



Sudan University for Science and Technology

College of Engineering

Department of Biomedical Engineering

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in biomedical engineering

**A Proposal of Standard operation procedures and
policies (SOPs) for Histopathology and Clinical Chemistry
medical laboratories instruments in Sudan**

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Abbreviation

SOP	Standard operation Procedures.
TEC	Tissue Embedding Center.
PPM	Parts Per Million.
PH	It is a measure of the acidity or basicity of an aqueous solution.
MOH	Ministry Of Health.
DPPC	Drug Policy and Planning Center.
LED	Light Emitting Diode.
OCT	Optical Coherence Tomography.
GHTF	Global Harmonization Task Force.
ISO	International Organization for Standardization.
FDA	Food and Drug Administration.
WHO	World Health Organization.
RPM	Revolutions Per Minute.
U.V	Ultraviolet.
IEC	International Electrotechnical Commission.
PC	Personal computer.
ETOH	Ethanol alcohol.
DBA	Decibel filter (A).
CSA	Canadian Standards Association Group.
OH	Hydroxyl Group.
ULC	Underwriters Laboratory Of Canada.
CFU	Colony-Forming Units.

ABSTRACT

Devices of clinical laboratory analyze body fluids for specific substances of interest and to report the results in a form which is of value to clinicians in the diagnosis and treatment of disease, Whilst Histopathology devices used for embalming, cutting tissue and check to see if there is a malignant disease or any type of disease infected tissue so to be treated.

The objective of this proposal is designing SOPs and provide guidance for which laboratories medical device that important for providing basic health service and which not absolutely important, creating technical specification and standards list of histology and clinical chemistry laboratories medical devices to improve the quality of instruments in terms of safety and performance, good riddance of waste which comes from the device to prevent contamination that may occur and to Improve health care system as general.

To apply SOPs for Clinical chemistry and Histopathology laboratory medical devices, this is the steps which has been followed to accomplish this project; device technical specification, device operation instruction, device Environment, the device Safety, Contamination, the Classification of the device and finally the device labeling.

The experimental results were a check for used histopathology and clinical chemistry devices in some hospital and used histopathology and clinical chemistry devices to check its possibility to entering Sudan. The results shows that all used histopathology and clinical chemistry devices in Sudan were not under the Sops. The SOPs for histopathology and clinical chemistry devices are important for safely healthcare and this work is the beginning step to improve the use of the histopathology and clinical chemistry devices to give a better work.

المستخلص

أجهزة الكيمياء السريرية تحلل سوائل الجسم لأغراض محددة وتقدم تقرير عن نتائج في شكل يمكن الأطباء من تشخيص وعلاج المرض، بينما أجهزة امراض الانسجة تستخدم لتحنيط، وقطع الأنسجة لمعرفة ما إذا كان هناك مرض خبيث أو أي نوع من الأمراض التي تصيب الأنسجة حتى يمكن علاجها.

الهدف من هذا الاقتراح هو تصميم إجراءات العمل الموحدة وتقديم التوجيه لمعرفة اي أجهزة المختبرات الطبية الذي يكون مهما لتوفير الخدمات الصحية الأساسية و جوهري للغاية، وخلق المواصفات الفنية و قائمة نموذجية للأجهزة الطبية في مختبرات امراض الأنسجة والكيمياء السريرية لتحسين جودة هذه الأجهزة من حيث السلامة والأداء، والتخلص الجيد من المخلفات التي تأتي من الجهاز لمنع التلوث الذي قد يحدث، وتحسين نظام الرعاية الصحية على النحو العام.

لتطبيق إجراءات العمل الموحد على أجهزة المختبرات الطبية للكيمياء السريرية وامراض الانسجة ، الخطوات التالية تم اتباعها لإنجاز هذا المشروع: أولا المواصفات الفنية للجهاز، و ثانيا تعليمات تشغيل الجهاز، و الخطوة الثالثة فكانت بيئة الجهاز، والرابعة سلامة الأجهزة ،و الخامسة كانت التلوث، والسادسة كانت تصنيف الجهاز وأخيرا وضع علامات تعريف للجهاز.

كانت النتائج التجريبية للتحقق من أجهزة امراض الانسجة و الكيمياء السريرية المستخدمة في المستشفى وبعض أمراض الأنسجة والأجهزة المستخدمة الكيمياء السريرية للتأكد من إمكانية دخولها السودان. بينت النتائج أن جميع أجهزة امراض الانسجة والكيمياء السريرية في السودان لم تكن تحت إجراءات العمل الموحدة. إجراءات العمل الموحدة لأجهزة امراض الانسجة والكيمياء السريرية هامة للرعاية الصحية وهذا العمل هو الخطوة المبدئية لتحسين استخدام اجهزة امراض الانسجة والكيمياء السريرية لتقديم عمل أفضل.

CHAPTER 1

INTRODUCTION

1.1 Project introduction

Medical equipment with all of its kind is the key elements of modern Health care Services. More than ten decades ago, the Medical Devices were entered to Sudan in a simple term of types, design and numbers, the need for it has increased as the increasing of needs to a better Health care and Patient care.

In the nineties of the last century there was a huge business of the Medical Equipment which entered without any rules or regulations and continued entering to Sudan for commercial reasons and not for the health care of patients. Now Federal Ministry of Health, Health Institution and State Ministers of Health Hospitals in the country have a lot of Medical Equipment most of this equipment do not match international standards, with a poor-efficient appliances and used devices which a considerable number of these devices the pollution is clear within it component's or on it's Surface's (the remnants of the blood), also some of it may not include some of the parts or major accessories, because the manufacturers merged in other companies or has been out of the market, or it's been manufactured since long periods.

Administration of pharmacy, Atomic Energy Authority, Medical Supplies and finally Sudanese Standards and Metrology attempts to lay the foundations and controls to bring in medical devices and management with no adequate coordination between them, which led to a kind of spacing ideas and inconsistencies in many cases leading to failure to achieve the hopes of the citizens which led them to search for the medication out of Sudan.

1.2 Project problem statement

The absence of specialized authorities that control and regulate operation of laboratory devices may cause many serious problems so this work introduces a proposal to SOPs for Histopathology and clinical chemistry laboratories devices in Sudan.

1.3 Thesis objectives

- Design sops and provide guidance for which laboratories medical device that crucial for providing basic health service and which not absolutely crucial.
- Creating technical specification and standards list of histology and clinical chemistry laboratories medical devices to improve the quality of instruments in terms of safety and performance.
- Good riddance from waste comes from device to prevent contamination that may occur.
- Improve health care system as general

1.4 Thesis organization

Chapter one: presented the project introduction.

Chapter two: presented the Introduction of the Clinical chemistry and Histopathology laboratories and SOPs was written.

Chapter three: presented the Literature review.

Chapter four: Described the of project methodology.

Chapter five: introduced the results and discussed.

Chapter six: Conclusion and the future work.