FAQS ON THE STANDARDS FOR THE PROVISION OF NUCLEAR MEDICINE, IMAGING, THERAPY AND ASSAY SERVICES ("THE STANDARDS")

PART A: APPLICATION AND INTERPRETATION **SECTION 1: APPLICATION** **SECTION 2: INTERPRETATION**	
Q1:	**What is the purpose of the Standards?**
A1:	These Standards are intended to ensure safer and better quality "Nuclear medicine, imaging, therapy and assay services" (or "NM Services"). The Standards assure the safety of patients who are provided NM Services by – (a) ensuring that Healthcare Institutions providing NM Services have, amongst other things, adequate personnel, facilities, equipment, product, policy and procedures, and Quality Management Systems; and (b) adopting a *"risk-based"* approach that tailors the relevant regulatory requirements according to the intended use of the radiopharmaceuticals and the type of radiopharmacy tasks being performed.
Q2:	**How were the Standards developed?**
A2:	The Standards were developed by the Advisory Committee on Nuclear Medicine ("Advisory Committee"), which was appointed by the Director of Medical Services ("DMS"), Ministry of Health ("MOH") in March 2015 to review and draft a set of standards on NM Services. The Advisory Committee comprised Nuclear Medicine specialists from public and private hospitals and a Medical Physicist. A list of the members of the Advisory Committee can be found in the APPENDIX of the Standards. The Advisory Committee developed the Standards after reviewing and drawing reference from the relevant international best practices, including the International Atomic Energy Agency ("IAEA") Basic Safety Standards. For a complete list of references, please refer to page 21 of the Standards. MOH also held a series of stakeholder consultations on the Standards from January to March 2017. Participants of the Focus Group Discussion ("FGD") led by the Chairman of the Advisory Committee included NM Services

	providers and the National Environment Agency ("NEA") which administers the Radiation Protection Act ("RPA"). Broad consultation was also conducted via email with licensees of hospitals, medical clinics and X-Ray laboratories, as well as professional bodies. The Advisory Committee subsequently deliberated on the feedback received, and revised the Standards where appropriate.
Q3:	**When will the Standards be enforced?**
A3:	MOH only intends to enforce the Standards with effect from the second half of 2020.
Q4:	**As there is still some time until the Standards are enforced, what should we currently do if we want to roll out these NM Services in our healthcare institutions?**
A4.	Healthcare institutions are recommended to work towards achieving the Standards in the interim, so as to achieve safer and better quality NM Services, and operational readiness for future regulatory compliance.
Q5:	**"Nuclear medicine, imaging and assay services" are currently listed under the 2nd Schedule of the Private Hospitals and Medical Clinics Regulations ("PHMCR") as specialised procedures or services that may be provided in private hospitals after prior approval has been obtained from DMS under reg. 18(1) of the same.** **If I am applying under the PHMCR to roll out these specialised procedures or services in my private hospital, do I need to abide by the Standards as well?**
A5:	The Standards are issued to provide guidance for *all* healthcare institutions providing and intending to provide NM Services, including private hospitals that provide "Nuclear medicine, imaging and assay services" as specialised procedures or services under reg. 18(1) of the PHMCR. While the Standards would only be enforced with effect from the second half of 2020, Healthcare institutions are recommended to work towards achieving the Standards in the interim, so as to achieve safer and better quality NM Services, and operational readiness for future regulatory compliance.

Q6:	**Would there be "tier-ing" of the quality and safety requirements based on the scope or scale of the NM Services provided? For example, to apply a less stringent criteria for facilities providing a limited scope of NM Services (e.g. bone scans only with no therapy services) and/or facilities of a smaller scale.**
A6:	The Standards adopt a *"risk-based"* approach to determine the appropriate facilities and equipment that must be present in each Healthcare Institution providing NM Services. Under this "*risk-based*" approach, regulatory requirements vary according to the Licensee's *intended use* of radiopharmaceuticals (e.g. diagnostic versus therapeutic) and the *type of radiopharmacy tasks* being performed in the Hot Lab (e.g. dispensing versus compounding of radiopharmaceuticals). Additional regulatory requirements apply for Healthcare Institutions that provide NM Services involving inpatient therapy (see paragraph 4.2 of the Standards).
PART B: NUCLEAR MEDICINE, IMAGING, THERAPY AND ASSAY (NM) SERVICES **SECTION 3: PERSONNEL**	
Q7:	**Can a medical doctor who is not registered as a Nuclear Medicine Specialist under the Medical Registration Act (Cap. 174) ("MRA") qualify to be the Physician-in-charge or Clinical Governance Officer ("CGO")?**
A7:	Medical practitioners who are *not* registered as Nuclear Medicine Specialists under the MRA may be considered to be the Physician-in-charge or CGO, if they apply and obtain specific approval from DMS *and* satisfy the other requirements in paragraph 3.1(b) and (c) of the Standards (see Table 1 - *Minimum personnel requirements for the provision of NM Services*). Each application shall be assessed holistically, taking into consideration, among other things: (a) the Licensee's *intended use* of radiopharmaceuticals (e.g. diagnostic versus therapeutic); (b) the *type of radiopharmacy tasks* being performed in the Hot Lab (e.g. dispensing versus compounding of radiopharmaceuticals); (c) the qualifications, training and experience in NM Services of the proposed candidate; and (d) whether the candidate holds a NEA L6 licence.

Q8:	**Can a Diagnostic Radiographer, Radiation Therapist or Nuclear Medicine Technologist ("NM Technologist") with less than 3 years of relevant clinical working experience in NM Services work independently in a NM service?**
A8:	Persons who satisfy the requirements in paragraph 3.2(1)(a) or 3.2(2)(a) of the Standards but have less than 3 years of relevant clinical working experience in NM Services *may* work in Healthcare Institutions providing NM Services as Diagnostic Radiographers, Radiation Therapists, or NM Technologists as the case may be, *provided* that they work under the close supervision of the Physician-in-charge; the Qualified Radiographer or Qualified Radiation Therapist; or the Qualified NM Technologist, when providing NM Services. Licensees are to ensure that the documentation of the supervision of such persons (e.g. regular competency review and assessment, re-training records of staff) are kept and made available to MOH at inspection or upon request.
Q9:	**What are examples of "other science subjects related to Nuclear Medicine" that can be considered to be acceptable requisite qualification of a NM Technologist?**
A9:	Examples include biomedical imaging, biomedical sciences, radiography and radiation therapy.
Q10:	**Who can be designated as the Radiation Safety Officer (RSO)?**
A10:	L6 or L5 licensees can be designated as RSOs without additional approval by NEA. Other suitably qualified personnel (e.g. nuclear medicine physician, medical/radiation physicist, diagnostic radiographer, nuclear medicine technologist) appointed by the L6/L5 licensee would need approval by NEA. For queries on approval of RSOs under the Radiation Protection Regulations, you may contact NEA via nea_rpnsd_licence@nea.gov.sg
Q11:	**Can the Physician-in-charge/ CGO be the RSO?**
A11:	The Physician-in-charge/CGO can also be designated as the RSO if he/she fulfils the criteria mentioned in A10 above.

Q12:	**Is there a minimum number of personnel required for the provision of NM Services? For example, is it compulsory to appoint a RSO, a Medical/ Radiation Physicist and/or a Registered Nurse?**
A12:	The minimum personnel requirements for Healthcare Institutions providing NM Services are set out at paragraph 3 (Table 1 - *Minimum personnel requirements for the provision of NM Services*) of the Standards. Licensees shall reflect the above personnel in their Organisation Chart. To ensure that there are adequate staff in the Healthcare Institution for the proper and efficient performance of examinations/procedures that it is licensed to undertake, and for its functions to be performed with accuracy, timeliness and safety, Licensees are advised to take into consideration the following *non-exhaustive* list of factors in their manpower resource planning: (a) the intended *use* of radiopharmaceuticals (e.g. diagnostic versus therapeutic); (b) the *type of radiopharmacy tasks* being performed in the Hot Lab (e.g. dispensing versus compounding of radiopharmaceuticals); and (c) the scale and workload of the NM Services being provided. Licensees are to also refer to paragraph 5.2(3) of the Standards on the requirement to have in place policies and procedures for "Future development of services and staffing needs (e.g. expansion of services)".
Q13:	**What are the appropriate clinical and radiation safety competencies required for nursing staff of NM Services?**
A13:	Licensees shall ensure that nursing staff have clinical and radiation safety competencies that are aligned with the scope of their work in relation to the NM Services being provided in the Healthcare Institution. For example, patient-handling nursing staff involved in the administration of radiopharmaceuticals must be competent in clinical procedures such as administering radiopharmaceuticals safely and the removal of cannula after administration of radiopharmaceuticals, as well as handling of radioactive spillage in accordance with the institution's radiation safety policies. Licensees shall ensure that documentary proof of clinical and radiation safety competency assessments of nursing staff for NM Services are made available to MOH at inspection or upon request.

SECTION 4: FACILITIES AND EQUIPMENT	
Q14:	**In Healthcare Institutions where only diagnostic procedures are performed (i.e. where nuclear medicine therapy is not provided as an NM Service), is it necessary to provide a separate "hot toilet" for patients?**
A14:	Yes. A "hot toilet" for the exclusive use of patients after the administration of radiopharmaceuticals is required under the Standards to minimize radiation exposure and prevent radioactive contamination of other persons (e.g. other patients, next-of-kin accompanying the patients).
Q15:	**Are scrub suits and disposable gloves sufficient to meet the PPE requirements under Table 2 of ANNEX 1 titled "Specific facility and PPE requirements for radiopharmacy laboratories according to category of radiopharmacy tasks"?**
A15:	Licensees are to ensure that the type of PPE used in their Healthcare Institution is aligned with the risk assessment they have conducted (see paragraph 5.1 (3) of the Standards) and the Institution's infection control and radiation safety policies (see paragraph 5.2 of the Standards).
Q16:	**What are the current legislation for the procurement and use of equipment used for NM Services?**
A16:	In Singapore, **medical devices** (e.g. PET/CT machines) are regulated by the Health Sciences Authority (**HSA**) to safeguard public health and safety. The laws which govern medical devices sold in Singapore are the Health Products Act (Act) and Health Products (Medical Devices) Regulations. All product owners are required under these laws to register their medical devices and obtain the dealer's licence with HSA before selling or dealing with them. For details, please refer to http://www.hsa.gov.sg/content/hsa/en.html. In Singapore, **NEA**'s Radiation Protection & Nuclear Science Department (RPNSD) is the national authority for **radiation protection**. It administers and enforces the Radiation Protection Act and Regulations through a system of licensing, notification, authorisation, inspection, and enforcement. HCIs are required to apply for the respective **radiation licence(s)** from RPNSD prior to the possession, operation and/or use of Ionising Radiation (IR) Irradiating Apparatus (e.g. PET/CT machines) & radioactive materials (e.g. Iodine-131)

	in Singapore. For details, please refer to https://www.nea.gov.sg/our-services/radiation-safety/overview .
SECTION 5: QUALITY MANAGEMENT SYSTEMS	
Q17:	**What are some examples of serious reportable events (SREs) and radiation accidents that must be reported to the relevant authorities?**
A17:	Examples of SREs: (a) Any nuclear medicine procedure (for diagnosis & therapy) delivered: (i) to the wrong patient or to the wrong tissue of any patient; (ii) using the wrong radiopharmaceutical; (iii) with a radiation absorbed dose or dose fractionation which differs by more than 10% from the prescribed value or which may lead to acute radiation effects for NM therapy; or (iv) with an exposure greater than 50% of the intended radiation absorbed dose or resulting in doses repeatedly or substantially exceeding the established normal doses for NM imaging. (b) Any radiological procedure that may result in unintended delivery of radiation to the foetus in a pregnant patient, as may occur due to failure to: (i) confirm the pregnancy status of the patient before carrying out the procedure; or (ii) adequately and appropriately shield the patient for the procedure. Examples of radiation accidents: (a) Any therapeutic treatment delivered — (i) to the wrong patient or to the wrong tissue of any patient; (ii) using the wrong radiopharmaceutical (iii) or with a dose or dose fractionation which differs by more than 10% from the value prescribed by the medical practitioner or which may lead to acute effects; (b) Any diagnostic exposure greater than 50% of the intended dose or resulting in doses repeatedly or substantially exceeding the established normal doses for diagnostic radiological examinations;

	(c) Any equipment failure, error, mishap or other unusual occurrence which has the potential to cause a patient to receive a dose significantly different from that intended; (d) An unplanned or unexpected uncontrolled high level of ionising radiation occurs as in the case of loss, by damage of the radiation shielding, of a sealed radioactive source; or (e) an individual enters a high radiation field by accident; or (f) loss of control of unsealed radioactive material causing a spillage / leakage of the radioactive material; or (g) the skin or clothing of an individual becomes contaminated; or (h) radioactive material is accidentally released into the environment in excess of the discharge level permitted by the authority, such that — (a) any individual has, or could have, received an effective or committed an effective dose which is equal to or in excess of one fifth of the appropriate dose limit specified in the Second Schedule of the Radiation Protection Regulations ("RPR"); (b) the skin or personal clothing of any radiation worker is contaminated in excess of 50 times the appropriate permitted contamination limits for skin or personal clothing specified in the Fifth Schedule of the RPR; (c) the skin or personal clothing of any other individual is contaminated in excess of 2.5 times the appropriate permitted contamination limits for skin or personal clothing specified in the Fifth Schedule of the RPR; (d) any area in the premises where work with ionising radiation or radioactive material is conducted is contaminated in excess of 50 times the permitted contamination limit for surfaces in such an area as specified in the Fifth Schedule of the RPR; or

	(e) any other area is contaminated in excess of 10 times the permitted contamination limit for surfaces in low level laboratories as specified in the Fifth Schedule of the RPR.
Q18:	**Which are the relevant authorities for the reporting of SREs and radiation accidents.**
A18:	The relevant authority for the reporting of SREs is the MOH. For MOH SRE reporting, please refer to the National Quality Assurance System (NQAS) online reporting system at: https://elis.moh.gov.sg/NQAS/login/login.action The relevant authority for the reporting of radiation accidents is the NEA. For NEA radiation accident reporting, please direct all queries to (a) nea_rpnsd_licence@nea.gov.sg; or (b) +65 91638842.
Q19:	**How often should the quality assurance programme and risk assessment be reviewed?**
A19:	These should be reviewed in accordance with the Healthcare Institutions policies and procedures as drawn up pursuant to section 5.2 of the Standards.
Q20:	**What is an example of a contingency plan?**
A20:	To have a prior written agreement with another Healthcare Institution for the scanning of a patient who has already been administered with a radiopharmaceutical but cannot be scanned due to an equipment failure.
Q21:	**What are commercially procured radiopharmaceuticals and what are examples of quality control (QC) documents to be retained for them?**
A21:	Commercially procured radiopharmaceuticals refer to radiopharmaceuticals that are not prepared in-house by the HCIs, but are procured from a local Good Manufacturing Practice (GMP)-certified facility, central radiopharmacy and/or overseas sources.

	Healthcare Institutions should retain all QC records and documents that accompany commercially procured radiopharmaceuticals. Examples of such QC documents include: (a) Certificate of Analysis (COA); (b) QC reports; and (c) Radiopharmacy Dispensing Records.
Q22:	**What are examples of quality control (QC) documents to be retained for in-house preparation of radiopharmaceuticals?**
A22:	Examples of such QC documents include: (a) Radiochemical Purity and pH records of radiopharmaceuticals; (b) Ge68 breakthrough records for Ge-Ga68 generators; (c) Molybdenum and Aluminium breakthrough records for Mo-Technetium generators; (d) Generators' product characteristics.
SECTION 6: RECORDS (DOCUMENTATION)	
Q23:	**What is the current National Guidelines for the retention of medical records?**
A23:	The current "2015 National Guidelines For Retention Periods of Medical Records" is published at https://www.moh.gov.sg/licensing-and-regulation.
Q24:	**What are examples of retention periods of medical records in the current National Guidelines?**
A24:	Examples of retention periods include: (a) Computerised/ Electronic Medical Records: Lifetime of patient + 6 years (b) Paper Hospital/ Inpatient records of Adults: 15 years (c) Paper Hospital/ Inpatient records of Minors: Until the patient is 24 years of age