STANDARDS OF RELIABILITY FOR MEDICAL APPARATUSES

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No technical standards of reliability have yet been established for medical apparatuses, mainly because there have been no clear-cut recommendations on the selection and definition of indices of reliability, and because of the inadequate development of methods for scientific determination of values for these indices.

Neither in this country nor abroad have the problems connected with the establishment of a sound basis for evaluating reliability requirements received adequate attention.

Existing recommendations on criteria for articles designed for general industrial use are not based on any clearly defined system, are not supported by exact calculations, and are therefore open to argument [1]. Furthermore, these decisions deal only with particular cases and are valid only in the particular branches of industry with which their authors were concerned. Most are inapplicable to biomedical engineering products.

A possible approach to the solution of this problem of establishing a sound basis for reliability requirements in respect to articles of medical equipment was first examined in a paper by Kabatov [2], in which it was suggested that these articles could be classified on the basis of reliability indices. From information contained in divisions of the classification on "purpose" and "consequences of failure" it should be possible to select certain groups of indices for each class, and, on this basis, to approach the question of giving them values.

The questions raised by Kabatov [2] require further development. The fact is that, in this paper, nomenclature and values of reliability indices were considered solely from the point of view of the needs of medical institutions for equipment of a given standard of reliability, and no assessment was made of another no less important aspect of the problem, namely the extent to which industry would be able to give technical guarantees in respect to these indices. An attempt is now made to clarify the problem from this standpoint.

Certain concepts and terms must first of all be defined. Terms such as "index," "criterion" and "reliability parameter" are to be found in the literature in connection with assessment of the reliability of various articles.

The authors are of the opinion that it would be best to use a single term—"index"—to characterize qualities of reliability. The term "criterion" will be used solely as a subsidiary standard or appraisal factor for the determination of indices, and for the selection of index values, e.g., time (in hours), cost (in roubles), efficiency in relation to the functions required (in points), and so on.

According to Kabatov [2], index nomenclature and values will depend on the purpose for which the article is intended, and on the efficiency and reliability with which it performs the functions required of it (conditions of use). In the case of medical instruments and apparatuses in constant use, the concepts of "designation of article" and "conditions of use" must be expanded for the following reasons.

1. Designation of Article. This must not merely define the actual functional task for which the instrument is designed, but it must include any special features in the way it performs this task, whether it is intended for continuous operation over a prolonged period, or merely for periodic use. Another important factor is how much maintenance apparatus will require.

2. Conditions of Use. These must be regarded as including not only the importance of the functions they perform, but also the frequency with which an apparatus will be used (time-load), as it is obvious that the breakdown of articles, the failure of which is extremely undesirable, may have consequences the seriousness of which will increase with frequency of use.
Designation and quantitative indices of reliability for medical apparatuses must obviously be determined on two counts, namely the need for medical services to have reliable equipment, and the ability of industries engaged in the construction of medical instruments to satisfy these requirements. Kabatov [2] has shown that perfectly adequate guidance, in the selection of correct designations and correct values for reliability indices, can be obtained from consideration of the purpose for which medical apparatuses are designed and their conditions of use.

Assessment of the extent to which industries producing medical equipment can satisfy medical requirements in respect to reliability of equipment can be based on methods for appraisal of indices of reliability and on steps which can be taken to ensure reliability.

The position is that indices of reliability, formulated in accordance with the purposes for which medical apparatuses are designed, cannot always be given a value, as methods for such appraisals are not yet available. Also, already known methods for assessing reliability often involve technically complicated and costly calculations and trials. Consequently, when requirements in respect to the reliability of an apparatus are being formulated, the exact designation of indices, as determined by the purpose for which the apparatus is designed, must be reduced to terms which are in accord with appraisal methods which can be regarded as possible and useful at the particular time. The values of indices for the reliability of medical equipment, as determined from the conditions in which they are used, may likewise, in some cases, be unattainable on practical grounds (e.g. as a result of impracticability at the present level of technical development, or the lack of requisite materials). Values, as determined by conditions of use must, therefore, be modified in the light of existing resources for ensuring reliability.

Indices based on the requirements of medicine may be termed absolute indices, and indices arrived at from consideration of practical constructional possibilities, rational indices. In the ideal case the designations and levels of absolute and rational indices should be the same, but in practice they may differ. In the latter case rational indices of reliability must be prescribed after consideration of both requirements and available means of meeting them. Such indices may be said to be fixed at optimum level. This distinction having been made, it can be stated that the exact terms of absolute indices will be governed by the purposes for which apparatuses are intended, while their levels will be determined by the conditions of use; the exact terms of the rational index will depend on assessment, and its level, on the practical extent to which reliability can be ensured. The following successive stages in the establishment of the reliability requirements for medical equipment can now be suggested.

I. Determination of Designation of Reliability Indices

1. Absolute indices are based on purpose.
2. The exact terms of rational indices will depend on evaluation of absolute indices.

II. Establishment of Normal Reliability Indices

In general, this will amount to determining the optimum levels for indices after consideration of all aspects.

1. Levels of absolute indices as determined by conditions of use.
2. Levels of rational indices as determined by practical possibilities.

Each stage can now be considered in more detail.

I. Determination of Designation of Indices of Reliability

The wide range of terms used to define the indices of reliability which require examination can be linked with the many aspects of the concept of reliability. Its meaning has been extended and given more exact definition as theory of reliability has developed. Many authors limit the concept of reliability to individual properties of instruments (e.g. non-liability to failure), and if this were accepted, only indices concerned with these particular properties would have to be considered in establishing reliability requirements.

The broadest concept of reliability yet published is that given, in appropriate terminology, in the scheme of official All-Union Standards [4]. It includes the properties of freedom from failure, ease of repair, and durability. In this interpretation of the problem, the main objective of properties of reliability is to ensure that the operational indices of instruments are maintained within certain limits. In the authors'