

**Survey of Biomedical Equipment Manufacturers for Year 2000 Compliance
0910-0417**

A. Justification

1. Need for Information

The Food and Drug Administration, on behalf of the government-wide Biomedical Equipment Subgroup of the Chief Information Officer (CIO) Council's Year 2000 Subcommittee, is requesting emergency approval from the Office of Management and Budget to survey manufacturers of biomedical equipment about the Year 2000 compliance of their products. The need for emergency clearance is critical because the existence of a Year 2000 date problem in biomedical equipment could pose potentially serious health and safety consequences. It is vital that there be no Year 2000 failures of biomedical equipment.

As a major consumer of biomedical equipment, the government must know if the medical devices and scientific laboratory equipment currently owned, as well as the products they may purchase, will function in the new millennium. Furthermore, the health care community at large will benefit from this collection of information because the Year 2000 compliance information will be posted to a web site available to the public.

The Biomedical Equipment Subgroup includes representatives from the Department of Health and Human Services, the Department of Defense, the Department of Veterans Affairs, the Department of Agriculture, the Department of Justice, the Nuclear Regulatory Commission, and the Office of Management and Budget. In the planning for this initiative, the Subgroup has consulted with several manufacturers' professional associations. The Subgroup will make the information available to the public through the use of a web site because the group realizes that private health care providers and researchers also use biomedical devices. This web site will improve the efficiency of obtaining compliance information for the health care industry by reducing the number of individual inquiries from health care providers and researchers to manufacturers.

The Food and Drug Administration (FDA) regulates medical devices and needs information regarding the Year 2000 compliance of these products. Under a previous Good Manufacturing Practices regulation and the current Quality System Regulation, effective June 1, 1997, manufacturers must investigate and correct problems with medical devices that present a significant risk to public health. This includes devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. Also, section 518 of the Food, Drug and Cosmetic Act requires notification of users or purchasers when a device presents a reasonable risk of substantial harm to public health. These regulations, however, do not apply to all biomedical equipment, such as scientific laboratory equipment, but only to medical devices. Therefore, a proactive collection of Year 2000 compliance information of all biomedical equipment is necessary to prevent a Year 2000 date problem from causing any public health risk in the patient care services and health research initiatives of the next century.

The FDA-operated Federal Y2K Biomedical Equipment Clearinghouse is a database on the World Wide Web that has been established to assist manufacturers in voluntarily providing information regarding the status or impact on product performance of the Y2K problem. The web site (www.fda.gov, then select Year 2000) is intended to give product users in healthcare facilities, research laboratories, purchasers of biomedical equipment and the general public one comprehensive source for information about the Y2K compliance of biomedical equipment. While the web site was originally planned to aid several agencies in the Federal Government that use and purchase medical device and laboratory equipment, it was quickly realized that the

private sector had the same needs for this information.

For the purpose of reporting product status to the Clearinghouse, Year 2000 compliant means that the product accurately processes and stores date/time data during, from, into and between the twentieth and twenty-first centuries, and the years 1999 and 2000, including correct processing of leap year data. The intent is that for products to be Year 2000 compliant they must function as intended or expected, regardless of the date. Please note: for the purposes of this collection, manufacturers are asked to provide information on their products that are NOT Year 2000 compliant.

“Biomedical equipment” is comprised of both medical devices AND scientific laboratory instruments. Although scientific laboratory instruments are not regulated by FDA, their failure due to Y2K problems has serious implications for patient health and safety as well as research activities. Examples of scientific laboratory equipment include:

**mass spectrometers;
oscilloscopes;
gas chromatographs; and
electron microscopes.**

Beginning in January 1998, the manufacturers of biomedical equipment were requested to provide:

**a certification that none of their products are impacted by date-related problems; or
information on products that they have identified as having a date-related problem.**

The database of Y2K non-compliant biomedical equipment was established to assist manufacturers in voluntarily providing information regarding the status or impact on product performance of the Y2K date problem. The web site is intended to provide product users in healthcare facilities, research laboratories, purchasers of biomedical equipment and the general public with a single, comprehensive source for information about the Y2K compliance of biomedical equipment.

In early 1998, the survey was mailed to 16,253 manufacturers of medical devices and scientific laboratory equipment. To further focus our efforts, CDRH identified a subset of 2,275 manufacturers most likely to produce Y2K vulnerable medical devices.

As of April 5, 1999, 1,569 (69%) of the 2,275 manufacturers most likely to produce Y2K vulnerable medical devices reported their product status to the Y2K non-compliant database. Of the 2,275 manufacturers, 438 reported all products as Y2K compliant; 650 reported that their products do not use dates (they are Y2K compliant); 258 reported date problems that are described in database; 223 reported date problems where product status is available at the manufacturers web site; 28 other; and, 678 manufacturers did not respond.

On March 3, 1999, CDRH contacted biomedical equipment manufacturers who had reported to the database as well as the 678 manufacturers who had not previously responded (above). CDRH requested additional information on Y2K status for non-compliant products. Comments from many biomedical equipment users, as well as CDRH review, indicated that much of the information on the Federal Y2K Biomedical Equipment Clearinghouse is not sufficiently complete or otherwise informative to adequately assist facilities in assessing the impact of non-compliant products. Manufacturers were asked to carefully review the Y2K product status information that they have already provided or that they intend to submit. In addition to obtaining data from additional manufacturers, manufacturers were asked to provide better descriptions of the product (what it is), as well as more detailed descriptions of how uncorrected date problems may affect the operation of those products.

Manufacturers have provided updated information and additional information in response to the March 3 request. However, there are still 150 manufacturers (out of 2,275) who have not responded to the survey, but who were identified by CDRH as likely to produce Y2K vulnerable medical devices. In addition, after review of the data that has been submitted, approximately 300 manufacturers have reported data that requires further clarification. For example, a manufacturer may have reported that a fix to a Y2K non-compliant product would be available on a particular date. If that date has passed and if the database has not been updated, it is critical to confirm that the fix is indeed available or to update the date on which it will be available.

This information collection was originally approved under OMB Control Number 0910-0003, which expired on June 30, 1999.

2. How Information Will Be Used

Manufacturers will be contacted by telephone. Manufacturers identified by CDRH as likely to produce Y2K vulnerable medical devices, but who have yet to provide information on their devices will be asked to post on a web site either a listing of products which have a Year 2000 compliance problem, including adequate information to accurately identify the product and any plan to make the product compliant, or provide notice that all of their products are compliant. They are also asked to provide a point of contact to discuss product information. Manufacturers may provide updated information in a format of their choosing or they may use the attached FDA forms.

The manufacturer may link their own web site to the government web site or mail the information to the Department of Health and Human Services for direct posting on the government web site. The provision of information signifies that the information provided is true to the best of the manufacturer's knowledge. Government agencies as well as the general public will have access to the web site and will use the information to assess currently owned equipment as well as to evaluate potential acquisitions. The posting of information on non-compliant products is designed to provide an opportunity for manufacturers to communicate and better serve customers in a responsible and proactive manner, and avoid the necessity for manufacturers and vendors to field numerous calls and letters from individual organizations. Furthermore, the use of exception reporting, that is the identification of non-compliant products only, minimizes the burden on manufacturers.

Manufacturers who have provided incomplete or preliminary information will only be asked to update that information.

3. Use of Improved Information Technology

As noted above, manufacturers will be encouraged to post their information directly to a web site which they can link to the government web site. Government agencies and the general public will have access to the web site that contains this data.

4. Efforts to Avoid Duplication

FDA is requesting this information on behalf of all the agencies represented in the Biomedical Equipment Subgroup, thus eliminating the duplication which would occur if each agency independently collected the information. Furthermore, the collection of this information provides a public benefit through the posting of the information on a web site. The government web site, with the links to manufacturers' web sites, will reduce the burden on both government agencies and the private health care industry by providing a single source of information on the Year 2000 compliance status of biomedical equipment.

Several agencies have already sent letters to manufacturers about the Year 2000 compliance of biomedical equipment. The data they collect will be posted on the web site when it suffices. However, if the agency collected the information without clarifying its availability to the general public, the manufacturer may still need to be contacted and asked to post the information on a web site to link with the government web site.

5. Small Businesses

In the collection of product information, manufacturers are asked to identify only non-compliant products, which eliminates the burden of listing every product they manufacture. Furthermore, the product information requested, along with the compliance status and compliance plans, includes only information needed to adequately identify the product. If all of their products are compliant, they may provide notice that none of their products are non-compliant, once again, eliminating the burden of listing every product they manufacture. By posting the information on a web site available to the public, the manufacturer will field a reduced number of calls and letters on product compliance from individual organizations. The burden reduction is true for all manufacturers but applies more significantly to small businesses.

6. Consequences If Information is Not Collected

This information is needed to prevent any potentially adverse health and safety consequences due to the malfunctioning of biomedical equipment as a result of the Year 2000 date problem. Without this information from manufacturers, government agencies as well as private health care organizations will not be able to assess whether their currently owned biomedical equipment is Year 2000 compliant nor will they be able to adequately assess choices for new acquisitions of this equipment. If individual government agencies and private health care organizations individually contacted manufacturers regarding their products, the burden for all involved would increase significantly. A single collection and a posting to the web site will provide the needed information in the most efficient and timely manner and therefore protect the health and safety of the public.

7. Special Circumstances

None

8. Consultation

The Federal Register Notice will be submitted at the same time as the Paperwork Reduction Act Clearance Request.

The Biomedical Equipment Subgroup has met with the Health Industry Manufacturers Association, the National Electrical Manufacturers Association, and the Medical Devices Manufacturer's Association to assess the level of awareness of the Year 2000 problem among the organization's membership as well as to learn whether manufacturers would voluntarily share information regarding Year 2000 compliance of their products. In the meetings, the Subgroup also addressed the type of information requested for product identification as well as the web site posting.

9. Remuneration

There is no remuneration of respondents.

10. Confidentiality

The letter and survey will inform manufacturers that the information they post on the web site or provide in writing for posting (because they do not have access to the Internet) will be available to government agencies as well as to the general public.

11. Sensitive Questions

The survey will not request sensitive information.

12. Burden Estimates

Table 1--Estimated Annual Reporting Burden¹

No. of Respondent	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
450	1	450	8	3,600

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

The estimated total annual burden levied on respondents for this collection of information is derived from estimates of the number of medical device manufacturers and the estimated amount of time needed for reporting.

FDA has identified 2,275 manufacturers who are likely to produce Y2K vulnerable medical devices. 150 of these manufacturers have not yet reported their product status. Further, based on an analysis of data already submitted to the Clearinghouse, 300 manufacturers have been identified for further followup to clarify information or to obtain updates.

The burden estimate incorporates the assumption that manufacturers will develop information on the Year 2000 compliance status of their products independent of this request. Therefore, the burden estimate includes simply the time to post information for a single product on the web site.

The estimated average time per response is 8 hours. The estimated percentage of responses collected electronically is 75 percent of the total estimated non-compliant products. The estimated percentage of the information collected through written responses is 25 percent of the total estimated non-compliant products. Therefore, the burden estimate is 450 respondents multiplied by 8 hours per response, for a total burden estimate of 3,600 hours.

13. Other Costs to Respondents

The estimated cost to respondents is \$43,050. This is derived using the same estimate of 8 hours per response.

The cost of five minutes of an employee's time for electronic responses and twenty minutes for written response is derived using the salary of a GS-7 step five, or \$27,500 a year, plus 10% as estimated benefits. Based on this salary, the estimated cost per hour is \$14.40. Multiplying \$14.40 per hour times 8 hours per response results in an estimated cost per response of \$115.20. Multiplying \$115.20 times the total number of responses results in a total estimated cost of \$51,840.

14. Government Costs

The estimated cost to the government for this survey and the necessary follow-up is \$200,000.

A government contractor will contact the manufacturers by telephone, soliciting the manufacturer's cooperation. The contractor will assist the manufacturers, as necessary in submitting and posting the desired information. Further the contractor will continue to maintain

the Clearinghouse through March, 2000.

15. Change in Burden

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

16. Plans for Analysis and Publication

No statistical analysis of the information is planned. There are no plans for publication of the responses. However, the following product information for non-compliant biomedical equipment will be posted on a web site available to the public: type of product, model number, specific serial numbers (if appropriate), software version number, description of Y2K impact, solutions to mitigate impact, time period covered by compliance (e.g. products on market less than 10 years), point of contact to discuss product information. If all products are compliant, the manufacturer will provide notice that all of their products are compliant. The web site will list the manufacturers which have all compliant products.

17. Display of Expiration Date

The expiration date will be displayed.

18. Exceptions to Certification

There are no exceptions to certification.

B. Justification for Not Employing Statistical Methods

The use of statistical methods is not appropriate for this survey. The purpose is not to take a sample or correlate noncompliance with any other factors. The purpose is to contact all biomedical equipment manufacturers and identify non-compliant products in order to ensure the health and safety of patient care and health research initiatives.