IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Standalone Medical Device Software: Key Definitions

Authoring Group: Standalone Medical Device Software Working Group

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

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This document is being released as a proposed document (PD) for public comment in July through August 2013. No comments will be accepted after August 30, 2013. All comments should be sent on the IMDRF Comment form to the Standalone Medical Device Software Working Group Chair, Mr. Bakul Patel at mailto: Bakul.Patel@fda.hhs.gov with a copy to the IMDRF Secretariat mailto: EC-IMDRF2013-SECRETARIAT@ec.europa.eu.

1.0 Introduction

Software for medical purposes is becoming increasingly important and influential in advancing public health. Such software can appear in many forms and on many computing platforms. For example, software can be embedded in (part of) a medical device while standalone medical device software (standalone software) appear on a wide variety of computing platforms such as a mobile phone, network server, or as a service through cloud-based computing. With disruptive advances in innovative computing technology, potential uses of standalone software pose increasing demands and challenges on regulators to fulfill their public health mission and provide continuous regulatory predictability and clarity to stakeholders.

Existing regulations adequately address public health risks of software when embedded in a traditional medical device. However, existing regulations do not readily translate or address the unique public health risks posed by standalone software nor assure an appropriate balance between patient/consumer protection and promoting public health by facilitating innovation. Existing regulatory controls can have limited applicability when software can be developed, distributed, and accessed in a distributed environment through the internet.

Some regulators have taken individual approaches to assure patient safety, effectiveness, and performance. While some of these individual approaches have common public health goals, differences in regulatory approaches currently exist.

This effort is to facilitate international regulatory convergence towards a smart, balanced regulatory approach that provides an optimal level of patient safety while fostering innovation and provides patient and providers with continued access to advanced health care technology that is safe.

2.0 Scope

This IMDRF document builds upon previous work done by the Global Harmonization Task Force (GHTF) and the different GHTF working groups which concluded its work in November of 2012. This document identifies key definitions starting with a common definition for "standalone medical device software." These definitions are intended to serve as a foundation for further IMDRF work (identifying a risk framework and controls needed to address risks) to be conducted by this workgroup.

3.0 References

Not required for this document.

4.0 Definitions

Not required for this document.

5.0 "Standalone Medical Device Software": Key Definitions

5.1 Standalone medical device software

The term "standalone medical device software" (SMDS) is defined as software intended to be used for one or more medical purposes and is able to perform its medical purpose without being embedded in a hardware medical device or being dependent on specific or proprietary medical purpose hardware.

Characteristics of standalone medical device software may include but are not limited to:

- capable of running on general purpose (non-medical purpose) computing platforms
- not necessary for a hardware medical device to achieve its intended medical purpose;

In addition the following may apply:

- may be used in combination (e.g., as a module) with other devices;
- may be interfaced with other medical devices, including hardware medical devices and other standalone medical devices software

NOTES:

- SMDS is a medical device.
- "Medical Device(s)" include In vitro diagnostic (IVD) medical device(s), thus select SMDS may be treated as an IVD medical device
- "Computing platforms" include hardware and software resources (e.g. operating system, processing hardware, storage, software libraries, displays, input devices, etc.).
- "Operating systems" that SMDS require may be running on a server, a workstation, a mobile platform, embedded system or other general purpose hardware platform.
- Software that meets the definition of SMDS and is part of another software, regardless if the other software has a medical purpose or not, is still considered as a SMDS (i.e. medical device)
- Software running on a general purpose computing platform that is embedded in a hardware medical device is <u>not</u> SMDS, instead is considered a hardware medical device. (e.g. EKG hardware device that uses windows CE operating system on a general purpose embedded x86 computer is considered an EKG device)

5.2 Medical purpose for software

The definition of "Medical device" in GHTF/SG1/N71:2012, identifies "medical purpose" for medical device and IVD device. Based on the GHTF definition, unless specifically excluded, medical purpose for software includes the following:

a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
c) investigation, replacement, modification, or support of the anatomy or of a physiological process,
d) supporting or sustaining life,
e) control of conception,

f) *disinfection of medical devices* ***(specifically excluded as a medical purpose for SMDS),***
g) providing information by means of in vitro examination of specimens derived from the human body,
h) to provide information for diagnostic, monitoring or compatibility purposes,
i) for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

The 2012 GHTF definition also identifies products which may be considered medical devices in some jurisdictions and would therefore be included under the term "medical purpose" but for which there is not yet a harmonized approach:

j) aids for persons with disabilities,
k) *devices for in-vitro fertilization or assisted reproduction technologies (**specifically excluded as a medical purpose for SMDS**).*

For SMDS, the following purposes are specifically **included** as medical purpose for software

- mitigation of a disease,
- provide information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities,
- aid in diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.
- aids for persons with disabilities

For SMDS, the following purposes are specifically **excluded** as medical purpose for software since these purposes are not foreseen for software

- *disinfection of medical devices*
- *devices for in-vitro fertilization or assisted reproduction technologies*

5.3 Software Changes

The term "software change" means any change made to software currently used or marketed for purposes that include corrective or adaptive purposes, or for change in functionality.

Software changes may include but are not limited to the following types:

- changes associated with defect fixes, aesthetics, usability enhancements, security patches or operating efficiency'
- changes affecting the software's original performance, safety and effectiveness, and/or intended use / purpose;
- changes to mitigate new risk(s) not previously identified, or change the probability that existing hazard(s) will occur;
- changes to adapt the software to new and / or different computing platforms (e.g., from an on-site server to an off-site "cloud" server.)

5.4 Standalone Medical Device Software manufacturer[1]

The term "standalone medical device software manufacturer (manufacturer)" refers to -- any natural or legal person with responsibility for design and/or manufacture of standalone medical device software (SMDS) with the intention of making the SMDS available for use, under his name; whether or not such a SMDS is designed and/or manufactured by that person himself or on his behalf by another person(s).

5.5 Intended use / intended purpose[2]

The term "intended use/ intended purpose" means the objective intent of the manufacturer regarding the use of a product, process, or service as reflected in the specifications, instructions, and other information provided by the manufacturer.

NOTE:

Although not specifically included in the GHTF definition, for SMDS, materials such as sales and marketing materials expressed by the manufacturer is considered as "information provided by the manufacturer" and therefore reflects the objective intent of the manufacturer.

[1] Based on the definition in GHTF/SG1/N55:2009 Definition of "Manufacturer"

[2] Based on the common definition in GHTF/SG1/N045:2008 / GHTF/SG1/N68:2012 / GHTF/SG1/N70:2011 / GHTF/SG1/N77:2012 GHTF/SG5/N6:2012.