ASPECTS OF THE PROBLEM OF DIRECT INTRODUCTION OF STANDARDS OF INTERNATIONAL ORGANIZATIONS*

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Social and economic reforms in the former Soviet Union have resulted in some basic trends in standardization of medical devices, primarily toward compliance with the requirements of the International Standards Organization (ISO), the International Electrotechnical Commission (IEC), and the standards of the European Community providing high levels of safety, compatibility, and unification of developed and produced medical devices and promoting quality improvement and competitiveness of domestic medical devices [1, 2, 7].

The Gosstandart resolution of May 1990 and USSR government resolution of December 1990 on the urgent introduction of international standards for medical devices started to be implemented by the approval of the first package of state standards prepared by the Technical Committee for Standardization of Medical Devices and Apparatuses (TK 11). This package of standardizing and technical documents introduces one ISO standard and several IEC standards:

- GOST R 50326-92 (IEC 513-76). Basic principles of electrical safety of medical equipment;
- GOST R 50267.4-92 (IEC 601-2-4-83). Medical electrical devices. Part 2. Specific safety requirements for defibrillators and monitoring defibrillators;
- GOST R 50267.6-92 (IEC 601-2-6-84). Medical electrical devices. Part 2. Specific safety requirements for microwave therapeutic devices;

The approved standardizing and technical documents introducing standard requirements of international organizations fall into three groups.

*Editorial note. This article is published as part of a discussion. Particular issues of the article are disputable. First of all, this concerns the so-called "folder" method of introduction of international standards for medical devices to domestic medical practice (i.e., by direct translation of the standards and their publication as standardizing documents). Nevertheless, at least one of the problems, the problem of coordination between domestic state standards for medical devices and international recommendations of ISO and IEC, is undoubtedly of topical importance. Advancement of new health service legislation which is to be approved by law-makers will definitely introduce corrections into the present situation. The Editorial Board of Meditsinskaya Tekhnika believes this article will lessen these problems and be welcomed by readers.

1. General safety requirements for medical equipment and electrical devices and also general requirements for medical personnel and administrative staff to comply with safety precautions for use of electromedical equipment (GOST R 50267.0-92, RD 50-517-92).

2. Specific safety requirements for certain groups of similar products (GOST R 50267.2...6-92).

3. Requirements for compatibility of interchangeable connectors providing functional capability of medical devices and increasing their safety (GOST R 50327.1-92).

The document RD 50-164-90 regulates organization and implementation of direct introduction of international standards (ISO and IEC) in this country [11]. As in other developed countries, the international standards are introduced into domestic practice through national standards.

Direct introduction of an international standard implies incorporation of its complete authentic text (in Russian) into the corresponding state standard. There are three variants of direct introduction of international standards through national state standards:

- direct application of international standards, i.e., their execution as an authentic text translated into Russian by the so-called 'folder' method;
- direct application of international standards with additional requirements and changes adapted to specific features of domestic industry and economy and arranged as appendices to the respective state standard;
- direct application of international standards as appendices to the corresponding state standard.

Thus, the three variants of direct introduction of international standards introduce no changes into the text of the standards.

Since a significant number of domestic materials and components of medical devices fail to qualify under the requirements of the international standards [10], direct application of international standards by the "folder" method seems very unlikely for the near future. Therefore, the majority of the approved state standards allow direct introduction of international standards with supplements that take into account specific features of domestic industry and economy.

The supplements specify the deadline for introducing the standard requirements for new production. They also specify the deadline for applying the requirements to all serially produced products. Such regulation is necessary because the currently produced serial products meet the requirements of the state standards for electrical safety of medical devices (GOST 12.2.025-76 [3]), for general technical requirements for medical devices, apparatuses, and equipment (GOST 20790-82 [4]), and for reliability and methods of testing of medical products (GOST 23256-86 [5]). Hence, it is stipulated in the appendices to the standards that it is not until January 1, 1996 that the standards will be applied to medical devices, apparatuses, and equipment whose production was approved before January 1, 1991.

The three standards mentioned above were simultaneously revised. The term of GOST 12.2.025-76 was extended to January 1, 1996 for medical products whose production was approved before January 1, 1991. Medical products whose production was approved after January 1, 1991 must meet the requirements of the standards of the international organizations.

GOST 23256-86 was canceled effective January 1, 1993. A number of its requirements was transferred into methodical recommendations (RD 60-707-91 [6]) and into revised GOST 20790-91, both being approved effective January 1, 1993.

Thus, from January 1, 1996 serially produced medical equipment is supposed to comply with the requirements of the international standards.

The second specific feature of the domestic standards for medical equipment is the obligatory incorporation of the clauses claimed by the principal customer (consumer) and specified in the tables appended to the standard. The tables contain lists of requirements and methods of testing at various stages in the life cycle of the device and types of its testing (see Table 1).

The life cycle of the device starts from the process of its development; therefore, the designer should be familiar with the entire volume of the respective standard. The next stage in the life cycle of the device is preliminary testing which follows manufacturing of the prototype model. The designer specifies the type and method of testing providing self-correction and preparation for inspection testing. The number of the standard clauses relevant to the designer's activity is reduced. The program and procedure of inspection testing is jointly specified by the designer and customer (principal consumer) together. The number of tested clauses is also reduced. Qualification testing is similar to inspection testing. Serially produced devices during reception-delivery testing are inspected by 5-10 standard clauses. Five more clauses are added during regular testing.

The third group of amendments takes into consideration the specific features of domestic industry and economy and definitions of the terms and parameters used, refines ranges of applications of standard requirements, presents diagrams of output power, enhances the list of devices used, phantoms, etc.