

Guidance for Industry

Guidance on FDA's Expectations of Medical Devices
Manufacturers Concerning the Year 2000 Date Problem

U.S. Department of Health and Human Services
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I. Background

Many medical devices employ or incorporate computer systems or microprocessor controls as aspects of their design. Some of these computer systems and software applications, including embedded microprocessors, may experience problems processing dates or date-related data due to their use of two digits to represent the year. This is becoming known as the "Year 2000 date problem" or the "Year 2000 problem" and is not unique to medical devices. These problems may be manifested on or after January 1, 2000, when the year 2000 is represented as "00" and the computer system or software cannot differentiate 1900 from 2000. Other date-related problems may occur, such as the failure to accurately address leap years (e.g., there will be a February 29, 2000) or the use of certain dates (e.g., September 9, 1999 [9/9/99]) as "flags" for specific computer actions. In addition to adversely affecting the functioning of some medical devices, the two-digit year format could also affect computer-controlled processes in device design, production or quality control activities, or studies to evaluate device performance.

During 1996, FDA reviewed the types of devices for which problems or potential risks to patients might arise due to the Year 2000 date problem. This review, based on FDA's knowledge of the function and design of all types of devices, did not identify many devices for which the use of a date is critical to the function of the device or for which incorrect date representation could have an adverse impact on patient safety. FDA experts are generally knowledgeable about the function and design of various devices; however, only the manufacturer has the detailed knowledge of the design of specific devices that is required to effectively evaluate the potential for risk to patients.

II. FDA's Goal Regarding Year 2000 Problems With Medical Devices

FDA is providing information regarding how manufacturers may meet regulatory requirements of FDA in addressing computer date representation problems. FDA's primary concern is focused on date-related problems that could pose a risk to health. While all manufacturers are responsible for ensuring the proper functioning of medical devices that they have manufactured, FDA is primarily concerned that manufacturers

correct date-related problems for those devices that, if unable to correctly process dates, could pose a risk to health.

As an example, little if any risk may be posed by devices whose only use of the date is to mark a record or record a date and where an error in date recording results only in an incorrect representation of the year. Records generated by a computerized device marked with a year of “00” to represent 2000 will not be confused with similar records from 1900 if the records are only intended for reading by humans. Human operators will know that there were no such computer-generated records in 1900. Of course, the risk would be different if the date record is intended for processing by another computerized device which might not correctly process a two-digit year representation. Similarly, if the date problem results in the Year 2000 being represented as some year other than 1900, say a base year for a computer, such as 1980, or represented in some other fashion, then the potential for confusion cannot be dismissed and such risks must be addressed.

Incorrect date representation or usage could present a risk when the date is used in a calculation or when records generated by a device are sorted automatically to present a patient’s condition over a period of time to a physician for diagnosis and treatment. Specifically, when the records are sorted by the date of recording, with the oldest record presented first in the presentation queue, the failure of the sorting device could place a record made on January 1, 2000, in the queue before another record made on December 31, 1999, because the sorting device could mistake the Year “00” as occurring before the Year “99.” Although the information contained in the records in the latter situation would be correct, the physician expects the records to be in chronological order, and this expectation could lead to a misdiagnosis or incorrect treatment. This potential patient risk must be addressed to eliminate any possibility of adverse health consequences.

Under the Quality Systems Regulation, device manufacturers must evaluate their entire line of medical equipment and software, not just currently produced or supported products, to identify and assess problems that could result from inaccurate date representation. This assessment should take into account date errors that might lead to device failure, such as failure to provide diagnosis or patient treatment, date

misrepresentation leading to incorrect records which might impact future treatment, or any process affected by the Year 2000 date problem that, if not corrected, has the potential to present a risk to health. Should the assessment indicate a risk to patient or public health by medical equipment unable to correctly process dates, device manufacturers must report corrective action taken in accordance with part 806 (21 CFR part 806), the regulation requiring reporting of device corrections and removals. Should the date-related failure present an unreasonable risk of substantial harm to the public health and the manufacturer fails to take corrective actions, section 518 of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) provides the authority for FDA to require the manufacturer to undertake corrective action at no charge to the device purchasers or owners. If the manufacturer's assessment reveals a date-related failure to conform to specifications or design, and the risk presented by the failure does not meet the threshold specified in section 518 of the act for a mandatory recall (i.e., the device presents an unreasonable risk of substantial harm to the public health), then FDA will not require a recall.

The agency has received inquiries as to the manufacturers' responsibilities under the act, with regard to actions they must take to correct or remedy products from past production that have a Year 2000 date problem and fail to function as designed. Section 518 of the act provides the agency with authority to require the mandatory notification of purchasers and recall of devices that, among other criteria, present an unreasonable risk of substantial harm to the public health. The agency notes that this authority has not been used often because manufacturers typically voluntarily correct problems that present risks which meet the criteria outlined in section 518 of the act. FDA anticipates that manufacturers will act responsibly to eliminate any risks to health posed by Year 2000 date problems.

For Year 2000 or other date-related problems that result in failure to meet specifications or to function as intended, but that do not present the risk to health contemplated in section 518 of the act, FDA has no mechanism to require correction of previously marketed devices. The agency encourages manufacturers to provide solutions where possible and economically feasible.

III. Earlier FDA Letter to Device Manufacturers

As a result of the review of the possible impact of date problems on medical devices, FDA issued a letter on June 25, 1997, to all medical device manufacturers. The letter defined the Year 2000 date problem, reminded manufacturers of requirements under existing regulations, made recommendations for assessing the safety and effectiveness of medical devices, and provided guidance for future premarket submissions. It also notified manufacturers that they must assess the function of all of their devices (both currently and previously manufactured) and identify those that could pose a risk to patients by the processing of date information. The letter is posted in its entirety on the World Wide Web (WWW) at the FDA web site, <http://www.fda.gov/cdrh/yr2000.html>.

This letter recommended that manufacturers take the following actions:

— For future medical device premarket submissions, manufacturers should assure that the products can perform date operations correctly and that computations will be unaffected by the Year 2000 date change.

— For currently and previously manufactured medical devices, manufacturers should conduct hazard and safety analyses to determine whether device performance could be affected by the Year 2000 date problem. If these analyses show that device safety or effectiveness is affected, then appropriate steps should be taken to correct current and past production and to assist customers who have purchased such devices.

— For computer-controlled design, production, and quality control processes, manufacturers should assure that two-digit year formats or computations do not cause problems.

The letter also provided the following advice regarding premarket submissions for changes to existing devices:

— Manufacturers need not submit premarket approval application supplements for class III devices to document that they have addressed Year 2000 date problems, provided that the modifications made in the device do not change other aspects of its performance.

— Manufacturers need not submit a new 510(k) (premarket notification) for Year 2000 date changes to an existing device, provided that the changes do not affect safety and effectiveness. This is in keeping

with the information provided in the Office of Device Evaluation guidance document entitled “Deciding When to Submit a 510(k) for a Change to an Existing Device,” available from the Division of Small Manufacturers Assistance and the FDA web site. (Note that changes to correct Year 2000 date problems should be included in any future 510(k) submission for a significant change to the device.)

Manufacturers were also reminded of the current Quality System Regulation, under which they must investigate and correct problems with medical devices. This includes devices that do not meet specifications because of inaccurate date recording and/or calculations. The authority for requirements conveyed in the letter is found in section 518 of the act, which requires notification of users or purchasers when a device presents an unreasonable risk of substantial harm to public health.

IV. Regulatory Responsibilities

1. Quality System Regulation

Under the Quality System Regulation (21 CFR part 820), device manufacturers must ensure and document the quality of their design and manufacturing processes. This regulation places a continuing responsibility on manufacturers to investigate device malfunctions and to prevent potential malfunctions, including those that could be caused by incorrect processing or recording of dates.

2. Reports of Corrections and Removals Regulation

The Reports of Corrections and Removals regulation (part 806), which recently became effective, requires manufacturers and importers to report promptly to FDA any corrections or removals undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. This regulation requires the reporting of corrections and removals related to the Year 2000 date problem designed to avert or correct a potential risk to health.

3. Medical Device Reporting Requirements

In situations requiring remedial action to prevent an unreasonable risk of substantial harm to the public health, the manufacturer is required to submit a 5-day report under part 803 (21 CFR part 803), the Medical Device Reporting (MDR) regulation. Information concerning a correction or removal submitted in a 5-day MDR need not be resubmitted under part 806.

4. Classification of Recalls

A manufacturer's action to correct a Year 2000 date problem, which is undertaken and completed before January 1, 2000, will not be considered a recall for purposes of FDA's Voluntary Recall regulation (21 CFR part 7). The agency will not classify such actions as recalls, provided the action addresses only correction of a date-related problem and is completed prior to any actual device failure as a result of the problem. However, manufacturers must still report or maintain records of such corrections and removals under § 806.20.

V. Department of Health and Human Services' Letter to Device Manufacturers

The Department of Health and Human Services issued a letter to biomedical equipment manufacturers, dated January 21, 1998, requesting information on the products affected by the Year 2000 date problem. It stated concerns for the continued functioning of biomedical and laboratory equipment into the next century. The letter provided an opportunity for manufacturers to identify specific products that will be affected and to share this information with interested parties through a Government-operated WWW site. Further information concerning this web site and reporting product status with regard to date problems may be found on the WWW at the FDA web site, <http://www.fda.gov/cdrh/yr2000/year2000.html>. FDA urges manufacturers to use this mechanism to communicate the status of their products that are affected by the Year 2000 date problem to public and Government purchasers and users of these products. This information will assist healthcare facilities to identify any impacted products and assist them in planning and taking remedial actions.

VI. Reporting Under the MedWatch Program

Under the Medical Device Reporting Regulation (part 803), medical device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed. Manufacturers are also required to report certain device malfunctions. In addition, medical device users and health professionals are encouraged to voluntarily report malfunctions or problems with devices under FDA's MedWatch Program. The program was established as a method of reporting adverse events by health professionals or other appropriate parties, and can be used to report devices that are

suspected or determined to fail and thereby present a risk to health due to the Year 2000 or other date problems.

Information on the MedWatch program, including procedures for reporting problems with medical devices, may be received by calling the MedWatch Office, 1-800-FDA-1088, or can be found on the WWW at the FDA web site, <http://www.fda.gov/medwatch>.