METROLOGIK TALABLARINI TIBBIY JIXOZLARNINING O‘LCHASH NATIJALARIGA TA’SIR QILUVCHI OMILLARI TAXLILI

Ubaydullayeva Gullola
Tayanch doktorant, Andijon mashinasozlik instituti
ugullola92@gmail.com

Yodgorbek Ismoiljonov
PhD tadqiqotchi, Andijon Mashinasozlik Instituti
yodgorbek93@gmail.com

ANNOTATSIYA.

Tibbiyot – maksimal aniqlikni talab qiladigan soha. Shuning uchun tibbiy texnika, oddiy gradusnik, tonometr, tarozilardan boshlab, ultratovushli tekshiruv, kompyuter tomografiyasi, rentgenografiya uchun mo‘ljallangan apparatlargacha – ma’lum texnik parametrlarga qat’iy to‘g‘ri kelishi kerak. Bunda ixtisoslashtirilgan uskunalarning barqaror va soz ishlashini ta’minlash, uning ishlab chiqaruvchilari tomonidan berilgan birlamchi sifatini saqlab turish zarur. Axir, diagnoz to‘g‘riligi, va bundan chiqdi belgilangan davolash usullarining samaraliligi uning ko‘rsatishlari aniqligiga bog‘liq.

Kalit so‘zlar: *Metrologik ta’minot, tibbiy jixozlar, tibbiy texnika, sog‘liqni saqlash.*

АНАЛИЗ МЕТРОЛОГИЧЕСКИХ ТРЕБОВАНИЙ ФАКТОРОВ, ВЛИЯЮЩИХ НА РЕЗУЛЬТАТЫ ИЗМЕРЕНИЙ МЕДИЦИНСКИХ ИЗДЕЛИЙ

АННОТАЦИЯ.

Медицина – область, требующая максимальной точности. Поэтому медицинское оборудование, начиная от простых транспортиров, тонометров, весов и заканчивая приборами, предназначенными для ультразвукового исследования, компьютерной томографии, рентгенографии, - должно строго соответствовать определенным техническим параметрам. В этом случае необходимо обеспечить стабильную и правильную работу специализированного оборудования, сохранить первичное качество, задаваемое его производителями.

Ведь от точности его показаний зависит точность диагноза, а значит, и эффективность назначенных методов лечения.

Ключевые слова: *метрологическое обеспечение, медицинская техника, медицинская техника, здравоохранение.*

ANALYSIS OF METROLOGICAL REQUIREMENTS OF THE FACTORS AFFECTING THE MEASUREMENT RESULTS OF MEDICAL DEVICES

ANNOTATION.

Medicine is a field that requires maximum accuracy. Therefore, medical equipment, starting from simple protractors, tonometers, scales, to devices designed for ultrasound examination, computer tomography, radiography - must strictly correspond to certain technical parameters. In this case, it is necessary to ensure the stable and correct operation of specialized equipment, to maintain the primary quality given by its manufacturers. After all, the accuracy of the diagnosis, and hence the effectiveness of the prescribed treatment methods, depends on the accuracy of its indications.

Key words: *Metrological supply, medical equipment, medical equipment, health care*

Measurements provide data from which decisions are made:

- To continue or stop a process
- To accept or reject a product
- To rework or complete a design
- To take corrective action or withhold it
- To establish scientific fact

Healthcare in Uzbekistan is one of the foreground directions of the inclusive social policy implementation which experienced major reform over the past two decades. Uzbekistan has a single statutory health care system, which includes public, private and other forms of non-public actors.

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

The priorities of the government of Uzbekistan, focused on comprehensive modernization of health system, continued gradual and targeted work on further reforming and developing of healthcare system. More attention is being paid to the protection of public health and strengthening of economic and technical base of medical institutions, as well as rendering high-quality medical services at modern requirements.

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 [2].

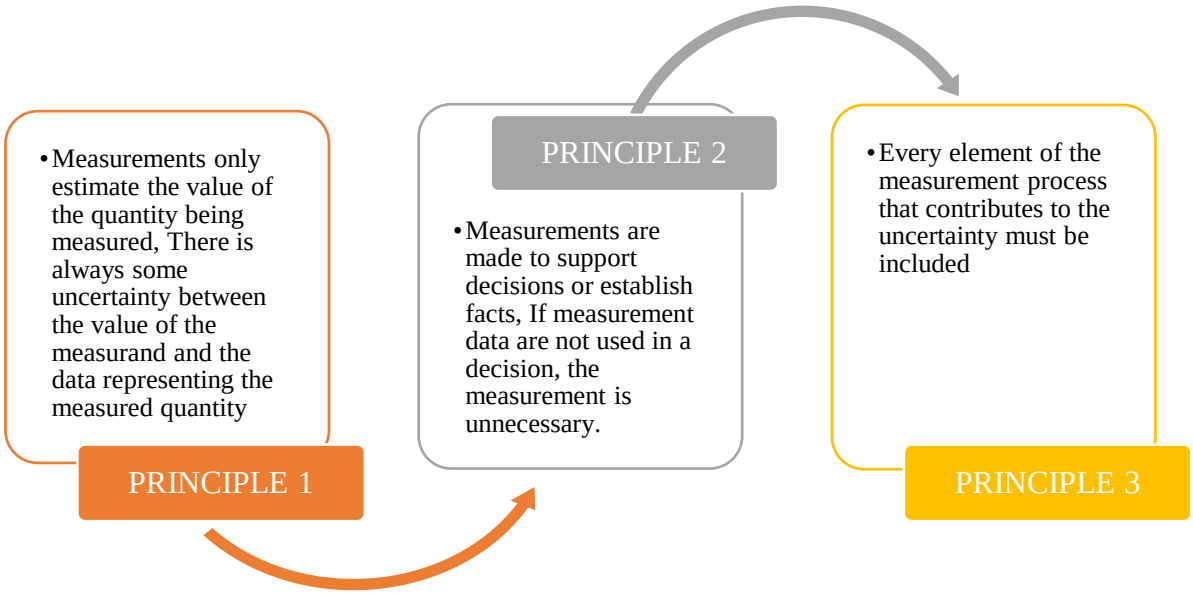

Figure 1. Principles of Measurement

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.

The objective of the measurement process for space systems is to monitor the integrity of the performance parameters of space hardware, instrumentation and ground support equipment, and to allow sound decisions for taking actions. The objective of calibration is to determine initial bias errors, correct for these, “and then to monitor and control the growth of measurement uncertainty. This assures that decisions being made

about the hardware from the measurement data are made within acceptable risk limits [3].

In order to achieve high accuracy in measurement, there should be clear concepts about measurement principles. Because these principles describe real meaning of measurement.

Determining measurement process requirements can be viewed as a ten-stage sequence that flows down in the table: [4]

Table 1. Measurement Requirements Definition Sequence

№	Stage title	Definition
Stage 1	MISSION PROFILE	Define the objectives of the mission, What is to be accomplished? What reliability is needed and what confidence levels are sought for decisions to be made from the measurement data?
Stage 2	SYSTEM PERFORMANCE PROFILE	Define the needed system capability and performance envelopes needed to accomplish the Mission Profile. Reliability targets and confidence levels must be defined.
Stage 3	SYSTEM PERFORMANCE ATTRIBUTES	Define the functions and features of the system that describe the System's Performance profile. Performance requirements must be stated in terms of acceptable system hardware attribute values and operational reliability.
Stage 4	COMPONENT PERFORMANCE ATTRIBUTES	Define the functions and features of each component of the system that combine to describe the System's Performance Attributes. Performance requirements must be stated in terms of acceptable component attribute values and operational reliability.
Stage 5	MEASUREMENT PARAMETERS	Define the measurable characteristics that describe component and/or system performance attributes. Measurement parameter tolerances and measurement risks (confidence levels) must be defined to match system and/or component tolerances and operational reliability.
Stage 6	MEASUREMENT PROCESS REQUIREMENTS	Define the measurement parameter values, ranges and tolerances, uncertainty limits, confidence levels, and time between measurement limits (test intervals) that match mission, system, and component performance profiles (Stages 2, 3 and 4) and the measurement parameter requirements (Stage 5.)

Stage 7	MEASUREMENT SYSTEM DESIGNS	Define the engineering activities to integrate hardware and software components into measurement systems that meet the Measurement Process Requirements, Definition must include design of measurement techniques and processes to assure data integrity.
Stage 8	CALIBRATION PROCESS REQUIREMENTS	Define the calibration measurement parameter values, ranges, uncertainty limits, confidence levels, and recalibration time limits (calibration intervals) that match measurement system performance requirements to detect and correct for systematic errors and/or to control uncertainty growth.
Stage 9	CALIBRATION SYSTEM DESIGNS	Define the integration of sensors, transducers, detectors, meters, sources, generators, loads, amplifiers, levers, attenuators, restrictors, filters, switches, valves, etc., into calibration systems that meet the Calibration Process Requirements. Definition must include design of calibration techniques and processes to assure data integrity.
Stage 10	MEASUREMENT TRACEABILITY REQUIREMENTS	Define the progressive chain of calibration process requirements and designs that provide continuous reference to national and international systems of measurement horn which internationally harmonized systems measurement process control is assured.

a) Instruments

While calibrations and preliminary checks can confirm that measuring instruments are behaving as they should before a measurement begins, a number of factors can impair their performance during the measurement itself. Electrical measuring instruments can be affected by electrical noise, either in the form of electromagnetic radiation or disturbances to voltage supplies. Proper earthing of equipment is also important, which can be tricky when several electrical instruments are involved in the same measurement, in which case common earths may need to be set up and checked, to avoid earth loops [5].

b) The object to be measured

Hardly anything that is measured is truly stable: many people shrink by over a centimeter over the course of a day, fruit and vegetables slowly dry out and their chemical compositions change as they ripen and rot, colors fade and shift, electrical resistance alters with temperature and so on [6].

c) Sampling, and other aspects of the measurement process

The measurement technique needs to be well designed and the people who use it well-trained to get the most out of a measurement. This is especially important in those cases where the thing to be measured varies across space and time – the noise inside a

car, the speed of the wind or the temperature of seawater can all be measured very accurately, but the answer will be of no value unless measurements are made in sufficient numbers, and at appropriate positions and times – that is to say, that they are representative [7].

d) Operator skill

Measurements involve human skills, and there are limits to these, no matter how well trained, diligent or highly-motivated the operator is. Often, setting up the measuring equipment and preparing the thing to be measured is even more challenging than carrying out the measurement itself.

e) Environmental factors

The environment – especially its temperature, air-pressure and humidity – can affect the results of measurements of many kinds, by altering the characteristics of the measuring instrument, the thing to be measured, or both. In some cases, for example where mass has to be very accurately determined, the measurement is carried out in chambers under which all these factors are controlled, at a precise temperature and sometimes in a vacuum (and hence zero air pressure and humidity).

Methods for Reliability Assessment of Medical Technical Technologies

The study reviewed various methods and techniques for assessing the reliability of medical technical technologies. These methods include reliability testing, reliability modeling, and reliability prediction. Reliability testing involves subjecting the medical devices to rigorous testing under controlled conditions to evaluate their performance and identify potential failure modes. Reliability modeling uses mathematical and statistical techniques to estimate the reliability of medical devices based on historical data or simulation. Reliability prediction involves using established models and databases to predict the reliability of medical devices during the design and development stages. Each of these methods has its advantages, limitations, and applicability depending on the context, and a combination of these methods can provide a comprehensive reliability assessment approach.

Reliability assessment of medical technical technologies involves evaluating the performance, safety, and durability of medical devices to ensure that they function as intended, meet regulatory requirements, and provide safe and effective care to patients. There are various methods and techniques that can be used for reliability assessment of medical technical technologies. Some common methods include:

- Failure Modes and Effects Analysis (FMEA)
- Reliability Testing
- Statistical Analysis

- Field Data Analysis
- Expert Evaluation
- Simulation and Modeling
- Compliance with Standards

Failure Modes and Effects Analysis (FMEA): FMEA is a systematic approach used to identify and prioritize potential failure modes of a medical device, assess their severity, occurrence, and detectability, and develop appropriate actions to prevent or mitigate their impact. FMEA helps in identifying potential failure modes, their causes, and their effects on the reliability of the device, and allows for proactive measures to be taken to prevent failures or minimize their impact.

Reliability Testing: Reliability testing involves subjecting medical devices to controlled and simulated conditions to assess their performance and durability over time. This can include accelerated life testing, environmental testing (e.g., temperature, humidity), mechanical testing, and other specialized tests depending on the type of device. Reliability testing helps in evaluating the performance and robustness of the device under different conditions, and identifying potential failure modes and weaknesses.

Statistical Analysis: Statistical analysis methods, such as statistical process control (SPC), can be used to analyze and monitor data collected from the use of medical devices to identify trends, patterns, and anomalies that may impact device reliability. Statistical techniques can also be used to calculate reliability metrics, such as mean time between failures (MTBF), failure rate, and probability of failure over time.

Field Data Analysis: Field data analysis involves collecting and analyzing real-world data from the use of medical devices in clinical settings. This can include data from post-market surveillance, adverse event reporting, and other sources. Field data analysis helps in identifying patterns of failures, adverse events, and other issues related to device reliability in real-world clinical settings, and provides valuable feedback for improving device reliability.

Expert Evaluation: Expert evaluation involves engaging subject matter experts, such as engineers, clinicians, and other relevant stakeholders, to assess the reliability of medical devices based on their experience, knowledge, and expertise. Expert evaluation can provide valuable insights into potential failure modes, design weaknesses, and other issues related to device reliability that may not be captured through other methods.

Simulation and Modeling: Simulation and modeling techniques can be used to assess the reliability of medical devices through virtual simulations and modeling of their performance under different conditions. This can include finite element analysis,

computational fluid dynamics, and other simulation techniques to assess the performance and reliability of devices in virtual environments.

Compliance with Standards: Compliance with international standards, such as ISO 13485, IEC 60601, and ISO 14971, can serve as a method for reliability assessment of medical devices. These standards provide guidelines and requirements for ensuring the reliability of medical devices throughout their lifecycle, and compliance with these standards can ensure that devices meet internationally recognized reliability standards.

These are some of the methods commonly used for reliability assessment of medical technical technologies. The choice of method(s) to be used depends on the type of device, the stage of the device's lifecycle, and the specific requirements of the regulatory environment in which the device is being used. Employing robust reliability assessment methods can help ensure that medical devices are reliable, safe, and effective, and contribute to improved patient care and outcomes.

Summary

In conclusion, the study has highlighted the significance of international standards, advanced foreign experience, and robust reliability assessment methods in ensuring the reliability of medical technical technologies. Taking a proactive approach, fostering collaboration among stakeholders, and embracing a culture of continuous improvement can contribute to enhancing the reliability of medical devices, ensuring patient safety, and improving overall healthcare outcomes.

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