

RESEARCH ARTICLE

ASSESSMENT OF DOSE CALIBRATOR PERFORMANCE FOR ACCURATE PATIENT DOSE ADMINISTRATION AND BETTER STAFF PROTECTION IN A BUSY NUCLEAR MEDICINE DEPARTMENT "QUALITY MATTERS"

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Manuscript Info

Abstract

Manuscript History Received: 06 June 2022 Final Accepted: 10 July 2022 Published: August 2022

Key words:-

Dose Calibrator, Quality Control, Geometry, Linearity and Dose Administration **Background:** To assess the performance of the Capintec- CRC-15R dose calibrator which is in use atLiaquat National Hospital (LNH) Karachi, Pakistan for patient dose administration.

Method: This quantitative study was conducted at Nuclear Medicine department, Liaquat National Hospital,Karachi during the period from July-December 2015. The quality control tests of calibrator were performed using standard sources i.e. Co-57, Ba-133 & CS-137 and data was analyzed for performance assessment of calibrator.

Results: Capintec CRC-15R calibrator was found in perfect working condition during daily physical inspections having consistent stable values with normal background readings. The precision test results were within the tolerance limits of \pm 5% and accuracy of Co-57, Ba-133 & CS-137 were (-0.36%, -0.36% & -0.43%) respectively. The constancy tests for all the three (03) standard sources were within the specified limits of \pm 10% and the activity-time graph was linear. The geometry test results were consistent upto 12 cm height (1.8%) and a sharp decrease of 11% was observed in activity at 20 cm height resulting in less activity measurements. The volume dependency results were consistent up to 3ml volume while a substantial deviation of 2.8% was observed at 5ml which was within the tolerance limit of \pm 10%.

Conclusion:The results of the quality control tests in our study for the dose calibrator- Capintec CRC-15R showed that the readings were within the specified limits and the calibrator was in good working condition which not only ensure right patient dose administration but also better staff protection.

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Introduction:-

Ionizing radiations innuclear medicine procedures plays a pivotal role in the diagnosis and treatment of various diseases ifused in a safe manner in-accordance with the standard protocols given by international regulatory body i.e. international Atomic Energy Agency (IAEA) [1, 2] and by national regulatory body i.e. Pakistan Nuclear Regulatory Authority (PNRA)[3, 4]. The benefits of ionizing radiations areassociated with clinicaljustification of the procedure i.e. the benefits of procedure overweight's the risk associated with the use of ionizing radiations. However, the detrimental effects of ionizing radiation cannot be ignored while using radioactive material for different nuclear medicine procedures. Therefore, the amount of radioactivity has to be determined exactly before it is applied to patients.

Accurate dose level must be known prior to administration of radiopharmaceuticals to the patients to fulfill radioprotection requirements and to ensure good quality image. In order to optimize the diagnostic image quality, optimizing the dose to the patient, a careful activity determination must be achieved using a dose calibrator [5]. The isotope calibrators have to measure the radioactivity of gamma and beta emitting isotopes with different energies precisely for high quality imaging and for applying the right amount of radiation to treat disease. The isotope calibrators should allow easy and fast operation in routine work as well as quick and effective cleaning in case of contamination [6].

One of the successful treatment of patients in the field of nuclear medicine is by giving the right dose according to the type and stage of cancer, volume/size of cancer cells. An overdose will cause side effects to the patient, damage healthy cells while an under dose will cause the treatment to be in-effective. Therefore, the dose should be accurate for cancer patients according to the type of cancer, the severity and volume of the cancer (cancer mass) [7].

Therefore, dose calibrator is an essential component of nuclear pharmacy for assaying activities in radiopharmaceutical vials and syringes and in other small sources. The quality control (QC) of dose calibrator is critically important as it ensures that the administered radio-activity is within a predefined acceptable range. It further ensures that delivered radiation dose to patient and technologist is within permissible limits [8]. The high quality isotope calibrators helps associated staff in nuclear medicine facilities to perform accurate activity measurements and to comply with the ICRP-60 requirements to keep the radiation doses as low as achievable for the patients. Hence, continuousquality control of isotope calibrators is mandatory according to international standards and guidelines such as international electro technical committee, IEC-61303 "Medical electrical equipment – Radionuclide calibrators – Particular methods for describing performance". Those methods include background measurement, accuracy, reproducibility and linearity checks as well as contamination tests etc. All these parameters influence the quality of activity measurements and consequently the radiation load for the patients [6].

In most countries, the standard of good practice is for the administered dosage to be within $\pm 10\%$ of the prescribed dosage. To help achieve this, the International Atomic Energy Agency (IAEA) recommends a calibrator precision of $\pm 5\%$ and the American National Standards Institute (ANSI) recommends an assay accuracy of $\pm 10\%$. AAPM Task Group-181 recommends that the assayed dosage be within $\pm 10\%$ of the prescribed dosage for diagnostic dosages and $\pm 5\%$ for therapeutic dosages when practicable [9-12]. Therefore, frequent quality control tests of dose calibrator is of utmost importance in achieving the above mentioned tolerance limits for optimum performance of calibrator and safe patient dose administration.

Thus, the basic purpose of this study was to assess the performance of dose calibrator (Capintec, Inc. CRC-15R) in terms of precision, accuracy, constancy, linearity, geometry (depth test)and volume dependency test for better patient dose administration and staff protection at nuclear medicine section, Liaquat National Hospital Karachi, Pakistan.

Material and Methods:-

The dose calibrator under investigation was Capintec, CRC-15R. The following quality control tests of the calibrator were performed i.e. Physical inspection, background check, Accuracy & precision, constancy, linearity, geometry and volume dependency check during the period from July-December 2015.

To perform the quality control tests, standard reference sources, Cobalt-57, Barium-133, Cesium-137 and Tc-99m were used as shown in [Table.01].

S.No	Source	Photon Energies	Half-life
1	Ba-133	81, 356 keV	10.51 Yr
2	Co-57	122 keV	271 Day
3	Cs-137	662 keV	30 Yr
4	Tc-99m	140 keV	6.02 hr
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Table 01:- Description of standard sources used for QC of Capintec, CRC-15R calibrator [IAEA—TECDOC – 602].

1. Daily Physical Inspection:Prior to start the services, dose calibrator was inspected for general condition like all controls, plug-in modules, push-buttons and switches, loose knobs, plug-in modules, all connectors, examine cables, plugs and sockets for evidence of damage also inspected for all accessories such as remote handling devices, source holders, Moly breakthrough kits are available as per IAEA guidelines.

2. Zero adjustment: Prior to start of measurements; voltage, zero adjustment and other tests were performed to check its proper functioning.

3. Background Test: The background measurement was performed basically to determine presence of any left-over activity in the vicinity of the dose calibrator which could affect the overall reading of the content of the radioactivity measured by the dose calibrator.

4. Response Time: The response time was measured to determine the time taken by the calibrator to give a stable reading. After every measurement it takes a small time to return to give stable reading. This test is essential to ensure appropriate dose for each individual patient. Stop watch was used to measure the time taken to give a stable reading.

5. Accuracy: The accuracy of a measurement shows how close it is to the true value. The standard sources were placed into the source holder by means of the remote handling device and the source holder is induced into the calibrator. The same steps repeated for 10 times for each source. Accuracy should be within $\pm 10\%$.

Accuracy % = $\frac{(\text{MeanMeasuredActivity} - \text{CertifiedActivity}) \times 100}{2}$

CertifiedActivity

6. Precision: Precision test is measurement of the spread of values obtained from a sequence of measurements. It is usually defined in terms of the standard deviation of a set of 10 consecutive measurements. The tolerance limit is \pm 5%.

7. Constancy: Constancy means reproducibility in measuring the activity of a standard source over a long period of time by placing them into the calibrator. The measured values are then compared with calculated values. Readings should be within the specified limits of $\pm 10\%$.

8. Linearity test: The purpose of this test is to check the linearity response of the activity of a radionuclide calibrator over the range of activities for which it is to be used. Tc-99m activity of 30 mCi (1110 MBq) was observed for 24hrsusing decaying source method and reading were noted for each hour accordingly.

9. Geometry Test: A point sourceof 2.5mCi (92.5 MBq) of Tc-99m taken in a syringe was measured at various depth positions in the dose calibrator to see variation in activity at different depths. At each height, activity was measured three times and average reading was taken. Activity versus height (distances) was plotted.

10. Volume dependency check: For the volume dependency check, 3mCi (111 MBq) of Tc-99m source having volume of 0.5ml was taken in a 3ml and 5ml syringeand then increased up to 3ml and 5 ml respectively. Activity of the source was measured by increasing the volume from 0.5 to 3 and 5ml with an increase of 0.5ml each time.

Results:-

The dose calibrator was found in proper working condition on daily physical inspections during the study period and all checklists were verified including controls, plug-in modules, push-buttons and switches, loose knobs, connectors, examine cables, plugs and free from damage and all accessories were inspected such as remote handling devices, source holders, and Moly-breakthrough kits for their availability.

Zero adjustment:

Zero adjustment was ensured prior to start measurements on dose calibrator for its smooth functioning and the values showed significant consistency during each measuring time [Table.02].

Trial No. 01		Trial No. 02	
Reading	Time (min)	Reading	Time (min)
1	3	1	2.5
2	2.5	2	2

3	2.3	3	2.9
4	3	4	2.8
5	2.6	5	3
Avg.	2.68	Avg.	2.64

Table 02:- Data for zero adjustment of Capintec, CRC-15R calibrator with respect to time.

Background test:

Background test showed negligible amount of left-over activities during study period as shown [Table .03]

Reading	Activity measured (µci)
1	0.56
2	0.75
3	0.95
4	1.10
5	1.30
Average	0.93

 Table 03:-Data for average background measurements.

Response Time:

The calibrator showedstable readingafter 10 second for Tc-99m and 12 second for I-131 having activities of 25mCi (925 MBq) for a set of five readings [Table.04].

Response time for Tc-99m		Response time for I-131	
Reading	Time (s)	Reading	Time (s)
1	8	1	14
2	10	2	10
3	13	3	13
4	10	4	11
5	9	5	12
Average	10	Average	12

Table 04:- Data for response time of calibrator for Tc-99m and I-131.

Precession and Accuracy:

The precision of Co-57, Ba-133 and Cs-137 have been plotted using Bold Altman's plot [Fig-01, 02 and 03] respectively while the accuracy was -0.36 % for Co-57, -0.36% for Ba-133 and -0.43% for Cs-137.



Figure 01:- Blond Altman plot for precision of Co-57.



Figure 02:- Blond Altman plot for precision of Ba-133.



Figure 03:- Blond Altman plot for precision of Cs-137.

Constancy Test:

The average percentage difference observed were 0.95% for Co-57 and 0.57 % for Ba-133 and Cs-137 respectively which are within the specified limits of \pm 10 % as shown in Fig. 4 and 5 for the study period



Fig. 04:- Constancy test for Capintec CRC-15R calibrator using Co-57 source.



Fig. 05:- Constancy test for Capintec CRC-15R calibrator using Ba-133 & Cs-137 Sources.

Linearity Test:



Fig. 06:- Activity-Time graph (Tc-99m) measured by Capintec CRC-15R Dose Calibrator.

The activity versus time graph and Ln activity versus time graph showed linear response with a percentage difference of 2.3 % between the calculated and measured activities [Fig 06, 07].



Fig. 07:- Ln Activity-Time graph (Tc-99m) measured by Capintec CRC-15R Dose Calibrator.

Geometry test:

The Geometry or depth test showed a consistent reading up to 12 cm height while a decrease of 11% was observed in activity at 20 cm height as shown in [Fig 08].



Fig. 08:- Activity-Position graph measured by Capintec CRC- 15R Dose Calibrator

Volume Test:

The volume dependency test showed a consistent result up to 3ml while a variation of 2.8 % was observed at 5ml which was within the tolerance limit of $\pm 10\%$ [Fig. 09, 10].



Fig. 09:- Activity-Volume graph measured by of Capintec CRC -15R Dose Calibrator for 3ml Syringe.



Fig. 10:- Activity-Volume graph measured by of Capintec CRC -15R Dose Calibrator for 5ml Syringe.

Discussion:-

The main objective in nuclear medicine applications is to get the best image with minimum and accurately measured radiation. The availability of dose calibrators and regular quality control tests in nuclear medicine centers is one of

the requirements of IAEA for the determination of these dosage amounts given to the patient in the most efficient way [14]. Thus basic goal of dose optimization in nuclear medicine procedures is achieved by keeping patient doses as low as reasonably achievable and should always be within $\pm 10\%$ of the prescribed dosage as part of standard practice. This will not only ensure safety of patients but will also enhance safety of staff as well.

To ensure right dose administration to patients in a busy nuclear medicine center in a tertiary care hospital, the performance evaluation of the dose calibrator was assessed in terms of various quality control procedures and the results showed no deviation from standards values provided by AAPM Task Group-181 and IAEA—TECDOC – 602 [13, 14]. This showed that our dose calibrator readings were consistent in-term of precision, accuracy, constancy, linearity, geometric and volumetric tests as per set standards which not only helped in right dose administration to patients but also to keep doses to staff working within the facility as low as possible.

The dose calibrator during the study period was found in good working conditions in terms of daily physical inspection and the zero adjustment was ensured each time before measurement were taken and showed the clock accuracy was within the limits as shown in [Table. 02]. The background reading also showed no presence of any left-over activity in vicinity [Table. 03]which reflects good practices as well as strict adherence of radiation safety guidelines in the facility as a result of dailyarea survey conducted at the time of leaving the suite to rule out any spill and left -over activity.

In our study, the precision and accuracy tests of the calibrator were calculated using three (03) sources i.e. Co-57, Ba-133 & Cs-137 and the values of precision test are in between the ± 2 SD which are within the specified limits of $\pm 5\%$ as shown in Fig [01, 02& 03]. While the accuracy values are -0.36%, -0.36% & -0.43% for Co-57, Ba-133 & Cs-137 respectively which are again within the $\pm 10\%$ tolerance limits. The constancy tests for the standard sources were measured and compiled for a period of five (05) months which have been shown in-terms of individual months in [Fig .04] and [Fig.05]. The results revealed that the constancy test monitored for dose calibrator during the study period were within the $\pm 10\%$ limits of the international standards and as per vendor specifications.

The linearity response of the dose calibrator was calculated using the decaying source method and the results were consistent as per the calculated time-dependent decrease of the Tc-99m radioactive source and the measured activity performed for a period of 60 hours (2.5 days) [Fig 06, 07] and an average percentage difference of 2.3% was observed between the measured and calculated values. The exponential decay of radioactive samplewas measured up-to ten (10) half-lives (2.5 days) and the equation of best fit was found to bey = $29.7621e^{-0.1163x}$ using the regression model and the relative coefficient $R^2 = 0.9998$ which showed strong correlation between the calculated and measured values resulting a linear response Fig [06] while the half-life was found to be 5.82 from the plot of the natural log of the activity versus time using decay constant, $\lambda = 0.1163$ hourthat was very close the actual value of the half-life of Tc-99m Fig.[07]

Geometry or depth test was measured by increasing the distance of dipper holding the eluted activity of 2.5 mci (92.5 MBq) from actual position of measurements within the well counter. This showed that the doses measured by the calibrator decreases as the radioactive material in the syringe moves away from the center of the well counter [Fig. 08]. The calibrator measured exact readings upto 5cm height with minimum deviation. A decrease in activity reading was observed beyond this point with a percentage decrease of 1.8% at a height of 12 cm from the actual position. A drastic decrease of 11% was observed at 20 cm height which showed that increase in height will result in less activity measurements. Hence, it is recommended to take measurements from the actual position of dipper inside the well counter to ensure accurate dose administration and to avoid unnecessary under doses to patients. This will affect the resolution as sufficient amount of photons will not reach the detectors resulting in sub-standard quality image.

Finally, for volume dependency test in our study [Fig.09, 10], the volume of syringe was instantly increased from 0.5 ml upto to 5 ml to observe the response of calibrator for activity measurement which showed minimum deviations upto 3ml volume while a substantial deviation of 2.8 % was observed at 5ml volume while for 3ml syringe, the deviation was not much significant and were well within the tolerance limit of $\pm 10\%$.

Quality control tests of dose calibrator are basic regulatory requirements for not only assessing the optimum performance of the calibrator but also of deemed importance in right patient dose administration. Thus the results of the measurements from quality control tests in our study for calibrator, Capintec CRC-15R showed that the

calibrator performance was good and the readings were within the specified limits. This reflects high quality diagnostic and therapeutic nuclear medicine services in our center which is being achieved through rigorous efforts all team members, high performance of device and by regularly conducting the quality controls procedures as per set protocols.

Conclusion:-

Quality controls tests in terms of precision, accuracy, constancy, linearity, geometry and volume dependency are of utmost importance for evaluation of the performance of the radionuclide dose calibrators and for right patient dose administration. According to the findings of our study, all the quality control tests performed at Liaquat National Hospital, Pakistan were within the acceptable range and the dose calibrator used was in good working condition complying all national and international regulatory requirements.

Acknowledgements:-

The authors wish to acknowledge with thanks the guidance and support of nuclear physician and nuclear medicine technologists for their cooperation and technical assistance during data acquisition and compilation phase.

Funding:

The authors disclose no funding source related to this article

Declarations

Conflict of interest: The authors declare no conflict of interest to this study and declare no relationships with any person/companies whose products or services may be related to the subject matter of thearticle

Human/animal rights:

This article does not contain any human or animal subjects performed by any of the authors

Informed consent:

There was no requirement of written informed con-sent for this study because this was a retrospective study on data with no names or identifiers

Ethical approval

Institutional Ethical Review Board approval was not required because this was a descriptive study on data with no names or identifiers

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