Medical Software Requirements at the New Cuban Regulations for Evaluation and State Control of Medical Devices

J. M. Santos Alonso[1], D. M. Martínez Pereira[2]

[1]Professor of Cuban University of Computer Science (UCI); Member of Scientific Commission of State Control Center for Medical Devices (CCEEM) and Bioengineering Society, Officer at Ministry of Computer Science and Telecommunications, Habana, Cuba
[2] Director of CCEEM; Member of Accreditation National Organ of Republic of Cuba, Habana, Cuba

***ABSTRACT*º— Paper discusses aspects of newly adoption of the Medical Software Requirements as annex of Cuban Regulations for Evaluation and State Control of Medical Devices, incorporate the strategies defined in the health policy and adopts a legislative dimension, in agreement with its own precepts and formulations. Defines the concepts of state control and evaluation of the medical software and adopts the medical software requirements, according with technological advances, and roll of software in safety. We should know that in the USA FDA's analysis of 3140 medical device recalls conducted between 1992 and 1998 reveals that 242 of them (7.7%) are attributable to software failures. Of those software related recalls, 192 (or 79%) were caused by software defects that were introduced when changes were made to the software after its initial distribution.**

Examples of established requirements: The medical devices being or including medical software must be designed to guarantee their function and efficacy according to the use they are intended to, complying with the specific requirements. Some others requirements should be considered for software evaluation: The existence and integrity of the information related to the medical software product, including: Critical analysis or risk classification, Risk analysis, Applied test cases, Testing plan, User documentation. The requirements keep in mind adoption of the international standard ISO/IEC 9126-1 and therefore the quality characteristics of software products as media to demonstrate effective and safety. At date, regulations about medical software requirement have been successfully applying as part of evaluation of medical software.

Key words— **medical software, requirement, regulation.**

I. Introduction

The Ministry of Public Health of Cuba (MINSAP), on behalf of the State of the Republic of Cuba is in charge of ensuring the health of the people and providing the highest protection and effectiveness within the National Health System to patients, health personnel and the general population when using the medical devices.

The regulatory activity of medical devices is implemented on a system that ensures their quality, safety, efficacy and effectiveness, as established by the Regulatory Program for Medical Devices.

The Regulation for the State Evaluation and Registration of Medical Devices is the guiding document of the Regulatory Program, enforced since the approval in 1992. These regulations, revised and updated according to the national and international practice, now the Regulations for Evaluation and State Control of Medical Devices [8], incorporate the strategies defined in the health policy of our country and adopt a legislative dimension, in agreement with its own precepts and formulations. It also defines the concepts of state control and evaluation of the medical devices as well as the performance of quality management and surveillance. Based on its contents, this document favors regulatory technical harmonization by applying international regulations and practices to ensure the safety of the medical device for a patient, with minimal risks during the medical practice.

Establishing the Regulatory Program for Medical Devices in Cuba and constantly improving the Regulations for the Evaluation and State Control of Medical Devices are an essential part of the development in the regulatory field, to ensure scientific novelty through the discussions in the international arena on the regulatory situation, scientific development and technological innovation.

The new regulations, the Regulations for Evaluation and State Control of Medical Devices, revised and updated according to the national and international practice and research -- as [6], European Directives and many others -- incorporate the strategies defined in the health policy of our country and adopts a legislative dimension, in agreement with its own precepts and formulations. It also defines the concepts of state control and evaluation of the medical devices as well as the performance of quality management and surveillance. Based on its contents, this document favors regulatory technical harmonization by applying international regulations and practices to ensure the safety of the medical device for a patient, with minimal risks during the medical practice.

The FDA's analysis of 3140 medical device recalls conducted between 1992 and 1998 reveals that 242 of them (7.7%) are attributable to software failures. Of those software related recalls, 192 (or 79%) were caused by software defects that were introduced when changes were made to the software after its initial production and distribution [1], [2].

In consequences, the new Regulations for Evaluation and State Control of Medical Devices has, together with well knowing "Essential requirements for the registration of medical devices", or "Classification rules of medical devices", complementary "Medical software requirements", according with technological advances [9]. Regulations are free available on site web of Center for State Control of Medical Devices (CCEEM): **www.eqmed.sld.cu.**

II. Vocabulary

MEDICAL SOFTWARE. The intellectual invention comprising the programs, procedures, rules and any documentation associated to the operation of a data processing system for medical purposes, so that it executes clinical functions or exerts an effect or a direct action on the diagnosis, therapy or preventive process. It applies whether it is a part of a computerized medical device or it is independently supplied as a product in itself [8], [10].

MEDICAL SOFTWARE ENGINEERING. Software engineering applied to medical software development [8].

III. Some articles of the regulation

ARTICLE 4. Is defined as medical device any instrument, equipment, implement, machine, implant, in vitro reagent or calibrator, software, material or any other similar or related article which is intended by the manufacturer to be used, alone or combined, in human beings for one or more of the specific purpose(s) [8]:

a) diagnosis, prevention, control, treatment or relief of a disease;

b) diagnosis, control, treatment, and alleviation or compensation of an injury;

c) investigation, replacement, modification, and anatomical support or to support a physiological process;

d) life support or preservation;

e) control of conception;

f) disinfection of medical devices;

g) to provide information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;...

ARTICLE 7. The medical devices being or including medical software must be designed to guarantee their function and efficacy according to the use they are intended to, complying with the specific requirements established for them and in this regulation [8].

IV. Medical software requirements

The Medical software requirements are [9]:

1. Devices constituting or including software, should be designed to ensure the repeatability, reliability and efficacy of these systems according to the intended use. In the event of a single fault condition in the system, appropriate measures should be adopted to eliminate or reduce consequent risks.

2. Medical devices (MD) using software for functioning should be classified, evaluated and registered according to the risk classification, as ruled in the MD Regulations.

3. Software products intended for medical purposes and used with standard computing media are included in the medical device definition of the MD Regulations, and should be evaluated and registered accordingly.

4. Software intended to be used in the National Health System, integrated with a medical device, should be strictly included in the Registry documentation of this computerized medical device.

5. Four essential requirements should be considered for software evaluation:

a) The existence and integrity of the information related to the medical software product, including:

- Specification of software requirements and cases of use
- Critical analysis or risk classification
- Risk analysis
- Applied and designed test cases
- Testing plan
- User documentation, including manuals
- Appropriate documentation of revisions, inspections and tests
- Quality System documentation, as established in Chapter III of MD Regulations

b) Requirement specifications and test results (from their respective metrics) should reflect the application of quality characteristics (functionality, reliability, usability, efficiency, mantenability and portability) and sub-characteristics, according to the quality standard and regulation currently in force (NC ISO/IEC 9126-1 [7], ISO/IEC 9126-1 [3]). The use of metrics to measure each quality sub-

characteristics should be demonstrated using standards as ISO/IEC 9126-2 [4] and ISO/IEC 9126-4 [5].

c) Safety characteristics of the software will reflect the safety critical functions implemented in the design, arising from a risk analysis (redundant medical software requirements controls, failure-safety mechanisms, troubleshooting, etc.). Elements documented should include risk analysis, safety testing plan and the record of risk management.

The level of evaluation should be related to the risk class assigned to software, depending on the risk it represents to a subject's safety, as follows:

- Risk Class I: Level D of evaluation
- Risk Class IIa: Level C of evaluation
- Risk Class IIb: Level B of evaluation
- Risk Class III: Level A of evaluation

The manufacturer is responsible for applying the techniques and specific methods, at appropriated levels, to evaluate, validate and carry out test that guarantee the software being effective and safe.

7. Techniques and methods used to evaluate, validate and test the software, and also results, should be presented to request the State Evaluation and Registry of a medical device as part of the documentation required:

a) A document (Certificate) of conformity evaluation of specifications is needed, prior to subjecting the software to the actual conditions of use.

b) The use of simulation programs and the test of the software in the finished intended medical device.

c) The test of the software under normal and abnormal working conditions, including any aspect negatively influencing its performance.

d) Results collection, analysis and statistical evaluation.

e) Software properties related to specifications of the manufacturer, regarding the final destination of the medical device, also including metrics for its evaluation.

f) Specification of acceptance limits for those aspects influencing software efficacy, safety and quality.

The inclusion of other products of the software, referring to new applications of the already registered medical devices, should be presented to the regulator following the same requirements demanded for extending the application field of an already registered medical device. New versions of the software, already included in the Registry documentation, will not be re-evaluated unless it is specified that substantial changes have being included.

V. Conclusions

Development of "Medical software requirements" has permitted encourage and complement the new Regulations for Evaluation and State Control of Medical Devices in the way of obtaining better State Evaluations of medical devices, and in consequence, more effective and safety medical software. It´s newly regulations at world level and represent the value of the Cuban human resources education in medical and computer science areas.

At date, it has been successfully applying to Evaluation of medical software from manufactures as UCI (MIC) and CIE (CITMA).

References

1. FDA-GPSV. General Principles of Software Validation; Final Guidance for Industry and FDA Staff Center for Biologics Evaluation and Research, Center for Devices and Radiological Health; Center for Devices and Radiological Health CDRH, Food and Drug Administration, U.S. Department Of Health and Human Services. 2002.
2. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf
3. ISO/IEC_9126-1 (2001). Software Engineering. Product quality. Part 1. Quality model. ISO, Geneva, Switzerland, 2003
4. ISO/IEC_9126-2 (2003). Software Engineering. Product quality. Part 2. External metrics. ISO, Geneva, Switzerland, 2003
5. ISO/IEC_9126-4 (2004). Software Engineering. Product quality. Part 4. Quality in use metrics. ISO, Geneva, Switzerland, 2004
6. Murphy E. et all, (1998) Qualitative Research Methods in Health Technology Assessment: Review Health Technology Assessment Vol. 2 No. 16 U.K. 1998.
7. NC ISO/IEC 9126-1, Ed. (2005). Ingeniería de software. Calidad del producto. Parte 1. Modelo de la calidad. Oficina Nacional de Normalización ONN, 2005
8. Reglamento de la Evaluación y el Control Estatal de los Equipos Médicos, Resolución 184, MINSAP, 2008.
9. Requisitos al Software Médico, Resolución No. 20 de fecha 11 de diciembre del 2008, del BRPS al amparo de la Resolución No. 184 de fecha 22 de septiembre de 2008 dictada por el Ministro de Salud Pública, que aprueba el Reglamento para la Evaluación y el Control Estatal de Equipos Médicos.
10. Santos, J. M. (2001). Medical Software. Evaluation. Regulatory Affairs Journal.

Autor: **José Manuel Santos Alonso**
Institute: UCI, MIC.
Ciudad: La Habana
País: Cuba
E-mail: jmsantos@uci.cu; santosal@infomed.sld.cu

Co-Autor: **Dulce María Martínez Pereira**
Institute: CCEEM, MINSAP
Ciudad: La Habana
País: Cuba
E-mail: dulcema@infomed.sld.cu