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Intercomparison of ^{99m}Tc, ^{18}F and ^{111}In activity measurements with radionuclide calibrators in Belgian hospitals

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ABSTRACT

This study presents current status of performance of radiopharmaceutical activity measurements using radionuclide calibrators in Belgium. An intercomparison exercise was performed among 15 hospitals to test the accuracy of ^{99m}Tc, ^{18}F and ^{111}In activity measurements by means of radionuclide calibrators. Four sessions were held in different geographical regions between December 2013 and February 2015. The data set includes measurements from 38 calibrators, yielding 36 calibrations for ^{99m}Tc and ^{111}In, and 21 calibrations for ^{18}F. For each radionuclide, 3 ml of stock solution was measured in two clinical geometries: a 10 ml glass vial and a 10 ml syringe. The initial activity was typically 100 MBq for ^{99m}Tc, 15 MBq for ^{111}In and 115 MBq for ^{18}F. The reference value for the massic activity of the radioactive solutions was determined by means of primary and secondary standardisation techniques at the radionuclide metrology laboratory of the JRC.

The overall results of the intercomparison were satisfactory for ^{99m}Tc and ^{18}F, since most radionuclide calibrators (> 70%) were accurate within ± 5% of the reference value. Nevertheless, some devices underestimated the activity by 10–20%. Conversely, ^{111}In measurements were strongly affected by source geometry effects and this had a negative impact on the accuracy of the measurements, in particular for the syringe sample. Large overestimations (up to 72%) were observed, even when taking into account the corrections and uncertainties supplied by the manufacturers for container effects. The results of this exercise encourage the hospitals to perform corrective actions to improve the calibration of their devices where needed.

1. Introduction

Nuclear medicine is an invaluable tool for diagnostic and therapeutic purposes. The most widely used radionuclide is ^{99m}Tc, accounting for approximately 80% of all nuclear medicine examinations and about 90% of those used for diagnostic purposes. In 2008, the world total number of procedures performed with ^{99m}Tc was estimated to range between 25 and 30 million annually, with 6–7 million of them taking place in Europe [1]. Other frequently used radionuclides for nuclear medicine in Europe are ^{18}F, ^{201}Tl, ^{123}I, ^{131}I, ^{67}Ga and ^{111}In [2] and the future holds an increasing interest in radionuclides for targeted therapy and theranostics, such as *e.g.* ^{177}Lu, ^{90}Y, ^{223}Ra, ^{225}Ac and Tb isotopes [3].

Administration of the correct activity of these radiopharmaceuticals is necessary for the optimization of patient healthcare. When handling radioactive substances, one applies the long-accepted ALARA principle to keep the doses "as low as reasonably achievable". Articles 55, 56 and 60 of the European Council Directive 2013/59/EURATOM on the principles of justification and optimization of medical exposures imply proper calibration of all sources giving rise to medical exposure [4]. After all, the use of diagnostic reference levels and the study of dose-effect relationships in therapeutic nuclear medicine procedures depend on the accuracy of the measurement of the activity to be administered. There is also an increased interest in quantification of SPECT and PET images for pre-therapeutic dosimetry of radionuclide therapy. This requires cross-calibration of measurement devices (*e.g.* gamma cameras, radionuclide calibrator, gamma counter) and a traceability chain.

The activity of radiopharmaceuticals is quantified prior to patient administration by means of a radionuclide calibrator (RC). This instrument consists of a well-type gas-filled ionisation chamber coupled to a high voltage supply, an electrometer, and a display unit. When a radioactive sample is introduced inside the chamber, an ionisation

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current is produced from the interactions between ionising radiation and the filling gas, the amount of which is proportional to the activity of the sample. The measured current is converted to an activity value by applying a calibration factor (CF) [pA.MBq^{-1}]. Already at purchase, the RCs are provided with factory-set CFs for different radionuclides. The manufacturer uses radioactive sources in standard containers with specific volumes of solution, thus establishing traceability to primary standards for those specific measurement conditions.

In clinical practice, however, activity measurements are carried out using a variety of non-standard containers which differ in shape, size, material and wall thickness; and which can be filled with varying volumes of solution. Since the response of the chamber is sensitive to the geometry of the source (container type, container wall thickness, volume of radioactive solution) and the position of the source inside the chamber, the traceability chain is broken and the validity of the CF is not guaranteed. The sensitivity of the calibration to geometrical changes depends on the radionuclide being assayed (*i.e.* energy and type of radiation emitted) and the physical characteristics of the ionisation chamber (*i.e.* thickness of inner chamber wall, gas pressure, chamber design and operating voltage).

Currently in Belgium the quality control (QC) program followed by most nuclear medicine departments does not include checks for testing the accuracy of activity measurements in clinical conditions (*i.e.* for the same radionuclides that are administered to patients, using typical clinical recipients and source geometries) [5]. Repeatability measurements for QC are typically performed with a long-lived nuclide (*e.g.* ^{57}Co, ^{60}Co, ^{133}Ba, ^{137}Cs) in a different geometry (*e.g.* a resin in plastic vial). Thus, the trueness of routine clinical activity measurements with medical RCs is usually unknown. There is an obvious need for intercomparison exercises of activity measurements using medical RCs to put in evidence the current performance achieved and to identify possible sources of error. Whereas several exercises have been conducted by the National Physical Laboratory (NPL) in the UK [6–9], up to now only one [10] has been performed in Belgium and dates back to over three decades ago. In 1989, a quality control of 20 RCs among Belgian hospitals with a standardised ^{57}Co (long-lived) solution revealed that half of the measurements deviated by more than 5% from the true value, and one fifth by more 10% [10]. It was then concluded that a quality assurance program would be helpful to improve the situation. Moreover, to the best knowledge of the authors, the accuracy of RCs in Belgium has never been systematically assessed using short-lived radionuclides of clinical relevance.

The present study aims at evaluating the accuracy of RC activity measurements in Belgian hospitals for three radionuclides commonly used in diagnostic applications: Technetium-99 m (^{99m}Tc), Fluorine-18 (^{18}F) and Indium-111 (^{111}In). A comparison was held involving 38 calibrators and two sample geometries for each nuclide. Four sessions were held in different geographical regions between December 2013 and February 2015. The reference massic activity of the samples was assessed at the end of each measurement campaign by means of primary and secondary standardisation methods.

2. Materials and methods

2.1. Preparation of samples

A set of samples of different radionuclide solutions was prepared at the beginning of the day of each intercomparison session. The ^{99m}Tc was extracted in aqueous (pertechnetate) solution from a ^{99}Mo-^{99m}Tc generator at the University Hospital of Leuven (UZ Leuven, Belgium) or the University Hospital of Liège (CHU Liège, Belgium). The ^{111}In chloride solution was acquired from Mallinckrodt Pharmaceuticals (Petten, The Netherlands). Solutions of ^{18}F were in the form of either ^{18}F-deoxyglucose (cyclotron-produced in UZ Leuven) or sodium ^{18}F-fluoride (Cyclotron Research Centre of CHU Liège). Two samples of each radionuclide were prepared in two clinical containers: a 10 ml glass vial with aluminum seal and septum (GREER, Lenoir, USA) and a 10 ml plastic syringe with Luer-Lock tip (Terumo Europe NV, Leuven, Belgium), as shown in Fig. 1.

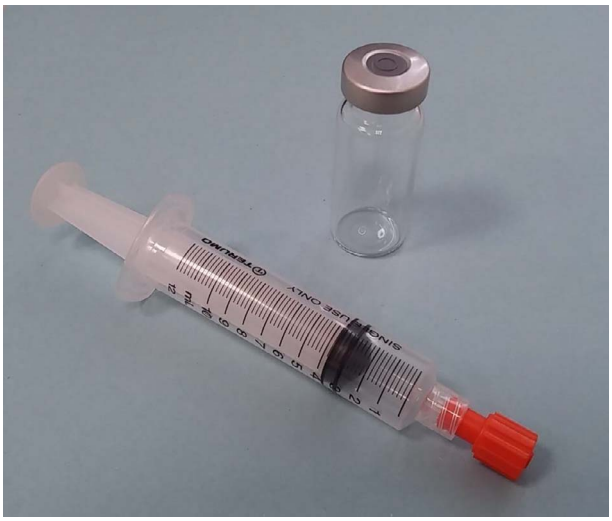

Fig. 1. Clinical containers used in this intercomparison: 10 ml glass vial with crimp seal (Greer) and 10 ml plastic syringe with Luer-Lock and orange combi stopper (Terumo).

Aliquots of about 3 ml of solution were transferred to the syringe and the vial containers. The same solution was used for all samples to ensure that their massic activity [MBq·g^{-1}] was the same. To determine the mass of each aliquot of solution, the containers were weighed before and after filling. This was done using a self-calibrated balance with 0.1 mg precision. In order to avoid leaks of solution during transport and manipulation of the syringes, the injection needles were replaced by a plastic Luer-Lock combi stopper after the syringes were filled. The initial activity in the vial and syringe samples was around 100 MBq for ^{99m}Tc, 115 MBq for ^{18}F and 15 MBq for ^{111}In. In this way, the activities measured in the hospitals on the same day were always above 10 MBq, the minimum level of activity recommended for testing RC accuracy [11].

2.2. Activity measurements with RCs

For each of the 4 measurement campaigns, samples were transported within one day to different hospitals in geographical proximity and their activity was assessed with the available RCs. A total of 38 RCs from 15 Belgian hospitals were tested, of which 36 with samples of ^{99m}Tc and ^{111}In and 21 with samples of ^{18}F. Of the 38 RCs, 21 were manufactured by former Veenstra Instruments (now Comecer Netherlands, Joure, Netherlands), 14 by Capintec (Capintec Inc, Florham Park, USA) and three by Comecer S.p.A. (Comecer S.p.A., Castel Bolognese, Italy). All Veenstra RCs had an ionisation chamber type VIK-202 (high pressure model used for general purpose nuclear medicine applications). An overview of relevant information is presented in Table 1.

The following measurement and calculation protocol was applied:

1. The CF used in clinical practice was selected for each radionuclide. For most RCs tested, this corresponded to the factory calibration settings (see Table 1). Some RC models were provided with different settings for assays in syringes and in vials. In this case, the setting for the corresponding type of container was selected.
2. A background measurement was taken before introducing the container into the chamber. No built-in background correction techniques were used.
3. The activity of the sample was assayed using the standard sample holder of the RC, also known as the dipper, and the standard protective insert, known as the liner. Whereas the vials were placed at

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