

**Survey of the Manufacturers of Computer-Controlled
Potentially High Risk Medical Devices
0910-0411**

A. Justification

1. Need for Information

Emergency clearance is requested for the collection of information from manufacturers of computer-controlled potentially high risk medical devices to determine the adequacy of device manufacturers' actions to avoid serious Y2K problems. FDA must take actions to independently verify manufacturers' Y2K assessments and the correctness or validity of Y2K upgrades, especially for life-supporting or life-sustaining medical devices. The independent verification of manufacturer activities is needed to increase the confidence of the public that medical devices with a potential risk to patients are being adequately addressed by their manufacturers and by the FDA. Further, independent verification will give healthcare facilities assurance that they can rely on Y2K compliance data from manufacturers. This information is needed immediately to respond to concerns from the General Accounting Office and others in the healthcare sector that FDA provide independent assurance that the manufacturers of computer-controlled potentially high risk medical devices have properly assessed the Year 2000 (Y2K) status of their computer-controlled medical devices and that they have developed and properly validated appropriate upgrades to correct any Y2K problem for those devices. This study must be completed as soon as possible and no later than September 6, 1999 in order to provide healthcare facilities and others with the assurances that they need to complete their own assessments of their vulnerability to Year 2000 problems and to take corrective actions, if necessary, well in advance of January 1, 2000. In addition, if the data show previously undisclosed problems with manufacturers' Y2K assessments of computer-controlled potentially high risk devices, that information will allow the government to undertake further actions, as necessary, to correct problems that might exist in order to protect the public health. It is vital that there be no Year 2000 failures of computer-controlled potentially high risk medical devices

Background

A key element of the U.S. Food and Drug Administration's (FDA's) mission is to protect the public health by helping to ensure that medical devices are safe and effective. The Center for Devices and Radiological Health (CDRH) is the FDA component responsible for enforcement of the Federal Food, Drug and Cosmetic Act (Act), as it applies to medical devices. Additionally, CDRH has an important role in keeping the public informed about the availability and the safety and effectiveness of devices.

The Act provides a variety of administrative, civil and criminal remedies by which to enforce compliance. For example, under the Act, a medical device is adulterated if not designed and manufactured in accordance with good manufacturing practices specified in the Quality System Regulation, Code of Federal Regulations, Title 21, Part 820. Among other provisions, this regulation requires that manufacturers take action to correct an identified quality problem and to prevent its recurrence. The regulation also requires that devices be developed in accordance with specified design controls, including risk analysis and both verification and validation of the design. Any changes to a design must comply with design controls, including validation of the change. FDA periodically inspects manufacturers' facilities to ensure that their quality systems are in compliance with the regulation.

Y2K and Medical Devices

Many medical devices incorporate computer systems or microprocessor controls. Some of these computer systems may experience problems processing dates or date-related data due to their use of two digits to represent the year. 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 to correctly process date-related data prior to the year 2000.

CDRH has taken a number of proactive steps to mitigate the impact of Y2K on medical device performance. For example, CDRH has formally notified manufacturers of their obligations under the law regarding Y2K and has developed the Federal Y2K Biomedical Equipment Clearinghouse, a publicly accessible database of Y2K compliance information voluntarily supplied by device manufacturers.

Y2K Corrections and the Quality System Regulation

CDRH is now seeking additional information about how manufacturers have addressed the Y2K problem for high risk medical devices. Until now, very limited resources have restricted both pre-market and post-market collection of such data. While manufacturers are normally required to obtain pre-market clearance for substantial changes to medical device designs, CDRH made a policy decision in June 1997 to not require premarket clearance for changes made to correct a Y2K problem. Instead, CDRH is relying on its Quality System Regulation, and especially those provisions relating to validation of design changes. This approach is consistent with the principle that manufacturers, given their access to detailed design information, are usually best equipped to determine the Y2K compliance of their products. FDA's regulation of medical devices relies on a systematic application of quality processes and procedures by the device manufacturer. FDA inspections examine the adequacy of manufacturers' quality systems, as well as the degree to which they adhere to their own quality processes and procedures. However, the number of quality system inspections has also been limited in recent years, have not been assigned based on the Y2K issue, and do not support any statistical inference regarding the Y2K status of devices industry-wide.

From inspectional experience for all types of devices and device issues, CDRH believes that the quality systems of manufacturers and the potential regulatory sanctions of the Act are sufficient to assure that manufacturers will take responsible action to correct serious Y2K problems in their devices. In addition to possible FDA enforcement action, manufacturers have very strong business and legal incentives to make sure any Y2K-related upgrade is safe and provides the correct performance needed for the device. These incentives include customer satisfaction and the potential liability that would result from an incorrect or inadequate upgrade to a product that results in harm to a patient. Also relevant is the added expense and adverse publicity associated with a device recall that would result when a problem is uncovered and corrections have to be implemented.

Potential Failures of High Risk Medical Devices

There are two conceivable situations in which a Y2K problem in a high risk medical device might adversely affect the public health. The first is the situation wherein a manufacturer states that a device is Y2K-compliant, but the device

actually has a latent Y2K problem that compromises its safety or effectiveness. The second situation is one in which a manufacturer incorrectly implements a Y2K upgrade, thereby failing to correct the problem, or even inadvertently creating a new problem. CDRH has become aware of a few situations of the first type, and one situation of the second type. These few situations involved serious adverse health consequences in devices that exhibited Y2K failures before being caught and corrected by the manufacturer, and resulted in device recalls to correct the Y2K-related problems. However, for the vast majority of alleged Y2K problems that have come to FDA's attention, the problem was falsely reported or the non-compliance involved ancillary functions of the device, and the resultant public health impact has been minor.

Despite assurances from both CDRH and manufacturers that their compliance with the Quality System Regulation can be relied upon to address this issue, the General Accounting Office (GAO), the Congress and many healthcare facilities remain unconvinced. In recent testimony before the Senate committee responsible for Y2K oversight, the GAO insisted that FDA needs to undertake an independent survey of device manufacturers to verify the adequacy of their Y2K assessment and remediation efforts, especially for high risk devices. To respond to these and other concerns, CDRH is undertaking a study through a contractor to survey a sample of manufacturers of high risk devices to determine the adequacy of their Y2K efforts. From that sample, a statistical inference will be drawn concerning the remaining manufacturers, and a decision will be made as to whether the survey program needs to be expanded.

2. How Information Will Be Used

The information obtained through this survey is intended to provide a high level of assurance that the manufacturers of computer-controlled potentially high risk medical devices (PHRDs) have:

- X properly assessed the Y2K status of their computer-controlled medical devices;
and
- X developed and properly validated appropriate upgrades to correct any Y2K problems for those devices.

Another principal objective of this survey is to establish public confidence in the information provided in the Federal Y2K Biomedical Equipment Clearinghouse by

examining its supporting documentation. Most manufacturers have posted Y2K compliance status information for their computer-controlled devices on the Clearinghouse. In making their decisions about what actions to take for their devices, healthcare facilities are reliant on the accuracy and completeness of information in the Clearinghouse, and on the adequacy and thoroughness of underlying Y2K assessments by manufacturers.

In assessing Y2K compliance for PHRDs, it is also important to understand the context in which any Y2K problem is manifested, and how that Y2K problem might impact on patient safety. For example, a high risk device may have a low risk Y2K problem, such as a "00" designation for the year in the date display or in date recording, that would be readily apparent to the user and would not be likely to pose a serious risk of injury. This study will concentrate on high risk situations where adverse Y2K impacts on internal calculations, records sorting, controls or other device functions may not be apparent to the device user, and if not properly corrected, could pose a safety risk to patients. A safety risk analysis is required by the Quality System Regulation. Based on FDA's notification, dated June 25, 1997, all device manufacturers are required to have documented the risk analysis for all their computer-controlled devices with any date related functionality.

Special consideration must be given to any PHRDs that have been declared "obsolete" by the device manufacturer, where no Y2K correction has been developed, and in some cases, no Y2K assessment has been performed. For obsolete PHRDs for which the manufacturer has performed a Y2K assessment, the surveyor will evaluate and report on the potential impact of a Y2K failure. The surveyor will carefully examine:

- X The manufacturer's risk analysis (if available) and design documentation to determine the exact nature of date functionality, the Y2K vulnerability in the device, and the potential impact of a Y2K failure.
- X How the manufacturer has notified customers that their obsolete PHRD has no available Y2K correction. If possible, copies of internal and external communications regarding obsolete PHRDs should be collected for inclusion in the audit report.
- X Any steps the manufacturer has taken to get healthcare facilities to remove their obsolete PHRDs from service.
- X Any evidence of the effectiveness of that effort to have obsolete PHRDs removed from service.

For a PHRD with date functionality, where no Y2K assessment has been performed, the surveyor will collect as much of the above information as may be available.

In summary, the overall objective of this study is to assure that the manufacturer has systematically:

- X identified all devices subject to a possible date related Y2K problem,
- X applied risk analyses to determine the appropriate remediation action to be undertaken,
- X validated any new hardware or software developed to fix the identified Y2K problem, and
- X properly communicated information on the Y2K remediation to affected customers.

This applies to all devices still in use in healthcare facilities - both current production and any previously distributed devices.

3. Use of Improved Information Technology

Because of the nature and purpose of this survey, the required information cannot be provided through questionnaires or other electronic collection mechanisms. Rather, the information is gathered by senior software (quality) engineers who are physically present at manufacturer sites to review records and to interview manufacturer representatives.

Where appropriate, however, information related to this survey is currently available electronically on the FDA-operated Y2K website. This includes a list of the types of computer-controlled potentially high risk medical devices and appropriate links to the Y2K non compliant or Y2K compliant data that have been supplied to the Federal Y2K Biomedical Equipment Clearinghouse by device manufacturers.

4. Efforts to Avoid Duplication

FDA's actions are taken on the behalf of all the agencies represented in the government's Biomedical Equipment Subgroup and the National Patient Safety

Partnership, thus eliminating the duplication that would result if each agency independently collected the information.

5. Small Businesses

Efforts have been made to minimize burden by focusing only on computer-controlled potentially high risk medical devices (PHRDs). Thus, the number of manufacturers subject to this survey has been reduced from approximately 20,000 to 700. Given this relatively small population, the need to draw statistically based conclusions regarding those firms not included in the survey, the high risk nature of the devices subject to this survey, FDA has not tried to stratify the sample based on firm size. As part of their normal implementation of the Quality System Regulation, manufacturing practices and their preparation for the Year 2000, both large and small manufacturers should already have conducted product testing and should have all of the required information readily available for all of their products. Firms that have not yet completed this work should be able to explain their timetable for completion and full implementation in healthcare facilities before January 1, 2000. This survey will assess the Y2K information that is currently available, but does not require creation of any new information.

6. Consequences if Information is Not Collected

This information is needed to provide a high level of assurance that manufacturers have properly assessed the Y2K status of their computer-controlled potentially high risk medical devices and have developed and properly validated appropriate upgrades to correct any Y2K problems for those devices. Without this survey, the government will only learn of Y2K failures of these high risk devices AFTER the failure has occurred. Further, if the information is not collected prospectively, it will be impossible to use information on the failure of a particular device to work with other manufacturers to prevent similar failures. For the device types included in this survey, any failure must be presumed to have a very high potential for death or serious injury to patients, unless shown otherwise through the manufacturer's risk analysis. One purpose of this survey is obtain information needed to quell public fears that Y2K failures of high risk devices could place patients at risk.

7. Special Circumstances

Not applicable.

8. Consultation

The Emergency Federal Register Notice will provide an opportunity for public comment.

9. Remuneration

There is no remuneration of respondents.

10. Confidentiality

By law, FDA investigators have access to manufacturers' facilities for purposes of inspection and investigation. However, that authority does not extend to FDA contractors. FDA expects that the contract surveyor may encounter resistance from some device manufacturers over this issue, and will need to gain the cooperation of the device manufacturer for voluntary access to their facility and their device design records. To aid this task, FDA is taking several actions:

- X Contractor staff who perform surveys will receive specific training from CDRH's ethics and integrity officer concerning conflict of interest and handling confidential information. In addition those surveyors and any other contractor staff who handle confidential information in audit reports will each be required to sign individual non-disclosure statements.
- X This study will be declared a "Special Year 2000 Data Gathering Request" under the Y2K Information and Readiness Disclosure Act. As such, the manufacturer's specific information collected by the contractor will be fully available to FDA, but will not be subject to release under the Freedom of Information Act. FDA will publicize aggregate information on Y2K compliance, but will seek clearance from the manufacturer before releasing any manufacturer specific information collected as a part of this study.
- X Pursuant to the Y2K Information and Readiness Disclosure Act, any information collected by the contractor cannot be used to support FDA regulatory action against the manufacturer. Moreover, minor problems found by the contractor will not increase the likelihood of inspection by FDA. However, FDA may choose to undertake a follow-up investigation on its own

where there is a serious safety concern, or in any high priority situations where there is a refusal to allow an audit by contractor staff. The results of FDA's inspection would not be subject to any protection under the Y2K Information and Readiness Disclosure Act.

- X FDA has contacted the major device industry trade associations and has solicited their help in seeking voluntary cooperation from device manufacturers.
- X FDA will provide a letter to device manufacturers, signed by the Commissioner or another high-level agency official, describing the survey and seeking voluntary cooperation.

11. Sensitive Questions

The survey will not request sensitive information.

12. Burden Estimates

Table 1--Estimated Annual Reporting Burden¹

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
	80	1	80	43	3,440

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents: Manufacturers of Computer-Controlled Potentially High Risk Medical Devices

Estimated Number of Manufacturers of Computer-Controlled Potentially High Risk Medical Devices: **724**.

Number of Manufacturers of Computer-Controlled Potentially High Risk Medical Devices in the Sample for the Survey: **80**.

Estimated Average Time to Prepare and Participate in the On-Site Survey: **43** hours.

Estimated Total Annual Burden: 3,440 hours.

The estimated total annual burden levied on respondents for this collection of information on biomedical equipment is derived from estimates of the number of manufacturers of computer-controlled potentially high risk medical devices (PHRDs); the estimated amount of time needed from the manufacturer for working with the surveyor, with allowance for variation in the number of PHRDs produced by a manufacturer; and time to review and respond (if desired) to the report of the survey.

The PHRD list developed by FDA includes **83** types of medical devices that have the potential for the most serious consequences for the patient should they fail. Inclusion of a type of device on this list does not mean that all devices of this type have a date-related problem (are Y2K non-compliant) or, if they are Y2K non-compliant, that they necessarily pose a significant risk to patients. Rather, this list includes those types of devices that could pose a risk to patients if the date-related failure affects the function or operation of the device.

The list includes the types of computer-controlled devices whose failure to function as designed or expected could result in immediate and serious adverse health consequences. These potentially high-risk devices are those that are:

- 1) Used in the direct treatment of a patient where device failure could compromise the treatment or could injure the patient, or
- 2) Used in the monitoring of vital patient parameters and whose data are immediately necessary for effective treatment, or
- 3) Necessary to support or sustain life during treatment or patient care.

The list does not include diagnostic devices whose failure would not result in immediate harm to the patient, even though the diagnostic information they provide might be unavailable or incorrect. However, a few diagnostic devices have been included, if the results of calculations or other information processing by the device would not be readily apparent to the user, and a Y2K failure of the device could reasonably lead to serious adverse health consequences before being detected by the user.

Using its databases, FDA determined that **724** manufacturers produce the device types included in the PHRD list. Of these manufacturers, **80** manufacturers will be surveyed as a statistical sample. A given manufacturer may make a single PHRD device or multiple devices.

Based on FDA's experience in conducting field investigations and audits of manufacturers under the Quality System Regulation, the FDA contractor in this survey will spend from 1 day to 4 days at the manufacturer's facility, with an average of 2.5 working days (20 hours). For this average survey, the manufacturer will typically assign an employee to accompany the contractor (20 hours); participate in entrance and exit interviews (2 hours); compile existing records and make them available to the FDA contractor (8 hours); participate in other interviews during the survey as required (5 hours); and review the contractor's report on the survey and prepare a response, if desired, (8 hours). Thus, the average burden for a single survey is 43 hours. The total burden is 80 surveys times 43 hours per survey or 3,440 hours.

At a cost of **\$50.00** per hour, the estimated cost to respondents is **\$172,000**. Note that the actual labor costs incurred by manufacturers for much of this effort will likely be less than \$50.00 per hour.

13. Other Costs to Respondents

No additional costs to the respondents are identified.

14. Government Costs

The estimated cost to the government for this collection and the necessary follow-up is **\$1,600,000**

All of the government costs are associated with retaining a contractor to conduct the survey.

15. Change in Burden

This is a new information collection resulting in a single time burden increase.

16. Plans for Analysis and Publication

The contract task order will be awarded on or about June 30, 1999, with planning and surveyor training to be conducted while the OMB clearance process is underway. This survey program is anticipated to begin immediately upon receipt of OMB clearance, and will be completed by September 15th. The contractor is to produce a final report of the survey results, which will be reviewed by FDA, DHHS, the GAO and will be provided to the Congress by October 1, 1999. A decision will be made at a later date regarding publication.

17. Display of Expiration Date

The expiration date will be displayed.

18. Exceptions to Certification

There are no exceptions to certification.

B. Collections of Information Employing Statistical Methods

1. The universe consists of 724 manufacturers who have been identified from FDA records as producing computer-controlled potentially high risk medical devices.

It is FDA's goal to survey 80 of those manufacturers. Prior to sampling, approximately 74 firms will be "removed" from the population to avoid conflicts with open FDA investigations, scheduled FDA inspections, compliance actions, etc. The contractor will draw an initial random sample of 100 manufacturers from the remaining population of 650 manufacturers. Of this number, it is assumed that 20% will be non respondents (i.e., will choose not to allow the surveyor to audit

their records). If needed, additional randomly selected firms will be chosen, to replace those firms who decide not to participate.

2. An FDA contractor will contact manufacturers who are included in the sample, and request permission to perform an on-site examination of their Y2K records for PHRDs. Examination procedures will include review of manufacturer records and interviews of the manufacturer's engineering and quality staff involved in Y2K assessment and remediation for PHRDs.

For each of the manufacturers, the surveys will verify that

- a) the manufacturer has properly assessed the Y2K status of their computer-controlled potentially high risk medical devices;
- b) the manufacturer has developed and properly validated appropriate upgrades to correct any Y2K problems for those devices; and
- c) in the event of any discrepancies, those discrepancies would NOT involve a substantial risk to patients.

Survey results will be examined by the contractor and by CDRH to determine whether any serious but previously unknown Y2K problem has been discovered.

Firms will be selected from the population based on a table of random numbers. The sample size is based on current available funding to support this effort, not on any particular desired degree of accuracy. FDA has examined the potential outcomes from a hypothetical population of 800 manufacturers, and a sample size of 80 surveys, assuming a binomial distribution of population outcomes (i.e., a firm either does or does not have a serious and as yet undiscovered Y2K problem). The statistics of this relatively small sample size are such that any serious undiscovered Y2K problem from the sample could lead to an expansion of the survey, possibly to the entire population of 724 firms. Certainly, based on FDA's past experience with them, it is anticipated that GAO would call for such an expansion, if there are any serious Y2K problems discovered through this survey program.

3. In order to maximize response rates (that is, the manufacturer voluntarily agrees to participate in the survey), FDA has contacted the major device industry trade associations and has solicited their help in seeking voluntary cooperation from device manufacturers. In addition, FDA will provide a letter to device

manufacturers, signed by the Commissioner or another high-level agency official, describing the survey and seeking voluntary cooperation.

By law, FDA investigators have access to manufacturers' facilities for purposes of inspection and investigation. However, that authority does not extend to FDA contractors. FDA expects that the contract surveyor may encounter resistance from some device manufacturers over this issue, and will need to gain the cooperation of the device manufacturer for voluntary access to their facility and their device design records. To aid this task, FDA is prepared to take several actions:

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 - X Pursuant to the Y2K Information and Readiness Disclosure Act, any information collected by the contractor cannot be used to support FDA regulatory action against the manufacturer. Moreover, minor problems found by the contractor will not increase the likelihood of inspection by FDA. However, FDA may choose to undertake a follow-up investigation on its own where there is a serious safety concern, or in any high priority situations where there is a refusal to allow an audit by contractor staff. The results of FDA's inspection would not be subject to any protection under the Y2K Readiness and Information Disclosure Act.
4. During the first week of a ten week contract, the contractor will develop their audit plan, training plan, audit procedures and any questions or survey checklists to be used. Contractor staff will then be trained in the procedures that will be used in the survey, and will be prepared to begin audits as soon as OMB clearance is received. The contractor has identified a manufacturer who has "volunteered" to serve as a test of the survey procedures. This is still being explored.
 5. Statistical Consultants include:

Harry F Bushar, Math Biostatistician, OSB/CDRH/FDA, 301-827-4361

Rob Orwin, Statistician, Battelle, 703-875-2979