quadramet®)
  - 3 I-131 sodium iodide
  - 4 Y90 ibritumomab tiuxetan (Zevalin®)
  - 5 Y90 microspheres (SIR-Spheres®, TheraSphere®)
  - 6 Ra223 Radium dichloride (Xofigo®)
  - 7 I-125 Seeds
- E Understand the indications, contraindications, and administration of interventional and adjunct pharmaceutical agents used in conjunction with nuclear medicine procedures**

- 1 dipyridamole (Persantine®)
- 2 adenosine
- 3 dobutamine
- 4 aminophylline
- 5 regadenoson (Lexiscan®)
- 6 captopril
- 7 enalaprilat
- 8 furosemide (Lasix®)
- 9 insulin
- 10 acetazolamide
- 11 cholecystokinin/sincalide/CCK
- 12 morphine
- 13 cimetidine/ranitidine/famotidine
- 14 ACD solution
- 15 heparin
- 16 contrast media (oral and IV)
- 17 Lugol's solution/SSKI
- 18 Thyroid Stimulating Hormone (TSH)
- 19 Lidocaine
- 20 Lidocaine (EMLA) cream
- 21 atropine
- 22 recombinant human TSH (Thyrogen®)

**F Label blood components with radiopharmaceutical according to protocol**

- 1 Labeling procedures
  - a. Required lab equipment and supplies
  - b. Anticoagulants and other additives
  - c. Chemical reactions
  - d. Cell washing
  - e. Required radiopharmaceuticals
  - f. Method: *invivo* or *invitro*
- 2 Calculation of labeling efficiency and administered dosage
- 3 Reinjection patient and sample verification

**G Understand the routes of administration**

- 1 Administration modes
- 2 Administration techniques (e.g., bolus, venipuncture, IV)

**H Prepare and administer non-radioactive agents**

- 1 Follow aseptic technique
- 2 Adverse side-effects and treatment
- 3 Antidote medications
- 4 Interventional pharmaceuticals
- 5 Non-radioactive agents (e.g., ACD solution, heparin, contrast media, TSH, atropine, etc.,)

**Domain IV: Instrument Operations and Quality Control****A Non-imaging equipment, components and operation**

- 1 Perform and evaluate quality control on well counters and probes
  - a. Calibrate and perform quality control on the sodium iodide scintillation detector
  - b. Conduct a gamma ray spectra and pulse height analysis
  - c. Apply formulas (e.g., energy resolution, sensitivity, Chi-square statistics, etc.,)
- 2 Determine operational status of survey meter
  - a. Survey meter operations and components
  - b. Survey meter quality control
- 3 Perform and evaluate dose calibrator constancy, accuracy, linearity, and geometry tests

**B Imaging equipment, components, and operation**

- 1 Gamma Camera quality control
  - a. Uniformity
  - b. Spatial resolution and linearity
  - c. Visual image quality
  - d. Phantoms
  - e. Artifacts
  - f. Assess system sensitivity
  - g. Pulse height analysis
- 2 SPECT and SPECT/CT imaging system
  - a. Attenuation correction
  - b. SPECT camera quality control
    - i. Center of rotation
    - ii. Field uniformity requirements
    - iii. Pixel calibration
    - iv. 3-D uniformity and resolution (e.g., Jaczak phantom)
    - v. Artifacts
- 3 PET and PET/CT imaging systems
  - a. Application of attenuation corrections
  - b. PET quality control (e.g., daily blank scan, normalization scan, 2-D/3-D well counter, artifacts, etc.)
- 4 CT imaging systems
  - a. Co-registration of images
  - b. CT quality control (e.g., contrast and spatial resolution, noise, uniformity, artifacts, etc.,)
- 5 Computer equipment (e.g., monitors, matrix sizes, printers, etc.,)
- 6 Networking and information systems (i.e., PACS and RIS )

**C Auxiliary equipment**

- 1 Laboratory equipment (e.g., pipette, fume hoods)

- 2 Patient care equipment
  - a. Intravenous infusion pump
  - b. ECG monitor
  - c. Pulse oximeter
  - d. Defibrillator
  - e. Glucose meter
  - f. Blood pressure equipment
- 3 Non-imaging equipment
  - a. Xenon delivery system and trap
  - b. Aerosol delivery system
  - c. Treadmill

## Domain V: Clinical Procedures

### A Knowledge and performance of nuclear medicine procedures

- 1 Pulmonary
  - a. Radioaerosol ventilation
  - b. Gas ventilation
  - c. Perfusion
  - d. Perfusion/Ventilation quantitation
- 2 Bone/Musculoskeletal scans
  - a. Limited
  - b. Whole-body
  - c. 3-phase
  - d. 4-phase
  - e. SPECT
  - f. NaF PET
- 3 Oncology
  - a. Ga67 tumor imaging, planar and SPECT
  - b. Monoclonal antibody imaging
  - c. Peptide imaging
  - d. Breast imaging
  - e. Lymphoscintigraphy/sentinel lymph node localization
  - f. Tumor imaging, PET
  - g. Neuroendocrine tumor imaging
- 4 Infection
  - a. Ga67 infection imaging
  - b. Tagged WBC imaging
- 5 Renal/Genitourinary
  - a. Cystogram, direct
  - b. Effective renal plasma flow (ERPF)
  - c. Glomerular filtration rate (GFR)

- d. Renal anatomy, planar, SPECT
  - e. Renal flow
  - f. Renogram (Lasix® and ACE inhibitors)
- 6 Endocrine
- a. Adrenal imaging
  - b. Parathyroid imaging, planar and SPECT
  - c. Thyroid imaging
  - d. Thyroid uptake
  - e. Whole body survey for thyroid metastases
- 7 Hematopoietic
- a. Bone marrow imaging
- 8 Cardiovascular
- a. Myocardial perfusion, planar
  - b. Myocardial perfusion, SPECT, attenuation and non-attenuation
  - c. Myocardial perfusion, gated SPECT
  - d. First pass for EF and wall motion
  - e. Gated cardiac blood pool, rest
  - f. Gated cardiac blood pool, stress
  - g. Gated cardiac blood pool, SPECT
  - h. Cardiac shunt
  - i. Cardiac CT SPECT
  - j. MIBG
  - k. Myocardial viability (thallium, FDG)
  - l. Cardiac PET
- 9 Gastrointestinal
- a. Gastric emptying (liquid/solid)
  - b. Gastroesophageal reflux
  - c. Gastrointestinal bleeding
  - d. Hemangioma
  - e. Hepatobiliary with and without GBEF
  - f. Peritoneal venous shunt patency
  - g. Liver-lung shunt mapping (arterial)
  - h. Liver-spleen imaging, planar and SPECT
  - i. Meckel's diverticulum
- 10 Central Nervous System
- a. Brain flow, brain death
  - b. Brain imaging, planar and SPECT
  - c. Dopamine receptor DaT scan
  - d. Cisternogram
  - e. CSF leak
  - f. CSF shunt patency
  - g. Brain PET

- 11 Radionuclide Therapy
    - a. Thyroid
    - b. Metastatic bone
    - c. Monoclonal antibody therapy (Zevalin®)
    - d. Embolic radiotherapy (labeled microspheres)
  - 12 CT Imaging Procedures
    - a. Attenuation correction /anatomical localization
    - b. Diagnostic
- B Schedule patient studies to accommodate sequencing of multiple procedures and special orders**
- 1 Schedule the camera time
  - 2 Schedule multiple radionuclide procedures for a single patient
  - 3 Schedule same-day multiple modality procedures for a single patient
- C Procure supply of radiopharmaceuticals, considering license possession limits and schedule**
- D Instruct patient, family, and personnel concerning procedures and precautions**
- E Receive, prepare, and provide care to patient**
- 1 Protect patient information and privacy according to the Healthcare Insurance Portability and Accountability Act (HIPPA)
  - 2 Perform basic patient care (e.g., vital signs, basic first aid)
  - 3 Practice correct patient transferring techniques
  - 4 Use and accommodate patient support devices
    - a. Intravenous infusion pump/lines
    - b. Supplemental oxygen
    - c. Foley catheter and drainage bag
    - d. ECG monitor
  - 5 Receive and prepare patient, verify patient identification and written orders for study
  - 6 Perform pre-examination screening including review of:
    - a. Verify patient preparations and identify contraindications
    - b. Medical history
    - c. Current medications
    - d. Allergic and adverse reaction history
    - e. Review relevant lab values
  - 7 Verify that informed consent has been obtained
- F Select and administer prescribed radiopharmaceutical**
- 1 Verify patient identification
  - 2 Calculate appropriate volume to deliver prescribed dosage when needed.
  - 3 Administer radiopharmaceutical using appropriate route and technique
- G Monitor and assess patient condition**
- H Implement emergency procedures (e.g., in case of fainting, seizure, cardiopulmonary arrest, etc.)**
- I Prepare equipment and perform examinations**

- 1 Position patient using anatomical markers and immobilization techniques
- 2 Establish imaging parameters for data acquisition
- J Evaluate image quality**
  - 1 Normal and abnormal scan patterns
  - 2 Identify artifacts and causes
  - 3 Co-registration of images (SPECT/CT and PET/CT)
  - 4 Repeat study and/or perform additional views
- K Perform post-procedure assessment**
- L Provide patient / caregiver education concerning discharge instructions and cautions**
- M Process and evaluate computer generated data**
  - 1 Data storage, transfer and retrieval
  - 2 Image formation (static, dynamic, ERNA, list mode)
  - 3 Image reconstruction (SPECT, PET)
  - 4 Image enhancement (e.g., filters, matrix, intensity, etc.)
  - 5 Quantitative analysis
    - a. Regions of interest and quantification
    - b. Curve generation and analysis
    - c. Image normalization and subtraction
  - 6 Display formatting (image size, number of images, intensity adjustments)
- N Prepare and perform cardiac monitoring and/or assist with stress testing**
  - 1 Basic electrocardiography (ECG)
    - a. Cardiac conduction system
    - b. Components of a normal ECG wave form
    - c. Recognizing and responding to changes on a resting or stress ECG
  - 2 ECG lead placements
  - 3 Treadmill stress techniques (i.e., Bruce and modified Bruce) and bicycle stress techniques
    - a. Contraindications
    - b. Duration/termination parameters
  - 4 Pharmacological stress protocols
    - a. Contraindications
    - b. Timing of pharmacological stress agent
    - c. Timing of radiopharmaceutical injection
    - d. Duration/termination parameters
    - e. Drug side-effects and appropriate treatment
    - f. Reversal agents and techniques
- O Obtain samples and/or data for non-imaging studies**
  - 1 Data specimen collection techniques, including timing, methods, containers, and storage
  - 2 Background correction
  - 3 External counting techniques
- P Calculate and evaluate the results of non-imaging studies**

- 1 Error analysis
  - 2 Calculations
- Q Prepare, survey, and clean radiotherapy administration and/or isolation room**





## **Scope of Practice for the Nuclear Medicine Advanced Associate 2009**

NMAA Scope of Practice Task Force of the NMAA Committee, SNM Technologist Section

The proposed NMAA Scope of Practice was developed by the Scope of Practice Task Force with members appointed by the SNMITS President. Members of the task force were: : Mark Wallenmeyer, MBA, Chair; James Bellamy, MPH, CNMT; Jeremy Flowers, NP, CNMT; David Gilmore, MS, CNMT, NCT, ARRT(R)(N), FSNMITS, Bennett Greenspan, MD; Jay Harolds, MD; Robert Henkin, MD; Lyn Mehlberg, BS, CNMT, FSNMITS; Mary Anne Owen, MHE, RT(N), FSNMITS; Martha Pickett, MHSA, CNMT, FSNMITS; Lynne Roy, MBA, CNMT, FSNMITS.

This document is not intended to modify or alter existing tort law; rather it should serve as a concise outline of the duties and responsibilities of the Nuclear Medicine Advanced Associate (NMAA).

### **NUCLEAR MEDICINE ADVANCED ASSOCIATE**

Nuclear medicine is the medical specialty that utilizes sealed and unsealed radioactive materials in the diagnosis and treatment of disease. This practice also includes the use of pharmaceuticals and other imaging modalities to enhance the evaluation of organ and molecular function. In addition, it includes the delivery of therapeutic radiopharmaceuticals to treat a number of pathologies.

A Nuclear Medicine Advanced Associate (NMAA) is an advanced-level nuclear medicine technologist working under the supervision of a licensed physician, who is also an authorized user of radioactive materials, to enhance patient care in the diagnostic imaging and radiotherapy environments.

The Nuclear Medicine Advanced Associate is an NMTCB- or ARRT-certified nuclear medicine technologist who has successfully completed an advanced academic program at the graduate level encompassing a nationally recognized NMAA curriculum and a nuclear medicine physician-, nuclear cardiologist-, or radiologist-directed clinical preceptorship.

The duties of the NMAA may include those of the Nuclear Medicine Technologist but with added responsibilities specific to the NMAA's advanced education and training. Accordingly, by implication the NMAA scope of practice incorporates all duties also identified in the Nuclear Medicine Technologist scope of practice, which is appended to this document for informational purposes. The NMAA has completed advanced coursework in the NMAA curriculum that includes, but is not limited to, patient care, clinical nuclear medicine, radionuclide therapy, nuclear cardiology, interpersonal and communication skills, practice-based decision making, professionalism, systems-based

practice, patient assessment, pathophysiology, pharmacology, contrast media, radiation biology and radiation safety.

Graduates of accredited programs are eligible to sit for the Nuclear Medicine Advanced Associate certification examinations offered by the *Nuclear Medicine Technology Certification Board*.

NMAAs work in general nuclear medicine settings as well as in specialty settings such as oncology and cardiology. They work in large research facilities and small rural settings, in in-patient and out-patient settings. Consequently, the spectrum of NMAA responsibilities varies widely across the country.

Practice components presented in this document provide a basis for establishing the areas of knowledge and performance for the NMAA. It is assumed that for all activities included in this scope of practice, the NMAA has received the proper education (in compliance with federal, state, and institutional requirements) supported with the proper documentation of initial and continued competency in those practices and activities. Continuing education is a necessary component in maintaining the skills required to perform all duties and tasks of the NMAA in this ever-evolving field of new equipment, radiopharmaceuticals, and applications.

## **THE SCOPE OF PRACTICE**

These competencies reflect the primary clinical tasks of an NMAA, but NMAAs may take on additional responsibilities at the discretion of the supervising physician. The supervising physician may delegate to the NMAA any procedures for which the NMAA is appropriately trained and qualified to perform and that are routinely performed within the normal scope of the physician's practice.

Under physician supervision, the NMAA performs patient assessment, patient management and selected nuclear medicine procedures as summarized below.

1. Perform and document a comprehensive review of clinical information, such as pertinent lab work, including blood, urine and other tissue samples and pathology studies, as well as correlative imaging studies to facilitate optimal interpretation of the nuclear medicine procedure by the supervising physician.
2. Perform, update, and document a 'history and physical' in the medical record, obtaining a comprehensive clinical history from the patient or medical record to optimize the clinical value of the requested nuclear medicine procedure.
3. Assist the supervising physician in obtaining informed consent for invasive and therapeutic procedures, as well as procedures involving more than minimal risk, as defined by state law and institutional policy.
4. Furnish adjunctive and interventional medications that enhance diagnostic imaging and therapeutic procedures, as defined by state regulations and institutional policy.
5. Perform minimal sedation (anxiolysis) and moderate sedation (as defined by the American Association of Anesthesiology) under the direct supervision of an appropriately credentialed physician as determined by state law and institutional policy.
6. Educate the patient undergoing invasive procedures, therapeutic procedures, and procedures involving more than minimal risk regarding pre-procedural preparation and post-procedural care, as defined by state law and institutional policy and documenting appropriately in the patient's medical record.

7. Perform pre- and post-procedure assessment and monitoring in patients undergoing invasive and therapeutic procedures, as well as procedures involving more than minimal risk, as defined by state law and institutional policy.
8. Under the direction of the supervising physician, perform invasive or therapeutic procedures as recognized through institutional policy and defined by state and federal law.
9. Monitor and supervise cardiac exercise or pharmacologic stress testing in association with diagnostic nuclear medicine imaging procedures.
10. Assess imaging procedure for quality, recommend additional views as necessary, and order additional diagnostic procedures as necessary to provide additional information to optimize the nuclear medicine procedure
11. Analyze the imaging, correlative and laboratory data provided and prepare a preliminary description of findings for the supervising physician to use when interpreting the results and formulating the written report.
12. Communicate report findings in the physician's finalized and authenticated reports to the referring physician and provide necessary documentation.

## **PATIENT CARE**

NMAA patient care responsibilities include but are not limited to the following:

1. Communicate effectively and demonstrate caring, respectful, and ethical behaviors when interacting with the patient, the family, physicians, and other health care professionals.
2. Counsel and educate the patient and family
  - A. Obtain patient informed consent for required procedures according to state law and institutional policy
  - B. Educate the patient on preprocedural preparation and postprocedural care
3. Make informed decisions about diagnostic and therapeutic procedures under the direction of the supervising physician and based on patient information and preferences, up-to-date scientific evidence, and clinical judgment
  - A. Gather and evaluate essential information, including correlative studies, about the patient and arrange follow-up as necessary under the direction of the supervising physician
  - B. Obtain history and perform physical examination
  - C. Evaluate findings for contraindications to testing and for indicators of additional patient pathology
  - D. Consult with the physician as needed
  - E. Counsel the patient and family as indicated
4. Determine and implement a plan of care
  - A. Use professional judgment to recommend or adapt protocols for procedures to improve diagnostic quality and outcome
  - B. Consult with the supervising physician or appropriate health care provider to determine a modified action plan when necessary
  - C. Report findings to the supervising physicians and the patient per protocol
5. Order and administer sedating pharmaceuticals under the direction of the supervising physician and monitor the patient who is receiving sedating pharmaceuticals as indicated by patient profile and diagnostic or therapeutic procedure as allowable by institutional, state, and federal statutes

6. Implement additional requirements for patient care for diagnostic or therapeutic procedures
  - A. Perform patient bladder catheterizations
  - B. Implement additional routes of radiopharmaceutical administration other than intravenous injection or oral
  - C. Monitor vital signs and physiologic parameters
  - D. Evaluate the need for contrast media in consultation with the supervising physician
7. Provide indicated intervention per patient emergency event
  - A. Provide supportive medical management
  - B. Basic life support
  - C. Advanced life support
  - D. Facilitate transfer to definitive care environment

### **GENERAL DIAGNOSTIC NUCLEAR MEDICINE**

NMAA responsibilities in general diagnostic nuclear medicine include but are not limited to the following:

1. Review requests and physician directives for nuclear medicine procedures
  - A. Review request for imaging procedures per protocol
  - B. Ensure the appropriate diagnostic study has been requested for the clinical presentation in consultation with the referring physician
  - C. Evaluate collaborative laboratory test results for indications/contraindications
  - D. Order or facilitate adjunctive pharmaceuticals for the imaging procedure under the direction of the supervising physician
2. Competently perform clinical nuclear medicine procedures considered essential in the area of practice
  - A. Perform routine nuclear medicine procedures
  - B. Perform sentinel node imaging and lymphatic mapping
  - C. Prepare the patient and ancillary equipment for radiation therapy planning using positron and multimodality imaging systems
3. Prescribe and administer pharmacologic and nonpharmacologic interventions under the direction of the supervising physician and as indicated by patient profile and diagnostic procedure as allowable by state and federal statutes
  - A. Perform preprocedure requirements and interventions as may be required
  - B. Perform intraprocedure requirements as may be required
  - C. Perform postprocedure requirements as may be required
4. Order complementary diagnostic procedures as indicated by patient testing results under the direction of the supervising physician
5. Analyze results of the procedure and prepare a preliminary description of findings for the supervising physician
  - A. Assess image quality and other associated data
  - B. Make a preliminary assessment
  - C. Document initial observations of imaging procedures according to protocol
  - D. Communicate initial observations as per the supervising physicians' discretion
  - E. Report findings to referring physicians and the patient per protocol
6. Manage pain and sedation for the patient receiving diagnostic testing or therapeutic treatment
  - A. Prescribe pharmacologic and nonpharmacologic interventions as allowable by

- state and federal statutes
- B. Monitor patient response to sedation and provide intervention according to accepted standards of practice
- 7. Administer radiopharmaceuticals for radionuclide cisternography, cerebrospinal fluid shunt evaluations, cerebrospinal fluid leaks, or intraperitoneal procedures using aseptic technique and radiation safety standards at the discretion of the supervising physician
  - A. Explain complete procedure to the patient/family
  - B. Ensure scheduled imaging timeline compliance
  - C. Prepare injection site, adhering to predetermined aseptic/sterile technique
  - D. Conduct a Joint Commission–recommended “time out” procedure
  - E. Monitor room, equipment, and personnel as per institutional Radiation Safety Guidelines
- 8. Participate in image-guided biopsy at the discretion of the supervising physician
  - A. Prepare sterile field and biopsy area using aseptic/sterile technique
  - B. Obtain informed consent for biopsy
  - C. Conduct a Joint Commission–recommended “time out” procedure
    - Evaluate for complications prohibiting safe biopsy
  - D. Identify appropriate instruments and use according to recommended standards of practice
  - E. Prepare biopsy tissue specimens for pathologic examination according to guidelines for specific tissue type, include appropriate transport media slide preparation and documentation
  - F. Close and dress the wound according to recommended standards of practice
  - G. Order appropriate follow-up imaging studies appropriate to biopsy site and procedure
  - H. Appropriately intervene for complications
  - I. Advise the patient of needed follow-up care

## **NUCLEAR CARDIOLOGY**

1. Successfully complete Advanced Cardiac Life Support credentialing
  - A. Assess normal electrocardiogram to determine patient safety for stress testing
  - B. Assess abnormal electrocardiographic conduction in preparation for stress testing
2. Develop procedural policies and standards for pre–cardiac arrest emergencies that might occur within the department as directed by institutional policy and practice standards
  - A. Identify the signs and symptoms of symptomatic bradycardia and symptomatic tachycardia
  - B. Follow a step-by-step course of action for the patient who develops asymptomatic bradycardia or tachycardia while in office (before, during, or after stress test)
  - C. Follow a step-by-step course of action for the patient who develops signs and symptoms of bradycardia or tachycardia while in office (before, during, or after stress test)
  - D. Identify the proper medications and dosages for stable cardiac rhythms
  - E. List contraindications and precautions of common cardiac medications
  - F. Follow a step-by-step approach to handling an ST elevated myocardial infarction
  - G. Follow a step-by-step approach to handling a stroke situation
  - H. Follow a step-by-step approach to handling other patient incidents

- I. Identify and delegate personnel to perform various tasks in preparation for cardiac emergencies
- J. Incorporate the appropriate federal, state, and institutional guidelines into departmental policies and procedures
- 3. Develop procedural policies and standards for cardiac arrest emergencies that occur within the department as directed by institutional policy and practice standards and provide indicated intervention for a cardiac emergency event
  - A. Establish intravenous access
  - B. Identify and administer the appropriate medications for commonly occurring cardiac arrhythmias under the direction of the supervising physician
  - C. Perform cardiac compression or defibrillate patient if required
  - D. Facilitate the ordering of laboratory tests or other tests as needed for a cardiac arrest event under the direction of the supervising physician
  - E. Facilitate admission of the patient to the hospital if necessary
- 4. Provide indicated intervention for noncardiac emergency events
- 5. Manage crash cart for compliance
  - A. Follow the appropriate guidelines in implementing regulation for managing the department's crash cart
  - B. Inventory crash cart components according to institutional policy
  - C. Properly dispose of expired drugs
  - D. Replace expired drugs
  - E. Perform quality assurance testing on defibrillator and document results
- 6. Take comprehensive patient history and evaluate for patient pathology
  - A. Interview the patient and document on department form a complete past and current cardiac history
  - B. Establish "nothing by mouth" compliance
  - C. Evaluate ambulatory ability
  - D. Review noncardiac history for prevalence to study requested
  - E. Perform physical assessment
- 7. Evaluate patient laboratory biochemical markers relevant to cardiac pathology
  - A. Review most recent laboratory test results relevant to cardiovascular diseases
  - B. Order relevant blood tests if necessary (including pregnancy testing)
- 8. Evaluate patient medications for contraindications to stress testing
  - A. Understand contraindications to each type of stress test and evaluate for each
  - B. Review patient medications for contraindications to exercise stress testing
  - C. Conduct preoperative evaluation for orthopedic or other surgery
- 9. Obtain patient informed consent as required for nuclear cardiology procedures according to state law and hospital policy
  - A. Understand the ethical and legal guidelines of informed consent
  - B. Determine the capability of the patient to give informed consent
  - C. Explain the procedure to the patient, including all components of a valid informed consent
  - D. Obtain the patient's or guardian's signature
- 10. Conduct treadmill testing per all protocol options under the direction of the supervising physician
  - A. Prepare the patient for exercise protocol
  - B. Determine type of exercise stress test
  - C. Monitor electrocardiographic tracings and blood pressure for specific pathology and cardiac events during stress testing
  - D. Use the appropriate termination protocols
  - E. Calculate the Duke Treadmill Score

11. Prescribe and administer interventional drugs for pharmacologic stress under the direction of the supervising physician
  - A. Explain the indications and contraindications for each pharmacologic stress agent
  - B. Identify the physiologic action of each pharmacologic agent as it relates to stress testing
  - C. Calculate total dose, volume, and dose rate for each of the most common pharmacologic stress agents
  - D. Set up drug administration pump
  - E. Prepare pharmacologic agents for administration utilizing sterile technique
  - F. Administer pharmacologic agents
  - G. Monitor patient response to pharmacologic agents and treat the patient appropriately in the event of an adverse effect
12. Analyze results of the stress test and imaging portion of the examination and prepare a preliminary description of findings for the supervising physician
  - A. Create a preliminary description of findings detailing the results of the stress portion of the test
  - B. Examine rotating raw data from both stress and resting image acquisitions and evaluate image quality
  - C. Review data for incidental finding outside of the heart
  - D. Compare and contrast stress versus resting processed images for perfusion defects
  - E. Determine if the heart-to-lung ratio and transient ischemic dilation are abnormal
  - F. Evaluate the wall motion of stress and resting images for ejection fraction and kinetic abnormalities
  - G. Review and evaluate bull's eye polar maps and summed stress scores
  - H. Create a preliminary description of findings detailing the results of the imaging portion of the test
13. Facilitate or recommend patient-specific cardiac-related procedures based on nuclear cardiology examination results (outcomes management) according to the supervising physician
  - A. Order or facilitate scheduling of complementary diagnostic procedures as indicated
  - B. Identify the clinical pathways as outlined by the American Medical Association/American College of Cardiology for cardiac disease

## **RADIONUCLIDE THERAPY**

An NMAA properly prepares and administers therapeutic radionuclides, radiopharmaceuticals, and pharmaceutical agents by oral and/or intravenous routes when these agents are part of a standard procedure that is required for treatment under the direction of an authorized user in accordance with federal, state, and institutional regulations, including but not limited to:

1. Review request for radionuclide therapy procedures under the direction of the supervising physician, analyzing the indications, contraindications, and complications for therapeutic interventions.
  - A. Interpret epidemiologic data, research, and trends related to incidence and prevalence of cancer
  - B. Identify risk factors for cancer.
  - C. Understand dosimetry and dosimetric consequences
  - D. Understand the physiologic and radiobiological mechanisms by which differing

- radioisotope therapies are effective
- E. Conduct imaging protocols and evaluate images and laboratory values for presence of disease and metastasis.
  - F. Evaluate clinical criteria for radionuclide therapy, including expected biodistribution of radiotherapeutic pharmaceutical.
2. Counsel and educate the patient and family regarding the proposed therapeutic intervention
  3. Explain in detail the processes, guidelines, and timeliness for the radioisotope therapy regimen according to institutional policy and guidelines.
  4. Obtain patient informed consent for required procedures according to state law and institutional policy.
  5. Educate the patient on pre-procedural and post-procedural care.
  6. Calculate appropriate therapeutic dosage based on dosimetry, patient well-being, diagnostic imaging, and laboratory results under the direction of the supervising physician, including but not limited to:
    - A. Calculate radionuclide therapy dose for benign thyroid disease.
    - B. Calculate radionuclide therapy dose for malignant thyroid disease.
    - C. Calculate radionuclide therapy dose for palliative bone therapy.
    - D. Calculate radionuclide therapy dose for non-Hodgkin's lymphoma.
    - E. Calculate radionuclide therapy dose for polycythemia.
    - F. Calculate radionuclide therapy dose for malignant effusion
    - G. Calculate radionuclide therapy dose for selective internal radiation therapy.
  7. Order or facilitate adjunctive pharmaceuticals for therapy.
  8. Administer therapeutic dose.
  9. Monitor therapy patient and provide post therapy interventions as needed.

## **RADIATION SAFETY**

An NMAA performs all procedures utilizing ionizing radiation safely and effectively, applying federal, state, and institutional regulations, including but not limited to:

1. Maintaining compliance with all applicable regulations.
2. Performing appropriate radioactive contamination monitoring and decontamination procedures.
3. Disposing of radioactive waste in accordance with federal, state and institutional regulations.
4. Participating in programs designed to instruct other personnel about radiation hazards and principles of radiation safety.



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