

*Guidance for
Off-the-Shelf Software Use
in Medical Devices*

DRAFT DOCUMENT

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Office of Device Evaluation

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[Note: This DRAFT document represents the agency's attempt to obtain public comment on the use of off-the-shelf software in medical devices. Comments and suggestions may be submitted at any time until the close of the comment period as specified in a notice of availability which will be published in the Federal Register in the near future. The comment period will be at least 90 days. Submit comments for agency consideration by writing to Dan Spyker, CDRH, 9200 Corporate Boulevard, HFZ-450, Rockville, MD 20850 or by e-mail to dxs@cdrh.fda.gov. For questions regarding the use or interpretation of this guidance, also contact Dan Spyker at (301) 443-8320.]

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Center for Devices and Radiological Health

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Numbers in square brackets [##] appearing in this guidance refer to citations in the Bibliography (Section IV)

I. Overview

2

A. Introduction and Background

4 Off-the-shelf (OTS) software is commonly considered for incorporation into medical devices as
the use of general purpose computer hardware becomes more prevalent. The use of OTS
6 software allows device manufacturers to concentrate on the application software needed to run
device-specific functions. However, it must be recognized that OTS software intended for
8 general purpose computing may not be appropriate for a given specific use in a medical device.
The medical device manufacturer using OTS software generally gives up software life cycle
10 control, but does bear the responsibility for the safe and effective performance of the medical
device.

12 This guidance document was developed to address the many questions asked by medical device
manufacturers regarding what they need to provide to the FDA when they use OTS software.
14 The response to these questions depends on the medical device in question and the impact on
patient safety when the OTS software fails. Thus, the answer to the question, "What do I need to
16 do or document?" will be based on the hazard analysis that is an integral part of designing a
medical device. The detail of documentation to be provided to FDA and the level of life cycle
18 control necessary for the medical device manufacturer increase as the hazard to the patient from
software failure increases.

20 This document lays out in broad terms how the medical device manufacturer should determine
what is necessary to do and to document for submission to the agency. A BASIC set of need-to-
22 do items is proposed for all OTS software, and a detailed discussion is provided on additional
(SPECIAL) needs and responsibilities of the manufacturer when hazards from OTS software
24 failure become more significant.

B. Purpose / Scope

26 This guidance document represents the agency's current thinking on use of OTS software in
medical devices. It does not create or confer any rights for or on any person and does not operate
28 to bind FDA or the public. An alternative approach may be used if such approach satisfies the
requirements of the applicable statute, regulations or both.
30

2 The **purpose of this document** is to describe the information that should be provided in a
3 medical device application involving OTS software. While this document is not intended for
4 compliance with Quality System (GMP) requirements, many of the principles outlined herein may
5 be helpful to device manufacturers in establishing design controls and validation plans for use of
6 off-the-shelf software in their devices. Further industry guidance on these subjects will be issued
7 by the Office of Compliance, CDRH. This guidance discusses key elements reviewers should
8 look for in the submission thereby providing a common baseline from which both manufacturers
9 and reviewers can operate. This document provides guidance in support of the Blue Book
10 Memorandum G97-___, *Use of Off-the-Shelf (OTS) Software in Medical Device Applications* [1].
11 This should improve predictability of agency interaction with sponsors regarding applications
12 involving OTS software.

13 **C. Definitions**

14 **Off-the-Shelf Software (OTS software)** -- A generally available software component, used by a
15 medical device manufacturer for which the manufacturer can not claim complete software life
16 cycle control.

Following a patient-based approach to hazard analysis, we define:

18 **Hazard** -- A possible source of danger or a condition which could result in human injury.

19 **Hazard Mitigation** -- Reduction in the severity of the hazard, the likelihood of the occurrence,
20 or both.

21 **Minimal Hazard** --Where failure, malfunction, or misuse of the OTS software poses no
22 possibility of serious injury to the patient, then the OTS software is said to present a MINIMAL
23 HAZARD.

24 **Safety** -- In the regulation of medical devices, safety means that the probable benefits to health...
25 for its intended use... when accompanied by adequate directions and warnings against unsafe use,
26 outweigh any probable risks. In this guidance we will use the words "safety and effectiveness" to
27 remind ourselves that safety is only meaningful in the context of the benefit-risk considerations
28 and the labeling.

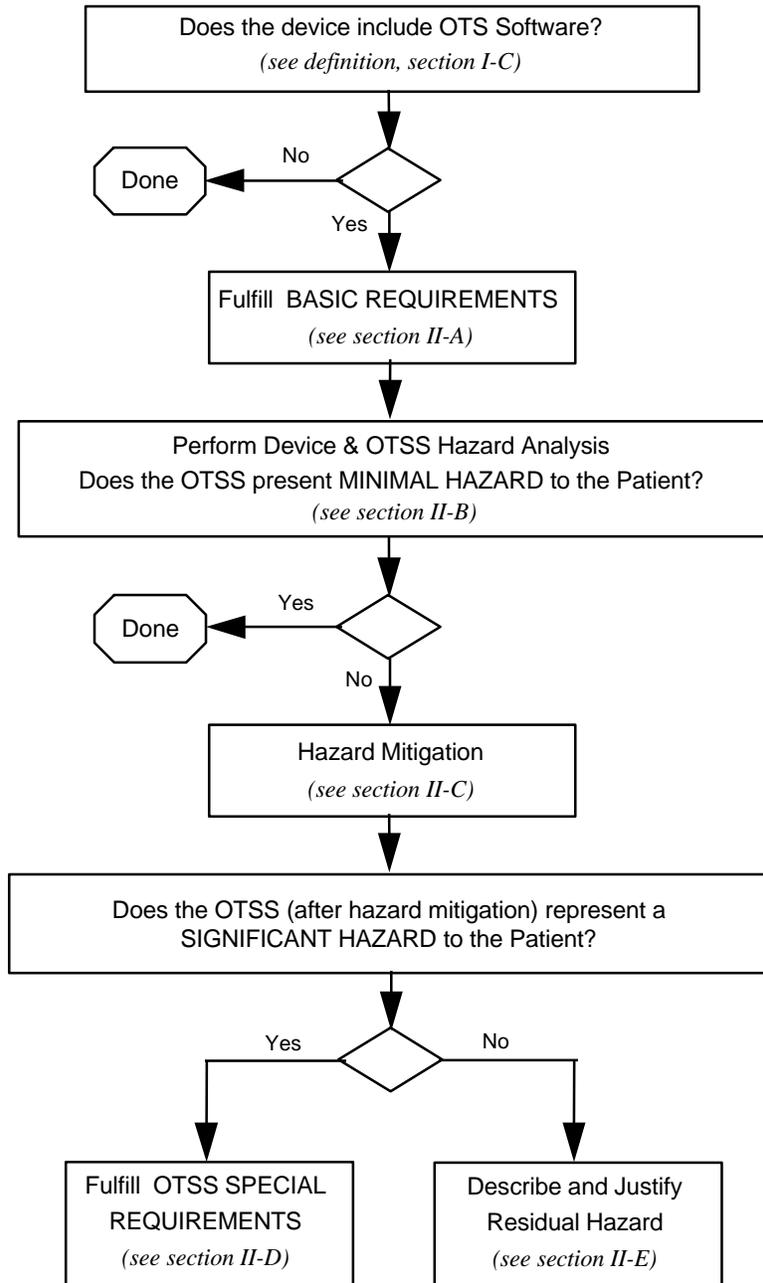
29 **Significant Hazard** -- Where failure, malfunction, or misuse of the OTS software is likely to
30 result in death or serious injury to the patient, then the OTS software is said to present a
31 **SIGNIFICANT HAZARD**

32 Other software terminology used in this document are defined in the *FDA Glossary of
Computerized System and Software Development Terminology* [2].

D. OTS Software Decision Schematic

- 2 The content of the medical device application supporting use of OTS software (OTSS) in a
- medical device depends on the results of the hazard analysis. Figure 1 provides a schematic of the
- 4 decision process and a table of contents for Section II of this guidance document.

Figure 1. OTS Software Decision Schematic



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As summarized in Figure 1, BASIC REQUIREMENTS should be fulfilled for any OTS software used in a medical device. If the hazard analysis shows that the OTS software failure presents only a MINIMAL HAZARD to the patient, then only the hazard analysis and BASIC REQUIREMENTS would be expected in the submission.

If the OTS software failure presents more than a MINIMAL HAZARD to the patient, then the sponsor will need to describe the measures taken in hazard mitigation. If, after the measures to mitigate hazards, any SIGNIFICANT HAZARD remains, then the medical device manufacturer should fulfill the SPECIAL REQUIREMENTS for OTS software.

If after the measures taken in hazard mitigation the residual hazard is not significant, then the OTS software falls in the “middle ground”. The application should then include the hazard analysis and a benefit risk assessment of the remaining hazard to the patient (see section II-A for examples).

II. OTS Software Use

A. BASIC REQUIREMENTS for OTS Software

The detail used satisfying these BASIC REQUIREMENTS should be appropriate to the hazard of the medical device.

The OTS Software BASIC REQUIREMENTS are intended to answer the following questions:

1. What is it? - For each component of OTS software used, specify the following:

- a) Title and Manufacturer of the OTS software;
- b) Version Level, Date, Patch Number and Upgrade Designation as appropriate; and
- c) OTS documentation (user manual) which will be provided to the end user.

Note: Unless documented by an approved “Software Change Request”, the medical device manufacturer should only use the OTS software as specified in the Software Requirements Specification (SRS). This requires verbatim compliance to name, version level, patch additions and tailored configuration.

2. What are the Computer System requirements for the OTS? - For the entire system, specify the following:

- a) Hardware requirements: processor, RAM, hard disk, other storage, communications, display, etc.
- b) Software requirements: operating system, drivers, utilities, etc. The SRS listing for each item should contain the name (e.g., Windows 95, Excel, Sun OS, etc.), specific version levels (e.g., 4.1, 5.0, etc.) and a complete list of any patches that have been provided by the OTS software manufacturer.

2 **3. What Actions must be taken by the End User?** - What aspects of the OTS software and system can (and/or must) be installed/configured?

a) What steps are permitted (or must be taken) to install and/or configure the product?

4 b) What are the acceptable and usual ranges of data which must be provided and the default values should no data be provided.

6 c) When will the configuration need to be changed?

4. What does the OTS software do? - For the entire system, specify the following:

8 a) What is the OTS software intended to do? The sponsor's design documentation should specify exactly which OTS programs, modules, units, routines and/or functions will be included in the design of the medical device. Specific attention should be directed at the error control and messaging interfaces.

10
12 b) What is the interface with other software including software outside the medical device (not reviewed as part of this or another application)? The interface to outside software should be completely defined for each medical device, module, unit, routine and/or function. The design documentation should include a complete description of the interface between the medical device software and any outside software.

5. What does the OTS software NOT do? - For the entire system, specify:

18 a) What are the expected / design limitations of the OTS software?

b) Is there a current list of OTS software problems (bugs) and access to updates?

20 **6. How do you know it works?** - Describe testing, verification and validation of the OTS software and ensure it is proper for the device hazard.

22 a) How was the OTS software tested?

24 Note: Software test, verification and validation plans must identify the exact OTS software (title and version) that is to be used. When the software is tested it must be integrated and tested using the specific OTS software that will be delivered to the user. This requirement applies at all levels of software testing (module, integration, and system)

28 b) What were the results of the testing which verify successful completion of the testing?

Note: If the manufacturer allows the use of the medical device with different versions of OTS software then the manufacturer is required to validate the medical device for each OTS software version.

- 2 **7. How will you keep track of (control) the OTS software?** - An appropriate plan should
answer the following questions:
- 4 a) What education and training are suggested or required for the user of the OTS
software?
- 6 b) What measures have been designed into the medical device to prevent the
introduction of any non-specified OTS software, e.g., word processors, games, etc.
8 Introduction of non-specified OTS software may be prevented by design, i.e.,
disabling input (floppy disk, CD, tape drives, modems).
- 10 c) What measures have been designed into the medical device to prevent the
introduction of incorrect versions? On startup, ideally, the medical device should
12 check to verify that all software is the correct title, version level and configuration.
If the correct software is not loaded, the medical device should warn the operator
14 and shut down to a safe state.
- d) How will you maintain the OTS software configuration?
- 16 e) Where and how will you store the OTS software?
- f) How will you ensure proper installation of the OTS software?
- 18 g) How will you ensure proper maintenance and life cycle support for the OTS
software?

20

B. Hazard Analysis and Hazard List

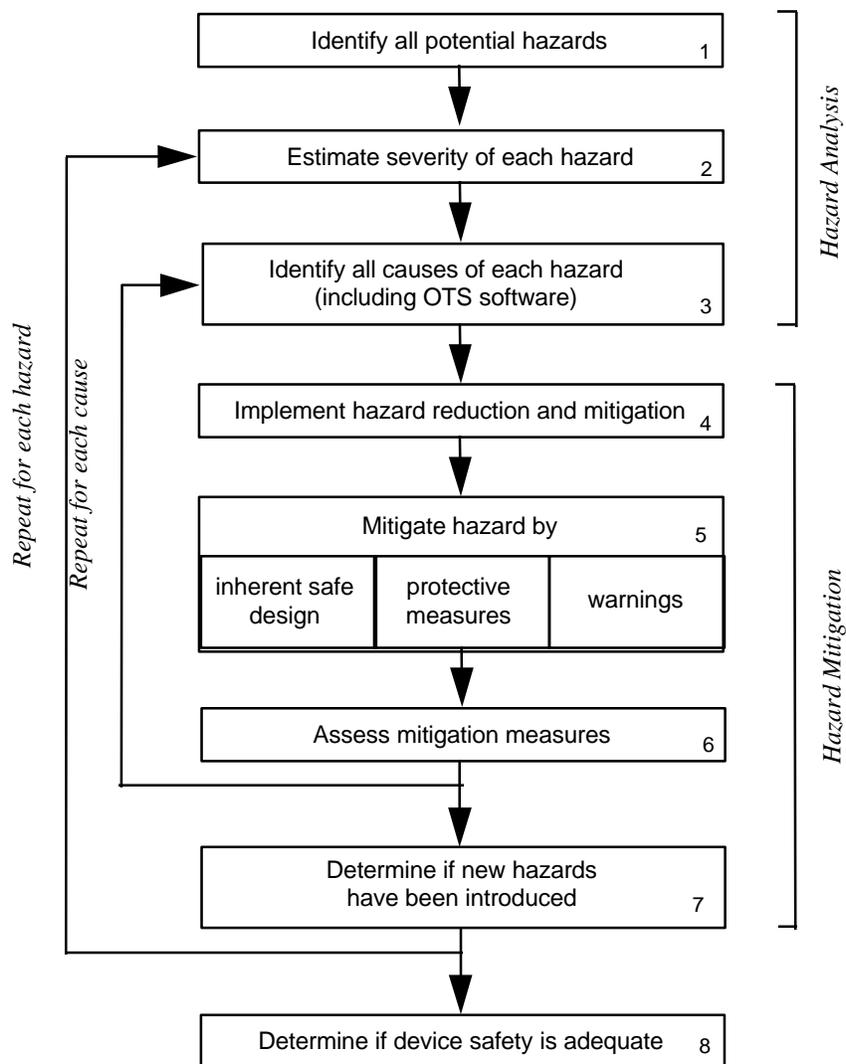
2 A comprehensive hazard management approach includes hazard analysis and hazard mitigation
 4 that continues iteratively throughout the life of the product. The manufacturer is expected to
 perform an **OTS software hazard analysis** as a part of a **medical device (system) hazard
 analysis**.

6 The OTSS hazard can be no greater than the hazard posed by the device itself. The hazard
 analysis for such a device may simply document the minimal hazard of the device.

8 Hazards to patient safety and effectiveness from OTS software failure, malfunction, or misuse
 must be identified. Figure 2 summarizes the hazard management process.

10

Figure 2. Hazard Management Schematic



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14 The submission should include the following information to document the medical device
 HAZARD ANALYSIS:

1. A list of all identified medical device hazards
2. The estimated severity of each identified hazard
3. Potential causes of each identified hazard

Note: A tabular format of the hazard management or a tabular summary will facilitate review.

Where failure, malfunction, or misuse of the OTS software poses no possibility of serious injury to the patient, then the OTS software is said to present a **MINIMAL HAZARD**, and the fulfillment of the BASIC REQUIREMENTS (see section II-A) will be considered sufficient.

C. Hazard Mitigation

Hazard mitigation activities may seek to reduce the severity of the hazard, the likelihood of the occurrence, or both. Hazard mitigation interventions may be considered in three categories with the following order of precedence:

- 1 - Design (or redesign)
- 2 - Protective measures (passive measures)
- 3 - Warning the user (labeling, active measures)

These approaches are by no means mutually exclusive and often may be used concurrently. The most desirable approach is to design in effective hazard controls, i.e., eliminate the need for a hazardous operation or component. Protective measures are considered passive (from the user's standpoint) since they do not require any action on the part of the user. Least desirable, is to depend on some action (or lack of action) on the part of the medical device user.

With implementation of each hazard mitigation, the residual hazard is assessed as well as assessment of any new hazards introduced.

The submission should include the following information to document the medical device

HAZARD MITIGATION:

1. A list of all identified medical device hazards associated with the OTS software
2. The steps taken to mitigate the hazard
3. The residual hazard

Note: A tabular format of the hazard management or a tabular summary will facilitate review. These results will typically be included as a part of the overall medical device hazard mitigation.

One example of a comprehensive approach to injury prevention in public health was developed around ten “countermeasures” [3]. Table 1 illustrates a generic approach to the hazard mitigation, in this case, to preventing injury-related energy release to patients.

Table 1. Injury Reduction Countermeasures

1.	Prevent accumulation of the energy.
2.	Reduce the amount of the energy delivered.
3.	Prevent inappropriate release of the energy.
4.	Modify the release of the energy.
5.	Separate the patient from the energy in time and space.
6.	Provide physical barriers between the energy and the patient.
7.	Change the surfaces or basic structures at the interface.
8.	Strengthen resistance of the patient.
9.	Provide rapid emergency response to injury.
10.	Improve medical care and rehabilitation.

Following the HAZARD MITIGATION steps, the sponsor needs to assess the remaining hazard.

Where failure, malfunction, or misuse of the OTS software is likely to result in death or serious injury to the patient, then the OTS software is said to present a **SIGNIFICANT HAZARD**. Likely here is taken to mean “more likely than not”.

Acceptable levels of hazard mitigation depend on the intended use of the medical device and the function performed by the software.

In the case of diagnostic tests, injury includes results which can lead to unnecessary invasive diagnostic testing (e.g., biopsy) or withholding or delaying important diagnostic or therapeutic procedures.

2 If the residual hazard from the OTS software presents **SIGNIFICANT HAZARD**, the sponsor
will need to fulfill **SPECIAL REQUIREMENTS (II-D)**, otherwise, the sponsor will need to
4 describe and justify the residual hazard (section II-E).

6 **D. SPECIAL REQUIREMENTS for OTS Software**

To fulfill **SPECIAL REQUIREMENTS** for OTS software the medical device manufacturer is
8 expected to:

1. Provide assurance to FDA that the product development methodologies used by the OTS
10 software developer are appropriate and sufficient for the intended use of the OTS software
within the specific medical device. This should include an audit of the OTS software
12 developer's design and development methodologies used in the construction of the OTS
software. This audit must thoroughly assess the development and qualification
14 documentation generated for the OTS software.

If such an audit is not possible, and the OTS software represents an unmitigated
16 **SIGNIFICANT HAZARD**, the use of such OTS software may not be appropriate for the
intended medical device application.

18 2. Demonstrate that the procedures and results of the verification and validation activities
performed for the OTS software are appropriate and sufficient for the safety and
20 effectiveness requirements of the medical device. Verification and validation activities
include not only those performed by the OTS software developer, but also includes those
22 performed by the medical device manufacturer when qualifying the OTS software for use
in the specific medical device.

24 3. Demonstrate the existence of appropriate mechanisms for assuring the continued
maintenance and support of the OTS software should support be terminated by the
26 original OTS software developer.

28 **E. Describe Hazard Level & Justify Safety and Effectiveness**

The sponsor should provide a detailed (complete) discussion of the hazard which remains.

30 The hazard related to the use of OTS software should be considered in relation to the hazard of
the alternatives, i.e., custom developed software. Any experience (data) with the use of the OTS
32 software in this or a related application should be presented and considered. Acceptable levels of
hazard mitigation depend on the specific medical device application.

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III. OTS Software in Marketing Applications

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A. Examples

4 Examples of medical devices using OTS software which have been cleared under 510(k)
6 applications are described in this section. These examples illustrate the reasoning which leads to
8 defining the level of hazard from a medical device and thus the kinds of development processes
which should be used and the information to be provided in a regulatory submission.

Corneal Topographer -- Minimal hazard medical device (II-A)

10 **Intended Use:** A corneal topographer provides images of the abnormalities in the curvature of
the cornea, the simplest being astigmatism.

12 **Description:** A corneal topographer consists of a hollow cone which the patient looks into
14 from the base looking towards the interior of the point (like looking into the big end of a
megaphone with one eye). The inside of the cone is white with black concentric circles.
16 The concentric circles reflect off the eye and are imaged by a camera with a computer
controlled lens situated at the point of the cone looking at the patient's eye. The shape
18 of the reflected concentric circles are used to develop a topographic map of the cornea
curvature which is printed out.

OTS software: An OTS operating system such as Windows is commonly used to interface the
20 user, the microcomputer hardware platform, the corneal topographer, data storage, and
output devices.

22 **OTS software Hazard:** A corneal topographer represents minimal hazard of direct harm to
the patient. The hazard of indirect harm from a misdiagnosis relating to medical device
24 malfunction is small since the worst case is an incorrect image which is considered
correct. The OTS software in this medical device thus represents a MINIMAL
26 HAZARD (see section II-B) and must satisfy BASIC REQUIREMENTS (see section
28 II-A).

Perineometer -- Minimal hazard medical device (II-A)

2 **Intended Use:** Perineometers are used to provide feedback to a patient performing muscle
strengthening exercises (Kegel exercises) for the treatment of certain types of urinary
4 incontinence.

6 **Description:** There are two types of perineometers: those which measure pressure, and those
which measure electrical activity (EMG) from muscles. Each device consists of a probe
that is placed into either the vagina or the rectum, and a monitoring unit. The pressure
8 devices use an air-filled probe connected to the monitoring unit by a piece of plastic
tubing. When the patient performs the exercise, the probe is compressed, and the
10 monitoring unit reports the change in pressure. The electrical devices use an electrode
to measure the electrical activity of the target muscles during the exercises, and this
12 information is reported by the monitoring unit.

14 **OTS software:** An OTS operating system, such as DOS or Windows, may be used to record
and display the data collected by the monitoring unit.

16 **OTS software Hazard:** Perineometers represent a minimal hazard of direct injury to the
patient, since no energy is applied by the medical device to the patient. The hazard of
indirect injury due to inaccurate feedback during the exercise session is expected to be
18 small, as these medical devices are only used as an adjunct to exercise therapy, and they
are used under clinical supervision. The OTS software in this medical device thus
20 represents a MINIMAL HAZARD (see section II-B) and must satisfy the BASIC
REQUIREMENTS (section II-A).

Implantable Medical Device Programmers -- Describe Hazard, Justify Safety and Effectiveness
(II-E)

24 **Intended Use:** An implantable medical device programmer provides interface and two-way
communication with an implantable cardioverter-defibrillator (ICD) or cardiac
26 pacemaker.

28 **Description:** An implantable medical device programmer consists of an electromagnetic
programming head which is placed over the implanted device and provides through-the-
skin communication with the implanted device, the personal microcomputer (PC)
30 interface, and the PC hardware and software. The programmer permits the physician-
user to:

- 32 • query the implant for performance history (device and patient), and, in some systems,
for print-out of the recorded electrograms;
- 34 • set the adjustable (programmable) characteristics of the implant;
- provide the induced shock for system initialization and diagnostic purposes; and
- 36 • verify implant operating characteristics and status (including battery) *via* signals from
the implant.

2 **OTS software:** An OTS operating system such as DOS or Windows is used to provide a user interface (sometimes graphical), interface to the PC (hardware platform), and interface with data storage, and output devices.

4 **OTS software Hazard:** The on-board software for the implant satisfies the definition of high-hazard software (life supporting/life sustaining) and would need to satisfy the SPECIAL REQUIREMENTS (see section II-D). Whether the device programmer can be considered of lesser hazard depends primarily on the protection designed into the implant. Steps taken to mitigate the hazard might include:

- 6 • design of the implant to minimize the possibility of misprogramming to inappropriate operational states;
- 8 • design of the programmer interface to minimize the chance of miscommunication including hardening of the hardware against electromagnetic interference (EMI);
- 10 • limiting the part of the OTS software which is utilized in the programming application;
- 12 • protecting the PC from use for other applications;
 - 14 - What are the software design features to protect against adding unwanted software, modification or system use?
 - 16 - What are the hardware design features to protect against unwanted system use?

18 **Other points which might be offered to support use of OTS software in the programmer might include:**

- 20 • documented experience (data) with use of the OTS software in this application
 - 22 - What was the system in place to detect and report problems?
 - 24 - What is the rate of problems reported compared to other (perhaps non-OTS software) systems?
- 26 • documented experience with the OTS software in other relevant applications
 - 28 - What are the reported problems (bug list) and how many are relevant to this application?
 - Has there been difficulty in developing work-arounds for the problems relevant to this application?

30 The review team must decide whether the overall programmer system as implemented satisfies the necessary system safety and effectiveness (see section II-E).

32 **B. 510(k) Issues with OTS software**

34 The conditions under which a new or changed medical device including OTS software will require a new 510(k) are the same as for a device not involving OTS software. These conditions are given in CDRH's guidance *Deciding When to Submit a 510(k) for a Change to an Existing*

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2 *Device* [4]. The section (B) on Technology Engineering and Performance Changes in the 510(k)
3 guidance is most applicable to OTS software.

Section B of the guidance includes the following questions:

4 B1 Is it (the modification) a control mechanism change?

B2 Is it an operating principle change?

6 B5 Is it a change in performance specifications?

B8 Is it a change in software or firmware?

8 **B8 Is it a change in software or firmware?** The types of changes identified at decision
9 points B4 through B8 have frequently been called design changes or engineering
10 changes. They encompass everything from the routine specification changes necessary
11 to maintain or improve medical device performance as a result of feedback from users,
12 field or plant personnel, etc., up to and including significant product redesign.

14 **B8.1 Does the change affect the indications for use?** As with an explicit labeling
15 change, if the change affects the indications for use, i.e., if it creates an implied new
16 indication for use, a new 510(k) should be submitted.

16 **B8.2 Are clinical data necessary to evaluate safety and effectiveness for purposes of**
17 **determining substantial equivalence?** Whenever a manufacturer recognizes that
18 clinical data are needed because bench testing or simulations are not sufficient to
19 assess safety and effectiveness and, thus, to establish the substantial equivalence of a
20 new design, a 510(k) should be submitted.

22 In the case of *in vitro* diagnostic devices, however, if a scientifically valid test of
23 clinical samples demonstrate that the medical device continues to conform to
24 performance specifications as contained in a voluntary standard or as described in a
previous 510(k), a new 510(k) is usually not necessary.

26 **B8.3 Do results of design validation raise new issues of safety and effectiveness?** All
27 changes to medical device design will require some level of design validation or
28 evaluation to assure that the device continues to perform as intended. The successful
29 application of routine design validation activities will logically result in manufacturers
30 documenting their efforts and proceeding with the design change, i.e., assuring that
no issues of safety or effectiveness are raised.

A yes answer to any of these questions in section B will require a new 510(k).

Typical OTS Software Changes Requiring a 510(k)

2 **For medical devices where the OTS Software represents a MINIMAL HAZARD, OTS**
3 **Software changes would not require a new 510(k).** However, the manufacturer is responsible
4 for validating the change.

5 For other medical devices, the decision as to whether a new 510(k) is required depends on the
6 intended use of the device, the function of the OTS software, and to what extent the hazards due
7 to OTS Software have been mitigated (see guidance on when to submit a 510(k) [4]).

Exemption of Laboratory Information Management Systems

8
9
10 Laboratory information management systems (LIMS) are Class I devices (21 CFR 862.2100,
11 Calculator/Data Processing Module for Clinical Use). They are included in the category of
12 electronic medical devices intended to store, retrieve, and process laboratory data. LIMS may
13 also handle scheduling, billing and other non-device functions. LIMS have been **exempted from**
14 **510(k)** since June 8, 1988. However, compliance to all other requirements is required, including
15 registration, listing, GMP, and MDR are applicable.

16 The LIMS exemption does not apply to applications of artificial intelligence or other algorithms
17 intended to assign a probability of diagnosis for the purpose of guiding therapy or further
18 diagnostic studies.

19 Clinical data management functions may be subject to FDA regulations as are blood establishment
20 software systems.

22 C. IDE Issues with OTS software

23 An IDE is required for the same conditions as for a medical device not containing OTS software.
24 The OTS software may be a component of a medical device or the OTS software may be the
25 entire medical device, e.g., diagnostic software. These conditions are specified in 21 CFR 812
26 and generally include changes such as to effect: the patient population for which the medical
27 device is intended, conditions of use of the device (including those recommended or suggested in
28 the labeling or advertising, the probable benefit from the use of the device weighed against any
29 probable injury or illness from such use), or the reliability of the medical device.

30 Some specific issues related to OTS software might include initial (beta) testing of an OTS
31 software medical device with clinical studies. Such a study must comply with applicable IDE
32 requirements. For non-significant risk medical devices, that includes approval by an institutional
33 review board and patient informed consent. For significant risk studies, the initial user testing
34 (beta testing) protocol would be included in an IDE submission to ODE. For example, beta
35 testing of radiation treatment planning software, including any OTS software modules, would be
36 conducted under a full IDE with FDA approval as a prerequisite.

Exemption of Diagnostic Devices

2 If the product incorporating the OTS software is a diagnostic medical device, it may be exempted
3 from IDE requirements, if it meets the criteria in section 21 CFR 812.2(c)(3). For example,
4 clinical (beta) testing of a noninvasive diagnostic device that does not require significant risk
5 invasive sampling procedure and that does not introduce energy into the body, is exempted from
6 IRB approval, patient informed consent, and other IDE requirements, if a medically established
7 diagnostic product or procedure is used to confirm the diagnosis.

8

D. PMA Issues with OTS software

10 The criteria and requirements for premarket approval applications are in 21 CFR 814. When a
11 manufacturer submits a premarket approval for a medical device, there must be valid scientific
12 evidence (including clinical evidence, if needed) to support a reasonable assurance of safety and
13 effectiveness of the device.

14 The OTS software used in a medical device is evaluated in the context of the overall medical
15 device. The extent to which the manufacturer must demonstrate conformance to appropriate life
16 cycle control depends upon the overall hazard of the medical device, the role of the OTS
17 software, and the hazard associated with possible failures of the OTS software component.

18 For example, a commercially available neural network used by a medical device manufacturer for
19 pattern recognition, would require extensive validation if used in a Pap smear screening device, in
20 computer-assisted radiology, or for computer-assisted analysis of EKG wave forms. The same
21 neural network, used for less critical computer-assisted analysis of EEG wave forms, might
22 require less rigorous software documentation. Likewise, a commercially available personal
23 computer operating system with graphical user interface, would require extensive documentation
24 and evidence of validation when intended for use in a cardiac pacemaker programmer. Less
25 documentation and verification of the OTS operating system would be required for programming
26 an artificial ear.

Artificial Intelligence

28 OTS knowledge-based software (artificial intelligence, expert systems, neural net software, et al)
29 are being developed for a number of medical applications. A typical system accepts clinical
30 findings (sometimes including imaging data) and generates probabilities of disease states and/or
31 recommendations for subsequent data gathering or treatment. The clinician may order a surgical
32 biopsy or other invasive tests or initiate therapy based on the system output. Such systems,
33 should be tested and reviewed in a manner consistent with both their safety and effectiveness of
34 their direct effects (recommendations) and indirect effects (missed appropriate diagnostic testing
35 and treatment). See *Diagnostic OTS software for Triage of Patients for Further Testing or
36 Therapy for Abnormal Pathophysiologic Conditions*, Section III-A and the software guidance
37 [5].

38

E. Product Labeling

2 The user's manual should specify the version(s) of the OTS software that can be used with the
4 medical device. Such specification would not be required for embedded software (i.e., the user
does not select the OTS software and cannot change the software provided by the medical device
manufacturer).

6 The user's manual should contain appropriate warnings to the user indicating that the use of any
software other than those specified will violate the safety, effectiveness and design controls of this
8 medical device. Such use may result in an increased hazard to users and patients. Further
description of what comprises a warning and how to write it are included in *Medical Device
10 Labeling -- Suggested Format and Content* [6]

When OTS medical device software is delivered on a magnetic/ user installable medium, the
12 package should include labeling that indicates the specific hardware platform on which the
software is validated to run (processor, memory, disk, interface etc.). The appropriate testing
14 for the user to assure proper installation should also be described in the labeling.

If the hardware on which the OTS software runs is a stand-alone computer, the user should be
16 warned against installing any other software (utilities or applications programs) on the computer if
they are not "locked out" by hardware or software system features.

18

IV. Bibliography

A. References for this Guidance

- 20 1. USPHS DHHS FDA CDRH: Use of Off-the-Shelf (OTS) Software in Medical device
22 Applications, Blue Book Memorandum G97-___, Issued ___, 2 pages. Abs: This document
contains the brief policy statement concerning the use of OTS software in medical devices. It is the cover
24 memorandum for this guidance document.
- 26 2. USPHS DHHS FDA ORA: FDA Glossary of Computerized System and Software
Development Terminology. The Division of Field Investigations, Office of Regional
Operations, Office of Regulatory Affairs, US Food and Drug Administration, August 1995, 36
28 pages. Abs: This document provides the definitions (except for OTS software) relied on in our OTS software
guidance. Available on the FDA Home Page at
30 http://www.fda.gov/ora/inspect_ref/igs/gloss.html
- 32 3. Haddon W, Baker SP: Injury protocol. in Duncan, Clark Brain, MacMahon (eds): Preventive
Medicine, New York, Little, Brown, 1979. Abs: A readable discussion of basic injury reduction
strategies from some of the most experienced in the field.

- 2 4. USPHS DHHS FDA CDRH: Deciding When to Submit a 510(k) for a Change to an Existing
3 Device. 510(k) Memorandum #K97-1. final Version, November 4, 1996. copies are
4 available as of ___ Abs: CDRH's final draft guidance was released 1/14/97, text version is available on the
5 FDA home page at <http://www.FDA.GOV/cdrh/ode/510kmod.html>.
- 6 5. USPHS DHHS FDA CDRH: ODE Guidance for the Scientific Review of Premarket Medical
7 device Software Submissions. Draft Version 1.2, March 13, 1996 copies of this work-in-
8 progress are available as of 3/4/96, Abs: This document provides the current guidance in the review of
9 software which comprises part of (or all of) a medical device. Available on the FDA Home Page at
10 <http://www.fda.gov/cdrh/ode/dtswguid.html>
- 11 6. USPHS DHHS FDA CDRH: Medical Device Labeling -- Suggested Format and Content.
12 DRAFT Version 4.2, copies of this work-in-progress are available as of March 4, 1997 Abs:
13 This document provides the current guidance on the policy, format and content of the labeling of medical
14 devices.

14 V. Appendices

16 A. Operating Systems

17 The purpose of this appendix is to provide background and comment on the use of OTS operating
18 systems for medical devices.

19 The **operating system** software is the primary software program which manages the basic
20 functions of the computer and its associated hardware, including peripherals. The operating
21 system provides a basic user interface, is responsible for managing applications programs and
22 tasks, controlling memory allocation and data storage devices, and providing input/output for the
23 computer as well as any additional peripheral devices which are present.

24 **Utility software** is associated with operating system software is, which is designed to work with
25 a specific operating system. Unlike applications software, utility software is intended to supplant
26 or enhance functions typically performed by the operating system. Examples of utility programs
27 are memory managers, file managers, and virus checkers. Networking software can also be
28 considered as utility software in that it allows multiple computers to access the same resources.
29 Operating systems can also be designed to support or enable network operations without any
30 additional utility software.

31 Off-the-shelf operating systems are commonly considered for incorporation into medical devices
32 as the use of general purpose computer hardware becomes more prevalent. The use of OTS
33 operating system software allows device manufacturers to concentrate on the application software
34 needed to run device-specific functions. However, it must be recognized that an OTS operating
35 system software is intended for general purpose computing and may not be appropriate for a
36 given specific use in a medical device. Developers of OTS operating systems typically design
37 their systems for general purpose business or consumer computing environments and tasks where
38 software failures and errors are more accepted. This acceptability of errors in the

2 general purpose computing environment may make the OTS operating system software
3 inappropriate for less error-tolerant environments or applications.

4 The incorporation of OTS operating system software **may also introduce unnecessary**
5 **functions and complexity** into a medical device. General purpose functional requirements
6 typically result in the OTS operating system software being large and unwieldy in the attempt to
7 incorporate more functionality into the operating system. This excess functionality is typically
8 never used for specific medical device applications and increases the likelihood that errors may be
9 introduced into the operating system. The basic functions of an OTS operating systems used for
10 medical device applications are typically the graphical user interface environment and the
11 hardware interface functions. There are a number of operating systems used for timing- or
12 resource-critical applications that provide the basic functionality needed to support user and
13 hardware interfaces, but do not have many of the disadvantages of general purpose business or
14 consumer operating systems.

15 Operating systems designed for "**open**" **hardware architectures**, such as the IBM PC or Apple
16 Macintosh type machines, are problematic because they are designed with a level of acceptable
17 variances in hardware tolerances and interface protocols that can adversely affect the operation
18 and performance of software. It is common for such operating systems and applications software
19 to perform well on one hardware configuration, but fail catastrophically on a slightly different
20 configuration. The existence of this "open" architecture environment makes it very important that
21 operating system software to be designed to be "robust" and perform appropriately on different
22 hardware configurations when there is no control by the medical device manufacturer of the
23 specific configuration of the target hardware platform.

24 **B. Utilities and Drivers**

25 The purpose of this appendix is to provide general recommendations and background for the use
26 of OTS utility and driver software packages in the medical device validation process that are the
27 responsibility of the medical device developer.

28 **OTS utility software packages perform the following** functions, math functions (fast Fourier
29 transform, sin, cos); display functions (graphic); management functions (copy, delete, store
30 various computer data/files); and the data manipulation function (transfer from one Boolean type
or both. The validation for these types of the software should include:

2 **Numerical type** - evaluate the maximum and minimum numerical boundaries for both input
and output values including the error handling process for out of the range values.

4 **Boolean type** - evaluate all the possible combinations for both input and output for patient
hazard. If the number of the possible modes is large, then develop a subset of the modes
including prevalent and worst case conditions.

6 **Either type** (data management and data manipulation) - validate functions within the system
qualification process for the final finished medical device (not the prototype or
8 development system).

10 **OTS driver software packages provide** interface functions between the CPU, operating system,
and the input/output peripheral. However, the performance and functionality of the OTS driver
software may be affected by the overall system configuration and the OTS hardware. In general,
12 OTS driver software packages can be classified into the following input/output interface types:
serial, parallel, video signal, telemetry, LAN, and internal bus. In most cases, a particular
14 software driver derives from a particular interface protocol and contains the data signals, control
signals, and timing signals for proper operation.

16 Since tests for most input/output interface/bus configurations require the particular bus analysis or
logic analysis, scope, and the knowledge of the particular interface protocol, it is recommended
18 that the validation process for the OTS driver software package be part of the system interface
validation process. This includes the verification of the data values in both directions for the data
20 signals; various mode settings for the control signals in both directions (if applicable); and the
input/output interrupt and timing functions of the driver with the CPU and operating system. In
22 addition, it is recommended that the system hazard analysis should include the involuntary
disabling or partial disabling of the OTS driver communication during the therapeutic or
24 diagnostic session of the medical device.

26 **C. Local Area Networks (LANs)**

28 The purpose of this appendix is to provide general recommendations and background for the
network aspects of OTS software use. Medical devices, particularly multi-parameter patient
30 monitors and imaging systems, are increasingly networked for clinical work groups, centralized
monitoring, and storage of patient medical data and records. LANs and other networks support
more and more communication and sharing of images, measurement data, audio, video, graphics,
32 text, etc. This heterogeneous media environment comes at a cost of more processing power,
higher bandwidth or network speed, sophisticated object-relational databases, security and access
34 considerations.

36 The evaluation of networked medical devices begins with a definition of the technical
requirements of the network application and the understanding of those requirements.

Requirements Analysis

- 2 1. Speed - The response time required for safe and effective operation determines the LAN
4 data rate (bandwidth) for the medical device system. The CPU processing power and
clock speed required at device monitors, workstations, and client machines must be
appropriate so that bottlenecks do not occur.
- 6 2. LAN Architecture - The size of the LAN (the number of user nodes) and the topology of
8 the LAN should be specified. The following questions might be considered in the design
of the LAN architecture:
 - 10 • Does the LAN need to be fault tolerant, e.g., when a workstation fails?
 - 12 • Does the LAN need to be scaleable, i.e., can new user nodes be added
without degrading system performance?
 - Will the main device software be computationally self-sufficient or
distributed?
- 14 3. Network Operating System (NOS) - Specify the NOS to be used. Whether off-the-shelf or
16 proprietary, this selection should consider the trade-off between robustness and
flexibility.
- 18 4. Data Integrity - One of the most important issues for any medical device operating in a
network is data integrity. The manufacturer must insure that the network system
20 software and hardware incorporate error checking, handling, and correction measures
commensurate with the intended use of the device.

Transmission of data packets and files should include error detection and correction.
22 Error detection methods include parity, checksum, and cyclic redundancy check (CRC).

Transaction rollback after non-committed changes or network failure, supports data
24 integrity in medical device LANs.

Critical data and files may be stored in duplicate at separate locations.
- 26 5. Network Management and Security - User authorization and authentication should precede
accesses to sensitive patient information.

28 The above five items are not independent. Decisions made in one item area may affect the
performance of the LAN in another area.

30 Implementation

32 The speed required by the medical device system dictates the hardware selection, the network
interface cards and transmissions protocols. For example, if the conventional Ethernet protocol
(maximum transmission speed of 10 Mbps) is too slow for the intended application, then a
34 different transmission protocol will be needed.

2 Simplicity of the LAN architecture versus fault tolerance is a trade-off that may arise in the
implementation of the networked medical device systems. The LAN could be implemented as a
4 linear bus network (perhaps the simplest scheme), but if any connecting link on the bus fails the
whole network can fail. A star topology with redundant centralized hub is an example of a more
complex but more robust network structure.

6 Segmentation of high bandwidth applications may be employed to improve LAN performance.
Limiting the data traffic to data intensive clusters reduces traffic throughout the overall LAN.

8 **D. Device Master Files**

10 Much of the information regarding development and validation of OTS software may not be readily
available to the medical device manufacturer who wishes to use the OTS software as a device
12 component. Commercial OTS software vendors who wish to make their OTS software available for
use in medical devices, but do not want to share the confidential and/or proprietary details of their
14 software development and validation with customers (medical device manufacturers) may direct the
information in a device master file to the FDA for clearance.

16 The master file should contain information regarding the OTS software development, validation and
known software bugs in support of use of the software by medical device manufacturers. The
18 intended level of hazard of potential device applications should guide the OTS vendor in deciding
what level of detail to provide in the master file.

20 The OTS software vendor should also consider which types of device applications may or may not be
appropriate uses of the OTS software as a component. The vendor can then grant permission to
22 specific device manufacturers to reference the master file in their premarket submissions. Information
regarding device master files is contained in DSMA's "Premarket Approval (PMA) Manual", or via
24 Facts-on-Demand or from the FDA home page (<http://www.fda.gov>).

26 **E. Maintenance and Obsolescence**

28 This appendix addresses relevant maintainability issues with regard to OTS Software in medical
devices. Normally maintenance activities are performed relative to a system baseline
configuration.

30 Maintenance activities are generally considered to begin subsequent to the establishment and
distribution of a medical device product baseline. There are many design issues related to
32 maintenance activities not generally of concern during the development of this product baseline.
Some of these issues are outlined in this section.

34 The distinction between maintenance and product development is an important one. Product
development design activities generally lead to a system structure of highly integrated components
36 and logic. Maintenance activities introduce changes into this structure which may lead to a loss in
the integrity of the structure. Structure integrity may be effected through changes due to new
38 design requirements, corrections, or environmental adaptations. These types of changes may
impact the integrity of the structure organization, architecture, logic, integration, or any

2 combination of these characteristics. Maintenance of products with OTS software components
3 may be particularly problematic for reasons discussed in the main body of this document, i.e. the
4 sponsor does not have control of the OTS software component life cycle process.

4 In particular, this section identifies general safety and effectiveness, design, verification /
5 validation, change, installation, and decommissioning profiles to consider. These profiles may be
6 applied to all regulated Programmable Electrical Medical Systems (PEMS) and stand-alone
7 medical software devices. Device specific profiles may subsequently be necessary for appropriate
8 evaluation.

Assumptions for this section include:

- 10 a) Manufacturer Good Software Development Practices (GSDP)s and Good Corrective
11 Action Practices (GCAP) are in place.
- 12 b) A product baseline exists
- 13 c) A new product baseline based on a prior product baseline is under review

14 **E.1 Profiles**

15 Each profile below maps to a product development life cycle phase. The profiles identify
16 fundamental maintenance concerns relevant to all regulated PEMS and stand-alone medical
17 software devices. Guidance in the main body of this document provides the procedural
18 foundation for profiles in this section.

E.1.1 Safety

20 Introduction of new or modified OTS components to a product baseline may impact the safety of
21 the product. Therefore a safety impact assessment must be performed and associated hazards
22 documented in a Failure Modes and Effects Analysis (FMEA) table. Each hazard's consequence
23 should be provided and expressed qualitatively; e.g. major, moderate, minor. Traceability
24 between these identified hazards, their design requirements, and test reports must be provided.

25 Analysis should include the review of release bulletins (known error reports), user manuals,
26 specifications, patches, literature and internet searches for other user's experience with this OTS
27 Software.

28 The submission should answer the following questions:

- 29 a) has a FMEA with traceability to requirements and test reports been provided?
- 30 b) are safety functions isolated from new OTS component(s)?
- 31 c) does the new OTS component affect system safety integrity?
- 32 d) what new human factors conditions are introduced with new OTS components?

2 **E.1.2 Design**

4 Introduction of new or modified OTS software components to a product baseline may impact the original design of the product. This impact may result from necessary changes to the product structure organization, architecture, logic, integration, or combination of these characteristics.

6 Problems attributable to structural changes include:

- 1) new system resource requirements, such as shared and/or fixed memory
- 8 2) new timing considerations
- 3) new memory organization (e.g., 16 bit to 32 bit to 64 bit words), partitioning
- 10 4) new human factor issues
- 5) new data integrity issues
- 12 6) new software required to create the final code (build tools)

Consequently the submission should answer the following questions:

- 14 a) How will the new OTS software component(s) change the performance characteristics?
- b) How will the new OTS software component(s) change the operational environment?
- 16 c) Is data integrity preserved?

E.1.3 Verification & Validation

18 As in the establishment of a product baseline, verification and validation (v&v) activities must occur when maintenance changes are made to a product baseline. Analysis of these changes
20 directs necessary v&v activities. New OTS software components in a product baseline introduce unknown logic paths and complexities into the product. “Black-box” testing of OTS software
22 components may allow some validation claims to be made. However, the unknown logic paths and complexities of OTS software components make it important to know that design structure or
24 logic elsewhere in the system are not impacted. This means a full system regression test should be performed. Results of these validation activities should be documented.

26 The submission should answer the following questions:

- 28 a) Do test reports provide objective evidence that identified OTS software component hazards have been addressed?
- b) Do test reports provide objective evidence that all identified SYSTEM hazards have been
30 addressed?
- c) Has a complete system regression test been performed?

E.1.4 Installation

2 Changes in a product baseline structure resulting from the integration of new OTS software
4 documentation changes to field upgrades. The reviewer should ascertain the impact of OTS
software component changes on fielded products.

6 The submission should answer the following questions:

- a) What is the impact of new OTS software components on fielded medical device products?

8 For example: Do new OTS software components correctly operate within the
specifications of medical devices currently fielded?

E.1.5 Obsolescence

10 Rapid technology changes, economics, and market demand are shrinking product life spans. A
12 direct consequence of these phenomena is that an OTS software component today may not exist
two years from now. Short life spans are a particular characteristic of software because it is
14 relatively easy to change. Obsolescence of OTS software components can have significant impact
on regulated products because the sponsor may lose the ability to properly support fielded
16 products. The sponsor needs to support fielded medical device products with OTS software
components.

18 The submission should answer the following questions:

- a) Is the old OTS software component still available for fielded medical devices?
- 20 b) Is there a retirement plan for OTS software components to be replaced/eliminated?
- c) Do new OTS software component(s) replace fielded components?

E.1.6 Change control

22 The submission must identify the product to be considered. Therefore, the product configuration
24 provided should specify:

- a) hardware platform
26 (e.g. microprocessor, minimum memory required, addressable word size)
- b) software platform
28 (e.g. operating system, communications, database's, necessary utilities, etc.)
- c) OTS component(s) other than (b) above
30 (See basic requirements in the main body of this document)
- 32 d) internally developed application(s)
----- end of guidance document -----

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**Center for Devices and Radiological Health
Food and Drug Administration**

4

Respectfully submitted,

The OTS Software Team

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