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Radionuclide calibrator measurements of ¹⁸F in a 3 ml plastic syringe

J.T. Cessna^{a,*}, M.K. Schultz^a, T. Leslie^b, N. Bores^c

^aNational Institute of Standards and Technology, 100 Bureau Drive MS8462, Gaithersburg, MD 20899, USA ^bPETNET Solutions, University of Tennessee Medical Center at Knoxville, Knoxville, TN 37920, USA ^cOak Ridge National Laboratories, P.O. Box 2008 MS6366, Oak Ridge, TN 37831, USA

Abstract

This paper discusses the calibration of Capintec radionuclide calibrators for the measurement of ¹⁸F in the pharmacy and clinic. In support of a planned regional comparison, a secondary laboratory was set up at Oak Ridge National Laboratories in Oak Ridge, TN. The laboratory was used to prepare 1 mL ¹⁸F-fluorodeoxyglucose sources in 3 mL plastic BD syringes (Becton, Dickinson and Company, Franklin Lakes, New Jersey, USA) and to determine dial settings in three models of radionuclide calibrators. Measurements were verified by comparing radionuclide calibrator measurements of a 5 mL ampoule source with previous results. The CIEMAT/NIST method of tritium efficiency tracing was used for activity determinations.

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1. Introduction

Positron emission tomography (PET) continues to be a popular imaging modality for a widening range of applications. The most commonly used radiopharmaceutical is $2-[^{18}F]$ fluoro-2-deoxyglucose ([$^{18}F]$ FDG). ^{18}F decays to stable ^{18}O by positron emission with a half life of 1.8288 (3) h and a probability of 96.86 (16)%. The positron maximum energy is 633.5 keV, with an average energy of 249.3 keV. Additionally, there is an electron capture branch with a probability of 3.14% (BIPM, 2004).

Lately there has been increasing scrutiny of PET imaging radionuclides from the US Food and Drug Administration. This coincides with an increasing interest in the field of quantitative PET, that is, where images are taken with an interest in assigning actual activities to data derived from images, rather than the main emphasis being in image quality. This need for quantitative activity data is being driven both by research into the use of change measurement as a biomarker in drug development as well as by research into patient-specific treatment planning. In order

E-mail address: Jeffrey.cessna@nist.gov (J.T. Cessna).

that meaningful comparisons can be made between images taken at different times on one or multiple instruments, the activity data derived from each image need to be traceable to primary radioactivity standards maintained by the National Institute of Standards and Technology (NIST). To date, these comparisons have not been possible for ¹⁸F in the US.

The starting point for these comparisons is the activity injected into a patient. Assay of the activity in these radiopharmaceuticals is performed with a radionuclide calibrator. These instruments are most often re-entrant ionization chambers and require the use of a calibration factor, or "dial setting", specific to the radionuclide and geometry being measured. Manufacturers supply suggested dial settings, but they are often for the measurement of 5 ml of solution in a thin-walled, 5 mL glass ampoule. The dial settings are also sometimes calculated instead of measured. It is important therefore for users to determine the setting for their own chambers and measurement geometries whenever practicable.

The NIST maintains the US standards for the measurement of radioactivity and these standards are disseminated in a number of ways, including the provision of Standard Reference Materials and calibration services. NIST also

^{*}Corresponding author. Tel.: +1 301 975 5539.

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offers a number of measurement assurance programs, including one operated through a Cooperative Research and Development Agreement with the Nuclear Energy Institute for the Radiopharmaceutical Industry. This program serves the needs of suppliers of radiochemicals and large radiopharmacies supplying unit doses of longerlived, relative to ¹⁸F, radionuclides used in imaging and therapy. Recently NIST has investigated the possibility of establishing similar programs at the level of measurements made in local radiopharmacies and at the clinical level. In order to demonstrate, to the regulatory bodies, the need for such programs, comparison exercises needed to be performed. Such a study for the therapeutic radiopharmaceutical ⁹⁰Y has recently been reported by Schultz et al. (2008). Although results in the ⁹⁰Y study fell within the large range of 20% allowed by the US Pharmacopeia, the opportunity for improvement of measurements was clearly established.

Because of the increasing popularity of PET radionuclides, the development of regional production centers has been necessary due to the short half-lives involved. As with the ⁹⁰Y situation, it was recognized that data was required to show the state of activity measurements of PET radiopharmaceuticals at the local pharmacy and clinical levels. This study describes the investigations that were conducted in order to prepare for a pilot comparison to be administered by secondary laboratories serving those regions. Knoxville, TN was chosen because of the proximity of Oak Ridge National Laboratory (ORNL) and opportunity for collaboration with the main facility of PETNET Solutions, a radiopharmacy subsidiary of Siemens Medical, Inc. In 2005, NIST opened the NIST/ ORNL Intercomparison Metrology Laboratory in the Quality division of the ORNL in Oak Ridge, TN, USA.

2. Experimental

2.1. General

The stock solution for this study was prepared by PETNET Solutions, University of Tennessee Medical Center at Knoxville, TN (UT). This facility operates a 12 MeV cyclotron for the production of short lived PET radioisotopes. Labeling of the ¹⁸F was performed using an Explorer Module (Siemens Medical, Knoxville, Tennessee, USA) and routine procedures. An [¹⁸F]FDG solution, approximately 9 GBq in 10 mL solution at time of delivery, was transferred by courier from UT to the ORNL lab.

A series of sources were prepared from this stock solution including two 1 mL sources in 3 mL plastic BD syringes, a point source for impurity measurements, 5 mL solution in a flame-sealed 5 mL NIST-type ampoule for ionization chamber measurements, and a dilution for liquid scintillation (LS) measurements. The geometry of 1 ml of solution in a 3 mL BD syringe was chosen because it represents the geometry most often shipped to the regional customers. All sources were prepared gravimetrically by the pycnometer method. A Mettler AE240 balance was transferred from NIST and installed at the ORNL laboratory. Before being put into service it was checked with masses traceable to the NIST by a technician from the ORNL Mass Group. The operator of the balance was shielded by a thick leaded glass window and the remainder of the work was performed in a fume hood also behind shielding. Because of the desire to produce syringe sources at the activity level normally measured at the production facility and concerns about personnel exposure, the number of sources produced was limited.

The syringes used had their barrel tips sealed with epoxy prior to adding solution. After adding solution, the plunger was inserted using a thin wire to allow the air to escape. To reduce the possibility of mass loss or external source contamination, care was taken to ensure the wire did not contact the solution. Approximately 45 min after receipt of the solution, one syringe was dispatched by courier for measurements in the UT radionuclide calibrator geometries.

2.2. LS counting

The laboratory at ORNL was equipped with a Packard Tri-Carb 2900TR LS counter that is maintained under their quality control program. For these reasons, the activity concentration in this study was determined by the tritium efficiency tracing CIEMAT/NIST method of LS counting, a method which has been used successfully in previous investigations by NIST (Zimmerman et al., 2001; Zimmerman and Collé, 1997).

A dilution for LS counting was prepared using sterile water, with a dilution factor of approximately 220. LS sources were prepared in two types of scintillant: Ready Safe (Beckman Coulter, Fullerton, California) and Opti-Fluor (PerkinElmer, Waltham, Massachusetts). Five ¹⁸F sources and one background source were prepared for each scintillant. The cocktails contained 10 mL of scintillant, nominally 16 mg aliquots of the LS dilution, nominally 16 mg of distilled H₂O, and between 5 and 17 drops of a 1-10 dilution of nitromethane in alcohol, as a quenching agent. The resulting aqueous fraction in the cocktails was between 0.5% and 3.5%, by volume. Sources were prepared in standard 20 mL low potassium glass LS vials. Samples were sequentially counted 10 min each for 10 cycles. Due to the long count time compared to the halflife, integrated decay corrections, of about 1.8%, were applied to each count.

An identical set of sources was prepared the following day using an NIST (1991) tritium standard reference material 4927F and inactive FDG. These sources were also sequentially counted 10 min each for 10 cycles. The ¹⁸F samples from the previous day were re-counted as well to look for beta-emitting impurities. After the first cycle, approximately 36 h from the reference time, the ¹⁸F vials were indistinguishable from background.

The efficiency tracing code CN2004 (Günther, 2004) was utilized for the analysis of the efficiency tracing

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