NUCLEAR MEDICINE DEPARTMENT

[redacted]

[redacted]

theRCT the Register of Clinical Technologists

The Register of Clinical Technologists

NUCLEAR MEDICINE EVIDENCE PORTFOLIO

[redacted]

Nuclear Medicine Technologist

[redacted]

March 2018

Abbreviations List

NM – Nuclear Medicine

SPECT/CT – Single Photon Emission Computed Tomography/Computed Tomography

[redacted]

[redacted]

[redacted]

NMD – Nuclear Medicine Department

RCT – Register of Clinical Technologists

SOP – Standard Operating Procedures

IR(ME)R – Ionising Radiation (Medical Exposures) Regulations

GFR – Glomerular Filtration Rate

MPE – Medical Physics Expert

PET/CT – Positron Emission Tomography/Computed Tomography

ARSAC – Administration of Radioactive Substances Advisory Committee

DRL – Diagnostic Reference Level

RND – Radionuclide Dispensary

QA – Quality Assurance

QC – Quality Control

GMP – Good Manufacturing Practice

LFC – Laminar Flow Cabinets

CRIS – Computerised Radiology Information System

WBC – White Blood Cells

RBC – Red Blood Cells

Beta Negative – β^-

COR – Centre Of Rotation

CT – Computed Tomography

SLN – Sentinel Node

IRR – Ionising Radiation Regulations

MARS 78 – The Medicine (Administration of Radioactive Substances) Regulations 1978

RSA 93 – The Radiation Substances Act 1993

CDG 2009 – Carriage of Dangerous Goods & Use of transportable Pressure Equipment Regulations 2009

RPA – Radiation Protection Advisor

HSE – Health and Safety executive

RPS – Radiation Protection Supervisor

[redacted]

SICP – Standards for Infection Control Precautions

BSLN – Breast Sentinel Node

COSHH – Control of Substances Hazardous to Health

QMS – Quality Management System

GSP – Good Scientific Practice

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1. Introduction

Throughout my degree, I acquired the theoretical competencies of each study in Nuclear Medicine along with the practical skills, which I developed through attending lectures and internships in different hospitals. I understand the justification for different investigations in Nuclear Medicine (NM), such as renal studies, skeletal studies, neurological studies, endocrine studies, and gastrointestinal studies, among others. As a clinical technologist, I know which radiopharmaceutical to select for each study and why the one chosen is preferred, why the patient should follow a specific preparation and how that will affect the study and which acquisition is the correct for each study (if it is a static image or a Whole-body and not only Single Photon Emission Computed Tomography/ Computed Tomography (SPECT/CT).

I have been employed in my current position as a Band 5 Nuclear Medicine Clinical Technologist at [redacted]) since March 2017. However, I worked in the same department as a locum between August 2015 and February 2017.

During my 4 year degree in Portugal and in my current role, I have developed not only my personal skills but also my professional skills

In this portfolio, I will outline my daily activities within the Nuclear Medicine Department (NMD) of the [redacted] and [redacted] to demonstrate my competency as a clinical technologist, and meet the criteria specified for the Register of Clinical Technologists (RCT) equivalence route for NM technologists. The job description of my current role, the organizational chart, my *Curriculum Vitae* and other relevant documents are submitted along with this portfolio.

2. Patient Preparation

As a clinical technologist, I have the responsibility to carry out any patient preparation required before a NM procedure. During my four year degree in Portugal, including my internships in different Hospitals and Investigation Centres, I have acquired all the skills required to perform my present role.

To correctly perform the procedures, including the patient preparation, I comply with the Standard Operating Procedures (SOP) of this department and with Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000 (revoked and superseded by The IR(ME)R 17 - More information in the **Legislation and Radiation Control Chapter**) **[A3, A8, C1].**

It is important to realise some scans require special preparation and checks prior to the radiopharmaceutical administration and that these must be thoroughly adhered to, otherwise, the whole study can be compromised. The studies performed at [redacted] and [redacted] with special preparation include **[C1]**:

- Gastric Emptying Studies: The patient should be fasted from midnight (between 8 and 12 hours) before the study. This ensures the results are accurate since the procedure is measuring the emptying speed of the stomach. Also, it is important to give advice to diabetic patients to bring their glucose monitors and insulin with them, which can be taken while ingesting the meal. Medications that cause a delay in the gastric emptying should generally be stopped 2 days before the scan (to prevent false positive test result) and prokinetic agents should also be stopped 2 days before the test unless the scan is performed to assess the efficacy of these drugs. However, at these departments this decision is made by the referrer. **[C1]**.
- Bile Duct and Gallbladder Studies: The patient should be fasted from midnight before the study to avoid a False Positive result **[C1]**.
- Sphincter of Oddi Disfunction Studies: The patient should be fasted from midnight before the study. They should not be driving on the day of the study as the Buscopan is a smooth muscle relaxant and may make their vision less able to adapt quickly, and they should not operate machinery for 6 hours following the test. If the patient has no alternative form of transport the scan will be re-appointed for another day. Buscopan is contraindicated in patients with a history

of underlying heart disease, heart failure, coronary heart disease, cardiac arrhythmia or hypertension and should not be given. Therefore it is important to check this information with the patient and the referral prior to the study **[C1]**.

- DATScan Studies: The patient should stop some medications (advice from *GE* such as *Benzatropine, Buscopan, Cocaine, etc*) prior to the scan and this should be checked with the patient when the study is booked. Patients under the age of 65 years old should receive thyroid blocking with 2 x 85mg Potassium iodate tablets 1 hour before the administration of the radiopharmaceutical to prevent overexposure of the thyroid to radiation (common biological distribution place of iodine) **[C1]**.
- Thyroid, Parathyroid and Whole Body Iodine Studies: The patient should stop any medication that interferes with the radiopharmaceutical uptake within the thyroid (e.g. *Thyroxine*) usually for three weeks prior to the date of the study. However, the medication suppression periods depends on the drug itself, and if the suppression is needed the patient is informed which drug they need to stop and for how long **[C1]**.
- MIBG Studies: The patient does not need to stop any medication. However, Potassium iodate (2 x 85mg) tablets are given to the patient at least 1 hour before and 24hours after the injection of the ^{123}I-MIBG, for the reason referred before for the DATScans studies. Furthermore, the injection should be given slowly (over 3-5 minutes) as it can cause severe tachycardia, and abdominal pain, amongst other symptoms because MIBG it is an analogue of noradrenaline and guanethidine **[C1]**.
- ^{111}In- Pentetreotide Studies: A check should be made as to whether the patient is receiving *Sandostatin* treatment (*Sandostatin LARS/Octreotide/Octreotide Acetate*). The imaging agent is also *Sandostatin* and therefore uptake of the imaging agent may be inhibited by the therapy. However, at these departments the patients do not need to stop the therapy though as the oncologist want us to test the patient on the drug. **[C1]**.
- Meckles Diverticulum Studies: The patient should not have had barium enema 2 days prior to the scan. At these departments, the patient should take 20mg *Losec*

(Omeprazole) the day before the scan (20:00 hours), then fast from midnight and another *Losec* should be taken on the morning of the scan (08:00) in order to suppress stomach uptake **[C1]**.

- Glomerular Filtration Rate (GFR) Studies: The patient should follow dietary restrictions including no diuretics (e.g. coffee, tea or cola – from 22:00 hours the evening prior to the study) and light, low protein breakfast (e.g. toast or cereal and milk). If the list of medications the patient is taking contains diuretics, aminoglycoside antibiotics, penicillins, sulphonamides or aluminium, this should be recorded and checked with a Practitioner/Medical Physicists Expert (MPE) prior to the test **[C1]**.

Other studies, such as Cardiac and Positron Emission Tomography/Computed Tomography (PET/CT) studies also need some special preparation; however they are not performed at my current role at [redacted] **[C1]**.

After the special preparations and checks it is important to correctly carry out the general steps (shown on **Table 1**) for patient preparation on the day of the study **[A3, A8, C1]**.

Table 1 - General steps for patient preparation

Patient Preparation	
Patient Identification	Under IR(ME)R, check the full name, date of birth and address to make sure the study is performed on the right patient preventing unnecessary radiation exposure. It Is important to ensure the clinical information present on the request form is in accordance with the study requested.
Female Patients of Childbearing age	Check if the patient is pregnant or breastfeeding (at this hospital, patients between 12-55 years old). If the result is positive, the ratio risk/benefit must be evaluated by a Practitioner in charge. If the study is to be performed,

	the dose must be reduced to the minimal activity necessary to ensure diagnostic quality. If the patients are breastfeeding, they are required to stop for a period specified in the Administration of Radioactive Substances Advisory Committee (ARSAC) guidelines and they are issued with an instruction leaflet.
Procedure Explanation	All the procedures should be explained in a simple and clear way ensuring the patient understands. Check if special preparations were followed before the administration of radiopharmaceuticals. Patients need to be informed of any preparation between the administration and the image acquisition (e.g. for bone scans, drink at least 1/1.5 litres of fluids and empty bladder often to ensure good image quality – increasing the target/background ratio; and also decreasing bladder radiation exposure).
Additional Information	Questions regarding presence of any symptoms, including pain; if they have had any previous scan; if they had previous fractures and/or bone diseases; etc. This information will help the physician/radiologist when reporting the scans.
Administration of the Radiopharmaceutical	It is important to ensure the dose administered to the patient is dispensed from the correct vial and that the activity is adjusted in accordance with ARSAC levels and Diagnostic Reference Level (DRL). This is important to ensure the minimum radiopharmaceutical activity needed to have good diagnostic quality in the non-imaging or imaging acquisition is used and the maximum activity recommended is not exceeded. When preparing the patient dose, I adhere to the SOP for each study and IR(ME)R 2000 Regulations.

Precautions after Scan	Advise to avoid contact with young children and pregnant women for a period of time (depending on the activity and should be indicated in the department) of the study for ^{99m}Tc and ^{123}I labelled radiopharmaceuticals, or following 3 to 4 days for ^{111}In labelled radiopharmaceuticals. Regarding other relatives the patient should be at 2 arms length of distance to reduce the radiation exposure of risk groups. To ensure bladder radiation protection and quicker tracer elimination the patients receive advice to ingest more fluids than usual for the rest of the day(s) of the scan and to use the toilet as often as needed.
Paediatrics Patients[1]	The procedure should be explained to the child in the presence of the guardian, who may be able to supply additional information with regards to the child's clinical history. The activity should be adjusted according to the weight of the child as per ARSAC guidelines.

[1] At [redacted] all the paediatrics scans are perform at [redacted] so I do not perform them in my actual role. However, I have performed Paediatrics studies in my internships during my degree in Portugal.

3. Radiopharmacy

During my radiopharmacy lectures (practical and theory) and internships I was trained to perform radiopharmaceutical preparation and administration. At [redacted] I successfully completed my venepuncture, peripheral Intravenous cannulation and intradermal injections training **(Appendix 12.1.1)**, allowing me to inject patients with radiopharmaceuticals and also to administer intravenous drugs in certain studies **[D1]**. At [redacted] and [redacted] I work under an ARSAC holder and IR(ME)R regulations to perform injections as part of my role. (**Appendix 12.1.2**)(More information in the **Legislation and Radiation Control Chapter**) **[A3]**.

In the [redacted], all radiopharmaceuticals are prepared in a central Radionuclide Dispensary (RND). Therefore, every day the department receive doses, as standing orders, including Tc^{99m} – MDP, Tc^{99m} – MAA and Tc^{99m} – PERT. Other individual patient's doses are ordered with the correct radiopharmaceutical, activity, volume and reference time required for the patients attending the following day (Daily radiopharmaceutical order form at **Appendix 12.1.3**). The Tc^{99m} doses and Cr^{51} can be ordered the day before the dose is required, however, for others isotopes the order needs to be made in advance **[C5]**.

At these departments the daily management of diary is simplified by our ability to pre-order the doses, however it is important to understand when some scans can be performed during the week taking into account the time between the administration and the image acquisition for the study, the time to perform the image acquisition and also if a special preparation prior to the administration is required. When booking an appointment for an Octreoscan study it is necessary to plan the administration time and the dates of the study, since it is a 3 days protocol (including administration and image acquisition at 24 and 48 hours). At [redacted] which is a two camera department, when a lengthy study is booked (e.g. gastric), where possible the other camera is kept for shorter studies to facilitate the appointing of urgent scan requests (e.g. lungs) **[C5]**.

3.1. Radionuclide Dispensary of the [redacted]

The RND currently operates under Specials Manufacturing Licence No. ML/18325/1 and all operations are required to conform to the rules and guidance for pharmaceutical manufacturers and distributors (Medicines & Healthcare products Regulatory Agency 2014)

and other pieces of legislation (More information in the **Legislation and Radiation Control Chapter**) **[A3].**

Though I do not prepare radiopharmaceuticals on a daily basis I had the opportunity to review my knowledge (acquired previously in Portugal) during a placement at [redacted] and observing all the daily tasks and necessary procedures to delivery doses for 16 NMD around [redacted] On a daily basis, some tasks performed in the RND include **[C7, C8, C9, C10, D2, D3]**:

- **Preparation or replacements trays** – All the trays and their contents, sterile saline, syringes, needles, kits, sterile alcohol wipes, shielding and settle plates should be sprayed with Klercide (sporicidal chlorine) and wiped with sterile alcohol wipes prior to transfer to the hatch and then prior to move inside of the cabinet, to prevent contamination and maintain aseptic environment **[D2]**.
- **Preparation of vials –** the labels of the vials for the individual patient's dose and the kits must be double checked the day prior to the labelling, including the kit batch number and sprayed before transfer to the clean room (**Appendix 12.1.4**) **[D2].**
- **Cabinets and rooms cleaning** – The cabinets and surfaces must be sprayed and cleaned with Klercide before every procedure and re-cleaned after **[D2]**.
- **Mo^{99}/Tc^{99m} Generator Elution** - load elution vial and shielding and record the generator reference number, elution number, saline diluents batch number and the activity of the elution (**Appendix 12.1.4**) **[C7, D3].**
- **Cabinet Daily Checks** – including radionuclide calibrator constancy tests and radionuclide purity of eluate (Mo^{99} breakthrough test) **[B4, C10]**.
- **Calculations and labelling kits** – determine the eluate volume needed to label each kit, label the kit following instructions for the correct preparation using appropriate shielding and tongs to decrease the radiation exposure **[C9, D3]**.
- **Daily Quality Assurance (QA)** – settle plates and finger dabs for environment check and QA/Quality Control (QC) of the final product **[C8, C10]**.
- **Weekly and monthly cleaning –** all cabinets, surfaces and floor must be cleaned every time it is in use and the ceiling and walls must be cleaned and checked with contact plates every two weeks **[C8, D2]**.

These daily tasks including cleaning are important to ensure the product's quality and sterility, which avoids irregular biological distribution within the body and prevents harm to patient. According to Good Manufacturing Practice (GMP)[2], operators and their garments are potentially the most significant sources of microbial contamination. Therefore, to prevent that, all operators entering the clean room are required, to scrub their hands thoroughly, wear special garments, sterile gloves and face mask, before any dispensing operations **[D2]**.

3.1.1. Radiopharmaceutical production

About 80% of the radiopharmaceuticals prepared and delivered are Tc^{99m} products. Due to the short-life of this radionuclide, activity is bought in the form of a generator system. These are sterile, pyrogen-free devices with a chromatography column, which contains Mo^{99}. Elution of the generator entails sterile saline passing over the column to draw the Tc^{99m} selectively and collection in a sterile vial. At present the RND have three 43GBq generators per week (Monday, Tuesday and Thursday), which provides the activity necessary for the dispensing of approximately 700 patient doses per week. The generators currently in use are supplied by Mallinckrodt. They use fission produced molybdenum and the column holding this material is shielded with lead and these are stored in a secondary lead shield to provide sufficient reduction of surface radiation dose **[D3]**.

To prepare a radiopharmaceutical, the Tc^{99m} must be labelled to another chemical to achieve the required biological distribution, resulting in a "kit". To prepare a radiopharmaceutical and taking into consideration the radioisotope decay factor, the required volume of Tc^{99m}–pertechnetate is withdrawn from the generator eluate and injected into the kit. The vial is then shaken and left until the Tc^{99m} complex is formed. However, with certain kits, a heating stage may be required, for example, MAG3 and SestaMIBI. Once reconstituted the kits are subdivided into individual patient doses before being issued. Many of the long-life radiopharmaceuticals are commercially available as single patient doses (e.g. Tl^{201}, In^{111}-Octreoscan), however, it is also common practice to purchase some radiopharmaceuticals in multi-dose containers (e.g. I^{125} – HSA, Cr^{51} – Chromate/EDTA) and then produce individual patient doses **[C9, D3]**.

[2] Rules and Guidance for pharmaceutical manufacturers and distributors 2017.

For radiopharmaceuticals preparation and patient dose calculation, it is important to consider a number of factors including **[C9]**:

- **Radioisotope decay factor** – varies with each isotope used.
- **Patient height and weight** – activity adjustment must be done for each patient as the body surface can influence the radiopharmaceutical count rate during image acquisition. Nevertheless, the standard DRL and ARSAC values should not be surpass and if a higher dose needs to be used a suitable justification has to be presented.
- **Study request** – the activities required varies with each study and radiopharmaceutical.

At this RND the method used to calculate the necessary activity for each kit and individual patient doses is based on the radioisotope decay factor, the activities and the volumes requested from the different NMD across the [redacted] **[C9]**.

To calculate the required activity the calculations are based on the regular Radioactive Decay Law Equation **[C9]**:

$$A_t = A_0 e^{(-\lambda t)} \leftrightarrow A_t = A_0 e^{\left(-\left(\frac{0.693}{T\frac{1}{2}}\right)t\right)}$$

A_0 – Initially activity (at t = 0)

A_t – Activity at a certain t time (time passed between the initial time and the time the dose is needed)

$T_{1/2}$ – Radioisotope physical half-life

λ – Radioisotope decay constant

However, during my visit to the RND I tended to work with volume and not only activity. To get the exact quantity of the final volume (V_f) I need to get my A_t I only have to use a simple cross-multiplication calculation. Through this calculation, I get the accurate result of V_f, which represents the volume needed to give the exact activity necessary. As an example, after the eluation of the generator instead of measuring the vial, a small volume (0.2 mL) is drawn in order to determine the total activity (A) present in the vial. This method prevents a huge exposure to radiation.

For example, I need to label a DMSA kit with 750MBq in 5mL and I know I have 209MBq in 0.2mL of generator eluate. Consequently, I need to know the V_f needed to prepare the kit. The calculations to obtain the V_f is shown bellow **[C9, D3]**:

209 *MBq* (A_0) _____ 0.2 *mL* (V_0)

750 *MBq* _____ V_f mL

$$V_f = \frac{750 \times 0.2}{209} \leftrightarrow V_f \approx 0.71\ mL$$

V_0 – Initial volume

V_f – Final volume required

To calculate the amount of activity necessary for a certain *t* when preparing the individual patient dose I use a Tc^{99m} decay table (**Appendix 12.1.5**) present in the RND and the same calculation method. To have a better understanding, the example below shows how to calculate the individual patient dose, including the required information in**Table 2 [C9]**.

Table 2 - Example of the required information to calculate the individual patient dose

DMSA kit	750 MBq in 5 mL
Radiopharmaceutical Required	Tc^{99}m – DMSA
Activity Required	80 MBq
Volume Required	3 mL
Reference time	12:00

The dose is prepared at 09:00 and the reference time is 12:00 (*t* = 3 hours), therefore the A_t required to have a 80 MBq in 3 mL at 12:00 should be 113 MBq (±10%) **[C9]**.

750*MBq* (A_0) _____ 5 *mL* (V_0)

113 *MBq* _____ V_f mL

$$V_f = \frac{113 \times 5}{750} \leftrightarrow V_f \approx 0.75\ mL$$

Finally, to achieve the total volume of the patient dose, 2.25 mL sterile saline is added in the vial and then the 0.75 mL of the DMSA kit. The vial must be measured in the dose

calibrator and the activity recorded in the master dispensing schedule (**Appendix 12.1.6**) **[C7, C9]**.

The patients' doses are double checked to ensure they are within the activity needed, allowing for the decay factor (**Appendix 12.1.7**) a consignor certificate for packages of radioactive material should be completed including information such as package number, package category, transport index, type of package, nuclide, product (and if is liquid, gas or solid), number of doses, activity per dose, reference time, reference date and activity on departure (**Appendix 12.1.8**). To transport the doses to the final destination they are inserted inside of a drum or a tin with polystyrene inserts, a sheet of absorbent material and the correct labels (More information in the **Transport of Radioactive Materials Chapter**) **[E1].**

3.1.2. Quality Control/Assurance

The radiopharmaceuticals intended for clinical use must be of the desired quality and an integral part of the supply of radiopharmaceuticals is the testing for quality, which shows the product to be safe and effective. Due to radiopharmaceuticals very short useful life after preparation, normally they are administered to patients before the results of quality control tests are obtained. To ensure the final product quality, great emphasis must be placed on the procedures used and the in-process controls that are undertaken, such as **[C8, C10]**:

1. **Tests on starting materials and the final product**
    - Measurement of radioactivity (±10%) of the activity stated on the label;
    - Radionuclide identity – gamma ray spectrometry;
    - Radionuclide purity;
    - Radiochemical purity (Example at **Appendix 12.1.9**);
    - Chemical purity;
    - Absence of foreign particulate matter;
    - Particle size;
    - Sterility (Carried out retrospectively);
    - Pyrogenes.
2. **Environmental and process controls**
    - Documentation – if consistently high quality radiopharmaceuticals are to be prepared it is essential that standard procedures are followed. The

documentation system should allow the complete history of the product to be traced;

- Purchase of radiopharmaceuticals and raw materials - All goods received should be carefully inspected on arrival including labelling and integrity of the packaging. Where possible licensed products should be used;
- Radionuclide calibrator performance – Capintec QC checks;
- Validation of operator performance – includes broth transfer trials and monthly hand hygiene technique.
- Environmental safety and quality – checking overpressures, particulate contamination, air flow rates, air changes, filter efficiency, operator protection tests, microbial contamination of environment and radioactive contamination of surfaces.

3.1.3. Downdraught airflow cabinets and Isolators cabinets

In the design of a radiopharmacy, both pharmaceutical and radiological factors must be considered together with relevant legislation. The areas where unsealed radioactive sources are in use must be suitable for safe working and facilities should also be designed and equipped to carry out the appropriate pharmaceutical procedures especially sterile products. It is important to achieve three important aims as protection of the product from the environment, the operator and other products; protection of the operator from the radioactivity and any other hazards associated with handling of the product, for example blood product; and protection of the environment, including equipment, from radioactive and microbial contamination **[D2]**.

In accordance with the recommended practice in UK, at this RND the process used to dispense radiopharmaceuticals is using unidirectional downdraught airflow cabinets (laminar flow cabinets – LFC[3]) and microbiological safety cabinets. In these units air is taken from the room in which the LFC's are housed and passed over a high efficiency particular filter. Preparation of doses is carried out within these cabinets and the work surface is being continually bathed with sterile particle free air to produce a sterile environment. The LFC's are housed inside a clean room which is a room with a filtered air supply as recognised in

[3] LFC must conform to British Standards including BS5295 for environmental cleanliness in enclosed places. In addition, should conform to BS5726 for microbiological safety, which is a measure of personnel safety.

Appendix I of the Guidance Notes for Hospitals – Premises and Environment for the Preparation of Radiopharmaceuticals (DHSS 1982) **[D2]**.

Isolator cabinets provide an alternative to the use of conventional aseptic suites for the preparation of radiopharmaceuticals and are microbiological safety cabinets with a filtered air supply complying with the highest standards. Normally, the enclosures are designed to operate in domestically clean rooms rather than pharmaceutical clean rooms as in the case of downdraught workstations. In these units, manipulations are carried out via glove ports and the integrity of the gloves is therefore critical **[D2]**.

In conclusion, the isolators are best suited to departments with a small workload and in situations where potentially hazardous materials such as blood products are handled. For this reason, at both departments, an isolator cabinet is used **[D2]**.

3.2. [redacted] and [redacted] Dispensary

When the doses arrive in the department they are added on the Computerised Radiology Information System (CRIS), and then they are measured in a radionuclide calibrator with the correct radioisotope calibration factor selected and the value is recorded in the daily radiopharmaceutical order form (**Appendix 12.1.3**) **[B6, C7]**. The regular plastic filter of the dose calibrator should be used for the daily QA calibration and all isotopes. For the correct measurement of I^{123}, a Thomson Copper filter must be used to prevent variations from the expected values. The ionisation chamber is sensitive to low energy emissions, such as I^{123} (low energy X-rays range 27-32 keV). The radionuclide calibrator has a calibrator factor for this isotope and the measurements should be reliable for every type of vial or syringe used, but is likely to be for a particular type of vial or syringe. Since the Thomson Copper filter is 0.5 mm thick, it removes these X-ray but only reduces the 159 keV emissions by 14% and the ionisation chamber needs to have a new calibration factor for the measurement of I^{123} **[C9]**.

Even without our own dispensary, I am trained to perform the dispensary tasks and cell labelling. On a daily basis, some tasks performed in dispensary include **[C5, C8, C9, C10, D2, D4, E1, E3]**:

- **General duties –** ordering the doses and pharmaceuticals, return the empty lead pots to RND with the appropriate label instead of radioactive label (**Appendix 12.1.10**) **[C5, E1]**.
- **Patient related duties -** dispensing doses, performing cell labelling and GFR procedures **[C9, D4]**.
- **Cabinet and radionuclide calibrator checks –** these include cabinets compressor leak test, settle plates for environment check and finger dabs of critical gloves, gloves checked after each session and changed weekly, dose calibrator constancy test (daily and weekly) **[B4, C8, C10]**.
- **Loading trays –** replenish syringes, needles, swabs, etc.
- **Daily clean and monitoring –** clean and monitor the dispensary, labelling room and cabinets (**Appendix 12.1.11** and **12.1.12**) **[D2, E3]**.

I also perform cell labelling, including proper cleaning, preparing the material beforehand and performing QA (settle plates and finger dabs) before and post-labelling. At these departments, white blood cells (WBC) labelling with Tc^{99m} - HMPAO and In^{111} - Chloride, red blood cells (RBC) labelling with $NaTc^{99m}O_4$ and blood volumes studies are also performed. I am fully trained to perform the WBC and RBC labelling. These studies involve different steps and the **Table 3** shows examples of the main differences between them. Although I do not as yet perform Blood Volume studies, I have included the procedure to highlight the different steps involved **[C1, D4]**.

Table 3 - Differences between labellings

	WBC Labelling	**Heat Damaged RBC Labelling**	**RBC Labelling**	**Blood Volume**
Clinical Indication	To assess pyrexia of unknown origin, abscess, source of sepsis or infection, and inflammatory bowel disease	To assess site of splenic tissue. Query Splenuncula, query accessory spleen in Splenectomy	To determine site of active gastric bleed with acute blood loss	To differentiate between True and Relative Polycythaemia
Cell Labelling	In *vitro*: cell labelling occurs outside the	In *vitro*: RBC preparation with	In vivo:	In *vitro*: cell labelling occurs

method	patient		pyrophosphate and labelling with the agent occurs outside the patient	RBC preparation with pyrophosphates and labelling with the agent occur within the patient	outside the patient
Agent	Tc^{99m} - HMPAO	In^{111} - Chloride	$NaTc^{99m}O_4$	$NaTc^{99m}O_4$	Cr^{51} - Chromate and I^{125} - HSA
Preparation	Not Applicable		Not Applicable	Injection of Sodium Pyrophosphate (PYP) intravenously 15 minutes before the administration of the radiopharmaceutical	Not Applicable
Blood Taking	Syringe prepared with anticoagulant agent (2 ml of Heparin 1000 u/ml) to prevent blood coagulation and 2ml Methocel to assist sedimentation of red cells.		Syringe prepared with anticoagulant agent (2 ml of Heparin 1000 u/ml) to prevent blood coagulation	Not Applicable	Syringe prepared with anticoagulant (0.5 mL of Heparin) to prevent blood coagulation
	50 mL blood sample should be taken to perform the labelling		20 mL blood sample should be taken to perform the labelling		3 mL blood sample should be taken to measure the Haematocrit, plus 20 mL blood sample should be taken to perform the labelling
	Transferred to the isolator cabinet and allow the cells to settle for 30 minutes before starting the labelling		Transferred to the isolator cabinet. Does not need time to settle		Transferred to the isolator cabinet. Does not need time to settle

Labelling	Centrifuge and isolator cabinet are needed.		Centrifuge, isolator cabinet and a water bath are needed	Not Applicable	Centrifuge and isolator cabinet are needed
	To ensure correct and effective labelling the departmental protocol must be followed				
Max Activity injected	200 MBq	20 MBq	100 MBq	400 MBq	0.8 MBq + 0.2 MBq, respectively
Image acquisition	1, 2.5 hours and 4, 24 hours may be required	4 and/or 24 hours	5 minutes	Immediately following administration of the radiopharmaceutical	Not Applicable

I am able to perform GFR studies including administration of radiopharmaceutical, the sample preparation and counting **[C1, C9, D1, D4]**.

For the GFR studies, 5 blood samples must be taken, including the baseline sample and blood samples at 120, 180, 210 and 240 minutes after the Cr^{51} - EDTA injection[4]. It is essential to record in the datasheet the exact time at which the sample was taken, the details of the standard dose, the diluting volume of the standard, the height and weight of the patient. These details are needed to enter into the computer program to produce the final calculated value of GFR. These blood samples should be centrifuged, the plasma should be carefully pipetted and counted in the gamma counter correctly to obtain an accurate result **[D4]**.

[4] Following the department protocol for GFR studies.

4. Imaging Acquisition and Non-Imaging equipment

As a result of my experience, I am competent in equipment management. I have used different types of Gamma Cameras (in Portugal and UK) and PET/CT systems (only in Portugal) to perform imaging acquisition and also auto-gamma counters for non-imaging studies such as quantitative determination of GFR studies (Competencies Form at **Appendix 12.2.1**) **[C2]**.

In my department, I have been trained to correctly operate all the equipment including the Imaging and non-imaging equipment **[C2]**.

I am able to operate *GE Optima 640* (at [redacted]) and *Siemens Symbia T* Gamma Cameras (at [redacted] and [redacted] correctly, including acquisition workstation and ppm, check the photopeak, use the worklist to select patient details before beginning an acquisition, select the most appropriate protocol, start and terminate an acquisition as necessary, rename a view if necessary, modify a view or add extra view(s) if necessary[5], set the area for an image zoom and acquire images with that zoom factor and change collimators safely. I am competent to independently perform a variety of diagnostic NM studies **[C2]**.

The most commonly performed studies in this NMD are:

- Bone Scans (including Three Phase Bone Scan and late phase only)
- Ventilation/Perfusion Lung Scan
- Renal Studies (Renogram and DMSA scans)
- Brain Scans (Brain SPECT and DATScan)
- Gastric emptying and Hepatobiliary Scans
- Thyroid and Parathyroid Scans
- Tumour Imaging Scans (Octreotide)
- Infection/Inflammation Scans
- Lymphoscintigraphies (Breast, Melanomas and Drainage)

Other scans are available in the department; however, they are not commonly performed (including, SeHCat, gastrointestinal bleeding, dacroscintigraphy scans, gallium scans, perchlorate discharge, salivary glands scans, Meckles Diverticulum scan, etc). My

[5] However, some scans need to be checked by a MPE or a NM Practitioner and only they can authorize a SPECT/CT.

understanding in performing these studies and the “sign off” of competencies in this NMD is obtainable on a competencies table (**Appendix 12.2**).

The non-imaging equipment include the *Wizard 3’’ 1480* Samples Counter for quantitative determination and the *Amercare Cabinet* for labelling. I have been trained and I am competent to use this equipment. Regarding the sample counter, I am able to perform the QA before sample counting, arrange the samples in the sample rack in the correct order (as defined in the SOP), attach the appropriate flag for the GFR counting protocol to the sample rack, load the racks into the auto gamma counter followed by a STOP rack and start the auto gamma counter. For the Amercare cabinet for labelling, I am able to check, for example, if the cabinet has been cleaned and passed all the relevant quality control checks before use. I use appropriate aseptic and radiation safety techniques at all times and understand the importance of balancing the centrifuge prior to use to ensure the centrifuge does not get damaged **[C2, C4]**.

5. Therapy

In Portugal, during my placements, I was involved in therapy studies with ^{131}I-NaI for patients with thyroid carcinoma, thyroid follicular adenoma, hyperthyroidism (over-activity of the thyroid gland), etc. I was able to carry out the pre-therapeutic scintigraphy with ^{123}I or ^{99m}Tc Pertechnetate (depending on the department) to determinate the thyroid uptake in order to calculate the therapeutic dose needed for each patient. I was also able to perform the explanation and administration of the therapeutic doses to patients under supervision. **[C3]**.

At my current post, the therapy studies are performed only at [redacted] and only for patients with hyperthyroidism and I am not involved in the therapeutic dose calculation, patient preparation and/or radiopharmaceutical administration but I am able to perform pre-therapeutic scans. These tasks, previously mentioned, should be performed by fully trained operator such as MPE and/or Senior Technologist who has been entitled by the Practitioner to administer the radioiodine **[C3]**.

Although not directly involved with thyroid therapy procedures at the moment, I know the therapeutic procedure and the importance of implementing some follow-up instructions for patients. ^{131}I-NaI has a physical half-life of 8.02 days, is a predominantly gamma-ray emitter of 364 keV and a beta negative (β^-) particle emission of 0.61 MeV. Consequently this radioisotope has a moderate to high Linear Energy Transfer[6] and the β^- particles are responsible for the majority of the local therapy effect. The therapy dose used is much higher than for a diagnostic study performed with this radioisotope and as a result it is important to verify if patients understands all the treatment process (including preparation prior to treatment), instructions to follow during the subsequent weeks after therapy and radiation protection measures to minimise radiation dose post-therapy to other people before starting any therapy (**Table 4**). All procedures and precautions explained prior to treatment are on the information leaflet given to the patient **[A8, C1, C3]**.

[6] Corresponding to the rate at which energy is transferred from ionizing radiation to soft tissue, expressed in terms of kiloelectron volts per micrometer (keV/μm) of track length in soft tissue.

Table 4 - Precautions prior and post therapy

Prior Therapy	Post Therapy
• Stop thyroid medication if required; • Pregnancy test (blood tests in all fertile women (age 12-55)) and should stop breastfeeding if applicable; • Verify if patients have urinary incontinence;	• Avoid unnecessary contact with people age <21 and minimal contact with children age <5; • Avoid travel by public transport and frequent entertainment places; • Sleep separately from other person/people (for a period of time depending on the activity administered) ; • Advise against procreation for 6 months after therapy; • Advice of possibility of alarms in airports/ports;

After the radioisotope administration, if the patient remains in the hospital, an isolated room is provided. Whenever possible, disposable materials such as cutlery and dishes should be used and the used bed linen is stored before being discarded or washed to prevent any contamination by radioactive body fluids and sweat. Finally, when the patient leaves, the room is monitored, washed and cleaned before the next usage **[A8, B6, C3]**.

The follow up should be done 6-8 weeks after treatment by thyroid blood tests and if necessary the radioiodine therapy should be repeated. If performing a second ^{131}I-NaI administration within any 12 month period a risk assessment should be performed **[A4, C3]**.

6. Equipment Management

As a NM technologist and an active member of a multidisciplinary team, I am involved in discussing and can give my opinion to my technical manager when the department is undergoing changes in use of equipment and accessories used on a daily basis **[B1]**.

Recently the department were purchasing new syringe shields and I was asked to give my opinion regarding the differences between them including pros and cons as I have worked with different brands between UK and Portugal **[B1]**.

All equipment used in both departments, including gamma cameras, bone densitometer, electrical equipment (e.g. computers and printers) and others (e.g. centrifuges, calibrators, probes and other equipments) are described in the Equipment Inventory System (**Appendix 12.3.1**) which is located in the departmental common disc area and within the QC system **[B2]**. Detailed information for the gamma cameras and bone densitometer are kept in folders in each camera room and has all the instructions and general QC performance schedules. A record of all engineering services and all calibration information for the cameras, dose calibrators and scintillation monitors, is kept by the physicists. An Equipment Inventory System and these folders are helpful to keep a record of all the equipment faults, calibration dates and service dates **[B2, C7]**.

It is part of my duties to be involved in fault finding, not only for NM equipments but also for other equipment present in the department and used regularly, such as oxygen systems, scales, etc. For NM equipment such as gamma cameras, if I find equipment is out of specification and/or has a fault I need to notify the duty physicist and the Technical Manager, to assess the equipment fault; if the fault/error persists the situation is recorded in the equipment diary and the engineers are notified and a service is booked **[B5]**.

6.1. Quality Assurance

Periodic tests are performed in both NMD including daily, weekly and/or monthly QA tests on gamma cameras, *Amercare* cabinets, gamma counters, radionuclide calibrators, gamma probes, contamination and dose rate monitors. These periodic tests are crucial to verify if the equipment is working under the parameters expected on a daily basis **[B8, C4]**.

The most performed reference test for gamma cameras are the extrinsic uniformity (performed daily and weekly) (see example at **Appendices 12.3.2** and **12.3.3**), the Centre Of Rotation (COR) alignment (this is performed weekly and the same set of collimators is

repeated on a 3 week cycle) (see example at **Appendix 12.3.4**), Computed Tomography (CT) check up and CT phantom (performed daily) (see example at **Appendix 12.2.3**) and intrinsic uniformity verification (performed weekly – if the results are greatly different from results recorded to date I need to inform the duty physicist and perform an intrinsic calibration). The tests guarantee the gamma cameras are working accurately on a daily basis. It is important to mention the scheduling of the QA tests is different for each department and they are performed as often as the department routine allows and, in my opinion, they are performed with a good frequency in one of the departments, however, I would increase the frequency of the CT phantom check and intrinsic uniformity verification in the other department **[B4, B8, C4, C7, C8].**

After performing the QA tests, as part of my daily duties, I need to record the values of all the tests performed, writing down in the correct folder for each gamma camera (with date, collimator used, name the person who performed the test and processed the values) and record in the corresponding *Excel* files the results of the test and compare them with the reference values (available in the same file), ensuring they are within the acceptable range (**Appendices 12.3.2, 12.3.3** and **12.3.4**) **[B4, C4, C7, C8]**. However, if by any chance one or more parameters are out of range, I should go through the following steps **[B4, C4, C7, C8]**:

9. Perform the test a second time - prior to doing the test, I need to identify what may cause the problem, such as distance between collimators was not the standard QC protocol, ^{57}Co flood positioning was not the most appropriate or the activity of the source was greater/lower than usual;
10. If the reference values are still out of range, I need notify my technical manager and the duty physicist, so that other action may be taken, such as other QC tests and evaluations of the software;
11. If the fault persists, the duty physicist will make the decision whether the camera should remain in service and contact the engineers of the company responsible for that equipment to fix the problem to perform a service on the equipment.

Regarding the gamma counter, at both departments, the Good Laboratory Practice (GLP) test and weekly QA are performed using a ^{129}I calibration source and I need to check the peak, efficiency and total CPM. In addition, prior to clinical use the ^{51}Cr peak must be

checked. If there is a problem with theses values I need notify my manager and/or the duty physicists. Another QA test performed on the gamma counter is the isotope normalisation; this procedure is performed every 6 months (or at least annually) on all isotopes in use in the departments and is carried out by one of the physicists **[B4, C4, C7, C8]**.

As for the *Amercare* cabinets, QA checks (such as microbiological monitoring, cleaning and daily checks, cabinet gloves, particle counting and leak tests) I have been performing them ever since my arrival at both departments and I perform them through the steps showed on the **Table 5 [B4, B8,C4, C7, C8].**

Table 5 - Amercare QA checks

***Amercare* QA checks**	
Microbiological monitoring	Should be performed every time any patient related procedure is performed within the cabinet or at least once per week if no patient procedure has been undertaken, by using agar plates (sent to Microbiology-Bacteriology Department (MBD)). The results are reported about two weeks later. The record should be signed by the chief technologist or MPE and be stored in the correct file. If the report from Bacteriology or Area QC indicates that there is no contamination then the appropriate entry in the weekly check sheet can be ticked off. If the report indicates that there is a degree of contamination, then procedures should be initiated for sterilising the laminar flow cabinet. Also, every six months the laminar flow cabinets are tested to make sure that they are still functioning correctly with the appropriate air flow. A copy of the certificate issued should be laminated and attached to the cabinet; the original copy should be stored in the filing cabinet kept in the Technical Manager's office.
Cleaning and daily checks	A full cabinet clean should be performed at the beginning of each work session including internal cleaning (cabinet, gauntlets/gloves, sterile gloves, centrifuge and other equipment) and external cleaning. At the end of cleaning, I need to check if the air change and pressures are within the acceptable limits, and if the cabinet is out of limits I notify

	the technical manager and/or duty physicist.
Particle Counting	As part of the QC protocol the cabinet filtration system is checked monthly. This is carried out on a monthly basis at [redacted] by the staff from [redacted] and at [redacted] by the technologists. After checking the cabinet, a report is issued and sent to the technical manager and will be checked and filed in the technical manager's office.
Leak tests	The cabinet automatically performs a daily leak test and the print out should be checked every day. If the result is acceptable, the print-out should be filed in the "current month" envelope attached to the side of the cabinet. If the test fails I need notify the technical manager and/or duty physicist.

If the radionuclide calibrator malfunctions, it can affect the activity given to the patient. Therefore, it is important that all the checks (background and constancy tests) be performed on a daily basis. These checks at [redacted] are performed through the use of a ^{226}Ra standard source for the daily checks for ^{99m}Tc and on a weekly basis for all other isotopes (**Appendix 12.3.5**). At [redacted] I use a ^{137}Cs standard source and the checks are performed for all the isotopes that will be in use that day. The QA is performed through the following steps **[B4, C4, C7, C8, C10]**:

- Check the background at the ^{99m}Tc setting;
- Activity is measured on the $^{226}Ra/^{137}Cs$ setting;
- Activity is measured on other isotopes settings (as required by the department)
- Values are recorded in the appropriate logbook and compared with the standards values (should be within ± 10%).

Regarding the linearity test of radionuclide calibrators (as a field instrument) this is performed annually in both departments by the physicists to guarantee the calibrators are measuring within specification. To perform the linearity test, 4 vials (2 low, 1 medium and 1 high energy) are measured in the radionuclide calibrator using the appropriate settings and the background is also measured over 3 hours. The activity at a specific calibration time and date is corrected to the testing date taking into account the decay. All values are recorded and a comparison between the measured and theoretical activities is made. The percentage

differences should be below the 5% tolerance, set for a field instrument, suggesting the linearity of the radionuclide dose calibrator is well within tolerance **[B4, B8, C4, C7, C8, C10]**.

The gamma probes used to identify sentinel nodes (SLN) in theatre should be checked weekly and also after use. The probe needs to be checked for sound, battery and for the number of counts recorded in 10 seconds (should be performed 3 times) and to perform the check I use a ^{57}Co pen and Perspex block. The values are recorded in the Excel QC file **[B4, C4, C7, C8]**.

Concerning the contamination and dose rate monitors, the QA tests are performed both weekly and annually. The weekly checks (which include the battery, speaker, background activity and activity measured with source) are performed by using a ^{90}Sr source (contamination monitors), ^{57}Co pen and ^{226}Ra source (dose rate monitors) and must be recorded in the Excel files. The contamination monitors are checked once a year by [redacted] The checks ensure that the monitors are appropriate for measuring radioactive contamination within the department and are suitable for the various radionuclides within the department. They also indicate the sensitivity of each instrument to radiation. This sensitivity can change from year to year and if it falls below a certain level, the monitor should not be used. As for the dose rate monitors within the department, they need to be checked annually by an external organisation such as Public Health England, to check the monitor's performance at a variety of energies **[B4, B8, C4, C7, C8]**.

Finally, when installing new equipment it is important to guarantee that the equipment meets the technical specifications by the manufacturer and to confirm this, acceptance tests are performed by the manufacturer's engineer and also by the physicists (commissioning checks are not part of my job description). The results should be traceable to National Electrical Manufactures Association (NEMA) performance standards. After any of the acceptances tests have been performed the results are used as a baseline for routinely performed tests such as daily, weekly and monthly quality control to help identify potential equipment failure or loss of image quality. If the equipment does not pass these acceptance tests, it should not be used **[B8, C4]**.

As I mentioned before, this task is not part of my current role, however the protocol used when performing the acceptance testing of a new SPECT/CT system is a Gamma Camera performance assessment protocol. In 1994, the Medical Devices Agency (MDA)

established the Gamma Camera Assessment Team (GCAT) to evaluate the performance of gamma cameras using the clinically-orientated protocols **[B8, C4]**.

Using the Gamma Camera Performance Assessment Protocol, our clinical scientists perform the following test on a new system **[B8, C4]**:

- Quantitative intrinsic spatial resolution;
- Quantitative system spatial resolution;
- Shield penetration;
- System no-uniformity;
- System sensitivity;
- Count rate performance;
- Variation in uniformity with camera angle;
- Variation in sensitivity with camera angle;
- Rotational performance assessment;
- Tomographic resolution;
- Tomographic non-uniformity;
- Tomographic system performance;
- Wholebody count rate variation;
- Wholebody resolution;
- Wholebody system performance;

7. Legislation and Radiation Control

7.1. Legislation in Nuclear Medicine

As a clinical technologist I am familiar with the pieces of legislation for the use of radionuclides in NM such as, Ionising Radiation Regulations 1999 (IRR 99), The IR(ME)R 2000, The Medicine (Administration of Radioactive Substances) Regulations 1978 (MARS 78), The Radiation Substances Act 1993 (RSA 93), Carriage of Dangerous Goods & Use of Transportable Pressure Equipment Regulations 2009 (CDG 2009) and The Health and Safety at Work etc. Act1974. However, some of these Regulations have been revoked and/or superseded **[A3]**.

IRR 99 was revoked and superseded by Ionising Radiation Regulations 2017 (IRR 17) which came into force on 1st of January 2018. The Regulations establishes a safe environment for all the working staff and the public through its regulations, by ensuring that the ionising radiation exposure on the workplace is kept "As Low as Reasonably Practicable" (ALARP concept) and provides new dose limits (**Table 6**) to ensure that sufficient measures are made to protect staff and members of the public from ionising radiation **[A3]**.

Table 6 - Annual Limit doses

	Employees and Trainees ≥ 18 years	**Trainees < 18 years**	**Members of public**
	Annual Limit on Equivalent Dose (mSv)		
Eyes (IRR 99)	150	50	15
Eyes (IRR 17)	20	20	15
Skin	500	150	50
Extremities	500	150	50
	Annual Limit on Effective Dose (mSv)		
Whole body	20	6	1

This document also states the Radiation Protection Advisor (RPA) who has suitable knowledge, experience and must hold a valid certificate of competence from an organisation recognised by the Health and Safety Executive (HSE) to provide advice to the NHS Trust (employer) about protection of employees and the public from harmful effects of

ionising radiation. Also, to individual departments a Radiation Protection Supervision (RPS) should be designated to ensure that local rules are followed. These local rules are drawn up by Heath Physics department in consultation with the local RPS and they provide information such as **[A3]**:

- Dose investigation levels for employees, trainees (aged under, of or above 18 years old) and other persons;
- Description of the controlled area (e.g. injection room, camera room, etc), supervised area (e.g. corridor) and the hazards present in the area;
- Description of contingency plans (in the event of a radiation spill and respective decontamination procedure, in the event of fire, etc);
- Names and contacts details of responsible people including the RPS.

Also, the Regulation regarding the Equipment used for medical exposure (IRR 17, Regulation 33) must be omitted since it is part of the new The IR(ME)R Regulations, (Regulation 15) **[A3]**.

The IR(ME)R 2000[7], was revoked and superseded by The IR(ME)R 2017 coming into force on 6th of February 2018. These Regulations impose duties on employers responsible for administering medical exposures of ionising radiation, such an establishment of general procedures, protocols and quality assurance programmes, clinical audits and accidental or unintended exposure, in order to protect the person undergoing the medical exposure from unnecessary overexposure, such as unjustified or excessive doses **[A3]**.

Consequently, every medical exposure must be justified in terms of an evaluation of the clinical information available, the potential benefits and the risks, not only for each patient but also for the carers and comforters. Also, the medical exposure should be optimised to ensure the minimum dose required to achieve the intended results is used. A practical example of the use of this legislation is the regular performance of V/Q scans on pregnant or breastfeeding women at [redacted]. However, for each patient, the ratio risk/benefit must be done and a decision towards the scan performance made by the Practitioner in

[7] The four duty holders involved in the use of ionising radiation are: employer, referrer, practitioner and operator. Also, the employer must ensure that a suitable MPE is appointed and involved, in relation to every type of exposure to which these Regulations apply.

charge. As referred previous, the radiopharmaceutical dose for both cases, must be reduced to the minimal activity necessary to ensure diagnostic quality **[A3]**.

MARS 78 has a result of, The IR(ME)R 2017 been revoked and is now included within IRMER, this states that medical exposures and prior-authorisation for the administration of radioactive substances for the purposes of diagnosis, treatment and research. These Regulations provide protection for patients by stipulating that the administration of radioactive substances must be under the direction of an ARSAC certification holder, this is the IR(ME)R practitioner, in order to guarantee the correct use of the radiopharmaceutical and the lowest radiation exposure. In both NMD the practitioner appoints the clinical technologist to act as operator in the administration of such substances. ARSAC certificates issued to a person under the MARS 78 which is valid on 6th of February 2018 is deemed to be a licence issued under these Regulations for as long as that certificate remains valid and to license the employer responsible for the medical radiological installation for the matter specified in that certificate**[A3]**.

The RSA 93 is designated to reduce the effects of radiation on the environment and the general public and is enforced by the [redacted] Under the act it is a requirement that all users of radioactive material, such as a NMD, is registered and must obtain a certificate for holding and an authorisation for disposing from [redacted] Detailed records of all stored and disposed waste must show the date, radionuclide, type and quantities disposed of and the disposal route.[8] This record keeping is required in order to provide suitable evidence of compliance at regular inspections by [redacted] **[A3]**.

The CDG 2009 state the regulations directed to the transport of dangerous goods from, to and within the UK, including radioactive materials [9]**[A3]**.

The Health and Safety at Work etc. Act (HSWA) 1974 is the piece of legislation covering occupational Health and Safety in Great Britain. The HSE was created to investigate accidents which includes nuclear incidents and enforces the IRR 99 described before **[A3]**.

7.2. Radiation Monitoring

As part of my daily duties, at the end of the work day, my colleagues and I are required to monitor (using a scintillation monitor) the injections rooms, acquisition rooms,

[8] Further information in Radiation Monitoring section.

[9] Further information in Transport of Radioactive Materials section

waiting rooms, dispensary, labelling room, waste disposal and therapy room (**Appendix 12.1.10**) **[B6, E3]**.

This alerts us if any area of the department is contaminated and an appropriate decontamination is necessary (as per local SOP, **Appendix 12.4.1**) **[B3]**. Clear signalization of the area contaminated and a record keeping of the event is required. Also, it is essential to inform all staff, manager and the duty physicist **[B3, B6, C7, E3]**.

The radioactive waste, such as sharps bins should be stored in the Waste Disposal Room and clinical waste bags and/or contaminated linen (with radioactive urine contamination, radioactive blood spillage, etc) should be stored in the designated area, Waste Storage Room, keeping a record on file of waste label, radioisotope, number of counts and date, in the case of contaminated linen **[B6, C7]**.

The sharps bins and the large bins that are in the Waste Storage Room should be monitored weekly[10] to see if they can be disposed. The waste can be discharged and transported as normal if the waste activity is below 1 MBq. If not it must be placed back in the store room to decay further. Following RSA 93 and the local rules, a record of all radioactive waste is kept within a folder in the Waste Storage Room **[A3, B6, E3]**.

7.3. Leak Test of Sealed Sources

In keeping with IRR 17 Regulation 28, both NMDs have a protocol for performing leak tests on sealed sources. It is a statutory requirement to perform leak test on every sealed sources (^{137}Cs, ^{57}Co, ^{90}Sr and ^{129}I) present in the department at least once every two years, although this procedure should also be performed when a new source arrives in the department and if any visible alteration or damage to the source is observed. This task is performed by the physicists and/or technologists, and the results presented to the RPS for review and to verify the safe performance of the source or instruct further action (see example of the results at **Appendix 12.4.2**). A wipe test is most widely used and removed

[10] The waste is monitored for activity using a calibrated contamination monitor at a fixed distance of 50cm and the background counts are also checked.

activity should not exceed 185 Bq [11]. The instructions for the performance of leak tests on sealed sources at both departments are **[A3, E2]**:

- Using a swab moistened with alcohol (MediSwab)[12] wipe the source or an appropriate area of the surface[13];
- The swab should be assayed, with a detector, appropriate for the type of radiation expected from the source. Samples are assayed using a sodium iodide detector, i.e. an auto gamma counter[14] with an open energy window.

A negative result for leakage is confirmed when no measurable activity above background[15] is detected, so if the value is above background (active swab) further tests should be performed to investigate the result. If the source demonstrates leakage, it is deemed unsafe for use. As a result the source should be taken out of service and stored safely in the Waste Disposal Room until it can be disposed of and an electronic record is kept on the common area of disk[16] **[A3, E2]**.

7.4. Transport of Radioactive Materials

The transport of radioactive material is regulated by the CDG 2009 legislation and in these regulations there are three types of packages (Excepted packages, Type A packages and type B packages) described. These regulations stipulate how the package design should reduce the risk of any radioactive contamination and all external radiation hazards should be kept to a minimum. All shipments should be traceable back to the sender through consignor notes **[A3, E1]**.

In [redacted] all the radiopharmaceuticals and Krypton (^{81}Rb) generator are delivered from the General RND. The majority of transport of radionuclide packages in [redacted] are Type A packages as they are for the transport of intermediate quantities of radioactive

[11] Specification is British Standard BS 5288 1976, Appendix D but this has been superseded with BS EN ISO 2919:20147

[12] MediSwab is the preferred swab since this should be wet and containing only alcohol to make sure the test is not compromised.

[13] To measure the exact level of contamination, allowance must be made for only a proportion of the leakage being removed by the swab (10%). Therefore all samples should measure under 19Bq.

[14] At both departments the gamma counter is used, which has a higher sensitivity than a gamma camera.

[15] Anything >19 cps above background warrants further investigation

[16] If there is damage to the source details of how the damage occurred should be sought.

material, whose dose rate exceeds 5µSv/hour. These packages have to undergo various performance tests, before the delivery, to ensure each container has the right characteristics, which include: a free drop test from a height of 1.2m for solids and 9m for liquids, a water spray test to simulate rain fall, a stacking test to stimulate storage conditions and a penetration test by a 6kg bar from a height of 1m for solids and 1.7m for liquids. Every morning, the RND's driver delivers the doses for patients' scans and therapies required for the day with the respective consignor note **[A3, E1]**.

At the end of each day, prior to returning a used ^{81}Rb generator (supplied on a Tuesday and Friday) and/or the lead pots kept in the department, I need to monitor the package to ensure that the dose rate of the surface of the package does not exceed 5µSv/hour (Excepted Package). The ^{81}Rb generator is stored in a cardboard box and the lead pots in a metallic drum. Stickers are applied to identify the level of activity or if there is no activity (**Appendix 12.1.8**). Also, they need to be marked with an appropriate UN number and have the consignor or consignee details (**Appendix 12.4.3**). The following morning, the driver collects the packages to return to the RND along with the appropriate consignor notes **[A3, E1, E3]**.

7.5. Radiation Incident Reporting

In the case of an incident or near miss (such as overexposure, unnecessary and/or unjustified radiation or contamination) an online Datix form should be completed as part of the Hospital policy, to ensure the incident is recorded not only on a Radiology information system but also on the hospital platform. I have observed and I have completed one of these reports in the past **[A5]**.

A patient attended for a bone scan and additional SPECT/CT was requested of lower extremities. The SPECT/CT images were acquired but CT field of view acquisition was incomplete due to unavoidable equipment failure and consequently did not cover the area of interest. Since it was an equipment failure the engineer was contacted by duty physicist and after an investigation a fault was found and the duty physicist received advice not to use SPECT-CT unit for CT scans until the fault was repaired. Therefore we repeated the patient scan on another gamma camera in order to obtain the images required, however, because of the repeat CT, the exposure to radiation increased and a radiation incident report had to be completed **[A5]**.

Further to this, as a reflection on lessons learned with this incident, staff continue to be encouraged to check all images before the patient leaves the department to ensure a complete data set has been acquired **[A5, A9]**.

8. Clinical Audits

To allow for quality improvement and to examine if healthcare is being provided in line with standards, to inform the staff and patients how well their services are being performed and where improvements could be made, an audit should be performed **[C6]**.

At both departments there are monthly audit schedules for different subjects, such as hand hygiene audit, cleaning audit, [redacted]QIP ([redacted] Quality Improvement Portal) audit, fire audit and IRMER audits. The hand hygiene, cleaning, LanQIP and fire audit is performed by technologists and nurses and the IRMER audits are normally performed by physicists **[C6]**.

The hand hygiene monitoring audit is important to ensure hand cleaning is performed at the right moments (e.g. before patient contact, before aseptic task, etc) and if compliance with the hand washing standards (e.g. liquid soap applied with hands wet, bin opened using the foot pedal when disposing of towels).

The cleaning audit is performed monthly and is important to guarantee if the rooms are cleaned in compliance with the standards after each patient and at the end of the day. At the end of the month the ratio cleaned/opportunities is analysed.

The [redacted]QIP audit helps us demonstrate our compliance against the Healthcare Quality Strategy for [redacted] and includes Standards for Infection Control Precautions (SICP's). The SICP's consist of 10 key elements (e.g. Personal Protective Equipment, Hand Hygiene, Safe Disposal of Waste, etc) to reducing the risk of infection for patients in all healthcare settings in [redacted] and are relevant in any care environment. This audit should be performed twice a year.

The fire audit assesses where there are deficiencies found in the department, problem/modification with equipment (such as fire extinguishers) and confirms if all staff on duty have received the adequate training and are aware of the emergency procedures **[C6]**.

To perform the IRMER audit, 20 different studies every month are investigated in order to analyse if all the required procedures, pregnancy/ breastfeeding verified, DRL activity, patient signature to consent with the scan and details (activities and scan of the cards), have been entered on CRIS **[C6]**.

In 2015 a review of Breast Sentinel Node (BSLN) imaging procedures at both departments [redacted] was performed and the results showed a large discrepancy

across sites for successful visualisation of BSLN. Because of this, an audit was carried out to determine the reasons for this discrepancy. The audit data and my comments in detail are presented in **Appendix 12.5 [C6]**.

The aim of these audits is to highlight any areas that require improvement and work on these to provide the best healthcare we can.

9. Safe Working Practice

[redacted] has mandatory training which all staff must complete yearly, through Learn-Pro and/or face-to-face attendance, such as Basic Life Support and infection control. When I started as a NHS employee in March 2017 I had the induction for all new staff (as show on **Appendix 12.6.1**) and the Learn-Pro statutory courses (**Appendix 12.6.2**), such as Healthy and Safety, etc. This training is essential for everyone working in a hospital environment **[A1, A2]**.

As a multidisciplinary team it is important to follow necessary measures to provide wellbeing not only for the patients but also for the staff. Every day, we deal with different patients with different requirements and it is necessary to do everything in our power to assure service quality without compromising the safety of the patients. Some patients need more attention and understanding of their health problems (including emotional health), specific moving and handling (including lateral transfer from trolley to the gamma camera bed, standing and walking, etc) and/or patients requiring more care to prevent and control infection. Therefore, the mandatory training is essential for all staff to help us to identify existing or possible risks when in contact with a patient. To guarantee patient safety and care, I follow the departments protocols directed to ensure Health and Safety and Risk Management (See examples at **Table 7**) **[A1, A2, A7, B3, B6, E3]**.

Table 7 - Example of actions that ensure Health and Safety and Risk Management

General Infection Control	Use hand disinfectant gel and to prevent infections, wash hands as often as required.
	Use personal protective equipment as often as possible for preventing contamination by fluids, especially with inpatients.
	Carry out equipment decontamination between patients and as often as required.
	Clean positioning equipment, pillows and equipment bed between patients and at the end of the day with wipes (Clinitex®).
	Weekly clean the gamma camera (including gantry and detectors), collimator cart(s) (sometimes dust can impede the collimator changing) and all work surfaces (including all items on desks and all

	dust gathering surfaces).
Infectious Diseases & MRSA	Gamma camera bed, pillows and all used equipment must be wiped and cleaned with Actichlor®.
	All laundry must be disposed in a red bag and then put this bag inside of a disposable white bag to keep separately from regular laundry.
	Staff must wash hands with water and soap and not only use the hand gel as it is not effective against certain viruses.
Clinical Waste	Separate and dispose the clinical waste (including contamination from blood spills and/or radioactive spills) in the designated places.
Radiation Spillages	Monitor the contaminated area, clean the area with wipes and Actichlor®, monitor again to check if radiation has reached background counts. If necessary cover area with Benchguard® and label appropriately.

9.1. Risk Assessment

The risk assessments are performed in both departments and in accordance with the IRR and HSWA. Clinical technologists and physicists are allowed to perform and write risk assessments although they must be checked by the RPS and the RPA if include exposure to radiation. At present, I have not be involved in a risk assessment, however, although not directly involved in the execution of these, I know the importance of them and I present detailed comments on a risk assessment about Sharps and Needlestick Injury (**Appendix 12.6.3**) and Control Of Substances Hazardous to Health (COSHH) risk assessment for Actichlor Tablets (**Appendix 12.6.4**) **[A4]**.

9.2. Clinical Practice

As a member of a team, I need to have effective communication and organisational skills since these are crucial when working within a multidisciplinary team. I have developed these competences not only throughout the internships and my actual work experience but also being a member of the organisational committee of the NM Seminars and being involved in volunteer projects **[A6]**.

As mentioned before, every day we work with patients with different needs and as a result our communication needs to be effective and understandable. Most of the patients do not have any knowledge of NM before coming to the department and therefore it is important to explain the procedures and what is going to happen during the acquisition of the images to help them to understand. I try to avoid technical terms when explaining the procedures. In addition, to make them as comfortable as possible it is important to inform the patient they would not be left on their own in the scanning room. For claustrophobic patients it is essential to find techniques to help the patient to comply with the scan, telling them to close their eyes and think of their favourite place and if necessary one member of staff can stay close to the patient during the acquisition of the images; if these techniques do not work, depending the procedure, protocol alterations can be made, for example, turn the head for one side when performing whole body scans or use a tissue paper to prevent the body contouring system coming too close to the patient when imaging head and chest **[A6, A7, A9]**.

Communication with patients and carers should be at appropriate level demonstrating empathy, support and conveying all the relevant information required. If patients suffer from deafness, blindness, age related medical condition, learning difficulties or if their first language is not English, they may have some difficulties in understanding. It is therefore appropriate to provide an explanation of the procedure and aftercare information for inpatients and outpatients to the staff and carers at the ward and home, respectively, in order to alleviate any concerns. For those whose first language is not English an interpreter should be booked for the patient, however, for patients of Portuguese native language I can provide help with the explanation of the procedure if they struggle with English **[A6]**.

This approach builds a relationship based on trust and effective communication with the patients and is essential to perform our role with the expected professionalism. At both departments we have satisfaction questionnaires about “what we did well”, “what we could have done better” and “overall how satisfied were you with your experience today” and apart from theses questionnaires, we also receive a great deal of positive feedback from patients for the help during the procedure. However, it is important to not be involved excessively and keep the information to the minimum to respect confidentiality **[A6, A7]**.

As part of my learning process, I strongly believe the reflective practice is important to improve my skills and also to prevent recurrence of the same mistakes in future situations.

However, I tend to learn from not only the negatives aspects but also the positives aspects of everyday situations.

These reflective practices include simple actions such as (**Table 8**) **[A9]**:

Table 8 –Examples of reflective practices actions

For patients performing whole body bone scans who have a collecting urine system	**For claustrophobic patients**
This bag should be positioned between patient's lower legs, to avoid overlapping bone structures. Previously I had a patient without mobility in the legs and I could not proceed with the normal protocol. The only solution was to put the collecting system to one of the side of the hip, checking it was not overlapping the hip or femur.	As mentioned previously, use of paper when performing imaging on the face or chest of the patient.

As part of my reflective practice I would like to include a situation which occurred about 2 years ago, when I still working as a locum. One of my colleagues and I were performing an Indium White Cell Scan on a patient who was receiving oxygen through a nasal cannula from a mobile oxygen cylinder. After the whole body scan we checked the images with one our physicists and SPECT/CT of the chest was required. At the end of the SPECT image the bed moved to perform the CT scan, however, for some unknown reason, the oxygen tube was trapped under the bed of the camera gamma and became wrapped around the patient's neck. To try to help the patient we had to hold the oxygen tube that was around the neck and try to release the part of the tube that was caught under the bed. In order to remove the patient we had to click on the button to unload the camera and bring the bed to the initial position. However, after the bed moved to the initial position, the detectors started rotate. The oxygen cylinder was very near the detectors resulting in a collision between the detectors and the oxygen cylinder. Reflecting on this, even if I know I have to give priority to the patient's needs, I am now more attentive to my surroundings and ensuring the area around the gamma camera is safe. As a direct result of this incident, the department introduced an "exclusion zone" around the camera which had an area of

flooring a different colour from the rest. This is to ensure that nothing is placed within this zone and therefore avoiding a repeat of this type of incident **[A9]**.

These skills acquired when working in a Hospital environment are important not only for the patients but also for the employee's personal improvement and safety. When working in a multidisciplinary team a good relationship and interaction between members of the staff contributes to a good environment as a team and consequently a better service delivery with the best diagnostic quality **[A6, A7]**.

10. Quality Management System

A Quality Management System (QMS) can be described as "a very powerful business tool, helping to ensure the best results or outcomes are achieved consistently, whether this relates to the organisation itself, an individual task, a process, products or services."[17] A QMS process provides integration of the organisation structure, procedures, processes and resources needed to fulfil a quality policy **[B7]**.

Even though both departments do not have an official QMS accreditation (ISO 9001), theses departments follow an in-house Quality System, which every member of the staff contributes to regularly to improve it. All acquisition protocols, QA procedures, equipment inventory, etc are available in the Q-Pulse (formal QMS - online platform) and electronic folders in a common area of disk. The implementation of our in-house QMS ensures all employees receive applicable training to their daily tasks and duties, ensures all requirements are documented, and updated if necessary, within the system, and produces proof that such requirements have been complied with. It also includes all updated protocols and audits, analyzing and correcting them when necessary which will improve the implemented system **[B7]**.

To guarantee the service delivery is to the maximum quality for our clients and to safeguard the patients and also the staff it is essential to have a QMS. The employment of trained technologists working under current legislation, training and certified protocols is important in order to ensure the correct implementation of a QMS **[B7]**.

[17] Sentences in quotes extracted from QMS - Management Specialists [redacted] accessed 01/11/2017).

11. Good Scientific Practice

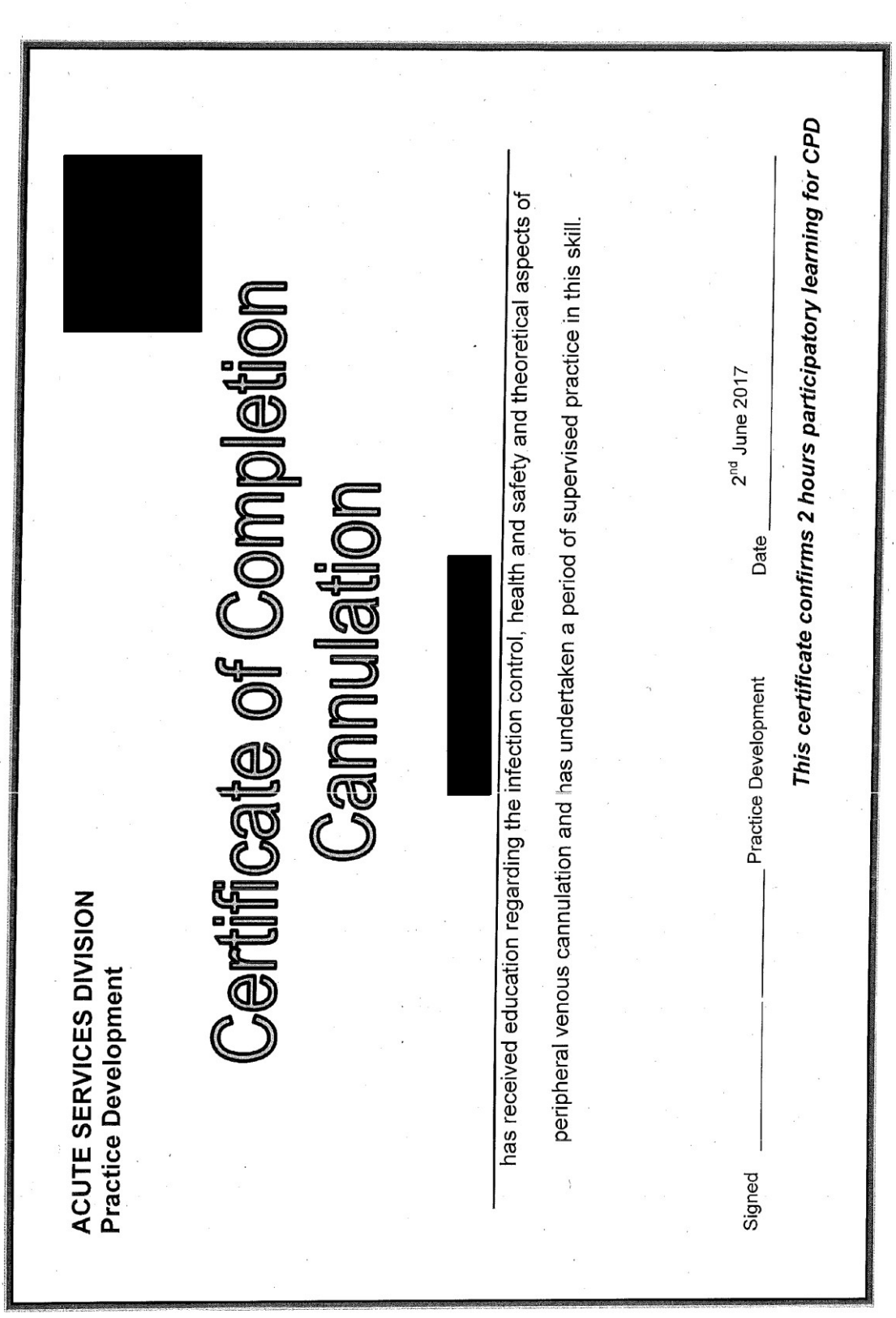
The Good Scientific Practice (GSP) is a document written by Academy of Healthcare Science and sets out the principles and values on which good practice is undertaken by the Healthcare Science Workforce. As a clinical technologist I perform my daily activities complying with GSP to ensure I conduct myself as a better professional at all times and in all aspects of my work. The domains of GSP are **[F1]**:

- Professional Practice (The patient is our first concern and should be treated with good standards of professional practice including ethical and conduct codes with the patients and also with work colleagues and trainees.)
- Scientific Practice (Keep the scientific and technical knowledge up to date to allow the development and investigation of new procedures, provide technical advice to ensure a safe and effective delivery of the services following quality standards.)
- Clinical Practice (Keep the clinical skills up to date and undertake the clinical duties appropriate to our role and understand the importance of them.)
- Research, development and innovation (To help meet all the daily challenges it is important to develop, evaluate, validate and verify new scientific, diagnostic, treatments, technical procedures, etc.)
- Clinical Leadership (Everyone has the right to expect the services are managed efficiently and effectively to meet the services needs.)

12. Appendices

12.1. Radiopharmacy

12.1.1. Cannulation and Venepuncture certificate



ACUTE SERVICES DIVISION
Practice Development

[redacted]

Certificate of Completion
Cannulation

[redacted]

has received education regarding the infection control, health and safety and theoretical aspects of peripheral venous cannulation and has undertaken a period of supervised practice in this skill.

Signed _____ Practice Development Date 2nd June 2017

This certificate confirms 2 hours participatory learning for CPD

Figure 1 - Cannulation Certificate

ACUTE SERVICES DIVISION
Practice Development

[redacted]

Certificate of Completion
Venepuncture

[redacted]

has received education regarding the infection control, health and safety and theoretical aspects of peripheral venepuncture and has undertaken a period of supervised practice in this skill.

Signed [redacted]

Practice Development Date 13th April 2017

This certificate confirms 2 hours participatory learning for CPD

Figure 2 - Venepuncture Certificate

12.1.2. Entitlement Letter

Figure 3 - Entitlement Letter – Part 1

Figure 4 - Entitlement Letter – Part 2

12.1.3. Record of Tc99m daily activities and standing orders

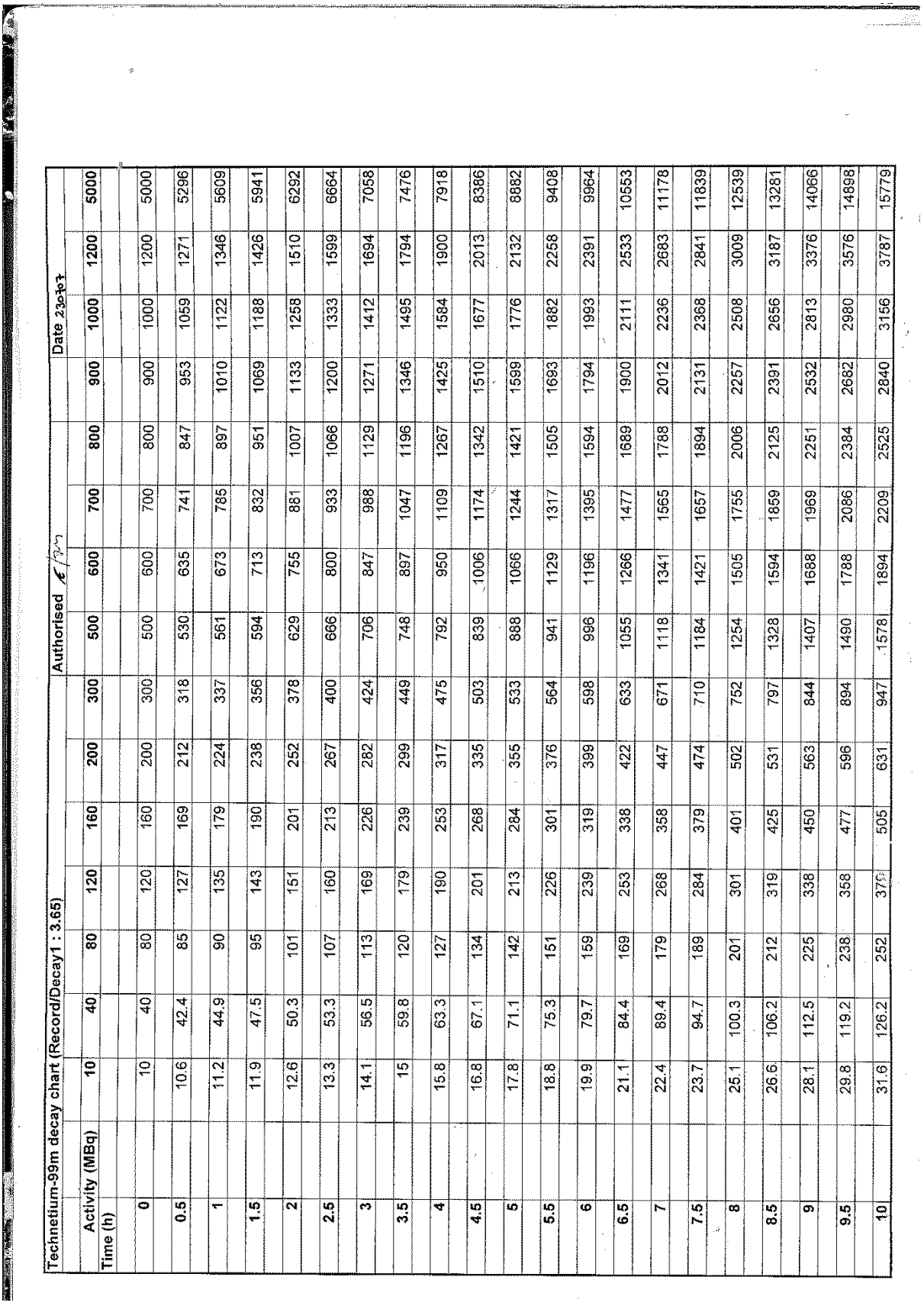
Figure 5 - Record of Tc^{99m} daily activities and standing orders at [redacted] – Part 1

Figure 6 - Record of Tc^{99m} daily activities and standing orders at [redacted] – Part 2

12.1.4. Daily Production Data Form

Figure 7 - Data production form at [redacted]

12.1.5. Tc^{99m} Decay Table



Technetium-99m decay chart (Record/Decay1 : 3.65) — Authorised — Date

Activity (MBq)	10	40	80	120	160	200	300	500	600	700	800	900	1000	1200	5000
Time (h)															
0	10	40	80	120	160	200	300	500	600	700	800	900	1000	1200	5000
0.5	10.6	42.4	85	127	169	212	318	530	635	741	847	953	1059	1271	5296
1	11.2	44.9	90	135	179	224	337	561	673	785	897	1010	1122	1346	5609
1.5	11.9	47.5	95	143	190	238	356	594	713	832	951	1069	1188	1426	5941
2	12.6	50.3	101	151	201	252	378	629	755	881	1007	1133	1258	1510	6292
2.5	13.3	53.3	107	160	213	267	400	666	800	933	1066	1200	1333	1599	6664
3	14.1	56.5	113	169	226	282	424	706	847	988	1129	1271	1412	1694	7058
3.5	15	59.8	120	179	239	299	449	748	897	1047	1196	1346	1495	1794	7476
4	15.8	63.3	127	190	253	317	475	792	950	1109	1267	1425	1584	1900	7918
4.5	16.8	67.1	134	201	268	335	503	839	1006	1174	1342	1510	1677	2013	8386
5	17.8	71.1	142	213	284	355	533	888	1066	1244	1421	1599	1776	2132	8882
5.5	18.8	75.3	151	226	301	376	564	941	1129	1317	1505	1693	1882	2258	9408
6	19.9	79.7	159	239	319	399	598	996	1196	1395	1594	1794	1993	2391	9964
6.5	21.1	84.4	169	253	338	422	633	1055	1266	1477	1689	1900	2111	2533	10553
7	22.4	89.4	179	268	358	447	671	1118	1341	1565	1788	2012	2236	2683	11178
7.5	23.7	94.7	189	284	379	474	710	1184	1421	1657	1894	2131	2368	2841	11839
8	25.1	100.3	201	301	401	502	752	1254	1505	1755	2006	2257	2508	3009	12539
8.5	26.6	106.2	212	319	425	531	797	1328	1594	1859	2125	2391	2656	3187	13281
9	28.1	112.5	225	338	450	563	844	1407	1688	1969	2251	2532	2813	3376	14066
9.5	29.8	119.2	238	358	477	596	894	1490	1788	2086	2384	2682	2980	3576	14898
10	31.6	126.2	252	379	505	631	947	1578	1894	2209	2525	2840	3156	3787	15779

Figure 8 - Tc^{99m} decay table at [redacted]