SPECIFICATION

E-Learning program and Learning Management System for post graduate training in Radiopharmacy

1 Scope

1.1 General

1.1.1 This Specification describes the requirements for an e-Learning program and a Learning Management System, hereinafter referred to as the "System". The System is intended to deliver in English, post graduate programs, i.e. Master of Science and Postgraduate Diploma in Radiopharmacy for radiopharmacists and radiopharmacy technologists respectively (the "Program").

1.1.2 The System is intended to be used by academic institutions, students, student supervisors based in IAEA's member States and the IAEA Technical Officers, hereinafter referred to as the "End Users".

1.2 Content of the Program

1.2.1 It is expected that the proposed Program is based on 'Blended learning' techniques, i.e. an education program that combines online digital media with traditional classroom methods such as workshops, maintenance of daily practical log books and online and face-to-face assessments.

1.2.2 The Program shall fully describe curricula and teaching methodology to be used (total duration of the course, learning objectives and outcomes for the course and for each module, pre-requisites, hours of study expected to cover each module, recommended assessment methodology, supplementary bibliography, videos or animations to be produced and face to face practical exercises to be ensured.

1.2.3 The Program shall be designed based on the Radiopharmacy Syllabus and applicable guidance documents published by IAEA (hereto attached as Annex 1).

1.3 Required Services

1.3.1 The Supplier is requested to provide a comprehensive solution including the development, testing and installation of the System.

1.3.2 The Supplier shall test all functionalities of the System at its own institution or at another institution with IAEA's agreement. The System shall be available for demonstration and verification of functionalities by the IAEA.

1.3.3 The System shall be installed at the following academic institutions selected by the IAEA: Supplier site for the testing and acceptance (phase 1), in addition to an African academic institution (Kenya or Tanzania) for the installation and training (phase 2).

2 Applicable Documents

2.1.1 The Syllabus contents shall include guidance documents published by the professional organisations such as the European Association of Nuclear Medicine (EANM), and the

International Society of Radiolabeling of Blood Elements (ISORBE). Other relevant Documents are listed in Annex 1, Section 3.

3 Definitions, Acronyms, and Abbreviations

The following definitions, acronyms, and abbreviations shall apply throughout this Specification unless defined otherwise hereinafter:

e-L (e-Learning program)	Post graduate program delivered with the support of Information and Communication Technology (ICT)
Blended learning	Blended learning is a teaching methodology that combines usage of online digital media with traditional classroom methods
LMS	Learning Management System
e-L and LMS	The System
MSc	Master of Science for Radiopharmacists
PGD	Post Graduate Diploma for Radiopharmacy Technologists
ECTS	European Credit Transfer and Accumulation System
WHO	World Health Organisation
EANM	European Association of Nuclear Medicine
ISORBE	International Society for Radiolabeling of Blood Elements
SCORM	Sharable Content Object Reference Model

4 Requirements

4.1 Functional and Performance Requirements

The System shall meet the following functional and performance requirements:

4.1.1 The Supplier shall review and update the proposed Syllabus (Annex 1) and practical experience requirements for MSc and PGD courses.

4.1.2 The System shall provide criteria for admission for the MSc and PGD programs.

4.1.3 The Supplier shall provide an online examination for admission of students for MSc and PGD programs. The System shall provide a mechanism for registering students on the post graduate program and for monitoring and assessing their progress during the course. The System shall provide 'pre-online-assessment' identity checking procedure for the participating students during the course.

4.1.4 The System shall be maintained by the Supplier.

4.1.5 The e-Learning program shall contain developed lecture materials as a series of presentations prepared by a team of subject matter experts, academics and practicing professionals in the field based on the Syllabus developed by the IAEA Experts and subsequently reviewed and updated by the Supplier.

4.1.6 The e-Learning program shall produce and incorporate explanatory videos of relevant aspects of radiopharmacy practices.

4.1.7 Based on the lecture materials, the e-Learning program shall provide an online examination such as Multiple Choice Questions (MCQs) and written exams.

4.1.8 The e-Learning program shall provide procedures for assessment and record keeping of examinations.

4.1.9 The e-Learning materials shall meet the applicable postgraduate training requirements in terms of contents and number of hours as required by the applicable ECTS academic standards.

4.1.10 The e-Learning material shall be developed using software package such as Adobe Captivate or similar authoring tools. The produced modules shall fulfil SCORM standards. The e-Learning program shall be delivered based on free software systems such as 'Moodle' in its latest tested version.

4.1.11 The e-Learning program developed shall be accessible via desktop, laptop, tablets and other mobile devices.

4.1.12 The e-Learning program shall provide a suitable "mobile App" as interface for tablet computers or mobile communication devices such as smart phones.

4.1.13 The e-Learning program shall be developed, tested and delivered as a product within a period of 18 months, including a pilot testing of the final product.

4.1.14 The supplier shall provide and maintain during the period of development the necessary software and hardware servers (physical servers or virtual machines in cloud space) to store and test the e-Learning material developed with necessary backup. The Supplier shall take the responsibility of the operating system at OS level, system level, application level and users support level.

4.2 Technical Requirements

The System shall meet the following technical requirements:

4.2.1 The Supplier shall provide the required server capacity to host, test and deliver the e-Learning program.

4.2.2 The hardware and software shall be maintained fully during the development phase and during subsequent trial period.

4.2.3 The e-Learning program shall have a built-in biannual review schedule of its contents and delivery system.

4.2.4 The Supplier shall develop necessary manuals and technical documentation for maintenance of the System and implementation of the e-Learning program.

4.3 Other Requirements (Intellectual Property Rights)

4.3.1 The e-Learning material shall remain property of the IAEA, available to be hosted at the IAEA selected academic institutions to deliver e-Learning (Supplier and Kenya or Tanzania).

4.3.2 The Supplier shall be required to provide online technical assistance for installation and running of the system at the selected academic institutions.

4.3.3 All source codes and instructions developed for setting up and for editing/reviewing the e-Learning program along with the associated Learning Management System software shall be property of the IAEA.

4.3.4 All above mentioned source codes shall be transferred to the IAEA. Documents containing technical background information to support migration of the source codes shall be provided by the Supplier.

5 Quality Requirements

The e-Learning program shall meet the Learning Management System applicable standards as listed under 4.1.

6 Testing and Acceptance (Phase 1)

6.1 The System shall be tested for required specifications by an IAEA expert at the Supplier site.

6.2 The results of the testing of the System shall be documented by the IAEA expert in an acceptance protocol that shall be signed off by the Supplier.

6.3 The Supplier shall be responsible for all costs related to such test, except for the expert related costs.

7 Installation and Training (Phase 2)

7.1 The Supplier shall install the e-Learning program on an independent server in an African academic institution (Kenya or Tanzania) and shall train during at least three (3) days, two (2) designated staff members of that institution in all operations of the System.

8 Deliverable Items

The following items shall be delivered:

8.1 Revised syllabi for the MSc and PGD programs meeting ECTS requirements.

8.2 A comprehensive e-Learning program, as specified above, meeting the revised syllabi requirements, as described above.

8.3 Videos covering practical aspects of daily radiopharmacy work in a clinical set up to support the e-Learning syllabus, as listed in Annex 1, Section 2.

8.4 All source codes and instructions developed for setting up, operating, editing, reviewing of course materials and the Learning Management System.

8.5 Documents containing technical instructions to support the migration and transfer of e-learning course materials and Learning Management System to any other academic institute.

Annex 1: Syllabus and Applicable Documents

1 Syllabus topics for production of e-Learning materials

Radiopharmacy Masters Course	Topics/Lessons	Competencies to be achieved
Basic (Applied) Pharmacy	1. Basic Pharmaceutical Technology 2. Good Manufacturing Practice (GMP) 3. Sterile Manufacture 4. Pharmaceutical microbiology 5. Parenteral Preparations 6. Formulation and Packaging 7. Pharmaceutical Analysis 8. Pharmacopoeia monographs 9. Quality Assurance and Product Performance 10. Quality Control Procedures 11. Stability and Shelf Life 12. Regulations and Legal Aspects 13. Marketing Authorizations 14. Responsibilities of Personnel	Be able to identify and plan pharmaceutical technology requirements for setting up a radiopharmacy service. Be able to plan and implement GMP and aseptic techniques in radiopharmacy. Be able to plan and implement Quality Assurance in Radiopharmacy. Be able to understand and apply national and international pharmaceutical and radiation regulatory requirements and quality standards to the radiopharmacy operations undertaken. Be responsible for manufacturing or quality control of radiopharmacy operations.
Radiopharmaceutical Chemistry	1. Basics on radiochemistry, Radiopharmaceutical Definition, Essential Properties of Radiopharmaceuticals – physical, chemical, biological, pharmaceutical properties 2. Production of Radionuclides - Nuclear reactor, Cyclotron, Radionuclide generators 3. Radiometal pharmaceuticals I - Radiopharmaceutical chemistry of 99mTc-Radiopharmaceuticals, 4. Radiometal pharmaceuticals II - Radiopharmaceutical chemistry: Re, Cu, In, Ga, Y. 5. Organic radiopharmaceuticals I - Introduction to PET, 11C-radiopharmaceuticals	Develop understanding of radiochemistry principles. Develop through understanding of radionuclide production processes. Develop through understanding of metallic and organic radiopharmaceutical radiolabeling techniques. Develop understanding of radiopharmaceutical localisation and radiopharmacology. Develop through understanding of diagnostic, therapeutic and biological radiopharmaceuticals.

	6. Organic radiopharmaceuticals II Radiofluorinations - 18F-radiopharmaceuticals 7. Organic radiopharmaceuticals III - Radiohalogenations: Br, I, At 8. Methods of radiolabeling, Specific factors, Kits 9. Basic Radiopharmacology – Mechanisms of Localization of Radiopharmaceuticals, Pharmacology Versus Mechanisms of Localization, Biological Basis of Distribution of Radiopharmaceuticals 10. Radiopharmaceuticals for Diagnostic Purpose 11. Radiopharmaceuticals for Therapeutical Purpose 12. Radiolabeled Blood Cells/elements.	Develop through understanding of radiolabeling techniques and associated quality control.
Nuclear Physics, Radiation Safety & Regulations	1. Structure and Properties of Atoms 2. Radioactivity, Radiation and Radioactive Decay, Decay schemes of Radionuclides Load in Nuclear Medicine, Units of Radiation Measurement 3. Radiation Calculations - Radioactivity Measurement and Counting Statistics, Radiopharmaceutical Preparation and Dispensing Calculations, Dosimetry, Quality Assurance Calculations 4. Interactions of Radiation with Matter 5. Instruments for Radiation Detection and Measurement 6. Health Physics Equations and Use 7. Principles of Radiation Protection 8. Occupational and Non-Occupational Exposure Radiation Protection Guides 9. Personnel Monitoring and Precautions 10. Area Monitoring (Personnel and Work Environment) 11. Radioactive Packages and Sources 12. Radioactive and Biohazardous Waste Disposal Methods 13. Radiation Safety, Radiation Accidents 14. Regulations – National, EU, IAEA standards	Develop through understanding of basic nuclear physics, interaction of ionising radiation with matter, instrumentation for radiation detection, radiation protection principles and practice. Develop through understanding of national and international radiation protection regulations as applicable to staff, patients, members of public and the environment. Develop through understanding of radiation regulations as applied to the transport of radioactive materials. Develop through understanding of radiation incident management as applicable to radiopharmacy operations.

Radiopharmacology	1. Medical terminology used in radiopharmacy 2. Basic principles of pharmacology 3. LADME process 4. Ideal qualities of radiopharmaceuticals, methods of radiolabeling 5. Principles of mechanism of localization of radiopharmaceuticals 6. The principles of imaging procedures using radiopharmaceuticals 7. The principles of therapeutic procedures using radiopharmaceuticals 8. Dosimetric aspects of radiopharmaceutical applications 9. New radiopharmaceuticals: from molecule to man	Develop through understanding of radiopharmacology principles including radiation dosimetry as applicable to the diagnostic and therapeutic radiopharmaceuticals. Develop through understanding of processes involved in developing new radiopharmaceuticals.
Animal models, disease models, animal protection regulations, ethical issues	1. Introduction of importance to use animal model in the research 2. Creation of appropriate cell-based and animal models of pathology and the clinical translation of the optimized concepts to help detect disease and therapeutic response in people 3. Ethics of animal experimentation 4. Welfare and experimental procedures 5. Preparation protocol (introduction) 6. Introduction to micro-surgery techniques. 7. Invasive and/or semi-automated chronic blood sampling techniques in rodents 8. Injection and administration techniques - administration of substances, suturing 9. Practical handling & restraining tech. 10. Guidelines for a safe transportation of laboratory animals around the world 11. Different caging systems for small laboratory rodents 12. Demonstration experimental techniques, collection of body fluids 13. Cryopreservation 14. Occupational health & safety program 15. Alternatives to animal procedures 16. Breeding of laboratory rodents 17. Anaesthesia 18. Methods of humane euthanasia	To develop through understanding of use of animals for clinical research in all aspects such as regulatory, ethical and practical.

	19. Analgesia and per-operative care 20. Statistics + methodology 21. Cost-Benefit analysis	
Radiation Biology	1. Interaction of Ionizing Radiation with Matter - Types of radiation, Interactions of Radiation with Emphasis on Biological Systems, Units of Energy Transfer, 2. Initial Physical and Chemical Actions of Imparted Energy (including application to RBE and Quality Factors) 3. Radiation Chemistry - General Concepts, Aqueous Systems, Ionization, excitation and formation of free radicals 4. Initial reactions (including influence of LET, oxygen and various compounds on free radical forming reactions) and Factors Affecting Reactions 5. Application to Dosimetry (including MIRD techniques) 6. Cellular Response - Effect on Cells, Sensitive Organelles, Concept of Target(s) and Radiosensitivity, Response to Increasing Radiation Dose, Factors Influencing Response 7. Effects on Nucleic Acids 8. Radiation Genetics (Hereditary Effects) 9. Effects of Ionizing Radiation on the Embryo and Foetus 10. Whole-Body Effects of Ionizing Radiation 11. Acute Effects of Ionizing Radiation 12. Delayed Effects of Ionizing Radiation 13. Low Level (Low Dose Exposure to Ionizing Radiation) 14. Basic Principles of Radiotherapy	To develop through understanding of basic radiation biology principles and their application to nuclear medicine and radiation protection.
Advanced radiopharmaceutical chemistry	Review of Current Radiopharmaceutical Chemistry research and future implications.	Develop understanding of current radiopharmaceutical research and future directions.
Imaging procedures, equipment quality control, associated radiation safety and image interpretations. Drug interventions and interactions/adverse	Prepare/administer radiopharmaceuticals. 2. Perform imaging and non-imaging nuclear medicine procedures. 3. Demonstrate patient care tasks in the patient care course lab setting. 4. Correlate different nuclear medicine procedures normal anatomy and	Develop through understanding of principles of pharmacovigilance and underlying mechanisms of drug interactions with radiopharmaceuticals, altered bio-distributions, adverse reactions and the regulatory and

reactions	abnormal pathology on a nuclear medicine image. 5. Demonstrate radiation safety techniques to minimize radiation exposure. 6. Demonstrate quality control procedures. 7. Perform patient nuclear medicine procedures with appropriate radiopharmaceuticals. Identify normal and abnormal patterns of radiopharmaceutical distribution. 8. Cite procedures, medications and possible adverse reactions for various nuclear medicine procedures. 9. Specify equipment required for performing nuclear medicine procedures. 10. Identify technical consideration for various nuclear medicine procedures. 11. Registration of interaction and adverse reaction 12. Pharmacovigilance in Radiopharmacy	professional reporting mechanisms.
Biopharmacy, radiotracer transport, pharmacokinetics, modelling	1. Drug absorption- gastrointestinal: mechanisms, anatomical and physiological consideration of the GI tract- physico-Chemical, Physiological factors in drug absorption, Food-drug and Drug-drug interactions in drug absorption. 2. Dosage form considerations in drug absorption-formulatory and manufacturing factors-Absorption of drugs from solutions and solid dosage forms-optimizing oral absorption, Biopharmaceutical considerations in drug product design. 3. Bioavailability and bioequivalence of drug products- Factors-Assessment-Experimental designs and protocols for bioavailability and bioequivalence studies. 4. Study of drug distribution, protein binding, metabolism and elimination of drugs-Kinetic considerations-clearance concepts-organ, total and renal clearance and excretion.	Develop through understanding of pharmacokinetic modelling as applicable to radiopharmaceuticals.

	5. Drug dissolution: dissolution of drugs from solid dosage forms-Factors and kinetics of dissolution- in vitro dissolution rate testing: Compendial methods, applications, models-correlation of in vitro and in vivo data. 6. Pharmacokinetics: Rate process in biological systems-Transport of drugs: 7. Mechanisms and kinetic considerations- compartment model-Kinetic considerations of one and two-Compartment models-Data analysis, i.v. and oral. 8. Pharmacokinetic parameters: Biological half-life, Apparent volume of distribution, Clearance concepts, total body clearance, Rate constants for elimination, Absorption rate constants-general considerations, methods of elimination, factors effecting, significance and use of the above parameters. Analysis of Blood and Urine data. 9. Kinetics of multiple dosing-Dosage regimens-Loading and maintenance doses-Kinetics of sustained release and continuous blood levels. Kinetics of drug interactions. 10. Multi-Compartmental models. Applications of Pharmacokinetic principles.	
Kit manufacturing for in-house, in-country and Global use	Cold kit manufacturing for in-house use, national use or international use	Develop detailed understanding of facility requirements, production methodologies and associated quality control for in-house production of radiopharmaceutical cold kits.

Radioisotope production and Radiopharmaceutical preparation	1. Definition of radiopharmaceuticals 2. Compounding radiopharmaceuticals 3. Essential components and additives, Conservation, Stability, Conditioning 4. Formulation of radiopharmaceuticals-pharmaceuticals dosage forms: capsules, parenteral preparations, oral solutions, suspensions, gases and aerosols 5. Pharmacovigilance 6. Kits formulations 7. 99m-Tc labelled radiopharmaceuticals 8. Other diagnostic radiopharmaceuticals 9. Radiolabeled blood cells as radiopharmaceuticals 10. Positron emission radiopharmaceuticals 11. Magistral preparations, Industrial radiopharmacy , centralized radiopharmacy	To develop through understanding of compounding of radiopharmaceuticals from cold kits and manufacturing of radiopharmaceuticals from pre cursors through chemical synthesis, purification, formulation. To develop through understanding of blood cell radiolabeling procedures and associated quality control.
Quality control (QC) of radiopharmaceuticals	1. Introduction to the QC of radiopharmaceuticals 2. QC for conventional radiopharmaceuticals 3. QC for PET radiopharmaceuticals 4. Principles of GLP 5. Methods of validation 6. Physical and chemical tests 7. Biological tests 8. Radiological tests 9. QA in radiopharmacy	To develop through understanding of Good laboratory practice, validation plan and methods, and quality control procedures as applicable to the compounding and manufacturing of radiopharmaceuticals.

Nuclear Medicine - aspects of clinical practice	1. In vivo kinetics of radiopharmaceuticals - Absorption, distribution, metabolism, elimination 2. Factors that affect/alter the kinetics of radiopharmaceuticals - Normal vs. abnormal kinetics 3. Specific procedures that employ radiopharmaceuticals - Indications for the procedure, Criteria for the selection of the appropriate radiopharmaceutical, Optimal imaging or therapeutic protocols, Interventional techniques that enhance the procedure 4. Interpretation of the procedure outcome and its effect on patient management- Sensitivity, specificity, and predictive value of diagnostic procedures 5. Expected benefits of therapeutic procedures 6. Preparation and monitoring of patients who receive radiopharmaceuticals 7. Dosage adjustment based on age, weight, body surface area, organ function, instrument sensitivity, etc. 8. Clinical problems associated with the use of radiopharmaceuticals - Adverse reactions / untoward effects, Misadministration / reportable events 9. Unusual or unanticipated Images or therapeutic outcomes – Artifacts, Altered radiopharmaceutical bio-distribution due to interference from drug therapy or surgical Intervention, Radiopharmaceutical formulation problems, Improper administration techniques, Variations in human anatomy 10. Correlation between the results of product quality control testing and clinical outcome of the procedure 11. Use of radiopharmaceuticals to monitor the safety and/or efficacy of specific drug therapy regimens 12. Drug information resources for nuclear medicine and nuclear pharmacy 13. The role of the nuclear pharmacist as consultant and provider of patient specific Information.	To develop detailed understanding of clinical nuclear medicine applications of radiopharmaceuticals. To develop through understanding of the role of a radiopharmacist in ensuring safe and efficacious use of radiopharmaceuticals in clinical practice. To develop through understanding of legal responsibilities of a radiopharmacist under applicable regulations.

Additional Theoretical Course - 1	Communication skills	To develop communication skills with own and other professional group and stakeholders.
Additional Theoretical Course - 2	Advanced design of SPECT and PET Radiopharmacy	Be able to design SPECT, and PET Radiopharmacies as per the national and international applicable regulatory requirements.
Good Manufacturing Practice	1. Good Manufacturing Practice: definitions, requirements and historical background 2. Quality assurance, quality management, design of quality systems 3. Principles for documentation in GMP, Site Master File, SMF, Monographs 4. Protocols (production protocols, standard operating procedures, SOP) 5. Quality control, chemical and radiochemical identity and purity 6. Risk analysis and risk assessment 7. Clinical trials 8. Qualification and validation 9. Introduction to basic microbiology 10. Microbiological test and quality control 11. Aseptic production, localities, clothing 12. Audit, monitoring, internal and external inspections 13. Alternative quality systems (nationally and internationally) 14. Good Manufacturing Practice in clinical trials 15. Exercises; production of monographs and standard operation protocol, SOP, including exercise in aseptic production 16. Requirements for radiolabeling of cell lines and proteins.	Develop through understanding of GMP principles and practice so as to be able to plan and implement Good manufacturing practice in radiopharmacy. Be able to develop comprehensive list of Standard Operating procedures for implementation of Good Manufacturing Practice for clinical and research applications. Be able to plan and implement Pharmaceutical Quality system and complete cycle of internal quality audits.
Regulations and Legal Aspects, Marketing Authorisations	EU and FDA Radiopharmacy regulations Marketing authorisation process Compounding and manufacturing of radiopharmaceuticals Regulatory audits 5. Regulatory inspections.	Develop through understanding of regulatory requirements of radiopharmaceutical product registration process, compounding and manufacturing of radiopharmaceuticals. Develop through understanding of practical aspects of external audits and regulatory inspections

		of radiopharmacy. .
Risk assessment	Quality risk management principles and practical aspects applicable to radiopharmacy practice.	Develop through understanding of Quality Risk management as applied to radiopharmacy.
Validation facility, protocols, people	Validation Master Plan Validation of facility and equipment and protocols 3. Staff training, update and validation.	Be able to develop and implement validation master plan.
Radiopharmacy Management	Management structure, responsibilities and governance.	Develop understanding of different operational management structures of radiopharmacy service and responsibilities of key personnel.
Quality Assurance and Product Performance	1. Statistics 2. Designing of experiments 3. Statistical quality control 4. Management of total quality 5. Planning 6. Documentation 7. Audits 8. Reliability 9. Product safety 10. Measurements and testing	To develop through understanding of quality assurance and the associated statistical analysis.
Blood cell labelling facilities and methodology	1. Blood cell labelling facilities and safety precautions. 2. Blood cell labelling techniques for red blood cells, white blood cells, platelets and stem cells. 3. Quality control as applicable to blood cell labelling technique.	Develop through understanding of facility and skill requirements for blood cell radiolabeling,
Blood cell labelling clinical applications	1. Clinical applications of radiolabeled red blood cells. 2. Clinical applications of radiolabeled while blood cells. 3. Clinical applications of radiolabeled platelets. 4. Clinical applications of radiolabeled stem cells.	Develop through understanding of clinical applications of radiolabeled blood elements.
Radiopharmaceutical preparation - SPECT radiopharmaceuticals	1. Orientation to Radiopharmacy Practice - daily routines and the functions, - procurement, - compounding,	Develop through understanding of practical aspects of manufacturing of PET radiopharmaceuticals.

	- quality control, dispensing and distribution of radiopharmaceuticals, - waste disposal and radiation safety procedures - routine functions for the development and testing of new radiopharmaceuticals and formulations. - participate in the transport and delivery of radiopharmaceuticals - visit the professional staff at nuclear medicine departments serviced by the Radiopharmacy Unit 2. Procurement of Radiopharmaceuticals - radioactive materials license - ordering radiopharmaceuticals - receipt of radiopharmaceuticals 3. Compounding of Radiopharmaceuticals - Tc-99m generator operations - Tc-99m kits - to set up the compounding and dispensing areas with proper shielding barriers, absorbent coverings and materials - Laminar airflow hoods - proper setup, opening, and maintenance of hood for radiopharmaceutical procedures - Aseptic and safety techniques - Compounding procedures - preparing non-kit and specially-prepared radiopharmaceuticals such as labelled proteins, blood calls, monoclonal antibodies and specific chemical entities - Radiation measurement - GM survey meter, Dose calibrator, Scintillation well counter, Single vs. multichannel counters	
Radiopharmaceutical preparation - PET radiopharmaceuticals	1. Orientation to Radiopharmacy Practice - daily routines and the functions, - procurement, - compounding, - quality control, dispensing and distribution of PET radiopharmaceuticals, - waste disposal and radiation safety procedures - routine functions for the development and testing of new radiopharmaceuticals and formulations. - participate in the transport and delivery	Develop through understanding of practical aspects of manufacturing of PET radiopharmaceuticals.

	of radiopharmaceuticals - visit the professional staff at PET departments serviced by the PET Radiopharmacy Unit 2. Principles of Positron Emission Tomography (PET) 3. PET Camera: Coincidence Counting and Selection of Detectors, Nuclear Physics and Tomography module, Attenuation of Gamma Photons; Transmission Scanning and Attenuation Correction 4. Positron-Emitting Nuclides 5. Principles of Cyclotron Operation/Radionuclide Production 6. Radioisotope Production module 7. Synthesis & Applications of 15O-, 13N-, and 11C-Radiopharmaceuticals 8. Synthesis & Applications of 18F-Radiopharmaceuticals 9. Synthesis & Applications of 18F-fluorodeoxyglucose, Automation and Quality Control 10. GC and HPLC as tools for purification and quality assurance 11. Accepted Clinical Applications of PET – Neurology and Neurology case studies Oncology and Oncology Case Studies, Cardiology and Cardiology Case studies 12. Quantitation of Physiological Parameters with PET: Tracer Kinetic Modelling 13. Generator-Produced Radionuclides (82Rb, 68Ga, 62Cu) 14. Regulatory Issues in PET (180-182) 15. cGMP Standards for Clinical PET Radiopharmaceuticals	

Radiopharmaceutical preparation - Therapeutic radiopharmaceuticals	1. Orientation to Radiopharmacy Practice - daily routines and the functions, - procurement, - compounding, - quality control, dispensing and distribution of radiopharmaceuticals, - waste disposal and radiation safety procedures - routine functions for the development and testing of new radiopharmaceuticals and formulations. - participate in the transport and delivery of radiopharmaceuticals - visit the professional staff at nuclear medicine departments serviced by the Radiopharmacy Unit 2. Procurement of Radiopharmaceuticals - radioactive materials license - ordering radiopharmaceuticals - receipt of radiopharmaceuticals 3. Compounding of Radiopharmaceuticals - to set up the compounding and dispensing areas with proper shielding barriers, absorbent coverings and materials - Laminar airflow hoods - proper setup, opening, and maintenance of hood for radiopharmaceutical procedures - Aseptic and safety techniques - Compounding procedures - preparing non-kit and specially-prepared radiopharmaceuticals such as labelled proteins, blood calls, monoclonal antibodies and specific chemical entities - Radiation measurement - GM survey meter, Dose calibrator, Scintillation well counter, Single vs. multichannel counters	Develop through understanding of compounding and manufacturing of therapeutic radiopharmaceuticals.
Operation of a GMP facility	1. Principle of GMP and facility design (planning and validation) 2. Quality assurance and quality management systems (including documentations) 3. Quality of the personnel 4. Premises and equipment	Develop through understanding of practical details of setting up and operating GMP compliant radiopharmaceutical facilities as a single non commercial facility or as a commercial radiopharmacy service provider.

Quality control of radiopharmaceuticals	1. Radionuclidic purity – be able to quantitate purity using gamma scintillation spectrometry or shielding methods 2. Radiochemical purity - be able to determine amount of radiochemical impurities - Thin layer chromatography, Solvent extraction, Column chromatography - low pressure and HPLC, Precipitation with filtration or centrifugation 3. Pharmaceutical purity – pH, Visual inspection, Chemical tests, Cell viability, Antigen excess 4. Instrument tests - Dose calibrator, G-M meter 5. Perform tests at appropriate intervals and record results 6. Equipment Tests - proper operation of laminar airflow hoods, exhaust hoods, centrifuges and balances through standard in house or independent laboratory test methods	Develop through understanding of practical aspects of quality control instrumentation, calibrations and use for implementing radiopharmaceutical quality assurance.

Clinical application of radiopharmaceuticals /NM	1. Diagnostic Imaging Procedures - Brain and cerebrospinal fluid - Endocrine organs (thyroid, parathyroid, adrenal glands) - Cardiovascular (including deep vein thrombosis) - Pulmonary (perfusion and ventilation studies) - RES (liver, spleen, bone marrow) - Hepatobiliary - Musculoskeletal - Genitourinary - Tumour/Abscess/Inflammatory processes - Gastrointestinal - Miscellaneous studies (e.g. lymphoscintigraphy) 2. In Vivo Function Studies - Thyroid uptake - Blood related parameters (e.g., RBC mass, plasma volume and RBC survival) - Glomerular filtration rate (GFR) - Effective renal plasma flow (ERPF) - Miscellaneous 3. Therapeutic Procedures - Hyperthyroidism and thyroid carcinoma - Polycythaemia Vera - Malignant effusions - Painful bone metastases - Radioimmunotherapy using radiolabelled monoclonal antibodies, peptides, or - molecular recognition units - Miscellaneous	Develop through understanding of practical aspects of radiopharmaceutical use for diagnostic and therapeutic applications in clinical practice.

2 Applicable videos required to be produced on the practical aspects of radiopharmacy

2.1 Practical aspects of radiation protection in all aspects of radiopharmacy (PET, SPECT, Therapeutic and Research applications)

2.2 Practical aspects of clean room operations.

2.3 Practical aspects of microbiological monitoring.

2.4 Practical aspects of SPECT radiopharmacy and associated quality control procedures.

2.5 Practical aspects of PET radiopharmacy and associated quality control.

2.6 Practical aspects of therapeutic radiopharmaceuticals and quality control.

2.7 Practical aspects of blood cell elements radiolabeling, associated quality control and special precautions.

2.8 Practical aspects of Good Manufacturing Practice and associated self-audits in radiopharmacy.

3 Applicable documents and websites

3.1 Operational Guidance on Hospital Radiopharmacy: A Safe and Effective Approach
IAEA publication 2008 PUB/1342; (ISBN:978-92-0-106708-1).

3.2 Competency Based Hospital Radiopharmacy Training. Training Course Series No. 39.
IAEA-TCS-39; Date Published: 2010

3.3 Cyclotron Produced Radionuclides: Guidance on Facility Design and Production of Fluorodeoxyglucose
(FDG)
IAEA Radioisotopes and Radiopharmaceuticals Series No. 3.
English STI/PUB/1515; (ISBN:978-92-0-117310-2): 2012.

3.4 Strategies for Clinical Implementation and Quality Management of PET Tracers.
IAEA/PUB/1344; (ISBN:978-92-0-107008-1), 2009

3.5 Cyclotron Produced Radionuclides: Emerging Positron Emitters for Medical Applications: 64Cu and 124I.
IAEA Radioisotopes and Radiopharmaceuticals Reports No. 1
IAEA/PUB/1717; (ISBN:978-92-0-109615-9): 2016

3.6 http://www.isorbe.com/index.php?pid=kat7

3.7 http://www.eanm.org/publications/guidelines/radiopharmacy/

3.8 http://aphameeting.pharmacist.com/sites/default/files/slides/Loveless%20Updates%20on%20Radio%20Pharm%20Sat%20rm%20340handout_1.pdf

3.9 https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM534811.pdf