UDC 389.14: 006.354

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CONTROL AND MANAGEMENT OF CLINICAL-DIAGNOSTIC LABORATORIES

The problem of quality assurance of laboratory research is one of the central problems of modern laboratory medicine. The basic requirement for such research is to provide reliable information to our customers. This, first of all, defines the requirement for the quality of clinical laboratory studies of clinical and diagnostic laboratories, which ensures the correct and timely assignment of a patient's analysis, performed at the appropriate analytical level with the necessary information for its interpretation. Only through a clear organization and high-quality laboratory studies, one can expect that each result, reflected in an authorized report, can be used by a doctor to make diagnostic decisions or decisions that change the treatment regimen.

One way to determine the competence of clinical diagnostic laboratories and the quality of their research is to conduct an independent quality assessment.

Formulation of the problem. In the modern world, clinic-diagnostic laboratories (KDLs) in medical health organizations throughout the year perform several billion laboratory tests for the appointment of doctors for patients in polyclinics, clinics, hospitals. For the quality of research results, serious problems arise from numerous objective and subjective factors. To eliminate them, a course has been taken to develop national standards in the field of laboratory medicine, using international experience in the development of standards that regulate the requirements for the organization of KDL activities and laboratory analysis tools.

The international standard ISO 15189, which establishes the requirements for the quality and competence of the KDL, was introduced in Ukraine from 01.01.2016, as DSTU EN ISO 15189: 2015 «Medical laboratories. Requirements for quality and competence. "Compliance with the requirements of this standard by the medical laboratory means that the CDL meets both the requirements of technical competence and the requirements of the quality management system [1].

In order to ensure the accuracy of the results of laboratory tests in the EU for a long time there are requirements of metrological traceability of calibrators and control materials and metrological provision of laboratory equipment, as well as research methods. The task of providing metrological traceability is to the manufacturers of equipment and control materials [2].

Medical laboratories that have implemented the quality management system in their practice confirm their competence by accrediting the laboratory to meet the requirements [1]. The development of the state system for quality management of clinical laboratory research in Ukraine began in 2010. Under the quality in laboratory medicine is understood the level at which a combination of inherent characteristics meets the requirements of ISO 15189: 2012.

Conclusions. According to the results of research, priority directions of improvement of medicine at the present stage are determined. In particular, the need for further close cooperation between state institutions of the medical sector and numerous private institutions is established, which not only raises the level of competitiveness of all subjects, but also solves the main task of improving the quality of medical services.

List of references

1. ISO EN ISO 15189: 2015 Medical Laboratories. Requirements for quality and competence (ENISO 15189: 2012, IDT)

2. On Approval of the Procedure for Verifying Legislative Instruments of Measuring Instruments in Operation and Designing Its Results", Order of the Ministry of Economic Development and Trade of Ukraine, February 08, 2016, Registered with the Ministry of Justice of Ukraine on February 24, 2016, No. 278/28408