NATIONAL COMPARISON OF ^{131}I SOLUTION MEASUREMENTS IN ROMANIAN NUCLEAR MEDICINE UNITS

Maria Sahagia, Anamaria C.Razdolescu, E.L.Grigorescu, C.Ivan, A.Luca

Institute for Physics and Nuclear Engineering, Bucharest, POB MG6, Romania

INTRODUCTION

The national comparison regarding ^{131}I solution activity measurement, organized by the Radionuclide Metrology Laboratory (RML) aimed at the quality assurance of the measurements of activity along the process of production, quality control, distribution and use of radiopharmaceuticals, Na^{131}I being one of the most used.

Such trial comparisons are often organized in various countries as a step for the assurance of the measurement traceability up to national and international standards. Their necessity was imposed by the fact that many errors are made in hospitals during the administration of radiopharmaceuticals, generally resulting in a supplementary irradiation of the patients [1-4]. RML , recognized as an authorized metrology laboratory, organized previously national comparisons regarding environmental radioactivity measurements[5-6].

The comparison involved the following steps: preparation, standardization, check and distribution of the solution, measurement and processing of the obtained results.

1. PREPARATION AND DISTRIBUTION OF THE SOLUTION

1.1. Preparation and standardization of the solution

The standard ^{131} I solutions had a radionuclidic purity superior to 99%. Three successive gravimetric dilutions were made, with a maximum uncertainty of the dilution factor of ± 0.1%. The third dilution solution was standardized absolutely, by using the $4\pi\beta$-γ coincidence method, in the variant of efficiency extrapolation. The activity concentration, a_{III} , was determined as the mean of nine sources prepared gravimetrically from the solution. The expanded uncertainty of the activity concentration was 0.52% (for a 99% confidence level). The concentration of the first and second dilution solutions, a_I and a_{II} , were calculated from a_{III} value, by using the dilution factor value. The activity concentrations and their expanded uncertainties , U, are presented in Table 1.

Table 1

Dilution	Activity concentration a, MBq/g	Expanded uncertainty, U,%
I	19.14	± 0.72
II	1.931	± 0.62
III	0.4837	± 0.52

1.2. Preparation of vials and check of activity

10 ml vials, normally used in the distribution of radiopharmaceuticals were selected to have as uniformly thick walls as possible; the selection was made by weighing empty vials; a difference of ± 0.5% from the mean weight was accepted. The solution was dispensed gravimetrically in vials, with a maximum uncertainty of ± 0.05%. The mass of solution in a vial m_i , was situated in the interval 4.8...5.2 g. The activities of the vials, A (MBq), were calculated according to the relationship

$$A_i = am_i \qquad (1)$$

where a is one of the values presented in the table 1 A total number of 36 vials were prepared. All were measured in the calibrated high-pressure ionization chamber CENTRONIC type IG12/A2. The measurements aimed at the assay of the weighing precision and uniformity of vial walls and of the dilution factors values used for the calculation of the values in Table 1.

The difference between the measured and calculated from weighing values was <±0.1%.

1.3. Distribution

The participants were selected as to cover the most important institutions involved in ^{131}I use and measurement, as our Radioisotope Department, as sole producer of radiopharmaceuticals in Romania, the National Institute of Metrology; the Control Laboratories of the Ministry of Health, 18 hospitals using mainly ^{131}I and ^{99m}Tc, analysis laboratories and the producer of Romanian calibrators. A form requiring detailed information regarding the type of the measurement equipment, calibration data, method of measurement, applied corrections, was issued. The participants were asked to asses the value of ^{131}I vial activity, in MBq, on the reference data, with the uncertainty value for a 68.3% confidence level and the possible presence of other contaminant radionuclides.

2. MEASUREMENT AND RESULTS

2.1. Assay of Radioisotope Department Calibrators

The first calibration, in the production department, is very important as in many cases this value is taken as reference when ^{131}I is administrated to the patients. Three calibrators (ionization chamber type), used currently in measurements, were verified. The check of calibration was made on a wide interval of activities A, situated between 2.4MBq and 95MBq, by using vials prepared from the three dilutions. The calibrations of the calibrators were made by their manufacturers and were verified regularly by using a reference source. Table 2 represents the obtained results, expressed as mean ratios between the measured activities, A_m , and A values on the whole interval

$$R = (A_m / A) \quad (2)$$

The standard deviation values, S_R , are presented, too.

Table 2

Calibrator	ROBOTRON,1989	ROBOTRON,1990	PITMAN,1978
R	0.969	0.986	0.948
S_R	±0.42%	±0.67%	± 0.58%

The conclusion is that all three calibrators assure calibration uncertainties less than 5.0%, generally declared by the manufacturers; however, a small underestimate of activity values can be noticed.

2.2. Measurements of the other participants

In contradiction with the literature reported intercomparisons, involving only hospitals and ionization chamber calibrators, in our case the area of participants was different, at the same time, the measurements were performed by using ionization chamber radionuclide calibrators, 12 results reported, and spectrometric Ge(Li) or NaI(Tl) systems, 6 results reported. The distributed vials had generally activities of about 10MBq with an expanded uncertainty of ±0.67%. In the case of calibrators, the measurements were made directly; no correction regarding background counting rate was applied. In the case of spectrometric measurements some elaborated procedures were applied. They included the following steps: preparation of measurement samples from the distributed solution; calibration of the spectrometric equipment using appropriate standards delivered by our laboratory [7] or other well-known laboratories as: IAEA, LMRI, Amersham plc, UVVVR. The measurements of samples were made generally by using the 364.5 keV quantum photopeak; all required corrections were applied. Table 3 represents the obtained R values, defined according to the relationship (2), by different participants, their reported uncertainties, S_R, measurement method and type of participant laboratory.

Table 3

No.of particip.	R value	S_R,%	Method of measurement	Type of lab.
1	1.276	10	Picker calibrator,10MBq vial	hospital
	0.768	10	Picker calibrator, 100MBq vial	

2	1.062	2.2	Picker calibrator	hospital
3	1.039	-	Mediac calibrator	hospital
4	1.007	1.6	Capintec CRC 12 calibrator	hospital
5	0.976	3.6	gamma spectrometry	control lab
6	1.007	1.4	standardized ionization chamber*	Metrology Institute
	0.997	0.94	gamma spectrometry	
7	0.998	-	Capintec CRC 15 calibrator	Control lab
	1.025	-	Pitman Calibrator	
8	0.906	-	calibrator	hospital
9	0.991	1.6	Robotron calibrator	hospital
	0.862	1.7	gamma spectrometry	
10	1.383	1.6	gamma spectrometry	analyses lab
11	1.669	-	Mediac calibrator	hospital
12	0.999	1.3	Romanian RI14G calibrator	manufacturer
13	0.978	2.5	gamma spectrom, point source	analyses lab.
14	1.006	3.2	gamma spectrom.point source	analyses lab.

*The same manufacturer as 12.

3. ANALYSIS OF RESULTS

The mean value, R , calculated from the tables 2 and 3 is R=1.040; S_R =±4.0%, and if we exclude the highly erroneous value R=1.669, the new result is R=1.008, S_R =±2.9%. The results are normally distributed near R=1.008 what denotes the fact that no systematic error is made during the measurements at the national level. The best results were obtained with Capintec and Romanian Calibrators and some spectrometric measurements, carefully made. By comparing the obtained results with the requirements of European and Romanian Pharmacopoeia [8,9] which impose an upper limit of measurement uncertainties of ±10% for radiopharmaceuticals, one may conclude that the ratio of laboratories measuring ^{131}I activity in a satisfactory manner is 76%. This figure is inferior to Germany 84% and the United Kingdom 96%. The situation of Romanian hospitals is worse, as we delivered samples to 18 hospitals and only 7 of them submitted results; the percentage of satisfactory results is only 66%. These situations were notified to these units and the correction was made.

CONCLUSIONS

1. The large scale ^{131} I solution national comparison demonstrated the traceability of methods and equipment of measurements to national standards; special attention must be paid in the future to the hospitals measurements.

2. The very good results obtained by some participants, using radionuclide calibrators and standard solutions delivered by well-known foreign producers proved once more, indirectly the traceability of our standards and measurement methods to the international standards.

REFERENCES

1.M.J.Woods, Int.J.Nucl.Med.Biol 10,2/3,103(1983)

2.M.J.Woods, S.E.M.Lucas, NPL Report RS(EXT)88 Jan.1987,UK

3.K.Debertin,H.Schrader, Nucl.Instr.and Meth. in Phys.Res. A312 ,241(1992)

4.J.C.Furnari,M.L.de Cabrejas,M.del Rotta et al., Nucl.Instr.and Meth. in Phys.Res. A312, 269(1992)

5.M.Sahagia, E.L.Grigorescu,C.C.Popescu, A.C.Razdolescu, Nucl.Instr.and Meth in Phys.Res. A339,38(1994)

6. M.Sahagia,A.C.Razdolescu,Roum.J.Phys.39,743(1994)

7. M.Sahagia,E.L.Grigorescu,Nucl.Instr.and Meth.in Phys.Res.A312,236(1992)

8. European Pharmacopoeia, 2-nd ed.Maisonneure, Saint-Ruffine 1982

9. Farmacopeea Romana, Editia a X-a, Ed.Medicala, Bucuresti,1993, in Romanian