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Clinical laboratory medicine — *In vitro* diagnostic medical devices — Validation of user quality control procedures by the manufacturer

Laboratoires d'analyses de biologie médicale — Dispositifs médicaux de diagnostic in vitro — Validation des recommandations du fabricant pour la maîtrise de la qualité par l'utilisateur



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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15198 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

Manufacturers of IVD medical devices often include quality control (QC) procedures in their instructions for use. These quality control procedures are intended to provide users with assurance that the device is performing within specifications, and therefore the results are suitable for their intended diagnostic use. For some devices, QC procedures can be an essential risk control measure. Depending on the design of the device, these quality control procedures can help users ensure the quality of results by:

- a) verifying the suitability of analytical systems (sample, reagents, instruments, and/or users);
- b) monitoring the precision and trueness of measurement results;
- c) preventing false-negative and false-positive results;
- d) identifying fault conditions that could lead to inaccurate results; and/or
- e) troubleshooting problems that require corrective action.

In addition, manufacturers often design IVD medical devices with the ability to detect potential failures and alert users to take corrective action. Such internal control systems could potentially reduce or even eliminate the need for users to run quality control samples to monitor the performance of the device.

This International Standard is written for manufacturers of *in vitro* diagnostic (IVD) medical devices as part of their design control and risk management programs. It will also enable manufacturers to provide validated quality control procedures for users in clinical diagnostic laboratories.

This International Standard describes how manufacturers can validate quality control procedures for their devices. Validation ensures that quality control procedures will perform as intended by the manufacturers and that manufacturers' recommendations fit the needs of particular devices, such as discrete systems, products with built-in electronic controls, and products with "on board" chemical and/or biological controls. Information about the validated quality control procedures increases user's understanding of devices' overall quality assurance requirements so that informed choices regarding suitable control procedures can be made.

Although laboratory directors have the ultimate responsibility for determining appropriate quality control procedures for their laboratories, manufacturers of IVD medical devices are responsible for providing adequate information to users about performance of devices as well as a means to control risks and to verify performance within specifications. Thus, in practice, quality control is a shared responsibility of IVD medical device manufacturers and users.

No single quality control procedure can cover all IVD medical devices, neither now, nor in the future, since the devices may differ fundamentally in design, technology, function and intended use. Quality control practices that developed over the years have provided laboratories with some degree of assurance that results are valid. Although widely accepted by laboratories, government agencies and accrediting organizations, these practices originated when laboratory analyses were performed manually and laboratories prepared their own reagents. They may not always be optimal for current IVD medical devices. Therefore, when quality control procedures are required, the manufacturer has the responsibility to design and validate quality control procedures appropriate for the device.

Quality system standards for medical device manufacturers have also evolved over time. Design control and risk management requirements, for example, are included in ISO 13485:2003 as well as in most contemporary regulatory schemes. Design controls require a risk analysis of the design, and, prior to introduction to the marketplace, require that the design be validated with respect to user requirements and intended use. Quality control procedures in the instructions for use should be viewed as an integral part of the design of an IVD medical device; and thus are subject to design validation requirements.