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An investigation on the performance of dose calibrators in nuclear medicine centers in Iran

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Background: To investigate the status of the nuclear medicine (NM) centers in Iran for the performance of dose calibrators, 18 out of 54 centers providing NM services in Iran were randomly selected and inspected in 1997. In the first phase of the study the selected centers were inspected for performing of quality control (QC) tests of dose calibrators. The linearity of the activity response, precision, accuracy, and the physical functions of the instruments, were studied. In the second phase of the study, carried out in 2006, 28 out of 75 NM centers were investigated for QC tests performance. ***Materials and Methods:*** The QC tests were performed by using standardized radio nuclides of Tc-99m and Cs-137 in the first phase, and Tc-99m and I-131 in the second phase of the studies. Standard procedures were used for carrying out the tests. ***Results:*** According to the obtained results in the first phase of the study, 10 centers were found to be in unacceptable situation. Following this study, all the concerned NM centers were informed about the results, and at the same time the repair and adjustment of the dose calibrators were requested. In addition, the appropriate training courses along with the QC testing manuals were provided to the centers. Based on the data of the second phase of the study, only 6 NM centers were in unacceptable situation. The results indicated the effectiveness of the improvements carried out in the working procedures of the centers during interval between the two phases of investigation. **Iran. J. Radiat. Res., 2008; 6 (2): 64-69**

Keywords: *Nuclear medicine centers, quality control, dose calibrator.*

INTRODUCTION

The radionuclide activity dose calibrators are routinely used in nuclear medicine practices to quantify the radioactivity dose of the radiopharmaceuticals to be administered to the patients. According to the current standards and regulations for NM worldwide practices, including those adopted by the international atomic energy agency [1-5], and national regulations such as those promulgated by the United States Nuclear Regulatory Commission (U.S.NRC) [5], the radioactivity of any radiopharmaceutical that contains a photon-emitting radionuclide must be measured by a dose calibrator prior to administration to patients or for human research purposes. Obviously, the administration of the prescribed amount of activity to the patient requires proper operation of the dose calibrator, which shall be verified by implementing the required quality control tests on the instrument. Several quality control tests are necessary to ensure the proper operation of the dose calibrators, among which the tests for the linearity of the response, accuracy, precision, and physical functioning of the instrument are of more importance [1-6]. The linearity of the response test confirms the ability of the instrument to measure a range of low to high activity doses with a required degree of accuracy. It is important that the linearity of the response of the dose calibrator to be ascertained over the range of its use between the maximum activity administered and 1 MBq [4]. It has been recommended that the test to be carried out upon acceptance, repair, and then annually. This test is mostly carried out by measuring a high activity, short-lived

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radionuclide for a given period of time by the instrument. Typically, Tc-99m is used for this purpose. Accuracy is a quality control measure performed upon acceptance, repair, and then annually, to ensure that the activity values determined by the dose calibrator are traceable to national or international standards of radioactivity within the indicated uncertainties. Precision test is to confirm that the random uncertainty of a single measurement is primarily determined by the random nature of radioactive decay. A larger than expected value indicates the possible presence of another random source of uncertainty that had not been anticipated. The recommended values for the above QC measures are within +/- 5 to 10 %, [1,7,8], depending on the radionuclide of interest and measurement conditions. In 1997, the National Radiation Protection Department (NRPD) of Iran, as the regulatory body in the field, paid its special attention to the implementation of the QC programs for NM practices in the country. This paper presents the results of the QC studies carried out on a number of dose calibrators being used in NM centers in Iran, in two phases during 1997-2006.

MATERIALS AND METHODS

During the first phase of the investigation, 18 NM centers have been randomly selected, among which 14 centers were State public and 4 centers were private. In the mentioned centers, 3 were using the Elscint, 5 were using the Picker, 4 were using the Siemens brands, and the rest were using other brands of the dose calibrators. It should be noted that in 20% of the centers, the instruments with over 20 year operating age were being used. In the second phase of the investigation, 28 NM centers were studied, among which, 16 centers belonged to the governmental, and 12 to the private sectors. None of the centers being investigated in this phase had instruments with over 15 years operating age. Among the centers studied, 10 were using the Siemens, 5 were using the Picker, 5 were using the Elscint brands, and the rest were using other instrument brands. All the centers which were studied in this phase were able to determine the types of the sources sent by the NRPD. The QC tests conducted in this work were in accordance with the internationally accepted standards for dose calibrators [1- 4]. The tests consisted of linearity of activity response, precision, accuracy and the physical inspection of the instruments [1,4,9]. The test for the linearity was conducted by the use of radioisotope ^{99m}Tc with the short half life of 6.02 hrs [10]. This test was carried out using an amount of 1.850 GBq (50 mCi) ^{99m}Tc as solution in a vial and measuring the activity by a dose calibrator for a relatively long period of time (minimum 72 hrs). If the measured error of the activities of the source by the dose calibrator exceeded 10% of the amount shown in the decay curve figure 1, the instrument was considered not to function properly [4]. The accuracy and precision tests were conducted by a calibrated reference source of ^{137}Cs with an activity of 925 kBq (25 µCi).

For this purpose the dose calibrator was set in the radionuclide ^{137}Cs, and the radioactivity of the source was measured

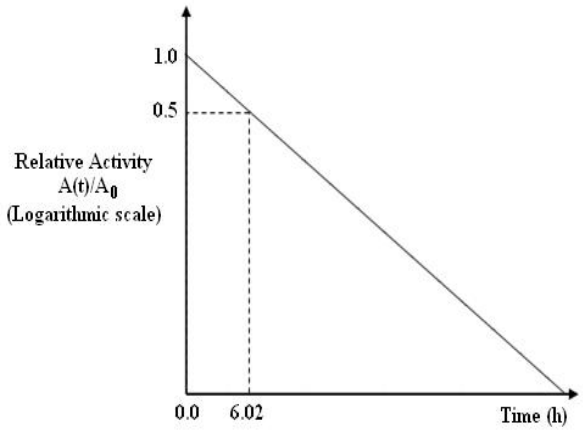

Figure 1. Linearity of Activity Response test, decay curve of ^{99m}Tc.

by the instrument for several times to determine the average value. For the physical inspection, certain functions of the instrument including controls, plug-in modules, push buttons, switches, connectors, source holders, fuses, and display devices were inspected [1]. After the completion of the tests in the first phase and the evaluation of the results, the repair companies were requested to repair the instruments which were failed in the tests. In this process, some outdated instruments were replaced by the new ones. The NRPD of Iran, through an action plan, attempted to establish instruction courses for the staff of the NM centers in order to update their knowledge on the latest standards applicable in the field of QC after being informed of the results. In the second phase of the investigation in 2006, the sources whose activities had been measured by means of an HPGe gamma spectrometer made by the U.S Canberra Company, with the measurement uncertainty of less than 1%, at the radioactivity measurement laboratory of the NRPD, were used for quality control tests. The sources were sent as unknown ones in two vials containing around 906.5 MBq (24.5mCi) of ^{99m}Tc and 179 MBq (4.85mCi) of ^{131}I, to 28 NM centers in order to determine their types, and measure their activities for a period of 72 hours (once in every 6hrs), and the NRPD was provided with the results. Based on the results presented by the NM centers, the error values for each test and radionuclide were calculated based on the radioactivity decay tables of ^{99m}Tc and ^{131}I. The maximum error values of the measurements were recorded.

RESULTS

The results of the QC tests carried out in the first phase of the investigation in 1997 are given in table 1. According to results, 6 centers were in an unacceptable situation in terms of the linearity of activity response test, among which 3 had 30% and the others had over 30% of errors, which was 3 times more than acceptable value for the QC measure. The other 12 centers were in an acceptable situation with the error values ranging from 4 to 8%. With regard to the precision and accuracy tests, 8 centers were in unacceptable situations; among which 2 had 70%, 4 over 30%, 1 had 28%, and the other 1 had 16% of errors in terms of measuring the activity of the calibrated sources. The other 10 centers were in acceptable situations with the error values ranging from 1 to 9 % for the later QC measures. For the physical inspection test of the instruments, 6 centers lacked the source holder, 2 were broken down in terms of switch and selectors and the other 2 had faced the display device problem. Eight centers were in acceptable situation for this QC test.

The results of the QC tests performed in the second phase of the investigation in 2006 are given in table 2. According to the results, 6 NM centers (one private and 5 public) were in unacceptable situations for accuracy test: 5 centers in terms of calibration of ^{99m}Tc, and 1 center in terms of calibration of ^{131}I. The other 22 centers studied in this phase had acceptable QC results. In addition, some other findings of the first and second phases of the investigation can also be compared as follows:

In the first phase, only 22% of the centers conducted QC tests by themselves, whilst in the second phase 53% of the centers had actually performed the QC tests by themselves. Generally, the state centers in comparison with to the private ones had shown more unacceptable situations, whilst the numbers of patients of these centers were much more than those of the private ones. According to the results of the second phase of the QC study, the errors in this phase are much less than those in the first phase and this fact is shown in figures 2 and 3.

Table 1. Results of the QC Tests in the First Phase.

Centers	Linearity of activity response error Source(s)	Status	Accuracy and Precision error Source(s)	Status	Physical inspection	Final results
A1	8%	A	30%	UNA	Lack of source holder	Unacceptable
A2	30%	UNA	16%	UNA	Lack of source holder	Unacceptable
A3	40%	UNA	28%	UNA	Switch break down	Unacceptable
A4	40%	UNA	1%	A	----------	Unacceptable
A5	7%	A	37%	UNA	Lack of source holder	Unacceptable
A6	5%	A	4%	A	Display device problem	Acceptable
A7	4%	A	58%	UNA	Switch break down	Unacceptable
A8	7%	A	5%	A	----------	Acceptable
A9	30%	UNA	39%	UNA	----------	Unacceptable
A10	7%	A	9%	A	Lack of source holder	Acceptable
A11	8%	A	70%	UNA	Display device problem	Unacceptable
A12	5%	A	4%	A	----------	Acceptable
A13	6%	A	2%	A	----------	Acceptable
A14	7%	A	2%	A	----------	Acceptable
A15	30%	UNA	9%	A	----------	Unacceptable
A16	5%	A	7%	A	----------	Acceptable
A17	7%	A	7%	A	Lack of source holder	Acceptable
A18	35%	UNA	70%	UNA	Lack of source holder	Unacceptable

A =Acceptable ,UNA =Unacceptable

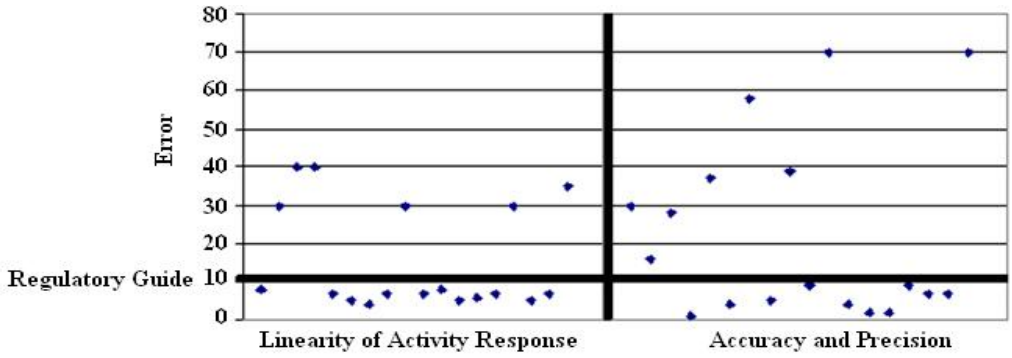

Figure 2. Results of the QC tests in the first phase.

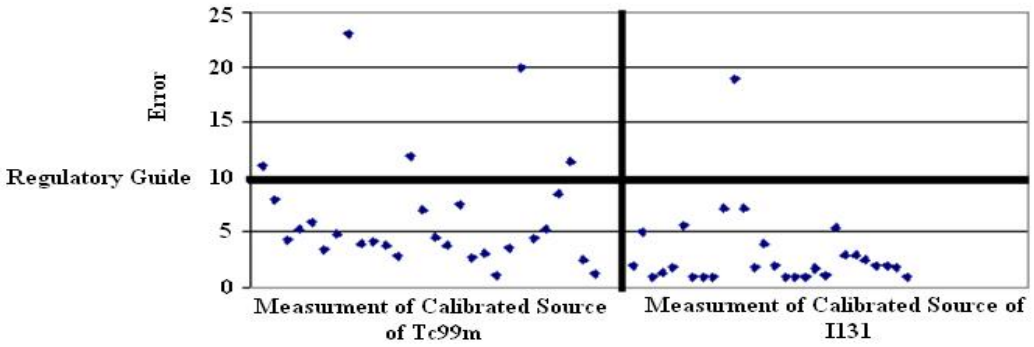

Figure 3. Results of the QC tests in the second phase.

Table 2. Results of the QC Tests in the Second Phase .

Centers	Measurement of calibrated source of ^{99m}Tc		Measurement of calibrated source of ^{131}I		Final results
	Error	Status	Error	Status	
B1	11.1%	UNA	2%	A	Unacceptable
B2	8%	A	5%	A	Acceptable
B3	4.3%	A	1%	A	Acceptable
B4	5.3%	A	1.4%	A	Acceptable
B5	5.9%	A	1.8%	A	Acceptable
B6	3.5%	A	5.7%	A	Acceptable
B7	4.8%	A	1%	A	Acceptable
B8	23%	UNA	1%	A	Unacceptable
B9	3.9%	A	1%	A	Acceptable
B10	4.2%	A	7.2%	A	Acceptable
B11	3.8%	A	19%	UNA	Unacceptable
B12	2.8%	A	7.2%	A	Acceptable
B13	12%	UNA	1.9%	A	Unacceptable
B14	7%	A	4%	A	Acceptable
B15	4.5%	A	2%	A	Acceptable
B16	3.8%	A	1%	A	Acceptable
B17	7.5%	A	1%	A	Acceptable
B18	2.7%	A	1%	A	Acceptable
B19	3.1%	A	1.7%	A	Acceptable
B20	1.1%	A	1.1%	A	Acceptable
B21	3.6%	A	5.4	A	Acceptable
B22	20%	UNA	3%	A	Unacceptable
B23	4.4%	A	3%	A	Acceptable
B24	5.3%	A	2.5%	A	Acceptable
B25	8.5%	A	2%	A	Acceptable
B26	11.5%	UNA	2%	A	Unacceptable
B27	2.5%	A	1.9%	A	Acceptable
B28	1.2%	A	1%	A	Acceptable

A =Acceptable ,UNA =Unacceptable

DISCUSSION

According to the results of the first phase of this investigation, the studied NM centers did not generally have acceptable situations in terms of the QC measures for dose calibrators [1, 4]. Considering the results of this phase, it can be realized that the range of errors was very wide. The most important factors contributing to this situation and suggested approaches to improve it are as follows:

Adequate budget is required to be allocated to the centers for the procurement of the state-of-the art instrumentations. An appropriate QC program has not been designed and performed on a routine basis by a significant number of NM centers. Considering great emphasis made during the recent years on the implementation of QA and QC programs in various radiological and nuclear facilities [1, 4], it is very important that both the regulatory body (NRPD) and the NM centers pay adequate attention to this requirement. The personnel of the NM centers are required to participate in training courses designed and implemented by the professional and regulatory bodies [3, 6]. This kind of courses will provide the NM staff with the knowledge on latest

developments in technical aspects, standards, and regulations in the field of NM. The regulatory body is required to provide NM centers with documents on the latest developments in regulatory requirements. In addition regular inspections in the framework of the responsibilities and functions of the regulatory body seems to be necessary [2, 3]. The findings of the second phase indicated that the present situation of the centers in 2003 (the beginning of the second phase of the study) in comparison with that of 1997 (the beginning of the first phase of the study) had improved in general, and regarding the performance of the QC program, in particular. Based on the recent findings only 23% of the instruments being applied at the centers were in unacceptable situation for QC testing, whilst in the first phase, this situation had covered 55% of the centers. In addition, according to acquired data in the second phase, more than 50% of the centers conducted the QC tests and recorded the results. Although the situation in NM centers has remarkably improved based on the results of the second phase, the performance of some NM centers did not comply with the accepted standards and regulations [1, 4]. It is, therefore, recommended that both the regulatory body and the staff of the NM centers make their attempts for the improvement of the NM practice in Iran steadily.

CONCLUSION

Considering the results and findings of this investigation the NRPD of Iran, has first prepared and formulated the QC system applicable in nuclear medicine practice in Iran, and then, by providing the relevant documentation to the centers, has forced them to implement a comprehensive QC program properly. Hopefully, this promising trend will be further strengthened and extended in future with the full assistance of the relevant bodies, as well as with the close cooperation of the centers.

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