بسم الله الرحمن الرحيم

Sudan University of Science Technology

College of Graduate Studies

Assessment of Radiation Dose Calibrator Performance in the Nuclear Medicine Department of the National Cancer Institute –Wad Madani

تقدير أداء جهاز قياس الجرعات الإشعاعية بقسم الطب النووي بالمعهد القومي للسرطان - ود مدني

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:By

Mawada Mohammed Elfadil

:Supervisor

Dr.salah Ali Fadlalla

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(سورة النور، الآية 35)

DEDICATION

This thesis is dedicated to

,My father

,My mother

,My husband

Sister and Friends

And

above all my teachers

Acknowledgment

I thank for my God for helping me to

.complete my project most successfully

I grateful to guidance of supervisor Dr: Salah Ali Fadlalla

I Deep thanks go to Dr:Siddig Mohammed Ahmed for here unlimited help , support

.,and cooperation

I also grateful my parent

List of Abbreviations

Bq	Becquerel
CEN	European Committee for Standardization
CENELEC	European Committee for Electro technical Standardization
Ci	Curi
CNEN	National Commission of Nuclear Energy
ETSI	European Telecommunication Standards Institute
IAEA	International Atomic Energy Agency
IEC	International Electro technical Committee
ISO	International standardization Organization
LCI	Calibration laboratory of institute
NCI	National cancer Institute
NM	Nuclear Medicine
NRC	Nuclear Regulatory commission
QA	Quality Assurance
QC	Quality control
WHO	World Health organization

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Abstract

Nuclear medicine uses many different radioactive isotopes for radiation diagnostic studies and for therapy . The amounts of radioactivity has to be determined exactly before it is applied to patients. The dose calibrator has to measure the radioactivity of gamma and beta with different energies precisely for high quality imaging and for applying the right amount of radiation to have good images which give good diagnosis and effective treatment of diseases .

This study was carried out to assess the performance of dose calibrator which is used in nuclear medicine in the National Cancer Institute –wad madani (Gazera state) . The study period was from October 2015 to February 2016 . Four quality control tests were carried out using standard radionuclide , ^{137}Cs . The tests included accuracy ,constancy ,linearity and Geometry .All results that were obtained from the study were compared with the international standard (±5%) and the results showed that the dose calibrator under the study was of good performance and there is no need for any correction tables or factors or maintenance for the time being.

المستخلص

يتم استخدام النظائر المشعة بمختلف الأنواع في الطب النووي لإجراء الفحوص الطبية التشخيصية ولعلاج بعض الأمراض . وينبغي أن يتم تحديد الجرعات الإشعاعية لهذه الأغراض قبل إعطائها للمريض . ويلعب مقياس الجرعة الإشعاعية دوراً كبيراً في هذا المجال حيث يقيس جرعات أشعة قاما وبيتا ذات الطاقات المختلفة بصورة دقيقة للحصول على صور ونتائج ذات جودة عالية وبالتالي الحصول علي تشخيص سليم وعلاج ناجع.

و قد تم إجراء هذه الدراسة لتقويم أداء جهاز قياس الجرعة الإشعاعية بالمعهد القومي للسرطان بود مدني (ولاية الجزيرة) في الفترة من أكتوبر 2015- إلى نوفمبر 2016م. وقد تم إجراء أربعة اختبارات أساسية باستخدام السيزيوم 137، واشتملت على اختبار الدقة، الثبات، والخطية والشكل الهندسي- للجهاز. وقد تمت مقارنة النتائج مع المعايير العالمية (±5%)، حيث اتضح أن الجهاز المعني يعمل بصورة جيدة ولا يحتاج إلى جداول تصحيح أو صيانة في الوقت الحاضر.

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Chapter one

:Introduction .1.1

Nuclear medicine procedures use many different radioactive isotopes for radiation diagnostics and for therapy. The amount of radioactivity has to be determined exactly before it is applied to a patient. The isotopes calibrators have to measure the radioactivity of gamma and beta emitting isotopes whit different energies precisely for high quality imaging and for applying the right amount of radiation to treat disease. They must be able to measure low isotope activities for patient application and high activities during isotope production. The isotope calibrators should allow easy and fast operation in routine work as well as quick and effective cleaning in case of contamination. Continuous quality control of isotope calibrators is mandatory according to international standards and guidelines such as international electro technical committee IEC61303 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. All these parameters influence the quality of activity measurements and consequently the radiation load for the patients. the high quality isotope calibrators assist responsible staffs in

nuclear medicine laboratories to perform precise activity measurements and to fulfill the ICRP 60 requirement to keep the radiation load as low as achievable for patients(PTW-

.(Company, catalog,2008/2009

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 (IAEA), and national regulations such as those promulgated by the United States Nuclear Regulatory commission (U.S.NRC),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. 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. 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 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 to10 % , depending on the radionuclide of interest and measurement conditions

.((Zeinaliet al, 2008

:Problem of the study .1.2

There are many problems related to the quality control of dose calibrators which are used for dose measurements in nuclear medicine departments in Sudan in general and in (NCI) in particular. Therefore many patients my take over dose due to this cause, to the best of the researches knowledge. Moreover, accuracy of radionuclide dose calibrator and reliability cannot be easily determined by the user.

1.3 Objectives of the study :-

1.3.1 General objective :-

The general objective of this study is to assess the performance of the dose calibrators that is being used in nuclear medicine department at NCI (Wad Madani).

1.3.2 Specific objectives :-

to measure the accuracy of dose calibrators at the NCI .

to test the dose calibrator linearity .

to perform geometry test to the dose calibrator .

.to measure the dose calibrator constancy .

-:Area of the study .1.4

This study was conducted in the National Cancer Institute-Gazira state.

-:Duration of the study .1.5

The study will take place during the period from October 2015 to February 2016.

-:Thesis outlines .1.6

The research skeleton will consist of five chapters: chapter one deals with introduction and problem, objectives , place , duration and outlines of the study . Chapter two deals with the literature review related to the current study. Chapter three shows the methodology upon which the thesis is carried out and the materials used . Chapter four showed

the results and chapter five showed the discussion , .conclusion , recommendations , references and appendices

chapter Two

literature Review

Theoretical Background 2.1

:Radionuclide generators 2.1.1

Radionuclide generator consists of apparent-daughter radionuclide pair contained in an apparatus that permits separation and extraction of the daughter from the parent. The daughter product activity is replenished continuously by

.decay of the parent and may be extracted repeatedly

The most important generator is the ^{99}Mo-^{99m}Tc system ,because of the widespread use of ^{99m}Tc for radionuclide imaging. Technetium 99m emits γ rays (140kev) that are very favorable for use with a gamma camera . it has a reasonable half life (6 hours), delivers a relatively low radiation dose per emitted γ ray, and can be used to label a wide variety of imaging agents. more than 1850 TBq (50,000 ci) of ^{99}Mo week are required to meet the worldwide

.requirements for nuclear medicine procedures

The parent ^{99}Mo activity in the form of molybdate ion , MoO_4^{2-} is bound to an alumina (Al_2O_3) column. The daughter ^{99m}Tc activity produced in the form of $^{99m}TCO_4^-$ (pertechnentate) , is not as strongly bound to alumina and is eluted from the

column with 5 to 25 ml of normal saline . (Alberto et al (1998).

Typical 75% to 85% of the available ^{99m}Tc activity is extracted in a single elution .Technetium-99m activity builds up again after an elution , and maximum activity is available about 24 hours ,however, usable quantities of ^{99m}Tc are available 3 to 6 hours later.

Commercially prepared generators are sterilized, well shielded ,and largely auto-mated in operation . typically they are used for about 1 week and then discarded because of natural decay of the ^{99} Mo parent.

Molybdenum -99 activity is obtained by separation from reactor fission fragments or by (n ,γ) activation of stable molybdenum (23.8% ^{99}Mo). The former ,sometimes called "fission moly ," has significantly higher specific activity and is currently the production method of choice.

The volume of alumina required in ^{99}Mo -^{99m}Tc generator is determined essentially by the amount of stable ^{99}Mo carrier that is present , Therefore, "fission moly" generators require much smaller volumes of alumina per unit of ^{99}Mo activity. They can be eluted with very small volumes of normal saline

(5ml), which is useful in some dynamic imaging studies requiring bolus injections of very small volumes of high activity (740 MBq,20m Ci) of ^{99m}Tc.

One problem with ^{99m}Tc generators is ^{99}Mo"breakthrough" that is partial elution of the ^{99}Mo parent along with ^{99m}Tc from the generator.

From the standpoint of ^{99}Mo patient radiation safety , the amount of ^{99}Mo should be kept to a minimum . Maximum amounts ,according to Nuclear Regulatory Commission regulation are 0.15 Bq ^{99}Mo per kBq ^{99m}Tc (0.15µCi ^{99}Mo per mCi ^{99m}Tc)(Alberto et al 1998).

It is possible to assay ^{99}Mo activity in the presence of much larger ^{99m}Tc activity using NaI(Tl) counting systems by surrounding the sample with about 3mm of lead which is an efficient absorber of the 140kev γ rays of ^{99m}Tc but relatively transparent to the 740-780 k ev γ rays of ^{99}Mo .Thus small quantities of ^{99}Mo can be detected in the presence of much larger amounts of ^{99m}Tc. Some dose calibrator are provided with a lead lined container called a"moly shield " specifically for this purpose . Other radioactive contaminants also are occasionally found in ^{99}Mo-^{99m}Tc generator elute.

A second major concern is breakthrough of aluminum ion , which interferes with labeling processes and also can cause clumping of red blood cells and possible micro emboli . Maximum permissible levels are 10 µg/ml of ^{99m}Tc solution. Chemical test kits are available from generator manufacturers to test for the presence of aluminum ion. .

.((Zanzonico,1995

2.1.2 Technetium 99m_labeled radiopharmaceuticals:

The ^{99}Mo-^{99m}Tc generator produces technetium in the form of $^{99m}TcO_4^-$,A number of "cold kits" are available that allow different ^{99m}Tc complexes to be produced by simply mixing the $^{99m}TcO_4^-$ and the contents of the cold kit together .The cold kit generally contains a reducing agent , usually stannous chloride, which reduces the ^{99m}Tc to bind to a compelling agent (also known as the ligand) to form the radiopharmaceutical .Using these kits ,a range of ^{99m}Tc – labeled radiopharmaceuticals that are targeted to different organ systems and different biologic processes can be

.prepared quickly and conveniently in the hospital setting

^{15}O requires in-house radionuclide production in a biomedical cyclotron and rapid synthesis techniques to

incorporate them into radiopharmaceuticals. On the other hand ,the relatively longer half life of ^{18}F permits its distribution within a radius of a few hundred miles from the site of production, thus obviating the need of a cyclotron in the nuclear medicine imaging facility.(Simon et al ,2003).

2.1.3Quality assurance and quality control in nuclear medicine:-

It is now widely recognized that the attainment of high standards of efficiency and reliability in the practice of nuclear medicine, as in other specialties based on advanced technology, requires an appropriate quality assurance programme.

The concept of quality in the term "quality assurance" expresses the closeness with which the outcome of a given procedure approaches some ideal, free from all errors and artifacts. Quality assurance embraces all efforts made to this end. The term "quality control" is used in reference to the specific measures taken to ensure that one particular aspect

of the procedure is satisfactory. A clear distinction between these terms should be made.

Hence, quality assurance in nuclear medicine should cover all aspects of clinical practice. Specifically, quality control is necessary in the submission of requests for procedures; the preparation and dispensing of radiopharmaceuticals; the protection of patients, staff and the general public against radiation hazards and accidents caused by faulty equipment; the scheduling of patients; the setting-up, use and maintenance of electronic instruments; the methodology of the actual procedures; the analysis and interpretation of data; the reporting of results and, finally, the keeping of records. .(IAEA-TECDOC-1991).

2.1.4. Radionuclide "dose" calibrators :- (activity meters)

-:Basic Principles .2.1.4.1

A radionuclide calibrator is in essence a well-type gas ionization chamber into the well of which a radioactive material is introduced for measurement. The activity of the material is measured in terms of the ionization current produced by the emitted radiations which interact in the gas. The chamber is sealed, usually under pressure, and has two co-axial cylindrical electrodes maintained at a voltage difference derived from a suitable supply, the axial space constituting the well In the associated electrometer, the ionization current is convert to a voltage signal, which is amplified, processed and finally displayed, commonly in digital form in units of activity - Becquerel (Bq) or curies (Ci). This is possible since for a given radionuclide, assuming a fixed geometry and a linear response, ionization current is directly proportional to activity. However, the response of an ionization chamber to the radiations from different radionucliedes varies according to the types, energies and abundances of these radiations, the primary consideration being the rate of emission of photon energy. Appropriate adjustment of the amplification of the voltage signal is thus necessary, if the display with different radionucliedes is always to be in units of activity. Most radionuclide calibrators have selector switches, selector push-buttons or plug-in modules for different radionucliedes, which achieve this

adjustment by selecting a fixed resistor determining the amplification. Alternatively or additionally, a continuously variable resistor (potentiometer) with a dial which can be set to a specified number according to the radionuclide to be measured may be provided.

Lead shielding around the ionization chamber provides protection to personnel against radiation hazards and reduces its response to environmental radiation, but a residual background response remains.(IAEA-TECDOC-1991). Some radionuclide calibrators have a continuously adjustable zero control by which this response may be "backed off". Otherwise, it must be noted and subtracted, if significant, from subsequently measured activities. A removable liner that can be easily cleaned in the event of accidental radioactive contamination of the chamber well is usually provided.

2.1.4.2. Operational Considerations:-

The accuracy of a radionuclide calibrator depends upon several factors. Every such instrument is factory-calibrated with a set of certified sources that, at best are within ±1% of their stated activities, but may be only within ± 3%, or even

± 5%, limiting the initial accuracy. This initial accuracy may change with time as a result of changing pressure of the chamber gas and slow electronic drift. The addition of lead shielding may also significantly affect the accuracy of a radionuclide calibrator because of the extra contribution of scattered radiation from the added shielding, necessitating changes in calibration settings. Further, the accuracy of any individual measurement is dependent upon the similarity of the measured material to the original calibration source. Especially with radionucliedes giving low-energy radiations, differing radiation absorption characteristics of the material may cause significant measurement errors. (IAEA-TECDOC-1991).

All radionuclide calibrators show some dependence on measurement geometry; this effect diminishes with increasing depth of the well. With many such instruments, tables are provided giving correction factors to be applied in measurements on different radionucliedes in syringes, vials and other containers of different sizes and types. However, nuclear medicine units should determine correction factors appropriate to their own situations. It should be appreciated that correction factors for syringes depend on whether or not a needle is attached. (IAEA-TECDOC-1991).

Simple operational checks of reproducibility of performance and background response are needed each day a radionuclide calibrator is used. In addition, regular quality control should cover its precision, its accuracy and the linearity of its activity response.

Table 2-1 lists the recommended quality control tests for a radionuclide calibrator, with suggested frequencies for the repetition of reference tests in routine testing. The operational checks should be carried out each day the instrument is used . (IAEA-TECDOC-1991).

Table 2.1 showing Test Schedule for Radionuclide Calibrator

Frequency in routine testing			Acceptance Reference	Test	Test No
Half-yearly	Quarterly	Weekly			
				Acceptance and Reference Tests	
			X	Physical Inspection	2.3.1.
X		X	X	Test of Precision and Accuracy	2.3.2.

X		X	X	Test of Linearity of Activity Response	.2.3.3
	X	X	X	Test of Background Response	.2.3.4
				Operational Checks	
				Check of Reproducibility	.2.4.1

:Quality control of ^{99m}Tc-eluate 2.1.5

Since ^{99m}Tc activity is used for humans, several quality control tests of the ^{99m}Tc-eluate are mandatory. These tests will be discussed below in some details.

:2.1.5.1.^{99}Mo breakthrough

This is ^{99}Mo contamination in the ^{99m}Tc-eluate and originates from the small quantity of ^{99}Mo that may be eluted with ^{99m}Tc. The US Pharmacopeia (USP 32) limit [also the Nuclear Regulatory Commission (NRC) limit] is 0.15 μCi ^{99}Mo/mCi (0.15 kBq/MBq) ^{99m}Tc at the time of administration. For ^{99}Mo-^{99m}Tc generators, the ^{99}Mo breakthrough needs to be determined only for the first elution. The ^{99}Mo contamination

is measured by detecting 740-keV and 780-keV photons of ^{99}Mo in a dose calibrator or a NaI(Tl) detector coupled to a pulse height analyzer. The eluate vial is placed in a lead pot (about 6-mm thick) to stop all 140-keV photons from ^{99m}Tc and to count only 740-keV and 780-keV photons from ^{99}Mo. The shielded vial is then assayed in the dose calibrator using the ^{99}Mo setting. Molybdenum-99 along with ^{98}Mo (from the molybdenum target) can also be detected by adding phenylhydrazine to the eluate and observing the color change due to the Mo-phenylhydrazine complex by the use of a colorimeter.

2.1.5.2- Other radionuclide contamination:

In generators using fission-produced molybdenum, a number of extraneous activities such as those of ^{103}Ru, ^{132}Te, ^{131}I, ^{99}Zr, ^{124}Sb, ^{134}Cs, ^{89}Sr, ^{90}Sr, and ^{86} Rb may remain in the eluate as contaminants. The USP 32 limits of these radionuclides in ^{99m}Tc eluate are ^{131}I: 0.05 mCi/mCi (0.05 Bq/kBq) ^{99m}Tc;^{103}Ru: 0.05 mCi/mCi (0.05 Bq/kBq) ^{99m}Tc; ^{89}Sr: 0.0006 mCi/mCi (0.0006 Bq/ kBq) ^{99m}Tc; ^{90}Sr: 0.00006 mCi/mCi (0.00006 Bq/kBq) ^{99m}Tc; other and emitting radionuclides: not more than 0.01% of all activity at the time of administration; gross a-particle impurity: not more than 0.001 nCi/mCi (0.001 Bq/MBq) ^{99m}Tc. These contaminants can be checked by a multichannel pulse height analyzer after

allowing ^{99m}Tc, ^{99}Mo, and other relatively short-lived radionuclides to decay completely. Usually these tests are performed by the manufacturer. (saha,2010).

2.1.5.3. Aluminum breakthrough:

The aluminum contamination originates from the alumina bed of the generator. The presence of aluminum in the ^{99m}Tc-eluate interferes with the preparation of ^{99m}Tc-sulfur colloid; particularly phosphate buffer in colloid preparations tends to precipitate with excessive aluminum. It also interferes with the labeling of red blood cells with ^{99m}Tc, causing their agglutination.

The USP 32 limit is 10 mg Al/ml ^{99m}Tc for fission-produced ^{99}Mo.

The presence of aluminum can be detected by the colorimetric method using aurin tricarboxylic acid or methyl orange, and can be quantitated by comparison with a standard solution of aluminum. Test kits are commercially available for the determination of aluminum. In these kits, strips containing a color completing agent are provided along with a standard solution of aluminum (~10 mg/ml). In a routine test, one drop each of the ^{99m}Tc-eluate and the standard aluminum solution are spotted on a test strip and

the intensities of the colors of the two spots are visually compared. If the ^{99m}Tc-eluate spot is 78 5. Radionuclide Generators denser than the standard aluminum spot, then the amount of aluminum is considered excessive and the ^{99m}Tc-eluate should be discarded. Excessive amounts of aluminum in the eluate indicate lack of stability of the column. (saha,2010).

:pH.2.1.5.4

The pH of the eluate should be between 4.5 and 7.5; this can be checked quantitatively with a pH meter or qualitatively with pH paper. The actual pH of the ^{99m}Tc-eluate from the generator is about 5.5. The pH of the ^{99m}Tc solution obtained by methyl ethyl ketone extraction is slightly higher (~6–7).

:radiochemical purity .2.1.5.5

The radiochemical impurities of the ^{99m}Tc eluate are different chemical forms of radioactivity other than $^{99m}TcO_4$.

These impurities should be checked by suitable analytical methods.(saha,2010).

2.1.6. quality control of radiopharmaceuticals:

As already mentioned, each radiopharmaceutical must pass several quality control tests before dispensing for human administration. Regular checks should be made for the sterility, a pyrogenicity, and radiochemical purity of all labeled products. Commercial vendors often guarantee the quality and efficancy of labeled compounds and in those situations, rigorous quality control tests are not needed at the receiving institutions. However, ^{99m}Tc labeled radiopharmaceuticals are prepared daily and the labeling efficiency must be determined by thin-layer or paper chromatography . Preparations with poor labeling should be discarded. Colloidal and macroaggregated preparations must be checked for particle size and preparations with inappropriate particle size must be discarded. New radiopharmaceuticals and investigational drugs require sterility and pyrogen testing besides radiochemical purity. For short-lived radionuclides, the sterility and pyrogen tests can be conducted on an “after-the-fact” basis. Such radiopharmaceuticals are administered to humans, while the biological tests are continued until the final results are obtained. If the results are positive, the subject is then

followed up for any symptoms for which remedial medications are instituted.(Callahan R J,1996).

2.1.7. assay of radioactivity for clinical use:

The accurate assay of activity prior to administration is one of several important processes required to assure that patients receive the correct radiopharmaceutical dosage. Assuming that the treatment or diagnostic study is appropriate and the prescribed radiopharmaceutical is being administered via the prescribed route to the correct patient, other processes include the determination of the appropriate activity to be administered and the successful administration of that activity.

Radionuclide or dose calibrators are the instruments most often employed to say the activity of a radioactive material prior to clinical use. The objective of the assay is to help assure that the patient receives the minimum absorbed dose compatible with obtaining a high-quality diagnostic image or with achieving a desired therapeutic outcome.

(Vienna ,Sustria 2006).

2.1.8. Dose Calibrator Quality Control:

Years ago, the NRC in 10CFR35 required timely quality control tests performed for calibration of the dose calibrator to validate its accurate operation and established criteria for these tests. However, current 10CFR35 requires only the dose calibrator to be calibrated according to the manufacturer's recommendations or nationally recognized standards. The following tests are essential for calibration of the dose calibrator.

1. Constancy (daily) (.
2. Accuracy (at installation, annually, and after repairs) (.
3. Linearity (at installation, quarterly, and after repairs) (.
4. Geometry (at installation and after repairs) (.

2.1.8.1 Constancy:-

The constancy test indicates the reproducibility of measurements by a dose calibrator, and is performed by measuring the activity of a sealed source of a long-lived radionuclide (^{226}Ra, ^{137}Cs, or ^{57}Co) on frequently used settings in the dose calibrator. A deviation of the reading by more than ±10% of the calculated activity may indicate the malfunction of the dose calibrator and hence repair or

replacement. The constancy test must be done daily and at other times, whenever the dose calibrator is used, using at least a 10 mCi (370 kBq) or more ^{226}Ra or a 50 mCi (1.85 .MBq) or more ^{137}Cs or ^{57}Co source

-:Accuracy .2.1.8.2

The accuracy of a dose calibrator is determined by measuring the activities of at least two long-lived reference sources at their respective isotope settings, and comparing the measured activity with the stated activity. The measured activity must agree with the stated activity within ±10%. .Otherwise, the dose calibrator needs repair or replacement

The activity of the reference sources must be accurate within ±5% and one of them must have energy between 100 and 500 keV. These sources are available from the National Institute of Standards and Technology and other manufacturers whose standards are of equal accuracy. The .typical reference sources are ^{57}Co, ^{133}Ba and ^{137}Cs

-:Linearity.2.1.8.3

The linearity test indicates the dose calibrator's ability to measure the activity accurately over a wide range of values. Normally, dose calibrators exhibit a linear response for activities up to 200 mCi (7.4 GBq) to 2 Ci (74 GBq), depending on the chamber geometry and the electronics of the dose calibrator, and tend to under estimate at higher activities. The linearity test must be carried out over the range of activities from the highest dosage administered to the patient down to 30 mCi (1.11 MBq). Two common methods for checking the linearity of the dose calibrator are described below:-

Decay Method:- In this method of linearity check, a source of ^{99m}Tc is usually used, the activity of which is at least equal to the highest dosage normally administered to the patients in a given institution. The source is then assayed in the dose calibrator at 0 h and then every 6 h during the working hours every day until the activity decays down to 30 mCi (1.11 MBq). The measured activities are plotted against time intervals on semi log paper and the "best fit" straight line is drawn through the data points The deviation of the point farthest from the line is calculated. If this deviation is more than ±10%, the dose calibrator needs to be replaced or adjusted, or correction factors must be applied to activities when measured in nonlinear regions.

Shielding Method: This method is less time consuming

.and easy to perform

A commercial calibration kit used in this method contains seven concentric cylindrical tubes or “sleeves.” The innermost tube is not lead-lined and therefore provides no attenuation of gamma radiations. The other six tubes are lead-lined with increasing thickness to simulate the various periods of decay. When these tubes are placed over the source of a radionuclide (normally ^{99m}Tc) in the dose calibrator, seven activity measurements represent activities at different times. From the first time measurements, calibration factors are established for each tube by dividing the innermost tube reading by each outer tube reading. For subsequent linearity tests, identical measurements are made

.by the kit using a source of the same radionuclide

-:Geometry .2.1.8.4

Variations in sample volumes or geometric configurations of the container can affect the accuracy of measurements in a dose calibrator because of the attenuation of radiations, particularly the weak gamma radiations such as those of ^{125}I and ^{201}Tl. Thus, the same activity in different volumes [1 mCi (37 MBq) in 1 ml or 1 mCi

(37 MBq) in 30 ml], in different containers (3-cc syringe or 10-cc syringe or 10-ml vial) or in containers of different materials (glass or plastic) may give different readings in the dose calibrators. Correction factors must be established for changes in volume or container configuration while measuring the activity of the radionuclide in question and must be applied to similar measurements, if the difference

(exceeds ±10%.(Saha,2010

Figure 2.1. A radionuclide dose calibrator, Biodex model Atomlab 500

2.1.9. Operation of a nuclear pharmacy:

The daily operation of a nuclear pharmacy involves the following steps:

(1) receiving of radioactive materials,

(2) preparation of radiopharmaceuticals,

(3) quality control tests of radiopharmaceuticals,

(4) storage.

(5) dispensing.

(6) radioactive waste disposal.

(7) infectious waste disposal.

Before the day's operation is begun, the nuclear pharmacist must ensure that all equipment in the nuclear pharmacy such as the dose calibrator, survey meter, and NaI(Tl) well counter are in good operating condition. This is accomplished by proper calibration of each device with standard radioactive sources (e.g., ^{137}Cs, ^{226}Ra, ^{57}Co, etc.). If a malfunction is noted in any instrument, it must be remedied before any measurement is made. All personnel in the nuclear pharmacy must wear a laboratory coat and

gloves while handling radioactive materials. A pair of long tongs should be used in the handling of high activity, preferably behind a lead barrier shield.(Saha ,2010).

2.1.10 radionuclides Impurities:-

Many commonly used radiopharmaceuticals contain radionuclides impurities that contribute to the measured ionization current. The magnitude of the chamber response depends upon the unwanted radionuclide(s), the percent radionuclides impurity(ies), and the chamber response to the impurity(ies). Since an ionization chamber cannot inherently discriminate radionuclides by photon energy, it is difficult to adjust the assay for this contribution.

The main significance of the presence of radionuclides impurities in a diopharmaceutical preparations is the associated absorbed dose received by the patient. In addition to additional absorbed dose to the patient, radionuclide impurities may have other dose consequences, e.g., the presence of I-125 in the breast milk following the administration of I-123 sodium iodide.

The presence of long-lived radionuclides impurities in radioactive waste complicates waste disposal by radioactive decay. Users should be aware of the radionuclides impurities

that are present in patient dosages and their potential significance.

2.1.11. calibration coefficients:-

A calibration coefficient is the coefficient used to convert the measured ionization chamber current to a nominal activity. The magnitude of a calibration coefficient depends upon the radionuclide, the physical characteristics of the ionization chamber (inner chamber wall thickness, gas pressure, chamber design, and operating voltage) and the source geometry (container type, container wall thickness, source volume, and position of the container in the chamber). Additional components common to commercially available radionuclide calibrators also influence the measured current, including lead shielding, the sample holder, and the removable liner. Calibration coefficients are often referred to as calibration factors. For a given radionuclide, the response of the chamber depends upon type of decay, particle(s) energy, and the decay scheme of the radionuclide. Source volume affects chamber response

due to attenuation and/or chamber position. For most commercially available radionuclide calibrators, calibration coefficients are available indirectly as

.(calibration(baker,2005

settings applied using buttons, dials, numeric keypads, etc. These calibration settings are initially determined by the calibrator manufacturer and are typically assigned by radionuclide .However, it is the response of the chamber to a given radionuclide in a specific source geometry that is correlated with a particular setting. Thus, in order to obtain an accurate activity reading for a selected radionuclide, calibration settings must be determined for that radionuclide

.in the specific geometry being used

12.1.2. international standards:-

International standard play a very important role in QC management. Many basic QC procedures are included in the international standards and it appears that the primary duty of those responsible for the quality of a product or service is

.to comply with requirements included in standard

Nuclear interments are a rather specialized topic, as they must meet not only general requirements concerning QC, but also strict rules related to ionizing radiation.

From among several tens of thousands of international standard, about five hundred connected with ionization radiation were found.(IAEA-TECDOC-1599,2007).

2.2 Previous studies:-

Many considerable studies were carried out in the scope of survey and assessment of the dose calibrator's performance through quality control tests.

H. Zamani Zeinali, N. Alirezazadeh , F . Atabi an investigation on the performance of dose calibrators in nuclear medicine centers in Iran was done to investigate the status of the nuclear medicine (NM) centers in Iran of 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.

According to the obtained result 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): 6469

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.

Another study by Ana Carolina Moreira de Bessal , Alessandro Martins dacosta, Linda V. E. Caldas3. Survey on quality control of radiopharmaceutical dose calibrators in nuclear medicine units in the city of Sao Paulo, SP, Brazil

To perform a survey on routine quality control tests of dose calibrators at nuclear medicine units in the city of Sao Paulo, SP ,Brazil. To evaluate the accuracy of measurements of seven dose calibrators activities, utilizing sources of clinically significant radionucliedes at the calibration .laboratory of Instituto de pesquisas Energeticas e Nucleares

The survey result on the quality control tests of the dose calibrators showed some inappropriateness, for example, the absence of daily reproducibility tests in all of the units. The accuracy tests for the seven dose calibrators showed results within the acceptable limit in compliance .(whit the national regulations (5%

According to the few nuclear medicine units participating in the survey, the dose calibrators quality control is unsatisfactory. The accuracy study of seven dose calibrators has not demonstrated any performance faults, and has established the calibration of these instruments for .the utilized sources

Then By Zhenya Krasteva 11SBALNP "Sv . Naum" , Sofia , Bulgaria the purpose of this study is to carry out quality control (QC) of dose calibrators in some nuclear medicine departments in Bulgaria .

The methods used for QC are based on established international and national recommendations. For each type of dose calibrator requirements of the producer are taken into account. Depending on the type of dose calibrator there might be a need to modify QC procedures. The following sources of photon radiation were used for the measurement Tc-99m , Cs-137 and Ba-133. To ensure the proper operation of a dose calibrator, four QC parameters must be tested: accuracy , precision, constancy and linearity.

The results from the measurements showed that the parameters that were traced for dose calibrators are within the Bulgarian and international standards. It is essential to perform daily testing for background activity and constancy. Deviations from normal values of these tow parameters is the first sing of degradation of the dose calibrator. Regular QC should cover precision, accuracy and linearity of the instrument . according to IAEA standards and Ordinance NO 30 (31 October 2005) of ministry of Health. That will

guarantee accuracy of the used patients radioactive doses .and therefore proper practice of nuclear medicine diagnosis

Chapter Three

Materials and Methods

This study is an experimental study designed and conducted in the National Cancer Institute which is located in Wad madani - Gazera state. The QC tests in this work were conducted in accordance with the internationally accepted standards for dose calibrators. The tests included constancy

(reproducibility) accuracy ,precision, background , linearity ,

.clock accuracy and geometry

:Materials.3.1

:Dose calibrator.3.1.1

The nuclear medicine department of the National Cancer Institute uses dose calibrator model PTW CURIEMENTOR3 Microprocessor controlled radionuclide activity measuring system with gas-filled pressurized well-type ionization chamber. The ionization chamber is a thin wall ,deep well, high pressure type 8 .3 weight, with dimensions 3.39 in x10.39 in x6.93 in ion chamber .The

.resolution of .001MBq

Table 3.1 shows the CURIEMENTOR 3 dose calibrator

PTW CURIEMENTOR 3	Specification
(Lower limit .1MBq(137Cs	Measuring range
(Upper limit 195GBq(137Cs	
400V	Chamber voltage
°C,(50-104)°F(10-40)	Temperature
hpa(700-1060)	Air pressure range
mm, 2.42 in 61.5	Diameter of well
mm, 9.92 in 252	Depth of well
Approx ,8.3Kg	Weight ion chamber

The display unit of the system consists of the display screen which is dot matrix liquid crystal type with direct reading in Bq or Ci. It contains 5 pre-set nuclear keys which include ,^{99m}Tc ,^{111}In ,^{131}I ,^{137}Cs and ^{201} Ti.(Figure 3.1).

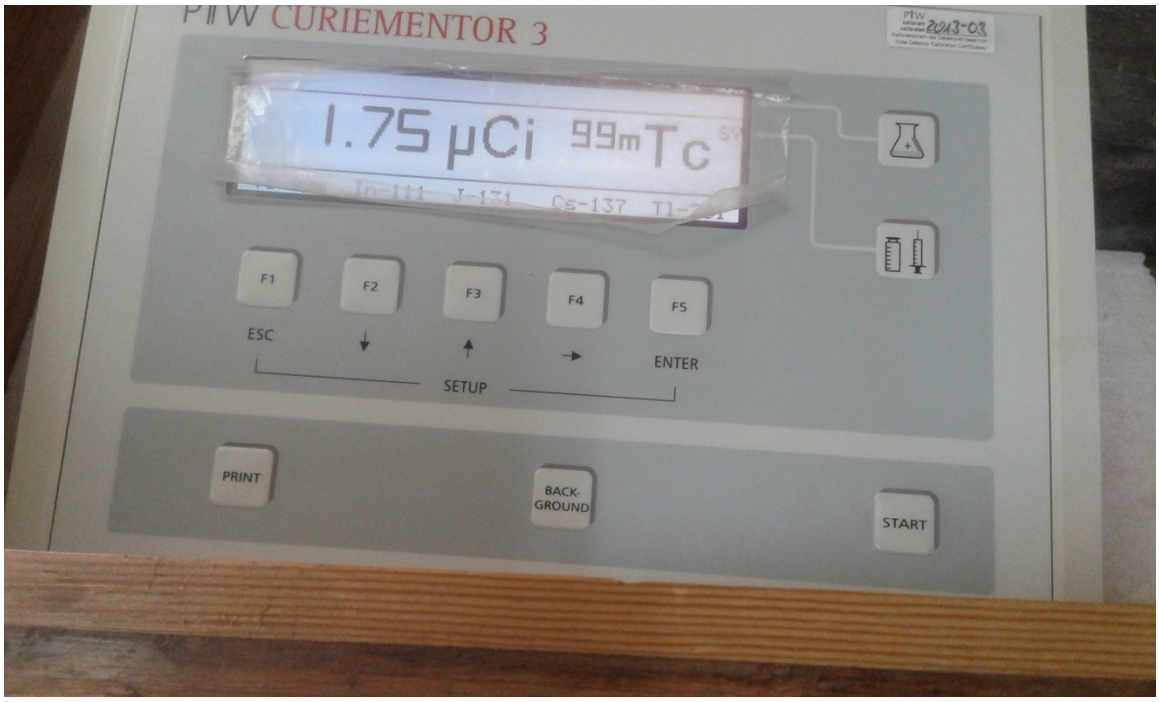

Fig 3.1 Shows the dose calibrator model PTW CURIEMENTOR3

-:Standard radionuclide source 3.1.2

Quality control tests are easily achieved and maintained by use of long-lived reference source.

The one standard radionuclide source was used in this study to perform quality control tests (accuracy and constancy) ^{137}Cs .standard source is only available in (NCI) ((see Fig 3.2.

.Fig 3.2 Shows standard radionuclide source 137 Cs

.Table 3.2 shows specifications of standard source

Activity			Principal	
Non-Si units	SI Units	Ha lf –life	photon energies	Radionuclide
200µCi	7.4MBq	30.0Y	662KeV	137Cs

Methods 3.2

-:Methods of data collection 3.2.1

The tests included constancy (Reproducibility) ,accuracy , Precision, Background , Linearity ,Clock accuracy and geometry on the dose calibrator using ^{137}Cs ,and ^{99m}Tc .

The dose calibrator was tested in place without any movement , and with some modifications to the quality control procedures according to the dose calibrator type and manufacturers recommendations .The methods of data collection included observation ,tests and references from IAEA .

-:Method of date analysis 3.2.3

The data were analyzed using Microsoft office 2007-Excel program under windows –xp ,in addition to equations and statistical methods like the mean ,SD .

Chapter Four

Results

The following chapter will show the general results in connection with the performance of dose calibrator used in the Nuclear Medicine Department of National Cancer Institute at Wad madani , as evaluated by four quality control tests.

4.1 physical inspection:-

Table 4.1.shows physical inspection test of the dose calibrator used:

PTW	MANUFACTURE PTW
CURIEMENTOR3	Model
Not mentioned	Power
(to240 220)	Volt
Not mentioned	Current
Available	Manuals
Available	Radioactive Check source
Ok	Condition
Available	Log book

:Background test 4.2

The background measurement determines the basic ionizing radiation in the vicinity of the measuring system(before inserting the sample).

-:Table 4.2 Shows background test

Reading in µCi	Particulars
3.68	First reading
3.67	Second Reading
3.675	Mean
005.	SD

-:Reproducibility (constancy) test 4.3

The test was carried out to check the daily reproducibility of performance of radionuclide calibrator in the measurements of commonly used radionuclides in N.M . departments for Q.C test

Table 4.3. Shows reproducibility test of radionuclide .calibrator using Cs-137

Reading in µCi	**S.NO**
63	1
62	2
63	3
63.9	4
63	5
63	6
63.26	7
63.69	8
63.3	9
63	10
63.31	Mean

0.51	SD

:4.4Clock accuracy

It is the stabilization of time between two measurements (time required for any measurement should be the same).

Table 4-4 Shows clock accuracy test of radionuclide calibrator

S .No	(Reading (seconds
1	3.52
2	3.27
3	3.42
4	3.58
5	3.56
6	3.43
7	3.35
8	3.32

3.30	9
3.19	10
3.39	Mean
0.123	SD

:**Accuracy 4.5**

The accuracy of a measurement determines how close

. (it is to true value .(reference condition

Table 4-5 Shows accuracy test of radionuclide using Cs-137

(Reading (µCi	No
63.42	1
63.28	2

63.19	3
63.20	4
63.19	5
63.18	6
63.22	7
63.23	8
63.30	9
63.26	10
63.22	12
63.20	13
63.25	14
63.24	15
63.23	Mean
0.0353	SD

:Calculation

: C at 10/11/2015 is equal

$T_{1/2}$ =30.17year

C_0 (certified activity)=67μCi at may/2013

$C = C_0 e^{-\lambda t}$

$\lambda = \ln 2 / T_{1/2}$

t =2.5 year

(A =Mean(From the reading

Accuracy% =A – C/C * 100

Accuracy% =0.04%

:Precision test 4.6

Precision test is a measure 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 .

Table 4.6 Shows precision test of radionuclide calibrator(TC-99m)

Reading in m Ci	S.No

7.670	1
7.668	2
7.667	3
7.666	4
7.665	5
7.665	6
7.664	7
7.664	8
7.663	9
7.663	10
7.664	11
7.664	12
7.664	13
7.662	14
7.663	15
7.665	Mean
0.007	SD

4.7 :-linearity test

The purpose of this test is to check the linearity of the activity response of a radionuclide calibrator over the range of activities for which it is to be used.

Table 4.7 shows linearity test of radionuclide calibrator, using Tc-99m

S.NO	(Time (hrs	Expected (reading(mCi	Calibration reading in mCi
1	0	Not found	254.4
2	1	226.7	227
3	2	201.9	201.4
4	3	179.9	180.4
5	4	160.3	160.7
6	5	142.8	142.7
7	6	127.2	126.8

Figure 4.1 shows the relation between time and activity

-:Geometry Test 4.8

Testing for geometry independence ensures that indicated activity does not change with volume or configuration

Table4.8 shows the geometry test

(Activity (m Ci	(Sample Volume(ml	NO
21.83	1	1
21.69	2	2

21.52	3	3
21.66	4	4
21.60	5	5
21.67	6	6
21.43	7	7
21.47	8	8
21.39	9	9
21.55	10	10

-:Comparison between Q.C test at RICK and NCI

:Table4.9 The background test in RICK and NCI

NCI	RICK	
3.675µci	87mci.	Mean
0.005µci	0.045mci	SD

:Table4.10 Reproducibility test in RICK and NCI

NCI	RICK	
µci 63.31	µci 155.08	Mean
0.51	0.579	SD

:Table4.11Clock accuracy test of radionuclide in RICK and NCI

NCI	RICK	
sec 3.39	sec 1.26	Mean
sec 0.123	sec 0.462	SD

:Table4.12 Accuracy test in RICK and NCI

0.039%	%RICK accuracy
0.047%	%NCI accuracy

:Table4.13 Precision test in RICK and NCI

NCI	RICK	
7.665	2.774	Mean

0.007	0.006	SD

Chapter five

5.1 Discussion:

Concerning the physical inspection test(table 4-1) the dose calibrator looks in a good condition.

It was clear that these features help in providing good outcomes in terms of imaging capacity of the department. It was found that imaging procedures were so organized that every particular study was usually done on a known separate day during the week, and this minimizes errors during a radiopharmaceutical preparation.

Table(4-2) shows background test, which showed that the result of test was in the normal exposure range(3.675±0.184µci).The implementation of radiation protection rules was good in some aspects of the work. The involvement of technologists directly in management may enhance the implementation of the rules concerning quality control of radiopharmaceuticals (IAEA-TECDOC-602).

Table (4-3) results concerning the reproducibility test of radionuclide calibrator, the day reproducibility of performance of radionuclide calibrator was within the normal .(range with very small error(63.31±0.51

Concerning clock accuracy test(table4-4) ,the stabilization of time between two measurements showed significant .(difference (3.39±0.123

In table (4-5) the result obtained concerning accuracy showed that the dose calibrator had an accurate reading and the percentage of error was 0.04% which is accepted according to the world standard (IAEA TECDOC-602 and1599). The percentage of accuracy of dose calibrator was .(easily detected by using accuracy equation (see table 4-5

The precision test (table 4-6) , was a measure of the spread of values obtained from a sequence of measurements. These results showed high precision in dose .calibrator

Table (4-7) showed linearity test of the radionuclide calibrator ,after time elapse in order to compare between the expected reading (according to equation) and .measured(true) reading calibrator

Table (4-8) showed geometry test to show if there is any change in the activity reading according to the increase of the activity volume. The test showed no change and the activity result was within the accepted range.

Table(4-9) showed comparison between the background levels at RICK and NCI. The test showed that the background radiation is lower at NCI.

Table(4-10) showed the reproducibility test at the centers showing almost the same results.,

Table (4-11) showed the clock accuracy test in RICK and NCI , in which the device accuracy is for better in NCI(0.123)than in RICK (0.462).(

Table (4-12) showed the accuracy test in RICK(0.04%) and in NCI (0.04%) , which agave the same results .

Table(4-13) showed the precision test in RICK (0.006) and in NCI (0.007) , which are almost the same .

:Conclusion.5.2

According to the findings of the study ,it was found that all the tests performed at the National Cancer Institute at Wad-madani ,Gazira state were within the acceptable range and the dose calibrator used is of a good condition and does not need any recalibration or maintenance for the time being .

As for comparison tests between RICK and NCI devices ,the test showed no significant difference in most of the results of the two centers .

5.3 Recommendations:

Considering the results and findings of this evaluation of the performance of dose calibrator which were included in

this study , the following recommendations could be proposed:

- Preparation and formulation of quality control system should be applied in nuclear medicine practice in Sudan for all nuclear medicine equipment.
- Providing the relevant documentation to the nuclear medicine centers to implement a comprehensive QC program properly.
- Encouraging the cooperation between the relevant regulatory bodies and nuclear medicine centers in Sudan.
- Encouraging the cooperation between the relevant regulatory bodies in Sudan and International Atomic Energy Agency, to provide technical support, training courses and quality control tools for nuclear medicine centers through regional and national projects.
- Q.C programs in the N.M department should be performed at daily , weekly and annually basis.
- Training programs to the N.M staff on Q.C should be set up and implemented in any N.M department in Sudan .

-:Study limitations

The tests were done using one radionuclide (137Cs) , because it was the only available radionuclide at the department under study .More than one radionuclide are usually used in these tests for more accuracy and dependence .

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:Appendices

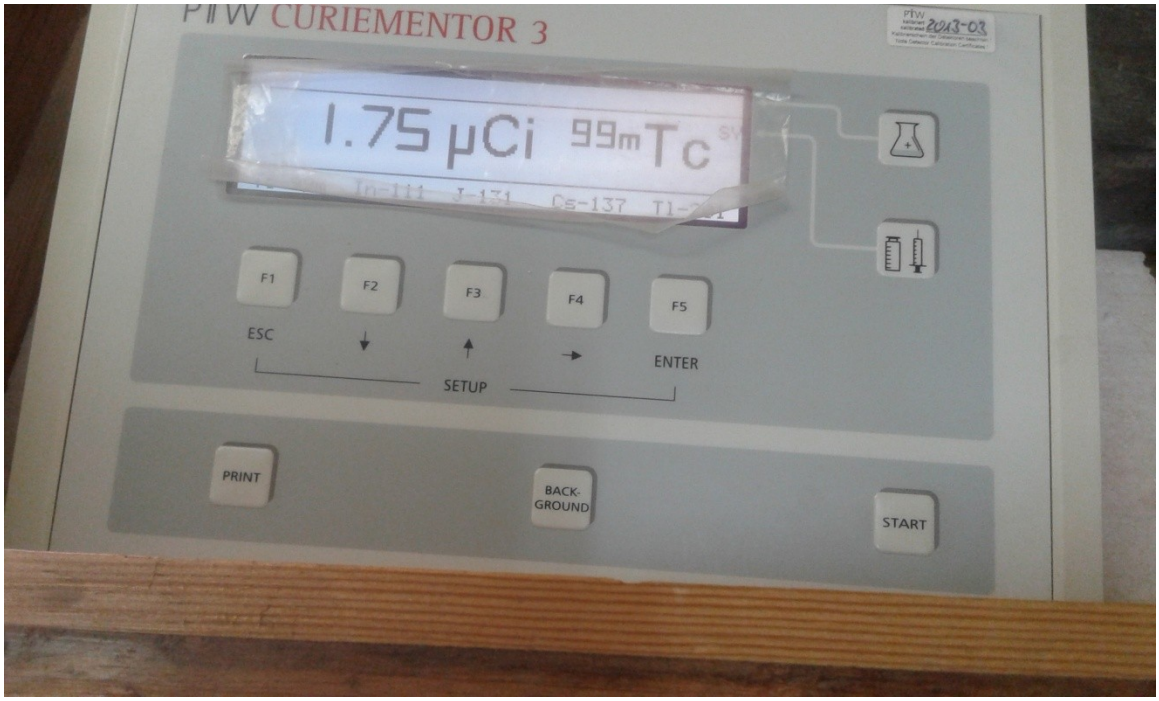

Fig 5.1 Shows the dose calibrator model PTW CURIEMENTOR3

Fig 5.2 Shows the dose calibrator model PTW CURIEMENTOR3

.Fig 5.3 Shows standard radionuclide source 137 Cs

.Fig 5.4 Shows standard radionuclide source 137 Cs

Fig 5.5 Shows the dose calibrator model PTW CURIEMENTOR3

Fig 5.6 Shows the dose calibrator model PTW CURIEMENTOR3