Sudan University of Science and Technology

College of Graduate Studies

Assessment of Dose Calibrator Performance in the Nuclear Medicine Department of Elnilein Medical Diagnostic Centre

تقويم أداء جهازقياس جرعات النشاط الإشعاعي بقسم الطب النووي بمركز النيلين للتشخيص الطبي بالخرطوم

A Study Submitted in Partial Fulfillment for the Requirements of M.Sc Degree in Nuclear Medicine Technology

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الآيـة

قال الله تعالى:

﴿وَ لَا تَمْشِ فِي الأَرْضِ مَرَحاً إِنكَ لَن تَخْرِقَ الأَرْضَ وَ لَن تَبْلُغَ الجِبَالَ طُولاً ﴾

صدق الله العظيم

سورة الإسراء، الآية ٣٧

Dedication

To my mother

If I had to choose between loving you and breathing, I would use my last breath to tell you I love you,,

To my father

For earning an honest living for us and for supporting and encouraging me to believe in myself,,

To my dearest friend; Hadeel

Who used to answer the call in the middle of the day or night,

I'm so grateful for having you,,

Acknowledgment

All praises to Allah, for all countless gifts that he gave us,,

It is a great pleasure to acknowledge my deepest thanks and gratitude to **Dr. AwadAdlan**, for his kind supervision, for his creative and comprehensive advice until this work came to existence, it is a great honor to work under his supervision.

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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 that is working in Nuclear medicine department of Elnilein Medical Diagnostic Center in Khartoum State.

Four quality control tests were carried out using two standard radionuclides $Cs^{١٣٧}$ and $Co^{٥٧}$. Tests included accuracy linearity, constancy and geometry.

All results that were obtained from the study were compared with the international standard (± ١٠٪) and results showed that the dose calibrator has good performance and there is no need for any correction tables or factors or maintenance for the time being.

ملخص الدراسة

يتم استخدام النظائرالمشعة بمختلف الأنواع في الطب النووي لإجراء الفحوص الطبية التشخيصية و لعلاج بعض الأمراض . وينبغي أن يتم تحديد الجرعات الإشعاعية لهذا الغرض قبل إعطائها للمريض. و يلعب مقياس جرعات النشاط الإشعاعي دوراً كبيراً في هذا المجال، حيث يقيس جرعة أشعة غاما وبيتا ذات الطاقات المختلفة بصورة دقيقة للحصول على صور و نتائج ذات جودة عالية و بالتالي الحصول على تشخيص سليم و علاج ناجع.

أجريت هذه الدراسة لتقييم أداء أجهزة قياس النشاط الإشعاعي المستخدمة في قسم الطب النووي بمركز النيلين للتشخيص الطبي في ولاية الخرطوم.

تم إجراء أربعة إختبارات ضبط جودة بإستخدام إثنين من النويدات المشعة المعيارية السيزيوم-١٣٧ و الكوبالت-٥٧، تضمنت الإختبارات إختبار الدقة، إختبار الخطية، إختبار ثبات القراءات و إختبار الشكل الهندسي لإبر الحقن والقوارير المستخدمة في تجهيز الجرعات الإشعاعية.

كل النتائج المتحصل عليها تمت مقارنتها بالمعيار العالمي لنتائج ضبط الجودة (± ١٠%)، و أظهرت النتائج أن جهاز قياس الجرعة المستهدف بالدراسة يعمل بصورة جيدة و لا يحتاج لجداول أو عوامل تصحيح أو صيانة.

Table of Contents

Topic	Page No.
الآية	I
Dedication	II
Acknowledgement	III
Abstract (English)	IV
Abstract (Arabic)	V
List of contents	VI
List of tables	VII
List of figures	VIII
List of abbreviations	IX - X
Chapter one: Introduction	١
Chapter Two: Section one – Literature Review	٥
Chapter Two: Section Two – Previous Studies	١٨
Chapter Three: Materials & Methods	٢٢
Chapter Four: Results	٣٥
Chapter Five: Discussion, Conclusion & Recommendations	٤٠
References	٤٤
Appendices	٤٦

List of Tables

Table	Page
١. Table ٤,١. Background test of radionuclide dose calibrator	٣٥
٢. Table ٤.٢. Accuracy test of radionuclide dose calibrator	٣٦
٣. Table ٤,٣. Constancy test of radionuclide dose calibrator	٣٨
٤. Table ٤,٤. Mean and standard deviation errors in source geometry of dose calibrators measured in Elnilein & RICK centers.	٣٩

List of Figures

Figure	Page No.
١. Fig ٢,١. Radionuclide dose calibrator	٨
٢. Fig ٣,١. The dose calibrator type CRC-٢٥R	٢٣
٣. Fig ٣,٢. Display unit of the calibrator system	٢٤
٤. Fig ٣.٣. Standard radionuclide sources ^{٥٧}Co, ^{١٣٧}Cs and ^{١٣٣}Ba	٢٥
٥. Fig ٣.٤. Standard radionuclide sources ^{٥٧}Co and ^{١٣٧}Cs in RICK centre	٢٦
٦. Fig ٤,١. The linearity of activity response test, decay curve of ^{٩٩m}Tc for CRC-٢٥R dose calibrator	٣٧

List of Abbreviations

ANZSNM	Australian and New Zealand Society of Nuclear Medicine
Atm	Atmospheric
Bq	Becquerel
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
Ci	Curie
CNEN	National Commission of Nuclear Energy
DTPA	Dithylenpenta acidic acid
ETSI	European Telecommunication Standards Institute
IAEA	International Atomic Energy Agency
IEC	International Electrotechnical Committee
ISO	International Standardization Organization
LCI	Calibration Laboratory of institute
MAA	Macro Aggregated Albumin
NM	Nuclear Medicine

NEMA	National Electrical Manufacturers Association
NRC	Nuclear Regulatory Commission
QA	Quality Assurance
QC	Quality Control
RICK	Radiation and Isotope Centre of Khartoum
WHO	World Health Organization

Chapter one

Introduction

Chapter One

Introduction

١,١. Introduction:

Nuclear medicine procedures use 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 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 radioactivity 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 electrotechnical committee, IEC ٦١٣٠٣ "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 ٦٠ requirement to keep

the radiation dose as low as achievable for patients. 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 ١ 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-٩٩m 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 +/- ٥ to ١٠ %, depending on the radionuclide of interest and measurement conditions (Zeinali*et al*, ٢٠٠٨).

١,٢. Problem of the Study:

There are many problems due to absence of quality control of dose calibrator which is used for dose measurements in Elnilein nuclear medicine department; Therefore many patients my take over doses due to uncertainties in dose, to the best of the researcher knowledge. Moreover, accuracy of radionuclide dose calibrator and reliability cannot be easily determined by the user.

١,٣. Study Objectives:

١,٣,١. General Objective:

- The main objective of this study is to assess the performance of the dose calibrator that is being used in Elnilein nuclear medicine departments.

١,٣,٢. Specific Objectives:

- To insure the accuracy of calibrator.
- To measure the deviation percent of calibrator from standard level.
- To measure background tests.
- To measure dose calibrator accuracy.
- To measure dose calibrator linearity.
- To measure dose calibrator constancy.
- To evaluate dose calibrator geometry dependency.

١,٤. Study organization:

The study consists of five chapters. Chapter one deals with introduction, problem of the study and objectives. Chapter two consists of the literature review related to the current study. Chapter three deals with materials and methods. Chapter four deals with the results and chapter five deals with conclusion, discussion and recommendations.

Chapter Two

Literature Review

Chapter two

Literature review

٢,١. Theoretical Background:

٢,١,١. Introduction to Radionuclide "Dose" Calibrators (Activity Meters):

Radiation detectors consist of a variety of devices used to detect radiation from a specific region of the electromagnetic spectrum. In nuclear medicine, the patient is the source of the radiation after receiving a radiopharmaceutical particular to the nuclear study. In addition to imaging, a technologist may have a variety of detection needs; therefore, a complete understanding of radiation detectors is required.

This detection needs to include the following:

- Measuring the activity of patient’s dose.
- Measuring the radiation exposure of a material or room.
- Measuring/ imaging the amount of activity within a patient.
- Measuring the amount of activity within a sample.

Proper operation of the detectors is maintained by scheduled quality control checks and troubleshooting. Quality control procedures are unique to each radiation detector. Published guidelines specify that quality control of equipment must be performed routinely and documented. These guidelines are issued by several organizations, including the Society of Nuclear Medicine, the American Society of

Nuclear Cardiology, the American College of Radiology, the Joint Commission on the Accreditation of Health Organizations, and the Nuclear Regulatory Commission, in addition to agreement states and other radiology societies. Specific procedures required for each instrument may be further defined by the manufacturer and the National Electrical Manufacturers Association (NEMA). In addition, current accreditation bodies indicate the minimum quality control to be performed on equipment; these bodies include the American College of Radiology and intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories, (Nichols et al ٢٠٠٦).

٢,١.٢. Basic Principles:

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 radionuclides 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 radionuclides is always to be in units of activity. Most radionuclide calibrators have selector switches, selector push-buttons or plug-in modules for different radionuclides, 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-١٩٩١).

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.

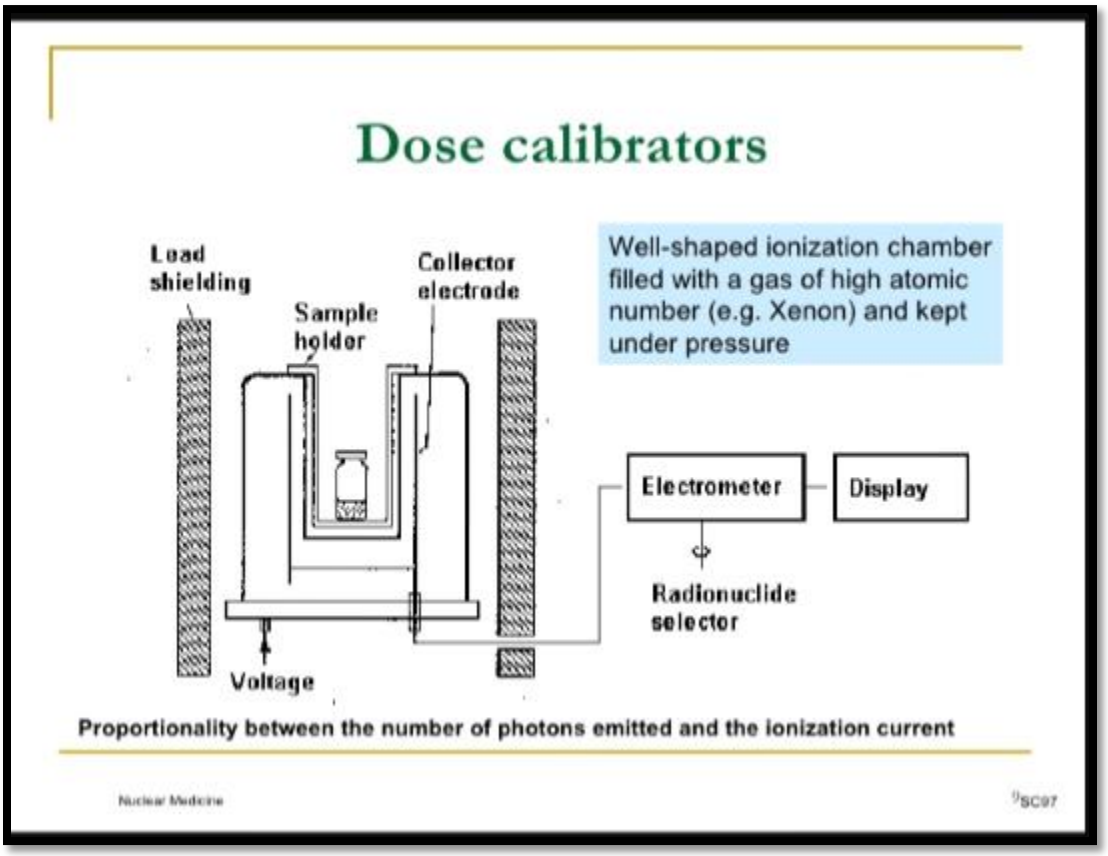

Fig ٢,١.Shows radionuclide dose calibrator

٢,١,٣. 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 ±١٪ of their stated activities, but may be only within ± ٣٪, or even ± ٥٪, 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 radionuclides giving low-energy radiations, differing radiation absorption characteristics of the material may cause significant measurement errors. (IAEA-TECDOC١٩٩١).

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 radionuclides 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-١٩٩١).

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 ٢-١ 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-١٩٩١).

٢.١.٤. International Standards:

International standards 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 the standards.

Nuclear instruments are rather specialized topic, as they must meet not only general requirements concerning QC, but also strict rules related to ionization radiation. From among several tens of thousands of international standards, about five hundred connected with ionization radiation were found (IAEA-TECDOC-١٥٩٩, ٢٠٠٨).

٢,١,٥. Organizations Developing International Standards:

There are several organizations developing international standards: ISO, IEC, CEN, CENELEC and ETSI.

ISO is a network of the national standards institutes of ١٥٤ countries on the basis of one member per country. ISO's international standards and deliverables supports, among other things, improvement of quality, safety, security, environmental and consumer protection.

IEC is the leading global organization that prepares and publishes international standards for all electrical, electronic and related technologies. One of the main IEC's objectives is to assess and improve the quality of products and services covered by its standards.

CEN, CENELEC and ETSI are three standardization bodies recognized as competent in the area of voluntary technical standardization. Together they prepare European standards and make up the "European standardization system". The European standards (EN's) must be transposed into national standards and conflicting standards should be withdrawn (IAEA-TECDOC-١٥٩٩, ٢٠٠٨).

٢,١,٦. Quality Assurance and Quality Control in Nuclear Medicine:

It is now widely recognized that the attainment of high standards 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 interference to 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 actual procedures; the analysis and interpretation of data; the reporting of results and, finally, the keeping of records (IAEA-TECDOC-٢٠٦, ١٩٩١).

٢,١,٧. General Principles of Quality Assurance:

Quality assurance (QA) is defined as: "all those and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality" (ISO).

According to WHO three main objectives should be envisaged when quality assurance programmes are considered:

١. Improvement in the quality of the diagnostic information;
٢. Use of a minimum amount of radionuclide activity to ensure the production of the desired diagnostic information;
٣. Effective use of available resources.

Quality is basically to fulfill the expectations the referring physicians and the patients have on the nuclear medicine service. QA is a management tool aimed to ensure that every examination or treatment is performed with a high medical quality and with respect to the general principles of radiation protection (justification and optimization). This should be achieved by using accepted clinical protocols, by having well trained personnel and using properly selected and functioning instrumentation. In more detail a QA programme in nuclear medicine should include:

a) **Procedure** (i.e. patient history and signs, diagnostic question, appropriateness of investigation, contraindications).
b) **Planning of procedure** (i.e. reliable administrative procedures, patient information, and patient preparation).
c) **Clinical procedure** (i.e. approved suppliers and materials, storage, preparation, clinical environment, patient handling and preparation, equipment performance, acquisition protocols, waste disposal).
d) **Training and experience** of nuclear medicine specialists, physicists and technologists and others involved.
e) **Data analysis** (i.e. processing protocol, equipment performance, data accuracy and integrity).
f) **Report** (i.e. image review, results and further advice).

g) **General outcomes:** (i.e. clinical outcome, radiation dose, patient satisfaction, referring physician satisfaction).

h) **Audit**: internal and external auditing for all procedures.

A quality control (QC) programme should be introduced and aimed to regularly check the outcome of different components of the QA programme.

Quality assurance is not only important for maintaining high standards of clinical practice in the use of ionizing in medical care, but also for maintaining high performance of equipment. In each department there should be a continuous review process to monitor clinical and equipment performance in accordance with national and international standards. There should also be routine and a policy for purchasing equipment.

The department's quality assurance programme for equipment should include acceptance rests carried out initially to provide a baseline of data, and subsequent routine tests carries out at appropriate frequencies to monitor the constancy of various aspects of performance (PAHO Washington D.C., ١٩٩٧).

٢,١,٨. Principles of quality control of instruments:

A fundamental principle in the quality control of nuclear medicine instruments is that it should be undertaken as an integral part of the work of the nuclear medicine unit and by members of the unit staff themselves. However, some aspects must be treated in collaboration with maintenance staff.

The quality control of each instrument should have as its starting-point the selection and acquisition of instrument itself, since instruments may differ widely in their performance. The choice of an appropriate site for installation of instrument should likewise be considered within the scope of quality control, in as far as it may influence performance.

Once received and installed, an instrument should be submitted to a series of acceptance tests designed to establish whether its initial performance conformed to the manufacturer's specifications. At the same time, reference tests should be carried out to provide data against which its subsequent performance can be assessed by routine testing weekly, monthly, quarterly, yearly ect. Finally operational checks, carried out each day the instrument is used, should be put in force. Careful records of the results of all these tests should be kept and, if these reveal unsatisfactory performance, appropriate corrective action should follow.

Such quality control does not, of course, obviate the need for the usual preventive maintenance procedure, which should still be carried out on a regular basis.

The success of such a scheme depends above all on is understanding and acceptance by all concerned. It farther requires a clear definition of responsibilities, strict adherence to test schedules and protocols, and proper facilities for the follow-up of test results (IAEA-TECDOC-٦٠٢, ١٩٩١).

٢,١,٩. Implementation of Quality Control:

The quality control programme must contain recommended schedules and protocols for acceptance and routine testing of different classes of instruments, such as radionuclide “dose” calibrator (activity meters), counting systems for gamma-radiation measurements in vitro, counting system for gamma-radiation in vivo, rectilinear scanners and scintillation cameras.

It is emphasized that the test schedules and test protocols presented are intended for guidance only. The choice of tests and the frequencies with which they are carried out have to take account of the situation in the individuals nuclear medicine unit and the status of its instruments. Furthermore, it is not possible to draw up detailed test protocols applicable to all instruments in particular class. Nuclear medicine units should, therefore, modify the given protocols to suit their own individual instruments and test devices. What is indispensable is that one appropriate individualized schedules and protocols have been agreed upon, they should be strictly followed (IAEA-TECDOC-٦٠٢, ١٩٩١).

٢,١,١٠.Dose Calibrator Quality Control:

It is important that dose calibrators provide an accurate indication of the activity administered to the patient. For diagnostic studies, too large a dose will result in unnecessary radiation exposure to the patient, while a dose which is too low may prolong the study time or result in sub-optimal image. For therapy doses, it is even

more important that the correct activity is administered to ensure that the therapeutic effect is achieved without excessive radiation burden to the patient (ANZSNM, Version ٥,٧, ١٩٩٩).

٢,٢. 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 Zeinali١, N. et al ١٩٩٧ conducted an investigation on the performance of dose calibrators in nuclear medicine centers in Iran to investigate the status of the nuclear medicine (NM) centers in Iran for the performance of dose calibrators, ١٨ out of ٥٤ centers providing NM services in Iran were randomly selected and inspected in١٩٩٧. In the first phase of the study the selected centers were inspected for performance 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 ٢٠٠٦, ٢٨ out of ٧٥ NM centers were investigated for QC tests performance.

According to the obtained results in the first phase of the study, ١٠ 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 ٦ 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., ٢٠٠٨; ٦ (٢): ٦٤٦٩

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 (de Bessa١, et al ٢٠٠٧). (Survey on quality control of radiopharmaceutical dose calibrators in nuclear medicine units in the city of São Paulo, SP, Brazil) was performed to evaluate the accuracy of measurements of seven dose calibrators activities, utilizing sources of clinically significant radionuclides at the calibration laboratory of Instituto de PesquisasEnergéticas e Nucleares.

The survey results 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 with the national regulations (±٥٪).

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.

Zhenya Krasteva١١SBALNP “Sv . Naum” , Sofia , Bulgaria carried 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 measurements Tc-٩٩m, Cs-١٣٧ and Ba-١٣٣. To ensure the proper operation of a dose calibrator, four QC parameters were tested: accuracy, precision, constancy and linearity.

The results from the measurements showed that the parameters that were traced for dose calibrators were within the Bulgarian and International standards. It was essential to perform daily testing for background activity and constancy. Deviations from normal values of these two parameters were the first sign of degradation of the dose calibrator. Regular QC should cover precision, accuracy and linearity of the instrument. According to IAEA standards and Ordinance **NO**

٣٠ (٣١October ٢٠٠٥) 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

Chapter Three

Materials and Methods

Introduction:

This study is an experimental study designed and conducted in Elneelain Medical Diagnostic Center which is located in Khartoum state. The QC tests in this work were conducted in accordance with the internationally accepted standards for dose calibrators. The tests included were constancy (reproducibility), accuracy, linearity, and geometry.

٣,١. Materials:

٣,١,١. Dose calibrator:

The nuclear medicine department of Elnilein Medical Diagnostic Center uses dose calibrator model CAPINTEC CRC-٢٥R, manufactured on July ٢٠٠٨ Fig (٣,١). This model's ionization chamber is a thin wall ,deep well, high pressure type ١٣,٦ weight with dimension of ٢٦ cm high and ٦ cm diameter and interconnecting cable of ٣,٧ m.

Measurement range is auto ranging with maximum activity of ٢٥٠GBq(٦ Ci), and resolution of ٠,٠٠١MBq(٠,٠١ µCi) maximum, response time within ٢ second, for very low activity sample ٤ - ١٦ seconds.

Fig ٣،١ shows the dose calibrator type CRC- ٢٥R

The display unit of the system consists of display screen which is dot matrix liquid crystal type with direct reading in Bq or Ci. It contains ٨ pre-set nuclear keys which include ^{٦٧}Ga, ^{٩٩m}Tc, ^{١٨}F, ^{١١١}In, ^{١٢٣}I, ^{١٣١}I, ^{١٣٣}Xe and ^{٢٠١}TI. It also contains ٥users, U١, U٢, U٣, U٤ and U٥ (Fig ٣،٢).

Fig ٣,٢ shows the display unit of the system consists of display screen with direct reading in Bq or Ci

The system memory contains ٤ standard sources, ^{٦٠}Co, ^{٥٧}Co, ^{١٣٣}Ba and ^{١٣٧}Cs. It also contains over ٨٠ nuclides with calibration numbers and half-lives.

٣,١. ٢. Standard Radionuclide Source:

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

There were two standard radionuclide sources used in this study to perform quality control tests (accuracy and constancy), Cs١٣٧ and Co٥٧. These standard sources are only available in the radiation and isotope center of Khartoum. Table (٣،١) contains specifications of the two standard sources that were used in the study.

The tests for the linearity and geometrical dependence were conducted by the use of radioisotope ^{٩٩m}Tc, which is available in the two centers with short half-life of ٦،٠٢ hours.

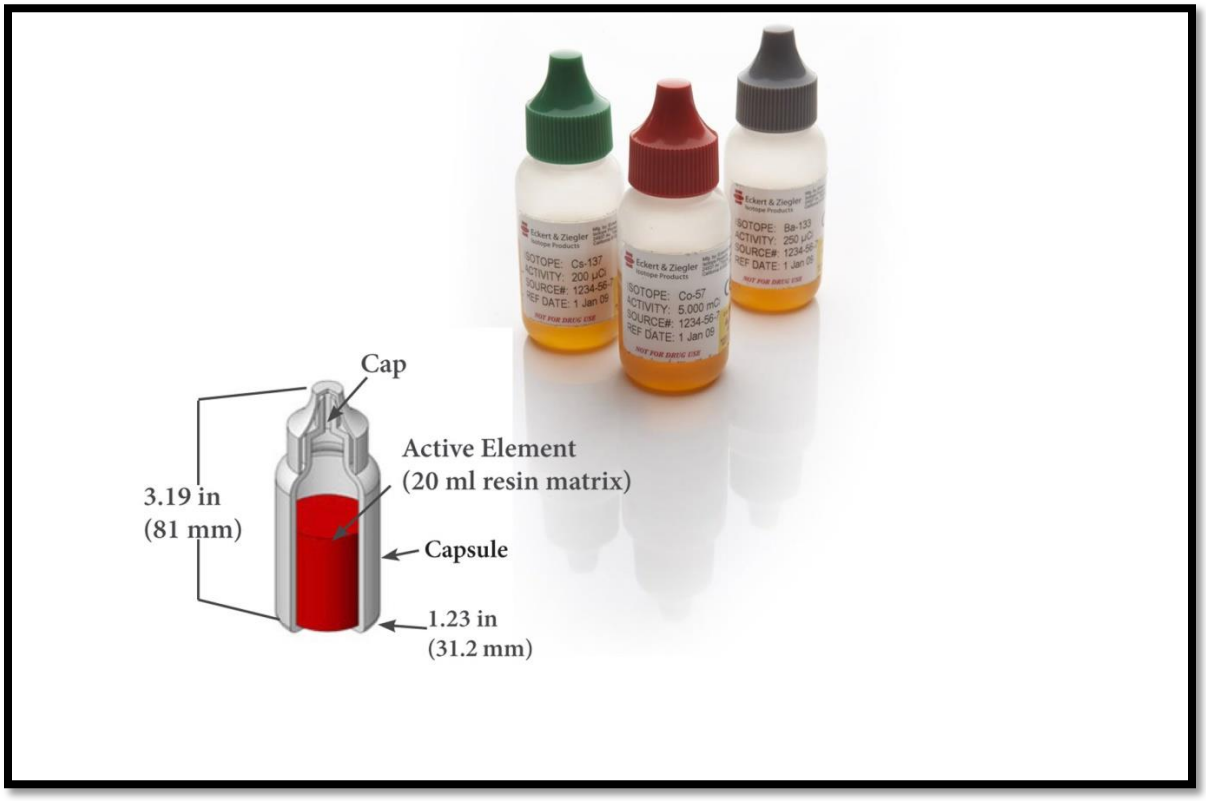

Fig ٣،٣ shows standard radionuclide source Co٥٧, Cs١٣٧ and Ba١٣٣.

Fig ٣،٤ shows standard radionuclide source ^{٥٧}Co and ^{١٣٧}Cs of RICK center.

٣,٢. Methods:

The researcher performed the following tests which included accuracy, constancy, linearity and geometry on CAPINTEC CII dose calibrator model CRC-٢٥R using $Cs^{١٣٧}$, $Co^{٥٧}$, and $Tc^{٩٩}m$ in form of pertechnetate ($NaTco_{٤}$).

The dose calibrator was tested in place without any movement; and with some modifications to the quality control procedures according to the calibrator and manufacturer recommendation.

٣,٢,١. Accuracy Test:

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. At least two sources with different principal photon energies (such as $Co^{٥٧}$, $Co^{٦٠}$, or $Cs^{١٣٧}$) should be used. The researcher used $Cs^{١٣٧}$ and $Co^{٥٧}$ according to the standard directions as follows:

١. Assay a calibrated reference source at the appropriate setting (i.e. use the $Co^{٥٧}$ setting to assay $Co^{٥٧}$).

٢. Insert the source into the source holder by means of the remote handling device and introduce the source holder into the instrument.

٣. Allow sufficient time for the reading to stabilize.

٤. Remove the source, this type of system subtract the background automatically.

٥. Record this measurement. Repeat for a total of three determinations.

٦. Average the three determinations. The average value should be within ± ١٠٪ of the certified activity of the reference source, mathematically corrected for decay.

٧. Repeat the procedure for the other calibrated reference source. If the average value does not agree, within ± ١٠٪, with the certified value of the reference source, the dose calibrator must be repaired or replaced.

Accuracy test records included:

a) The model and serial number of the dose calibrator;
b) The model and serial number of each source used and the identity of the radionuclide contained in the source and its activity;
c) The date of the test;
d) The results of the test;
e) The instrument settings; and

f) The name of the individual performing this test.

٣,٢,٢. Constancy Test:

Constancy means reproducibility in measuring a constant source, usually Cs١٣٧, over a long period of time. The Cs١٣٧ source is measures every day. Values are recorded in the dose calibrator logbook and are compared with recent values to determine if the instrument is maintaining constancy on a daily basis. The researcher performed this test for three days to each model according to the following instructions:

١. Assay reference source using the appropriate dose setting (i.e. use the Cs١٣٧ setting to assay Cs١٣٧).
٢. Confirm the proper operation of the automatic background subtract circuit, to give accurate net activity of Cs١٣٧ source.
٣. Log in a book the net activity of Cs١٣٧ source.
٤. Repeat the above procedure for all commonly used radioisotope settings using Cs١٣٧ source.
٥. Log the results. The regulation requires repair or replacement if the error exceeds ± ١٠٪.

Constancy check record included:

a) The model and serial number of the dose calibrator;

b) The identity and decay corrected activity of the radionuclide in the check source;

c) The date of the check;

d) The activity measured;

e) The percent error;

f) The instrument settings; and

g) The initials of the individual who performed the check.

٣,٢,٣. Linearity Test:

Linearity means that the calibrator is able to indicate the correct activity over the entire range of use of the calibrator. The test is performed at installation and at least every three months thereafter.

The test was inducted by the use of radioisotope ٩٩mTc with the short half-life of ٦,٠٢ hours.

This test was carried out using an amount of ١,٨٥٠ GBq (٥٠ mCi) ٩٩mTc as solution in a vial and measuring the activity by a dose calibrator in period of time (٧٢ hrs). If the measured error of activities of the source by the dose calibrator exceeded ± ١٠٪, the instrument was considered not to function properly.

The researcher performed the test using the decay method:

١. Assay the ٩٩mTc, vial in the dose calibrator; background subtracted automatically to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity.

٢. Repeat the assay after ١ hour, two hours, ٣ hrs, ٦ hrs, ……

٣. On a sheet of semi-log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed.

٤. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line using the following equation:

$$\frac{\boldsymbol{A\ observed - A\ line}}{\boldsymbol{A\ line}} = \boldsymbol{deviation} \qquad (\mathbf{1})$$

٥. If the worst deviation is more than plus or minus ٠,١٠, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by dose calibrator "true activity".

Linearity test records include:

a) The model and serial number of the dose calibrator;

b) The calculated activities;

c) The measured activity;

d) The data of the test; and

e) The name of the individual performing this test.

٣,٢.٤. Geometry Test:

Testing for geometry dependence ensures that the indicated activity does not change with volume or configuration. This test must be performed, upon installation, over the range of volumes and volume configurations for which it will be used and should be done using a syringe that is normally used for injections. It is also performed after service or dose calibrator movement.

Procedure:

A) Syringe test:

The following test should be done with ٥ml plastic syringe.

١. Place a small sample (٠,٥ ml) of $Tc^{٩٩m}$ in a syringe. Measure the activity of the sample.

٢. Remove the syringe from the calibrator, draw an additional ٠,٥ ml of non-radioactive saline to the original volume (total volume ١ ml) and repeat the measurement. Record the reading.

٣. Repeat (step ٢) by adding ١ ml four times until final volume ٥ ml.

٤. Select as a standard the volume closest to that normally used for injections (٠,٥ ml). For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor.

٥. All of the volumes should be within ±١٠٪.

٦. If any correction factors are greater than ١,١٠ or less than ٠,٩٠, or if any data points lies outside the ١٠ percent error lines, it will be necessary to make a correction table or graph that will allow conversion from "indicated activity" to "true activity".

B) Vial test:

The following test will be done with ١٦ ml glass vial.

١. Draw ١,٠ ml of the $Tc^{٩٩}m$ solution into a syringe and inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

٢. Remove the vial from the calibrator and, using a clean syringe, inject ٢,٠ ml of non-radioactive saline, and assay again. Record the volume and millicuries indicated.

٣. Repeat "step ٢" by adding ٢ ml, until final volume ١٥ ml. the entire process must be completed within ١٠ minutes, or, if not, decay-correct the activity.

٤. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits (١٠ ml). For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor.

٥. All of the volumes should be within ±١٠٪.

٦. If any correction factors are greater than ١,١٠ or less than ٠,٩٠, or if any data points lies outside the ١٠ percent error lines, it will be necessary to make a correction table or graph that will allow conversion from “indicated activity” to “true activity”.

Geometry dependence test records include:

a) The model and serial number of the dose calibrator;

b) The configuration of source measured;

c) The activity measured for each volume;

d) The data of the test; and

e) The name of the individual performing this test.

Chapter Four

Results

Chapter Four

Results

This experimental study dealt with the evaluation of quality control program of Technetium-٩٩m dose calibrator. The aim of this study was to highlight the importance of the quality assurance program in nuclear medicine department. In addition to its role in improving the image quality and reducing the dose to patient that could not be reached without quality control especially in Technetium-٩٩m dose calibrator.

٤,١. Background test:

The background measurement determines the basic ionizing radiation in the vicinity of the measuring system.

Table ٤-١. Shows background test

First reading	٠.٨٣mCi
Second Reading	٠,٩٢mCi
Mean	٠,٨٧٥mCi
SD	± ٠,٠٦٣

٤,٢. Accuracy:

The accuracy of a measurement determines how close it is to the true value (reference condition).

Table ٤-٢. Shows accuracy test of radionuclide calibrator

Reading No.	***Reading (µCi)***
١	١٥٥,٠
٢	١٥٥,٤
٣	١٥٥,٧
٤	١٥٥,٢
٥	١٥٥,٥
٦	١٥٥,٨
٧	١٥٥,٢
٨	١٥٥,٦
٩	١٥٥,٤
١٠	١٥٥,١
Mean	***١٥٥.٣٩***
SD	± ٠,٢٦

٤,٣. Linearity test:

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

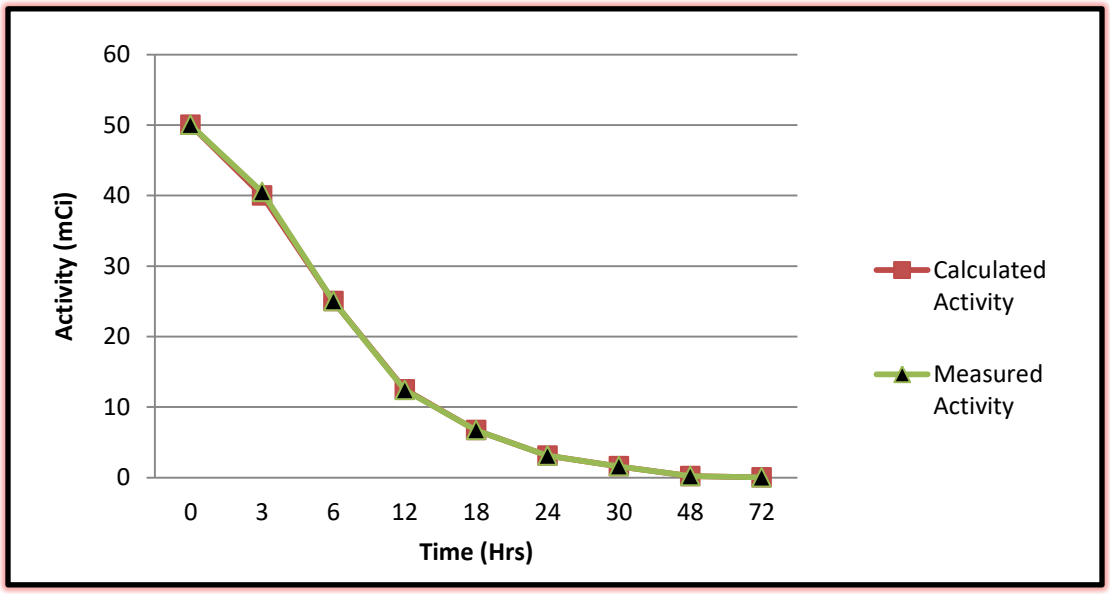

Fig٤,١. Shows the linearity of activity response test, decay curve of ^{99m}Tc for CRC-٢٥R dose calibrator

٤,٤. Constancy Test:

The constancy test checks for drift of the dose calibrator over time. It is performed by measuring a long lived radionuclide (e.g. Co٥٧, Cs١٣٧) on a daily basis. The daily readings are plotted vs time on a semi-log graph which has also the decay line and ±١٠٪ acceptance limits superimposed on

it. Any readings which fall outside the acceptance limits showed be repeated. If the repeated reading also falls outside the acceptance limit, the problem should be investigated and rectified.

Table ٤-٣. Shows constancy test of radionuclide calibrator

Reading No.	***Reading in µCi***
١	١٥٥,٣
٢	١٥٥,٨
٣	١٥٥,٧
٤	١٥٥,٧
٥	١٥٤,٦
٦	١٥٤,٧
٧	١٥٤,٤
٨	١٥٥,١
٩	١٥٥,٤
١٠	١٥٥,١
Mean	***١٥٥,٠٨***
SD	***± ٠,٥٧٩***

٤,٥. Geometry Test:

Table ٤-٤.Shows the mean and standard deviation of errors in Geometry testof dose calibrator measured in Elnielin Center and Radiation Isotopes Center of Khartoum (RICK)

	Elnielin Center	**Percentage**	**RICK**	**Percentage**
Mean	١,٢٥	٪٤,٩	٠,١٧٢	% ٣,٦٢
Standard Deviation	٠,١٢١		٠,٧١	

Chapter Five

Discussion, Conclusion and Recommendations

Chapter Five

Discussion Conclusion and Recommendations

٥.١. Discussion:

Quality control is required to ensure that nuclear medicine equipment is functioning properly. These quality control tests are intended to detect problems before they have impact on clinical patient studies.

For radionuclide dose calibrators, the researcher managed to evaluate the performance of the dose calibrator working in nuclear medicine department of Elnilien Medical Diagnostic Centre. The tests included were accuracy, constancy, linearity, and geometry. These four tests were performed using Capintec CRC-٢٥R.

The results of the quality control tests revealed that the parameters that were traced for dose calibrators were within international standards (±١٠٪). It is essential to perform daily for background activity, constancy and accuracy. A deviation from normal values of these parameters is the first sign of degeneration of the dose calibrator.

Regular QC should cover precision, accuracy, linearity and geometry of instrument, according to IAEA standards e.g.(IAEA TECDOC-٦٠٢ and ١٥٩٩),that

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

٥,٢. Conclusion:

The results concerning quality control of Dose Calibrator in Alnilein Medical Diagnostic Center were obtained by different methods. Departmental organization requires long-term planning. It is good to find a solution when a problem arises, but it is better to foresee the problem so that it can be avoided. Short-term policy often leads to confusion among personnel, and this reduces motivation. Diagnostic procedures in nuclear medicine should be correct the first time. Concerning the physical inspection test was good, 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 are so organized that every particular study is usually done on a known separate day during the week, and this minimizes errors during a radiopharmaceuticals preparation. Concerning the background test, the result of test was good and in normal exposure range (٠,٨٧٥ ± ٠,٠٦٣ mCi) as showed in table ٤-١. The implementation of radiation protection rules was good in some aspects of the work. No in-house preset standards that were available in printed manuals and also no check lists and permanent records. The involvement of technologists directly in management may increase the implementation of the rules concerning quality control of radiopharmaceuticals. Concerning the training of

staff, it is better to increase it by short training courses, especially in area of quality control in nuclear medicine. The results obtained concerning accuracy showed that the dose calibrator had accurate reading and the percentage of error was ٠,٣٩٪ which is accepted. The percentage of accuracy of dose calibrator was easily detected by using accuracy equation. The results concerning the constancy test of radionuclide calibrator, the performance of radionuclide calibrator was good with error of (١٥٥,٠٨ $\pm$ ٠,٥٨) as showed in table ٤-٣. These results showed high precision in dose calibrator. The Geometry test of dose calibrator was done by the researcher to ensure that the calibrator is giving correct readings throughout the entire energy scale that was likely to encounter. High energy standards Cs-١٣٧ was measured in the dose calibrator using appropriate settings. Standard and measured values are compared. The results were in accepted range (table ٤-٤).

٥,٣. Recommendations:

Considering the findings of this evaluation of the performance of dose calibrator that was included in the study, the researcher proposed some recommendations as follow:

- Preparation and formulation quality control system should be implemented in nuclear medicine practice in Sudan for all nuclear medicine equipments.
- Relevant documentation should be provided in the nuclear medicine centers to implement a comprehensive QC programme properly.
- Cooperation between the relevant regulatory bodies and nuclear medicine centers in Sudan should be encouraged.
- Cooperation of the relevant regulatory bodies in Sudan with International Atomic Energy Agency should be encouraged to provide technical support, training courses and quality control tools for nuclear medicine centers through regional and national projects.

References:

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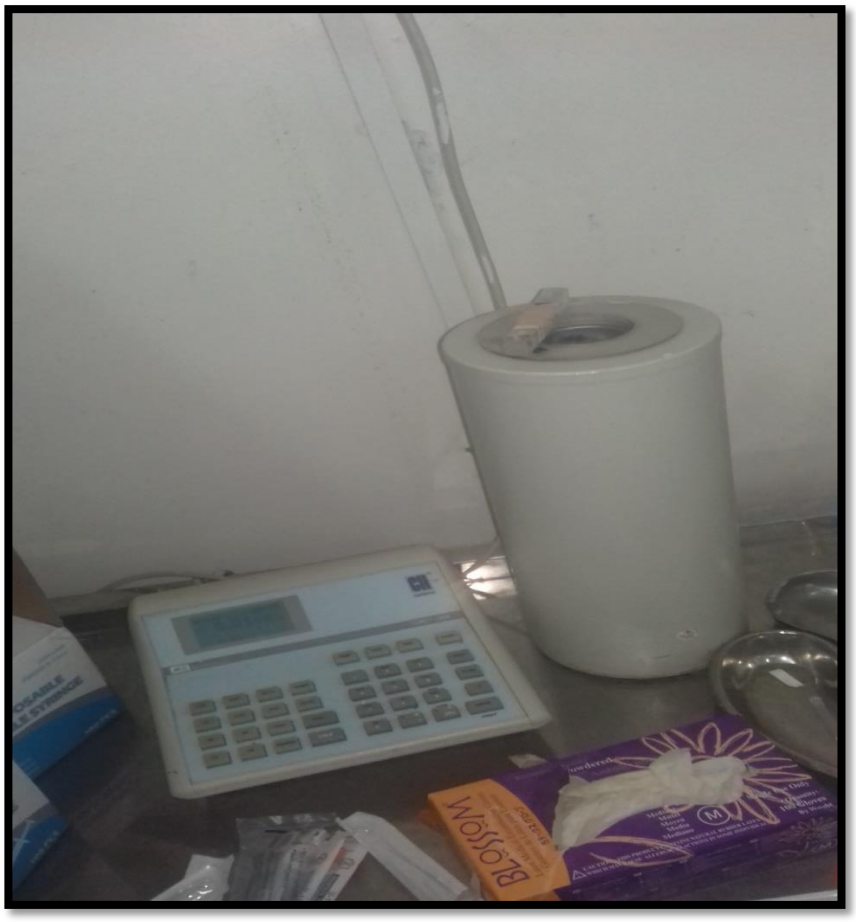
Appendices

Appendices:

Appendix ١: Shows radionuclide dose calibrator model CAPINTEC CRC-٢٥R of Elnilein Medical Diagnostic Centre.



Appendix ٢: Shows radionuclide standard source of Co^{57}

Appendix ٣: Shows display unit of the system consists of screen with direct reading in Bq or Ci

Appendix ٤: Shows dose calibrator model CRC-٢٥R

Appendix ٥: Shows standard radionuclide cobalt ٥٧ ($Co^{٥٧}$) source used in RICK