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**ПОРАЖЕНИЕ ПЕЧЕНИ ПРИ КОВИД-19
(ПАТОФИЗИОЛОГИЧЕСКИЕ АСПЕКТЫ)**

**СОВЕРШЕНСТВОВАНИЕ ТЕХНОЛОГИИ
МЕДИКО-СОЦИАЛЬНОЙ РЕАБИЛИТАЦИИ
БОЛЬНЫХ С АМПУТАЦИОННОЙ КУЛЬТЕЙ БЕДРА**

**МАММОГРАФИЧЕСКИЙ СКРИНИНГ
В УЗБЕКИСТАНЕ: ПИЛОТНЫЙ ПРОЕКТ В БУХАРЕ**

**ОСОБЕННОСТИ РЕАБИЛИТАЦИИ
ДЕТЕЙ С COVID-19**



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АКТУАЛЬНЫЕ ВОПРОСЫ ОТОЛАРИНГОЛОГИИ	TOPICAL ISSUES OF OTOLARYNGOLOGY
КЛИНИКО-ФУНКЦИОНАЛЬНОЕ ИССЛЕДОВАНИЕ БОЛЬНЫХ С ХРОНИЧЕСКИМИ СТЕНОЗАМИ ГОРТАНИ К.М. Рuzматов, Дж.Ф. Шамсиев	CLINICAL AND FUNCTIONAL STUDY OF PATIENTS WITH CHRONIC STENOSE OF THE LARYNX K.M. Ruzmatov, J.F. Shamsiev
РАЗВИТИЕ ТИМПАНОСКЛЕРОЗА У ДЕТЕЙ С ХРОНИЧЕСКИМ ГНОЙНЫМ СРЕДНИМ ОТИТОМ Ш. Амонов, Ф. Н. Назиров	THE DEVELOPMENT OF TYMPANOSCLEROSIS IN CHILDREN WITH CHRONIC SUPPURATIVE OTITIS MEDIA Sh. Amonov, F. N. Nazirov
КОХЛЕАРНАЯ ИМПЛАНТАЦИЯ У ДЕТЕЙ ШКОЛЬНОГО ВОЗРАСТА А.А. Абдукаюмов, Д.У. Мухамедов	COCHLEAR IMPLANTATION IN SCHOOL-AGED CHILDREN A.A. Abdukayumov, D.U. Mukhamedov
СОВЕРШЕНСТВОВАНИЕ УХОДА ПОСЛЕ ОПЕРАЦИИ РИНОПЛАСТИКА Н. А. Ибатов, Дж.Ф. Шамсиев	IMPROVING CARE AFTER RHINOPLASTY N. A. Ibatov, J.F. Shamsiev
ПРОБЛЕМНЫЕ СТАТЬИ И ОБЗОРЫ	PROBLEMATIC ARTICLES AND REVIEWS
ОСОБЕННОСТИ РЕАБИЛИТАЦИИ ДЕТЕЙ С COVID-19 Т.А. Бобомуратов, Д.Ж. Шарипова, Н.С. Султанова	FEATURES OF THE REHABILITATION OF CHILDREN WITH COVID-19 T.A. Bobomuratov, D.Zh. Sharipova, N.S. Sultanova
ВЛИЯНИЕ ЭНДОКРИННОЙ ПАТОЛОГИИ НА РАЗВИТИЕ И ТЕЧЕНИЕ ЗАБОЛЕВАНИЙ ПОЛОСТИ РТА.ОСОБЕННОСТИ ОКАЗАНИЯ СТОМАТОЛОГИЧЕСКОЙ ПОМОЩИ. Х.И.Ирсалиев, Л.Х.Наврзуова	INFLUENCE OF ENDOCRINE PATHOLOGY ON THE DEVELOPMENT AND PROGRESS OF Oral CAVITY DISEASES. FEATURES OF DENTAL CARE PROVIDING. Kh.I. Irsaliev, L.Kh. Navruzova
МЕТРОЛОГИЧЕСКИЙ КОНТРОЛЬ МЕДИЦИНСКИХ ИЗМЕРИТЕЛЬНЫХ СРЕДСТВ И ОБОРУДОВАНИЕ В СИСТЕМЕ ЗДРАВООХРАНЕНИЯ В. Нишонов, Н. Муминов, Х. Абдужалилова	METROLOGICAL CONTROL OF MEDICAL MEASURING DEVICES AND EQUIPMENT IN THE HEALTH CARE SYSTEM V. Nishonov, N. Muminov, H. Abduzhalilova
СУДЬБА МЕДИКО-ГУМАНИТАРНОГО ОБРАЗОВАНИЯ В РОССИИ В.И.Моисеев, О.Н.Моисеева	THE FATE OF MEDICAL AND HUMANITARIAN EDUCATION IN RUSSIA V.I.Moiseev, O.N.Moiseeva
ОЦЕНКА ПРОГНОСТИЧЕСКОЙ ЗНАЧИМОСТИ ОКИСЛИТЕЛЬНОГО	EVALUATION OF THE PREDICTIVE IMPORTANCE OF OXIDATIVE STRESS

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METROLOGICAL CONTROL OF MEDICAL MEASURING DEVICES AND EQUIPMENT IN THE HEALTH CARE SYSTEM

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МЕТРОЛОГИЧЕСКИЙ КОНТРОЛЬ МЕДИЦИНСКИХ ИЗМЕРИТЕЛЬНЫХ СРЕДСТВ И ОБОРУДОВАНИЕ В СИСТЕМЕ ЗДРАВООХРАНЕНИЯ

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SOQ'LIQNI SAQLASH SOHASIDA TIBBIYOT O'LGHASH VOSITALARI VA QURILMALARINI METROLOGIK TEKSHIRUVI

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ABSTRACT

The article describes one of the actual and important issues of modern medicine - the correct organization of metrological control, ensuring and measuring reliability in the healthcare system. The correct exploitation of diagnostic, measuring and other medical devices and equipment in the field of healthcare in the Republic of Uzbekistan, highlights and analyzes the problems that need to be solved related to the organization of metrological control in the healthcare system.

Key words: health care system, diseases, diagnostics, metrology, metrological control, uniformity of measurements, medical devices, testing, monitoring, treatment, international standards.

АННОТАЦИЯ

В статье описывается одним из актуальных и важных вопросов современной медицины – правильной организации метрологических служб, обеспечения и измерения надежности в системе здравоохранения. Правильное эксплуатация диагностических, измерительных и других медицинских приборов и оборудования в сфере здравоохранения в Республики Узбекистане, освещены и анализированы проблемы, которые необходимо решить, связанное с организацией метрологических служб в системе здравоохранения.

Ключевые слова: система здравоохранения, болезни, диагностика, метрология, метрологическая контроля, единство измерений, медицинские изделия, испытания, мониторинг, лечения, международные стандарты.

АННОТАЦИЯ

Maqolada zamonaviy tibbiyotning dolzarb va muhim masalalaridan biri - metrologik xizmatni to'g'ri tashkil etish, sog'liqni saqlash tizimida o'lchashlar va ularning ishonchliligini ta'minlash haqida so'z boradi. O'zbekiston Respublikasida sog'liqni saqlash sohasida tashxislashda qo'llaniladigan o'lchash va boshqa tibbiy asbob-uskunalar hamda jihozlardan to'g'ri foydalanish, sog'liqni saqlash tizimida metrologik xizmat ko'rsatishni tashkil etish bilan bog'liq hal etilishi zarur bo'lgan muammolarni yoritib beradi va tahlil qiladi.

Kalit so'zlar: Sog'liqni saqlash tizimi, kasallik, tashxis, metrologiya, metrologik tekshiruv, o'lchashlarning yagona birligi, tibbiyot o'lchash vositalari, sinov, nazorat, davolash, xalqaro standartlar.

Introduction

Uzbekistan has a unified health care system, existing legal and regulatory framework for functioning and a structure that includes state, private and other forms of non-state actors.

Nowadays the share of national budget expenditures for healthcare is as high as 15,7 %, and represents 4,1 % of GDP. It is expected that the total health-care expenditures in the country would grow 4 times by 2022, and 10 times by 2030. This will result in the increase of the share of health-care expenditures in GDP to 10% in 2021 and 12% in 2030 [1].

The Ministry of Health of the Republic of Uzbekistan is the central organ for state management of health care and subordinates its activities to the Cabinet of Ministers of the Republic of Uzbekistan.

Today in the republic over 1,000 inpatient health institutions, 4,000 polyclinics and outpatient institutions, 501 rural outpatient posts, 2,606 rural health clinics and other health institutions are providing qualified public health services [1].

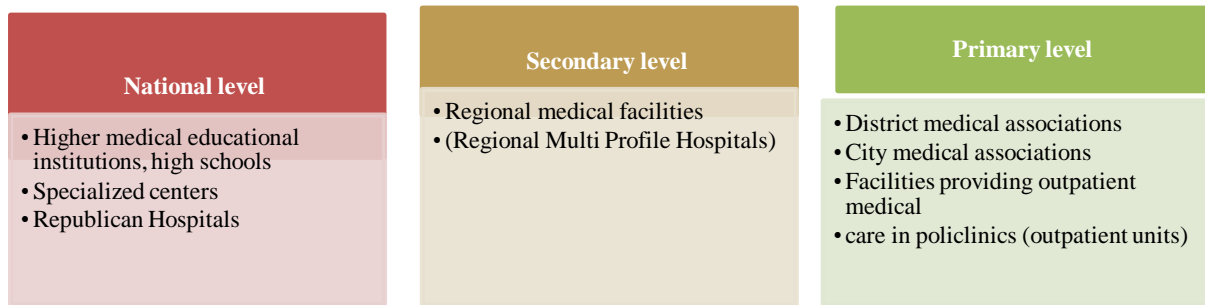


Figure 1. Public health system of the Republic of Uzbekistan.

The country features high natural demographic growth rates, which total 1-1,5% per annum according to the projections. Approximately 615,000 newborns are expected annually in the next five years, whereas, 607,800 are expected annually in 2015-2020, and 596,700 annually in 2020-2025 [1, 2].

These and other factors related to health care lead to higher demand for new technologies, modern equipment and high quality medications essential for treatment of pediatric diseases, mandatory vaccination of newborns and children, and treatment of diseases typical for the elderly – cardiovascular, oncologic, and neurological diseases.

In recent years, the emergence of various diseases associated with the emergence of unexplored species and types, mutations of viruses (Coronavirus) requires more effort and attention from healthcare workers to conduct various types of diagnostic and preventive laboratory tests and measures, respectively, with certain medical devices and equipment.

Proceeding from these points, the importance and need for a qualified metrological control in the system of medicine will sharply increase at the same time.

Medical devices and their types

The term “medical devices” includes everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors.

Several different international classification systems for medical devices are still in use in the world today. The World Health Organization (WHO), with its partners, is working towards achieving harmonization in medical device nomenclature, which will have a significant impact on patient safety. This is particularly important to be able to identify adverse incident reports and recalls [3].

A few years ago, the medical equipment were fully utilized with human participation, which was used only for the control of the patient, the study of internal organs, the performance of ordinary measurements, and the recording of the drug. Stethoscopes, thermometers, and several surgical instruments can be examples for the first medical devices.

Table 1. Medical Device Type

№	Type of medical device	№	Type of medical device
1	Apparatus and equipment for traumatic and mechanical treatment	13	Respiratory and anesthetics, intensive care units, devices and equipment
2	Water treatment equipment	14	Pharmacy equipment
3	Instruments, apparatus and equipment for hemorrhage and neurosurgery	15	Instruments and tools for laboratory, morphological research, sanitary epidemiology
4	Disinfection equipment	16	Endoscopic equipment
5	Clinical Diagnostic Instruments and Apparatus	17	Instruments, apparatus and equipment for physiotherapy
6	Cosmetology equipment	18	Hearing aids
7	Otorhinolaryngology devices and equipment	19	Ophthalmology equipment, apparatus and equipment
8	Medical furniture	20	Sterilizing equipment
9	Radiology devices, apparatus and equipment	21	Devices, apparatus and equipment for tomography
10	Urology and blood purification apparatus and equipment	22	Instruments and tools for dental surgery
11	Functional diagnostic tools, apparatus and equipment	23	Laser apparatus and equipment
12	Instruments, apparatus and		

equipment for obstetrics, gynecology and neonatology	
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Today, medical equipment are much more complex and diverse. The reason is that the their functions of sensing, receiving, processing, storing and transmitting data are combined with electronic systems and operate on electrical, mechanical, chemical and radiation sources.

Additionally, the need for measurements with high accuracy of the physiological parameters of the disease is becoming an imperative demand while every doctor is giving guidelines for diagnoses and treatments of disease.

As a result, the number and type of medical equipment is growing steadily. It can be approved by taking as an example the table of medical device type (Table 1) [4].

Why we are giving huge consideration to the type of medical devices in the article, because increasing the number and type of medical devices effects the quality of metrological control in the field of medicine.

Use of standards in medical device regulations

Medical devices intended for global use should follow international standards. For example, the ISO Technical Report (ISO 16142:2000) lists a number of significant international standards that may be suitable for demonstrating compliance with certain features of the essential principles of safety and performance of medical devices.

International standards are a building block for harmonized regulatory processes to assure the safety, quality and performance of medical devices. To achieve this purpose, the following principles are recommended [5]:

- Regulatory Authorities and industry should encourage and support the development of international standards.
- Regulatory Authorities should provide a mechanism for recognizing international standards.
- The use of standards should preferably reflect current, broadly applicable technology while not discouraging the use of new technologies.

A good approach to setting a clear direction for all stakeholders is to establish a comprehensive national policy or guideline on medical device management. The government can subsequently bring in legislation and enforcement to suit the country's conditions and needs. Five principal activities are identified [6]:

1. Increasing the knowledge of the medical device sector
2. Establishing basic regulatory programs
3. Drafting a comprehensive policy/guideline including the recognition and use of standards
4. Promoting compliance and cooperation
5. Setting priorities for regulatory program development

Measurement requirements and the factors effecting measurement results

To assure adequate space system performance, it is essential that technical requirements be developed, defined and documented carefully. Clearly defined measurement requirements lead to the high reliability and quality needed to assure successful system performance and mission achievement.

Measurement — The set of operations having the object of determining the value of a quantity. Measurements are subject to varying degrees of uncertainty, the uncertainties need to be estimated, from the estimate, the validity of the measurement can be assessed, the risks associated with decisions based on these measurements quantified, and corrective actions taken to control growth in the measurement uncertainty [6]. In order to achieve high accuracy in measurement, there should be clear concepts about measurement principles. Because these principles describe real meaning of measurement. The right measurements, the right tools, the right people, regular review, demonstrable consistency and the right procedures can be reliable aspects for the improvement of quality of metrological control (Figure 3) Therefore, special attention of metrology bodies should be given to these aspects.



Measurements are central to clinical practice and medical and health research. They form the basis of diagnosis, prognosis and evaluation of the results of medical interventions.

A decision-maker must know that the measure used is adequate for its purpose, how it compares with similar measures and how to interpret the results it produces.

Figure 3. Six guiding principles for the measurement

The field of medicine is extremely diverse. There are so many different diseases, and we all know that health is not just the absence of disease. The WHO officially defined health as “a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity”[3].

Measurements are performed in clinical practice and for research purposes. This broad scope is also expressed in the types of measurements. Measurements vary from questions asked about symptoms during history-taking, to physical examinations and tests, laboratory tests, imaging techniques, self-report questionnaires, and so on [7].

Conclusions and recommendations

The aspect of accuracy of medical devices in health care systems around the world is regulated by different agencies or by applying international managing standards for health care institutions, which ensure that accuracy of medical devices is checked once a year.

As a part of preventive service, an authorized service center performs also certification of devices. A certification process report is usually a work order document. This document only reports the result of the certification: whether the device passed or failed.

The work order document contains neither any information about device output values measurement, nor the reference to the certification standard.

From this point of view, we aimed to develop inspection and evaluation of medical devices all the time, not only in the surveillance control.

Based on the results of a study related to the medical metrological service, the following recommendations have been developed:

A) In order to operate in a competitive marketplace with increasing end-user demands for features and usability, medical device manufacturers operate in a highly regulated environment.

Regulatory bodies look for evidence that medical devices are developed under a structured, quality-oriented development process. By following software validation and verification the best practices, manufacturers can not only increase the likelihood that they will meet their compliance goals, they can also enhance developer productivity.

One of the most important verification tools that medical device manufacturers can deploy is source code analysis technology. Source code analysis tools provide an automated method to detect a significant number of software bugs or security vulnerabilities early in the development process and before any code is delivered to the testing team.

B) There should be clinical engineer in every hospitals, clinics and diagnostic centers in order to provide safety and effectiveness of medical devices. Besides, profession of clinical engineering will be main factor for the strengthening the metrological control. Because they will be bridge between metrological organizations and hospitals, clinics, diagnostic centers. From this point of view objectives of clinical engineers are given below:

1. Acquisition, maintenance and repair of the medical equipment.
2. Evaluation and assistance in acquiring new technology for patient care.
3. Coordination of preventive maintenance and repairs by outside service personnel.
4. Maintaining familiarity with regulatory codes and standards.
5. Collaboration with clinical staff to provide the highest level of patient safety.
6. Ensuring that applicable accreditation standards are met.

7. Ensuring departmental policies and procedures are followed.
 8. Assistance in the management of the computerized maintenance management system.
 9. Maintaining the stock of repair parts to ensure appropriate maintenance of equipment.
 10. Ensuring timely completion of preventive maintenance.
 11. Instructing hospital personnel on safe and proper operation and maintenance of medical equipment.
- C) Joint scientific and technical seminars should be organized and hold on periodically. Theme of seminars should be concentrated on the problems of metrological support in the field of health and medical instrument making with the participation of metrologists, clinical engineers, representatives of medical institutions and manufacturing enterprises, as well as relevant representatives of local bodies of state administration and insurance medicine.
- D) Expand the scope of metrological control in the field of medicine in actively cooperation with the Ministry of Health and National Metrology Institute and providing application of metrological control for the whole cycle of a single technological process (development, production, testing, approval, operation, disposal of medical devices) [8].

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