



Primary standardization of Radionuclide ^{123}I

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Abstract: Short half-life radionuclides are essential for Nuclear Medicine. These radionuclides are mostly incorporated into more complex molecular or cell structures possessing specific pharmacological characteristics. This resulting compound is named a “radiopharmaceutical” and has been applied for diseases diagnoses and therapy. The use of radiopharmaceuticals involves exposure to ionizing radiation, which, although carefully controlled, poses potential health risks to patients and healthcare professionals. To minimize these risks while maintaining the benefits of radiopharmaceutical use, administered doses must be highly accurate and precise. This requirement compels new demands on National Metrology Institutes (NMIs) in order to improve primary standardizations methods for these short half-life radionuclides, ensuring the standards used to calibrate activity meters in hospitals and nuclear medicine clinics achieve the highest possible precision. Iodine-123 (^{123}I) is currently used for several applications in radiodiagnosis, primarily for evaluating pathologies and thyroid tumors. This work presents the primary standardization of ^{123}I performed by the $4\pi\beta(\text{LS})\text{-}\gamma(\text{NaI}(\text{TI}))$ live-timed anticoincidence counting method. High-resolution gamma-ray spectrometry detected no significant radionuclidic impurities. Thus, through this work, LMNRI/IRD prepared for the key comparison of the BIPM K4 series using the SIRT1 instrument.

Keywords: Nuclear Medicine, Radiopharmaceuticals, Primary Standardization, Iodine.



Padronização Primária do Radionuclídeo ^{123}I

Resumo: Radionuclídeos de meia-vida curta são essenciais para a Medicina Nuclear. Esses radionuclídeos geralmente se ligam a uma estrutura molecular ou celular mais complexa e com características farmacológicas; esse conjunto é chamado de "radiofármaco" e tem sido aplicado no diagnóstico e terapia de doenças. O uso de radiofármacos envolve exposição à radiação ionizante, que, embora cuidadosamente controlada, apresenta riscos potenciais à saúde de pacientes e profissionais de saúde. Desse modo, para minimizar esses riscos e manter os benefícios do uso de radiofármacos, a dose administrada deve ser determinada com alta exatidão e precisão. Essa necessidade impõe aos Institutos Nacionais de Metrologia (INMs) o requisito de aprimorar as técnicas de padronização primária desses radionuclídeos, de modo que a calibração dos medidores de atividade em hospitais e clínicas de medicina nuclear tenha a maior acurácia e precisão possível. O iodo-123 é utilizado para diversas aplicações em radiodiagnóstico, sendo as principais o diagnóstico de patologias e tumores da tireoide. Neste trabalho apresenta-se a padronização primária do ^{123}I realizada por contagem em anticoincidência $4\pi\alpha\beta(\text{LS})\cdot\gamma(\text{NaI}(\text{TI}))$ em tempo vivo, na qual impurezas radionuclídicas significativas não foram detectadas por espectrometria de raios gama de alta resolução. Com esse trabalho o LMNRI/IRD preparou-se para a comparação-chave da série K4 do BIPM utilizando o instrumento SIRTl.

Palavras-chave: Medicina Nuclear, Radiofármaco, Padronização Primária, Iodo.

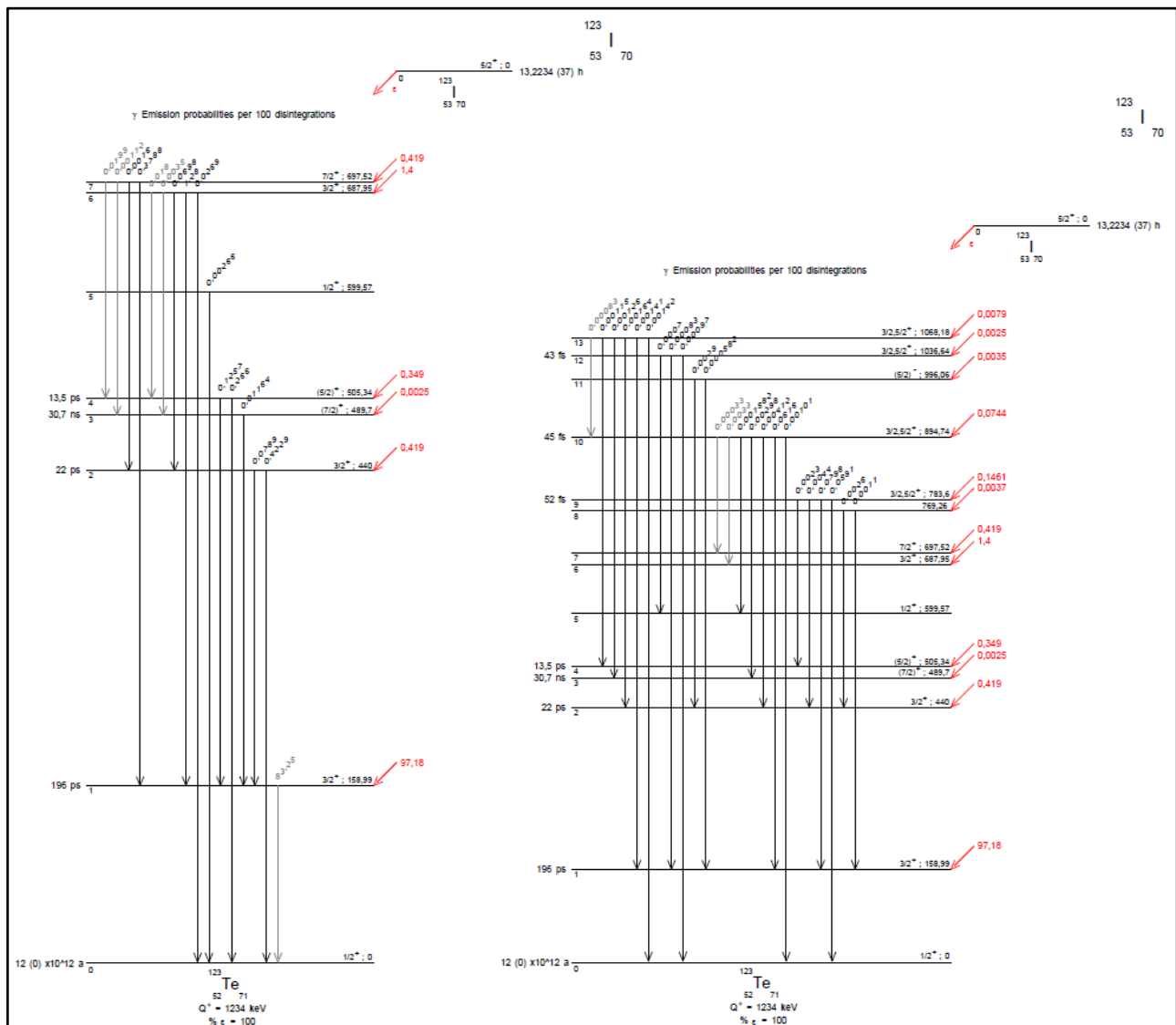
1. INTRODUCTION

Short half-life radionuclides are essential for Nuclear Medicine. These radionuclides are mostly linked to a more complex molecular or cell structure, forming a “radioactive tracer”. Radioactive tracers with pharmacological characteristics are named “radiopharmaceuticals” and have been applied in Nuclear Medicine for the disease diagnoses and therapy. As the field expands with increasing accessibility of these radionuclides, this compels National Metrology Institutes (NMIs) to implement new requirements in which primary standardization of short half-life radionuclides needs high accuracy to ensure the standards used to calibrate activity meters in hospitals and nuclear medicine clinics achieve the highest possible precision [1]. The *Laboratório Nacional de Metrologia das Radiações Ionizantes* (LNMRI/IRD/CNEN) is designated by *Instituto Nacional de Metrologia, Qualidade e Tecnologia* (INMETRO) as Brazil's reference institute for ionizing radiation.

It is also fundamental establishing metrological equivalence and traceability of these measurements to the International System of Units (SI), which is only possible through international key comparisons under the auspices of the *Bureau International des Poids et Mesures* (BIPM) and its Consultative Committee for Ionizing Radiation (CCRI). Since non-European countries cannot ship radionuclides ampoules with half-lives shorter than 7 days to the BIPM's *Système International de Référence* (SIR), the portable SIR Transfer Instrument (SIRTI) is sent to participating NMIs to perform international key comparisons. Developed by the BIPM, this secondary standard device transfers radionuclide activity. Its detector consists of a well-type 3" × 3" NaI(Tl) crystal (Saint-Gobain Crystals, France), featuring a well 5 cm deep and 2 cm in diameter. The crystal is coupled to an ETL 9305 photomultiplier tube (PMT). A BIPM-designed tripod supports the detector assembly, utilizing an aluminum clamping annulus and layers of aluminum tape for precise adjustment during tightening [2]. The SIRTI plays a vital role in facilitating these comparisons.

Iodine-123 (^{123}I) is a short half-life radionuclide and has several applications in radiodiagnosis, with primary uses being in pathologies and thyroid tumors [3]. It is produced in Brazil at the cyclotron facility of the “*Instituto de Pesquisas Energéticas e Nucleares*” of the “*Comissão Nacional de Energia Nuclear*” (IPEN/CNEN) by proton irradiation of a ^{124}Xe target [4]. ^{123}I has a half-life of (13.2234 ± 0.0037) hours and mainly disintegrates (97 %) by electron capture via the 159 keV state of ^{123}Te [5]. The complex nuclear decay scheme of ^{123}I is shown in figure 1.

Figure 1: Iodine-123 nuclear decay scheme (Source: DDEP)



The success of standardization, as well as execution of this SIRTI-based key comparison, faces significant challenges, particularly for volatile radionuclides like ^{123}I . Iodine-123 losses during source preparation (dispensing, dilution, sealing), handling, and storage due to adsorption/desorption or container micro-leaks [6,7], directly impacting measurement accuracy.

The combination of high transportation costs for SIRTI to distant locations like Brazil and the inherent challenges of ^{123}I standardization creates a high-risk scenario for comparisons. To mitigate risks of logistical failure, source degradation, and protocol flaws, we advocate mandatory preparatory testing before formal SIRTI key comparisons involving the volatile and short-lived ^{123}I radionuclide. This safeguards resources and ensures reliable, comparable data for international equivalence. A well-designed preparatory test phase is a critical risk mitigation strategy, it significantly increases the probability of a successful, scientifically valid outcome in this SIRTI-based international key comparison.

2. MATERIALS AND METHODS

An uncalibrated stock solution of ^{123}I (estimated activity: $\geq 37 \text{ MBq}\cdot\text{g}^{-1}$) was obtained from the Radiopharmacy at IPEN/CNEN. From this solution, we prepared two dilutions using the pycnometer method by means of differential weighing, as detailed in Gomes' master's dissertation [8]. Aliquots (2.65 g) of the diluted solutions were transferred into glass ampoules, designated as "LNMRI ampoules." The dilution scheme for source preparation and measurement within LNMRI/IRD/CNEN systems is presented in Figure 2.

One undiluted (dilution factor, $\text{DF}=1$) sealed LNMRI ampoule was prepared for measurement in an ionization chamber (IC) [9] to determine the activity per mass of the stock solution. A dilution factor of approximately 20 was applied to reduce the activity per mass to $\sim 2,500 \text{ kBq}\cdot\text{g}^{-1}$ of ^{123}I solution for the first dilution. This activity level enabled preparation of eight liquid scintillation sources, prepared according to

table 1, each containing 15 mL of Ultima Gold™ scintillation cocktail for measurement using the $4\pi\beta(\text{LS})-\gamma(\text{NaI}(\text{Tl}))$ live-timed anticoincidence counting (AC) system. As a primary standardization system, anticoincidence (AC) counting employs live-timing and anticoincidence logic to overcome limitations of conventional coincidence methods for radionuclides with metastable/isomeric states. It resolves critical timing constraints (dead time, resolution limits, accidental coincidences) that preclude coincidence counting for excited states with half-lives $>10^{-10}$ s. By applying a delayed gate ($2T$) to the gamma channel after each beta signal, uncorrelated gamma events are isolated; true coincidence rates derive from subtracting uncorrelated from total gamma counts. For delayed-gamma emitters, extending the gate to $(T + \tau) = (m \text{ half-lives})$ reduces unwanted coincidences probabilistically to $\leq 2^{-m}$, enabling semi-automated standardization while eliminating metrological artifacts such as the Gandy effect through implementation of Bryant's live-timed anticoincidence method by da Silva at LNMRI/IRD-CNEN [10].

Figure 2: Dilution scheme for source preparation.

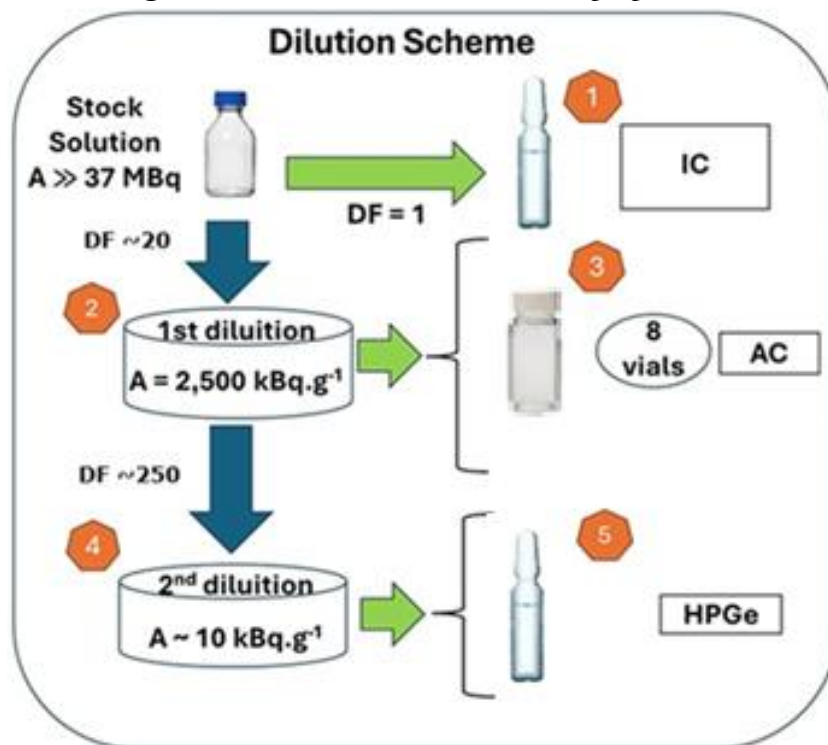


Table 1: Details of liquid scintillation sources for $4\pi\beta(\text{LS})-\gamma(\text{NaI}(\text{TI}))$ anticoincidence counting.



Source Code	Iodine-123 mass (g)	Source Code	Iodine-123 mass (g)
77CL23	0.024732	81CL23	0.038092
78CL23	0.024988	82CL23	0.038494
79CL23	0.024789	83CL23	0.036795
80CL23	0.026211	84CL23	0.036224

The second dilution was prepared from the first dilution according to activity requirements for SIR ampoules (3.5 g fill mass of ^{123}I solution), as defined in the BIPM.RI(II)-K4 key comparison protocol [12] (Table 2). A dilution factor of ~ 250 from the first dilution (~ 5000 from stock solution) yielded an activity per mass on the order of $10 \text{ kBq}\cdot\text{g}^{-1}$. This solution filled one sealed LNMRI ampoule for gamma-spectrometric impurity detection. Table 3 lists all prepared LNMRI ampoules. Both dilutions used $0.1 \text{ mol}\cdot\text{dm}^{-3}$ NaOH solution containing the carriers: $53 \text{ }\mu\text{g}\cdot\text{g}^{-1} \text{ LiOH} + 37 \text{ }\mu\text{g}\cdot\text{g}^{-1} \text{ Na}_2\text{SO}_3 + 37 \text{ }\mu\text{g}\cdot\text{g}^{-1} \text{ KI}$.

Table 2: Activity of sealed SIR ampoules containing 3.5 g of solution for each radionuclide (Source: BIPM.RI(II)-K4 Protocol).

Radionuclide	Activity (kBq)
^{11}C	20 – 30
^{13}N	20 – 30
^{18}F	10 – 25
^{64}Cu	60 – 130
$^{99\text{m}}\text{Tc}$	15 – 25
^{123}I	15 – 25
^{153}Sm	50 - 100

Table 3: LNMRI ampoules details, the dilution factor is calculated from the stock solution of ^{123}I received from radiopharmacy of IPEN/CNEN.

Source Code	Item	Dilution	Dilution Factor (DF)	Mass (g)
82L23		none	1	2.662529
89L23		2 nd	4548.818654	2.640750

LNMRI ampoule 82L23 was measured in the LNMRI reference ionization chamber (IC) to calibrate the stock solution and the result of IC was used to prepare the 1st dilution with an activity by mass of approximately 2,500 kBq·g⁻¹ for the ¹²³I that is suitable for measurements in anticoincidence counting. The LNMRI/IRD reference ionization chamber is a well type Centronics model IG11 with argon at 20 ATM and it is coupled to a 6517A Keithley electrometer which is controlled by a homemade LabVIEW program.

Eight liquid scintillation vials prepared from the first dilution with 15 ml of Ultima Gold™ scintillation cocktail were measured in the 4πβ(LS)-γ(NaI(Tl)) live timed anticoincidence counting to determination the activity of stock solution. All the eight sources were counted in the region of the ¹²³I photopeak NaI(Tl) window, corresponding to gamma energy of 159 keV. Calibration results were used to determine the calibration factor of the LNMRI ionization chambers. To determine the calibration factor, equation (1) was adopted, which is similar that proposed by Schrader [12]. In each determination the correction for decay and background were made.

$$F = \frac{I_P \cdot C_{Geom}}{A \cdot m} \cdot \frac{I_{RaRT}}{I_{RaRX}} \quad (\text{Eq. 1})$$

Where:

I_P : Current produced by ¹²³I standard solution;

C_{Geom} : Geometry correction factor, which in the standard measuring geometry is equal to 1;

A : Activity per mass of the standard solution;

m : Ampoule mass;

$\frac{I_{RaRT}}{I_{RaRX}}$: Relation between ²²⁶Ra current check source at the time when the system begins to operate at the time of calibration determination.

LNMRI ampoule 89L23 from the second dilution was measured in the HPGe detector to check impurities of gamma-emitting radionuclides of the stock solution and calibration of the second dilution.

3. RESULTS AND DISCUSSIONS

The activity per mass from the first dilution, measured via $4\pi\beta(\text{LS})-\gamma(\text{NaI}(\text{Tl}))$ live-timed anticoincidence counting, was $2,820.823 \text{ kBq}\cdot\text{g}^{-1}$ with a combined standard uncertainty of 0.70% ($k=1$) at the reference date of 14 December 2023, 12:00 UTC.

Anticoincidence extrapolation curve was performed by plotting activity concentration against the efficiency parameter $(1-\epsilon_\beta)/\epsilon_\beta$, where ϵ_β is the efficiency of the β -channel detector. β -channel counting efficiencies were varied using electronic discrimination, with the discrimination level increased from 0.1 V to 1.0 V in increments 0.1 V. Each data point in the extrapolation curve (Figure 3) represents the mean of five independent 120 s live-time measurements of the ^{123}I liquid scintillation source. The uncertainty budget for this method is provided in Table 4."

Figure 3: Anticoincidence extrapolation curve for ^{123}I .

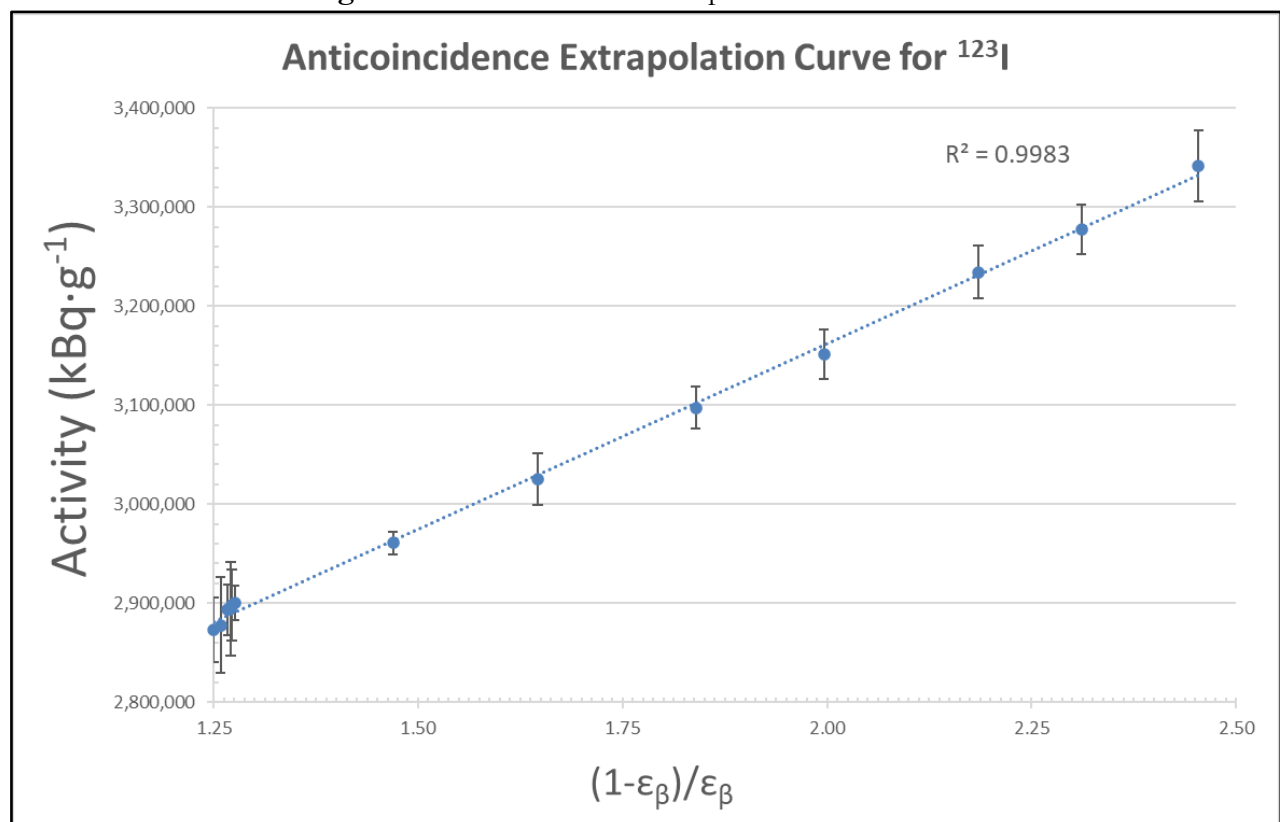


Table 4: Uncertainty budget for the $4\pi\alpha\beta(\text{LS})-\gamma(\text{NaI}(\text{Tl}))$ live-timed anticoincidence counting.

Uncertainty component	Type A (%)	Type B (%)
Counting statistics	0.54	
Extrapolation curve	0.44	
Background		0.065
Live time		0.010
Half-life		0.0057
Mass		0.05
u_c % (k=1)	0.70	

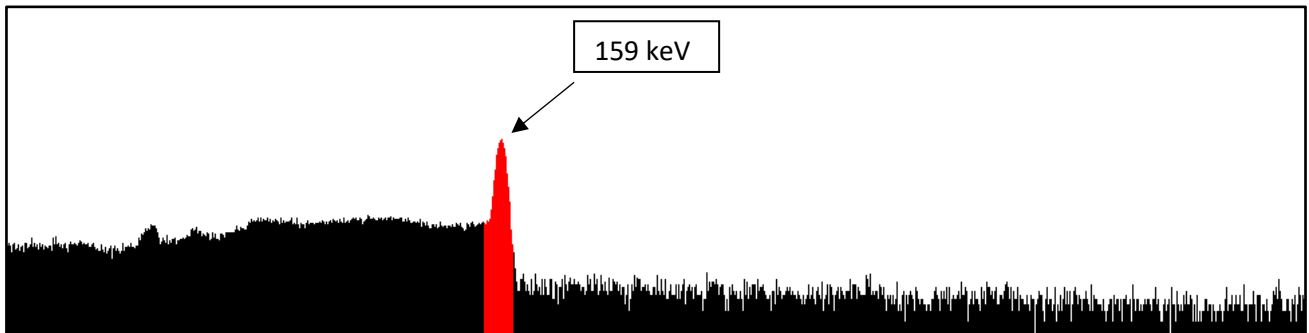
The sealed LNMRI ampoule (code 89L23), prepared from the second dilution, was measured using a coaxial HPGe detector with 70 % relative efficiency (compared to NaI(Tl) at 1.33 MeV for ^{60}Co) at a source-to-detector distance of 15 cm in the energy range of 30 to 2,600 keV. This yielded an activity per mass of $8.361 \text{ kBq}\cdot\text{g}^{-1}$ with a combined standard uncertainty of 0.76% (k=1) at the reference date of 14 December 2023, 12:00 UTC. The corresponding uncertainty budget is detailed in Table 5.

Table 5: Uncertainty budget for gamma-ray spectroscopy measurements of ampoule code 89L23 at the 159 keV photopeak energy.

Uncertainty component	Type A	Type B
Counting statistics	0.45	
Background		
Efficiency		0.58
Weight - geometry		0.20
Half-life		4.2×10^{-4}
Gamma emission probabilities		0.25
u_c (k=1)	0.76	

Spectral analysis in the 30–500 keV energy range with background subtraction revealed no significant gamma-ray impurities. The detection limit of the HPGe detector used in this measurement is 100 Bq. Figure 4 shows the gamma spectrum of the sealed LNMRI ampoule (code 89L23) without background subtraction, highlighting the 159 keV photopeak of ^{123}I .

Figure 4: Spectrum of sealed LNMRI ampoule 89L23 (30 - 500 keV, no background subtraction).



Activity measurement for undiluted sealed LNMRI ampoule 82L23, obtained using the LNMRI/IRD ionization chamber was $38,259.854 \text{ kBq}\cdot\text{g}^{-1}$ with a combined uncertainty of 1,1 % ($k=1$) at reference date 2023-12-14 12:00 (UTC). The corresponding uncertainty budget is detailed in Table 6.

Table 6: Uncertainty budget for measurements in LNMRI ionization chamber.

Uncertainty component	Type A (%)	Type B (%)
Counting statistics	0.17	
Calibration factor		1.1
Weighting		0.050
Dilution		0.071
Half-life		0.010
Long term stability		0.21
u_c % ($k=1$)	1.1	

The calibration factor for the LNMRI/IRD ionization chamber was determined as $(8.689 \pm 0.061) \times 10^{-18} \text{ A}\cdot\text{Bq}^{-1}$ ($k=1$), deviating by 1.0 % from the 2011 reference value $8.600 \times 10^{-18} \text{ A}\cdot\text{Bq}^{-1}$. The corresponding uncertainty budget is detailed in Table 7. This variation falls significantly below the laboratory's maximum permissible threshold of 1.5 % for inter-calibration intervals, confirming exceptional long-term stability of the primary standard. The observed divergence is attributed to the 2018 data acquisition system upgrade.

ISO 17025 compliance is demonstrated through this consistency [13], with the 1.0 % inter-calibration agreement directly supporting the critical $\pm 2\%$ activity accuracy requirement for ^{123}I thyroid uptake studies [14]. This metrological alignment ensures

therapeutic efficacy while minimizing patient radiation exposure, particularly significant given ^{123}I 's 13.2-hour half-life and 159 keV gamma emissions, which contribute 83% of the thyroid absorbed dose [15].

Table 5: Uncertainty budget to determine the LNMRI/IRD ionization chamber calibration factor.

Uncertainty component	Type A (%)	Type B (%)
Current and background	0.07	
Normalization factor	0.08	
Long term stability	0.21	
u_A activity	0.70	
u_B activity		0.08
Background		0.04
Timing		0.05
Half-life		0.01
Mass		0.05
u_c % (k=1)	0.75	

Table 8 presents the activity of the stock solution, calculated as the product of the dilution factor and measured solution's activity. The percentage differences fall within the propagated combined measurement uncertainties ($k=1$).

Table 6: Comparison of measurement systems for stock solution activity determination.

Measurement System	Source Code	Dilution Factor	A (kBq.g-1)	U (%) (k=1)	Δ (%)
Anticoincidence (AC)	(77-84) CL23	13.566108	38,267.589	0.70	-
Ionization Chamber (IC)	82L23	1	38,259.854	1.1	-0,020
HPGe Detector	89L23	4548.818654	38,032.673	0.76	-0.614
Reference date: 2023- 12-14 12:00 (UTC)					

Activity standardizations performed at LNMRI/IRD demonstrated high consistency, with all results agreeing within their respective measurement uncertainties, maximum standard uncertainty 1.1 % ($k=1$). Calibration systems deviated by no more than 0.61 % relative to the absolute $4\pi\beta(\text{LS})$ - $\gamma(\text{NaI}(\text{Tl}))$ anticoincidence counting reference, demonstrating excellent inter-system agreement.

These results validate LNMRI/IRD's capability to participate in the BIPM.RI(II)-K4 key comparison for ^{123}I . Nevertheless, the radionuclide's volatility and 13.2-hour half-life necessitate stringent risk management. Success will enable LNMRI/IRD to deliver ^{123}I calibrations at metrologically traceable levels ($\leq 0.75\%$ uncertainty) and launch Brazil's first dedicated Traceability Program for this radionuclide.

4. CONCLUSIONS

Both the LNMRI/IRD reference ionization chamber and gamma-spectrometric systems demonstrated rigorous metrological traceability to the primary $4\pi\beta(\text{LS})-\gamma(\text{NaI}(\text{Tl}))$ live-timed anticoincidence counting standard. Concurrently, gamma-spectrometric analysis confirmed the absence of significant gamma-emitting radionuclidic impurities in the ^{123}I solution, validating methodological integrity.

This study establishes a new calibration factor for the LNMRI/IRD ionization chamber, demonstrating metrological equivalence to the 2011 reference value well within the laboratory's maximum permissible variation limit for inter-calibration intervals.

The result complies with ISO/IEC 17025 quality thresholds and enhances traceability confidence for clinical ^{123}I dosimetry applications where $\pm 2\%$ activity measurement accuracy impacts therapeutic efficacy. The calibration factor inter-calibration consistency ensures compliance with the $< 2\%$ activity accuracy requirement for ^{123}I thyroid uptake studies.

We standardized ^{123}I activity and verified ionization chamber calibration factors at LNMRI/IRD/CNEN's Radionuclide Metrology Laboratory, national reference in radionuclide activity, gamma-emitting impurities in an IPEN/CNEN-supplied ^{123}I sample (São Paulo) were also quantified. This preparatory work supports Brazil's participation in the BIPM.RI(II)-K4 key comparison SIRTI-based.

Metrological traceability of ^{123}I measurements to the International System of Units (SI) is essential for ensuring high accuracy administered doses in nuclear medicine. Accuracy

in standardization guarantees therapeutic and diagnostic efficacy while minimizing risks to patients and occupationally exposed individuals, in full compliance with the ALARA (As Low as Reasonably Achievable) radiation protection optimization principle.

CONFLICT OF INTEREST

We have no conflicts of interest to disclose, and all authors declare that they have no conflicts of interest.

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