Center for Devices and Radiological Health

Report on

The Y2K Readiness Survey of Manufacturers of Essential Medical Supplies

November 15, 1999
Food and Drug Administration

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Report on the Y2K Readiness Survey of Manufacturers of Essential Medical Supplies

Purpose of the Y2K Readiness Survey

In June 1999, the Food and Drug Administration (FDA) initiated an assessment of preparations by manufacturers of essential medical supplies to address the Year 2000 date problem and to assure the continued availability after January 1, 2000, of products vital to the delivery of healthcare. The FDA sought information on the status of preparations by manufacturers of essential medical supplies to assure that all of their mission-critical systems, such as automated manufacturing systems and business management systems, would continue to function through the transition into the Year 2000. This information was needed to provide assurance of the continued availability of these supplies, including consumable and disposable devices, and to determine whether action was needed by the FDA to address any vulnerable segments of this market. This report describes the process used to conduct this assessment and the results and conclusions drawn.

Year 2000 Date Problem

Many medical devices use computer systems and software applications, including embedded microprocessors. On or around January 1, 2000, these medical devices may experience problems processing dates or date-related data due to their use of two-digit fields to represent the year. This has become known as the "Y2K date problem." In addition to adversely affecting the functioning of some devices, the Y2K problem could also affect computer-controlled design or manufacturing processes, or other systems critical to the production and distribution of essential products that are not themselves computerized. The Y2K Readiness Survey focussed not on the vulnerability of specific computerized products, but rather, on preparations by manufacturers of essential medical supplies to assure uninterrupted business operations.

CDRH Activities Related to the Year 2000

Through its regulatory oversight, FDA's Center for Devices and Radiological Health (CDRH) is responsible for helping assure the safety and effectiveness of medical devices and radiation-emitting electronic products in the U.S. CDRH is working with the medical device industry, the healthcare community, and other government agencies to minimize any effect of the Y2K date problem on the functioning of medical devices and the delivery of healthcare.

In order to provide medical device users with important information regarding the Y2K status of products, the Federal Year 2000 Biomedical Equipment Clearinghouse was created. The Clearinghouse contains information or manufacturer web-site links for Y2K

non-compliant products and information on specific product models that are Y2K compliant. The Clearinghouse is located on the World Wide Web at www.fda.gov/cdrh/yr2000/year2000.html. Other information regarding CDRH activities to address the Y2K date problem is also provided on the CDRH web site.

Identifying Essential Medical Supplies and Their Manufacturers

The survey focussed on those manufacturers that produce essential medical supplies. These were defined as devices that are used and consumed on a recurring basis during the delivery of essential healthcare services and whose immediate availability is critical to the uninterrupted delivery of healthcare and patient welfare.

Devices were identified as essential supplies using the five-tier classification of the Canadian Year 2000 National Clearinghouse for Health (CYNCH) for medical supplies.[1] Those devices found to meet criteria #1 (critical life-support or resuscitation devices - serious harm if unavailable for immediate use) or criteria #2 (devices with significant impact on patients - unavailability does not pose immediate harm to patients but could within hours/days) of the CYNCH classification were designated essential medical supplies. Types of medical devices meeting these criteria were identified by product specialists in the CDRH Office of Device Evaluation and compiled into a draft list of types of essential medical supplies.

This list of essential medical supplies was provided to the Veterans Health Administration of the Department of Veterans Affairs, the American Hospital Association, and the Health Industry Manufacturers Association. These organizations were asked to review the list of essential medical supplies and to provide comments on its accuracy and completeness. Based on the comments and suggestions received, the list was revised.

Manufacturers of essential medical devices were identified from the Medical Device Registration and Listing System, which contains names of medical device manufacturing establishments and the types of devices they produce. From this system, 3,070 manufacturers were identified as producers of one or more types of essential medical supplies.

Assessing the Readiness of Manufacturers of Essential Medical Supplies

An assessment of the industry was made in two phases. The first phase consisted of surveying the manufacturers of essential medical supplies to develop an overall picture of readiness. The second phase consisted of an audit program. The audit program was intended to verify the information provided by manufacturers in the written survey responses obtained in the first phase. Both programs were voluntary on the part of those

1 LGS Group Inc., Supply Chain Risk Class, Canadian Year 2000 National Clearinghouse, March 8, 1999. (www.cynch.org)

surveyed. However, several steps were taken to obtain a response rate high enough to be representative of the industry.

The Agency designated much of the information related to a particular company gathered under the survey and the audit programs as confidential under Section 4(f) of the Year 2000 Information and Readiness Disclosure Act. However, aggregate data that do not identify individual respondents may be disclosed.

Methods Used to Conduct the Survey and Audit Programs

Survey Program

A survey was developed to determine the overall readiness of the industry (Attachment A). The survey was designed to be brief enough to ensure a high completion rate and yet be comprehensive enough to ensure the collection of meaningful information. Question 1 of the survey was developed as the primary question of readiness (i.e., "Has your company developed a comprehensive plan and are you taking the appropriate steps, within your control, to assure that the information technology and automated systems used to produce products and distribute products in the United States will be Y2K compliant and therefore continue to function as intended after December 31, 1999?") Other questions were developed to reinforce and confirm the answer to Question 1.

On June 18, 1999, the survey was distributed to 3,070 medical device manufacturing establishments identified as producing essential medical supplies with a cover letter from the Commissioner of Food and Drugs requesting the voluntary participation of the industry. The survey requested a reply within 15 days following receipt.

FDA contracted for the services of Booz-Allen & Hamilton Inc. to assist with the production and mailing of the survey and to receive and compile written responses from manufacturers. They provided further assistance by following-up incomplete responses and soliciting participation from those high priority firms described below that did not respond to the initial survey request.

Of the 3,070 manufacturers of essential medical supplies, 225 manufacturers of products for which there are three or fewer manufacturers were initially identified (referred to as "few-source manufacturers"). Of the 225 few-source manufacturers, we also identified 57 manufacturers of products for which there is only a single manufacturer (referred to as "single-source manufacturers"). Priority attention has been given to these manufacturers in the audit program and in the evaluation of the criticality of products.

Several actions were taken to communicate with manufacturers in order to maximize the response rate:

- On June 18, 1999, a copy of the survey and cover letter were sent to three medical device trade organizations (Health Industry Manufacturers Association, National

Electrical Manufacturers Association, and Medical Device Manufacturers Association) for further dissemination to their membership.

- On July 23, 1999, a reminder notice, with another copy of the survey, was sent to 2,082 domestic and foreign nonrespondants (Attachment B).

Audit Program

The second phase of the assessment program involved the audit program. This was intended to provide a validation of the written survey results through extensive telephone interviews and site visits for a sample of those firms that responded to the survey request. An August 6, 1999 letter from the CDRH Director describing the audit program was sent to these 279 firms (Attachment C).

FDA contracted with the Battelle Memorial Institute to coordinate the audits of manufacturers' responses. Battelle Memorial Institute subcontracted with Unisys Corporation for the actual conduct of the audits. Information technology experts familiar with the software development processes, Year 2000 assessment, remediation, and contingency planning for manufacturing systems conducted the interviews and site visits. FDA's contractors interviewed the individuals in the company who were familiar with the company's Y2K efforts. A structured interview format was used to assure consistency, to verify the survey responses, and to provide further information on the industry's readiness for the Year 2000 (see Attachment D).

279 manufacturers were initially selected for the audit program. The sampling included all 53 single-source manufacturers (four of the 57 manufacturers originally identified reported that they did not manufacture essential medical supplies), a sampling (109) of few-source manufacturers who responded to the survey, and a random sampling of 117 non-priority firms.

Single-source and few-source manufacturers who indicated on their readiness surveys that they would not be ready for the Year 2000 until after October 31, 1999 were selected for site visits; the remaining single-source and few-source firms were selected for telephone interviews. Non-priority firms selected for audit were randomly subdivided into two subsamples; one for site visits and the other for telephone audits.

If a few-source or single-source manufacturer declined to participate after initial contacts from the contractor, several attempts were then made by FDA staff to encourage voluntary participation. Only 19 firms of the 279 selected for audits declined to participate in the audit process of either an extensive telephone interview (16 firms) or an on-site visit (3 firms).

As of November 5, 1999, a total of 212 of the initial goal of 279 audits (76%) had been completed. Based on the favorable results obtained to date, the delays encountered in scheduling the audits with some firms, and the need to complete the study and announce the results, a decision was made to conclude the audit program as of November 5, 1999 for

the purposes of completing this report. FDA will continue to review those single-source or few-source manufacturers that have not responded to the survey or declined to participate in the audits. Follow-up actions will be taken to clarify the Y2K status for any manufacturer whose products are determined to be unique and critical to continued delivery of patient care.

During the telephone and on-site visits, the interviewer assessed the status and completeness of the firms' activities in the following areas:

1. Project Management – Master Project Plan
2. Inventory Collection Process
3. Assessment Phase
4. Remediation, Repair, Replace, Retire Phase
5. Year 2000 Application Testing
6. Integration Testing
7. Contingency Planning

In each of these areas, the interviewer assigned a rating and an overall impression of the status and completeness of the firms' activities. These were subjective judgements based on the results of the structured interview and the responses from the company. The interviewers provided to FDA the individual ratings and the overall assessment for each firm assessed. The interviewers also compared information obtained from the interview to the written survey response.

At the conclusion of the telephone interview or site visit by the contractor, the interviewer assigned a rating to each of the areas of preparation and an overall rating to the firm's Y2K preparation effort. The rating categories listed below were used:

- Green: Item on track, issues known and appropriate actions planned (with Caution: Minor Issues);

- Watch: Potential major issues (no known problems, but there may be trouble lurking);

- Yellow: Critical issue impacting success (trouble identified); and

- Red: Item is behind, out of control, or well over budget (serious difficulty that will likely prohibit success).

The final interview/site visit report was sent to the manufacturer to ensure that there was no misrepresentation of information.

Results of the Survey Program

Survey Responses

Overall Response

Overall, manufacturers of essential medical supplies were very cooperative in responding to the survey. For the 2,917 manufacturers with valid addresses (the initial mailing to 3,070 firms had 153 returned due to incorrect addresses), 2,007 (68%) responded, either completing the survey, or by reporting that they did not produce essential medical supplies. The following table summarizes the overall responses:

Table 1 – Y2K Readiness Survey Response Information
As of November 5, 1999

Responses	All Manufacturers	Few-Source Manufacturers	Single-Source Manufacturers
Total Surveys Received[1].	2,160	199	50
Surveys with missing and/or conflicting information.	170	14	3
Surveys that were "Return to Sender/Unknown Address."	153	5	1
Surveys Analyzed and Processed.	1,837	180	46
Surveys where manufacturer reports that they **do not** produce essential medical supplies.	368	17	4
Surveys that are completed	1,469	163	42

[1]Includes surveys that were "Return to Sender/Unknown Address".

Attachment E contains the detailed results of the survey. The survey results summarized in Tables 1 and 2 are also presented in Attachment E, Tables E1, E3, E5.

The initial mailing list was developed from the Medical Device Registration and Listing System. This system is dependent on the industry to provide updated information (e.g., new addresses, change in status of business, change in status of product line). Thus, a small percentage of surveys were returned in the mail. In addition, another small percentage of manufacturers indicated that they do not manufacture essential medical supplies. This was not unexpected, as the product codes used with the Registration and Listing System to identify products were general in nature and not necessarily specific. Another small percentage of surveys could not be analyzed because of missing information or because conflicting information was reported in the survey. These have not been resolved to date and are not included in this analysis.

Few-Source Manufacturers Response

A high response rate was obtained for few-source manufacturers; 88.2 percent of the firms answered the survey questions or indicated that they do not manufacture essential medical supplies.

Single-Source Manufacturers Response

A high response rate was also obtained for the single-source manufacturers; 87.5 percent of the firms answered the survey questions or indicated that they do not manufacture essential medical supplies.

Survey Responses Regarding Readiness

Question 1 of the survey was developed as the primary question regarding readiness – "Has your company developed a comprehensive plan and are you taking the appropriate steps, within your control, to assure that the information technology and automated systems used to produce products and distribute products in the United States will be Y2K compliant and therefore continue to function as intended after December 31, 1999?" Table 2 summarizes the response to Question 1.

Overall, 98.3 percent of firms submitting completed surveys indicate that they have comprehensive plans in place to address Year 2000 issues and are taking appropriate steps to assure continued operations. Only nine firms indicate that they have no plan in place and five firms did not respond to this question. The remaining 11 firms described partial plans or activities, but not a comprehensive plan.

96.9 percent of few-source manufacturers and 95.2 percent of single-source manufacturers indicate that they have comprehensive plans in place to address Year 2000 issues and are taking appropriate steps to assure continued operation.

Table 2 - Y2K Readiness Survey Results
As of November 5, 1999

Responses to Question #1 – Developed a comprehensive plan and are taking the appropriate steps.		
Overall (based on 1,469 completed surveys)	Few-source (based on 163 completed surveys)	Single-source (based on 42 completed surveys)
Yes 1,444	158	40
No 20	3	1
Manufacturers answered "no", but have stated that one or more of the Y2K program phase(s) is completed, underway, or not started.		
11	1	0
Manufacturers answered "no" and have stated that none of the Y2K Program phases is part of their plan.		
9	2	1
Manufacturers did not answer		
5	2	1

Completion of Y2K Preparations

Question 1 also asked when manufacturers planned to be finished with their Y2K program phases. These phases include: awareness and assessment; renovation or development of alternative solutions; testing and validation of renovations, new systems, or alternative sources; implementation of new systems, renovated systems, or alternative solutions; and development of contingency plans. Tables 3 and 4 summarize completion dates for all respondents and for the few-source and single-source manufacturers.

Table 3 – All Manufacturers' Responses Regarding Completion of Their Y2K Program
As of November 5, 1999

	All Manufacturers Reporting		
Projected Completion Date	Number Completed	Percent Complete, %	Cumulative Percent Complete, %
By 5/31	765	53.0	53.0
6/1 to 6/30	4	0.3	53.3
7/1 to 7/31	20	1.4	54.6
8/1 to 8/31	45	3.1	57.8
9/1 to 9/31	200	13.9	71.6
10/1 to 10/31	198	13.7	85.3
11/1 to 11/30	92	6.4	91.7
12/1 or after	118	8.2	99.9
Incomplete	2	0.3	100.0

Of 158 few-source manufacturers with plans, 140 (88.6%) indicated that their Y2K program would be completed, and they would be ready for the Year 2000 by November 30, 1999. Of 40 single-source manufacturers with plans, 34 (85.0%) indicated that their Y2K program would be completed, and they would be ready for the Year 2000 by November 30, 1999.

Table 4 - Few-Source and Single-Source Manufacturers' Responses Regarding Completion of their Y2K Program
As of November 5, 1999

	Few-Source Manufacturers				Single-Source Manufacturers		
Projected Completion Date	Number Completed	Percent Complete %	Cumulative Percent Complete %		Number Completed	Percent Complete %	Cumulative Percent Complete %
by 5/31	50	31.6	31.6		13	32.5	32.5
6/1 to 6/30	1	0.6	32.3		1	2.5	35.0
7/1 to 7/31	2	1.3	33.5		0	0.0	35.0
8/1 to 8/31	4	2.5	36.1		0	0.0	35.0
9/1 to 9/31	34	21.5	57.6		13	32.5	67.5
10/1 to 10/31	30	19.0	76.6		3	7.5	75.0
11/1 to 11/30	19	12.0	88.6		4	10.0	85.0
12/1 or after	18	11.4	100.0		6	15.0	100.0
Incomplete	0	0.3	100.0		0	0.3	100.0

Table 5 – Comparison of Survey Results
As of November 5, 1999

	Overall Responses	Few-Source Manufacturers	Single-Source Manufacturers
% Responding[1]	68.8	88.2	87.5
% Completing Survey[2]	50.4	74.0	75.0
% Will be ready by 11/30/99[3]	91.7	88.6	85.0

[1]Based on the number of surveys received (including surveys with missing and/or conflicting information and surveys where the manufacturer reports that they do not produce essential medical supplies) divided by the number of surveys sent less those returned in the mail (Return to Sender/Unknown Address) (Reference Table 1).

[2]Based on the number of completed surveys divided by the number of surveys sent less those returned in the mail (Return to Sender/Unknown Address) (Reference Table 1).

[3]Based on manufacturers responses to Question #1(a-e) (Reference Tables 3 and 4).

Comparison of Results

Table 5 compares survey responses for all responding manufacturers, the few-source manufacturers, and the single-source manufacturers.

Responses to the Other Survey Questions

The second question in the survey was intended to gauge the thoroughness and quality of manufacturers' Y2K preparations by requesting information on the use of an independent organization to review all or portions of the Y2K preparation activities. Of the 1,298 responses to this question, only 29 percent indicated the use of third party review. As shown in Attachment E, the proportion of few-source and single-source manufacturers describing the use of independent review was slightly higher. In retrospect, this question may have been unclear and open to interpretation as to the meaning of "independent" and some respondents may have incorrectly interpreted it to mean a group outside the corporate structure of the responding firm. It is also probable that many of the smaller firms represented in the sample did not consider independent review necessary due to the lack of complexity in their required preparations.

The third question of the survey attempted to develop information regarding the dependence of the manufacturers of essential medical supplies on foreign sources of essential materials or components. Approximately 55 percent of the respondents indicated dependence on foreign sources. Of these 801 firms, almost 92 percent have consulted with their foreign suppliers regarding Y2K readiness. Of those firms that had not contacted their foreign suppliers at the time of the survey, 90 percent plan to complete this activity by December 1, 1999.

The status of contingency planning, the testing of contingency plans and consideration of business partners and foreign suppliers in contingency planning was the focus of the fourth question in the survey. Of the 1,197 firms responding to this question, about 49 percent reported that they have contingency plans that have been developed and tested. More than 89 percent will have contingency plans developed and tested by December 1999.

The fifth and last question in the survey explored the ability of firms to either expand production to meet an unexpected demand for products or to increase production in anticipation of increased demand. More than 90 percent of the firms report the ability to increase production if necessary, while slightly more than 40 percent are planning increased production. These responses provide a general impression that many firms could respond to increased demands. However, a product-by-product analysis was not feasible due to the 30 percent of manufacturers of essential supplies that did not respond to the survey.

More detailed results of the survey program are shown in Attachment E.

Results of the Audit Program

As described above, the audit phase of the survey was designed to provide an independent verification of the survey responses and a detailed assessment of the preparations for a sample of the firms responding to the written survey.

After conducting several pilot telephone interviews, the audit phase was initiated on August 17, 1999. Manufacturers of essential medical supplies were also cooperative in participating in this program.

Telephone interviews or site visits were planned with all of the 53 single-source manufacturers, a sample of 109 of the few-source manufacturers, and 117 non-priority firms. As of November 5, 1999, 212 assessments have been completed. Results to date are positive and have confirmed the survey results and our expectation that the industry has taken necessary steps to prepare for the Year 2000. Of those audits that have been completed and rated by the contractor, 90.6% rated green, 6.1% rated green with caution, 2.4% rated watch, 0% rated yellow, and 0.5% rated red.

Results of the audit program are shown in Attachment F.

Conclusions

The results of the audits indicate that a high level of confidence can be placed in the written survey responses. Based on the 212 assessments, we can conclude from the written survey results that manufacturers of essential medical supplies are taking appropriate steps to assure the continued availability of their products. The audits reveal a small number of firms with some minor areas of concern as described by the contractor in the individual assessment reports provided to the FDA. These concerns were communicated to the firms following the interview. FDA does not consider them serious enough to warrant further action by FDA. The only firm with a high level of concern regarding the Year 2000 preparations, as indicated from the audits, is a small, non-priority firm that produces a product which upon review was determined not to be an essential medical supply.

This FDA survey strongly confirms the conclusions reached at the June 7, 1999 Roundtable Meeting of government agencies, medical device industry representatives and healthcare organizations to discuss the readiness of the medical and surgical supply system for the Year 2000 date change. The June 7th meeting prompted an Open Letter to the Healthcare Community (August 13, 1999) signed jointly by the Chair of the President's Council on Year 2000 Conversion and the Deputy Secretary of the Department of Health and Human Services, in which they express confidence that the medical device industry was working cooperatively and diligently to prepare for the Year 2000 transition. The letter, available at the Council on Year 2000 Conversion web site at http://www.y2k.gov/new/081399PRLS.htm, suggested that purchasers of medical supplies should continue to purchase in normal quantities in anticipation of an available and continuing supply of essential medical supplies.

Attachment A Documents

June 18, 1999 Survey and Cover Letter
http://www.fda.gov/cdrh/yr2000/cdrh/letters/990618/pdf/y2kreadiness-survey-letter.pdf

Federal Y2K Special Data Request
Y2K Readiness Survey of Manufacturers of Essential Medical Supplies
Instructions for Medical Device Manufacturer Y2K Readiness Assessment Survey
http://www.fda.gov/cdrh/yr2000/cdrh/letters/990618/pdf/y2kreadiness-survey-instructions.pdf

Year 2000 Readiness Assessment Survey
http://www.fda.gov/cdrh/yr2000/cdrh/letters/990618/pdf/y2kreadiness-survey.pdf

Attachment B – July 23, 1999 Reminder Letter

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

July 23, 1999

☆☆ REMINDER NOTICE ☆☆

Dear Medical Device Firm President/CEO:

I would like to take this opportunity to remind you of Commissioner Henney's June 18, 1999 letter requesting your assistance in assuring the Agency and the American public that your firm has addressed the Y2K readiness of your mission-critical automated manufacturing and distribution systems. This is to assure that an adequate quantity of essential medical supplies will be available into the year 2000. A copy of the letter and survey are enclosed. The full text of the June 18, 1999, letter and Y2K Readiness Survey can also be found on our web site at www.fda.gov/cdrh/yr2000/cdrh/letters.html.

As of July 23, 1999, we have not received your response to our survey request. Please complete the survey and fax it to:

Y2K Coordinator, HFZ-Y2K
Fax: 301-881-1848

Once again we would like to remind you that this survey is a special Year 2000 data gathering request under Section 4(f) of the Year 2000 Information and Readiness Disclosure Act. The details of the information submitted by your firm in response to this survey will not be available to the public. Please be aware, however, that Y2K readiness information related to manufacturing processes should be readily available for FDA review during possible inspections.

In order to provide the healthcare community and the public with comprehensive and accurate information while recognizing the limited time available before the Year 2000, please return your completed Y2K Readiness survey as soon as possible but no later than **August 6, 1999**.

I know that you share our commitment to the uninterrupted availability of essential medical supplies and look forward to your prompt response to this request.

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and Radiological Health

Enclosures

Attachment C – Letter to Manufacturers Regarding the Audit Program

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 6, 1999

Federal Y2K Special Data Request:
Y2K Audit Program of Manufacturers of Essential Medical Supplies

Dear Medical Device Firm President/CEO:

I am writing to you regarding our Year 2000 outreach efforts to reassure the American Public and Congress of the availability of essential medical devices now and into the new millennium. I am requesting your participation in a program to examine device manufacturers' assessments and corrections of Year 2000 (Y2K) problems with **automated manufacturing and distribution systems.** This audit program will be conducted by the Battelle Memorial Institute and their subcontractors, Unisys Corporation and LGS Corporation. All three organizations have extensive experience in information technology and Y2K verification and validation.

Why This Audit Is Needed

Congress, the General Accounting Office (GAO), healthcare facilities and the public continue to express concerns about the Y2K readiness of the medical device industry. This is especially true for manufacturers of essential medical supplies, where Y2K problems could cause serious disruptions in the supply of essential medical devices. Many have urged that FDA take additional actions beyond a survey program that will provide independent assurance of the adequacy of manufacturers' Y2K assessments and any resulting Y2K corrections. This audit program is part of that effort.

How Your Firm Was Selected

We are auditing a random sample of all manufacturers who responded to the recent Y2K Readiness Survey, as well as several manufacturers who were specifically selected for audit based upon responses to the survey. Your firm has been chosen for participation in the program.

What Will Happen during the Audit

The contractor will contact your firm to request a voluntary audit of your company's Y2K readiness.

Each contract examiner, and any other contractor or subcontractor personnel who will handle confidential trade secret information from your firm, has signed a non-disclosure agreement that is on file at the FDA. All the examiners have participated in a joint contractor/FDA training program to ensure consistency in study performance, data collection and reporting.

FDA's Use of Audit Results

This audit is designated a Federal Y2K Special Data Request under the Year 2000 Information and Readiness Disclosure Act. Under this law, FDA will not use the results of this study for any civil action, and FDA will not publicly release your specific study results unless we receive your consent for disclosure of that information.

The FDA will prepare a report of this study for the Congress, the GAO and the public, with aggregate results from all participants. We expect to complete that report in October 1999. If you have any questions regarding this audit program, please contact Gary E. Blanken at 301-594-1284, Ext. 129.

I want to stress that this audit serves two purposes. First, it will bolster public confidence in the medical device industry's efforts to identify and resolve Y2K problems with their products; and second, it will also provide confidence to healthcare facilities that manufacturers are adequately assessing Y2K compliance and implementing appropriate Y2K upgrades and/or corrections. We are asking that you cooperate in this effort and allow our Y2K contractor access to your firm's personnel and records so that they can complete this crucial study quickly and efficiently. I hope we can count on you.

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and Radiological Health

Attachment D - Telephone Interview Questions

Year 2000 Readiness Telephone Interview Script

Section 1 -Project Management – Master Project Plan

1-1. What definition of Y2K compliance did you use in your analysis?

1-2. Has a Year 2000 Master Project Plan been developed and approved?
When was, or will the plan be developed?
When was, or will, the plan be approved?
Who approved the plan (name and position)?

1-3. At what level does the plan have commitment within your organization?
Approval:
What is the highest level officer (or group of officers) which approved the plan. What are their titles and where are they in the organization?
Responsibility:
What is the highest level officer (or group) responsible for the implementation of the plan. What are their titles and where do they fit in the organization?

1-4. What does your Year 2000 Master Project Plan address?
Does the plan cover?
Buildings
Supply Chain
Computer Hardware and Software
Firmware
Interfaces
What else does the plan cover?

1-5. Is Year 2000 project status accurately reported to project sponsor, and other internal stakeholders?
What is the process for reporting Y2K status to the project sponsors and internal stakeholders?
Examples: Is there a periodic report to all customers? Is there an internal web page or shared database? Etc.

1-6. Are Year 2000 project status meetings held on a regular basis? How frequently?
Who is invited?

1-7. Is Year 2000 project manager documenting decisions and processes to support Y2K mitigation strategies and due diligence?
If so, how?
If not, what process is being used to document the work being performed?

1-8. Are official files maintained as part of your process?
If so, where are they stored? Are duplicates (paper, digital or microfiche) stored elsewhere?

1-9. Is there a formal Year 2000 Quality Assurance Plan?
Is it:
A specific Y2K plan
A modification of your standard QA plan
Or was the original QA plan used?

1-10. What does the QA Plan address?
Does it cover?
Documentation
Configuration Management
Contingency Planning
Testing
What else does it cover?

1-11. Was there an independent assessment?
If so, who performed it?
Was the independent party from inside or outside the company?
If not, what steps were taken to assure an objective viewpoint of the assessment?

1-12. Is there a documented Configuration Management Plan?
If so, is it:
A specific Y2K plan
A modification of your standard plan
Or was the original CM plan used?

1-13. Is there a Change Control process in place?
If so, is it:
A specific Y2K process
A modification of your standard process
Or was the original Change Control process used?

1-14. Is there an automated tool(s) used for source code version control?
What is the tool and who developed it?
What computer platforms did it support?

1-15. Is there an issue/trouble reporting/resolution tracking process in place?
Please briefly describe the process and the participants

Section 2 Inventory Collection Process (Inventory of items to be assessed, replaced or remediated)

2-1. Is the inventory collection process defined?
Is there a corporate-wide program or is there more than one?

2-2. Have the prioritization criteria been established?
What are those criteria?

2-3. What is the inventory collection status, milestone dates, % complete?
If it is not complete, when do you expect to complete it.

2.4. Do you have an inventory tracking system or documentation?
Where are the results maintained and tracked?

2-5. Have technology product/service suppliers been identified and inventoried?
What information is kept?
Is it on paper, on line and how do the internal users of these products and services access this information

2-6. What inventory validation technique is used?

2-7. What was the result of your inventory?
How many systems or tools had to be changed?

Section 3 Assessment Phase

3-1. What procedures did your organization use to determine what to address in your Y2K assessment?
Who was involved?
What groups participated?
What was the final product (Report/Database, etc.)?

3-2. Did you work with your vendors to obtain vendor product readiness status?
What was the level of contact and cooperation?
Did they simply refer you to a web page or did they actively participate in your assessment?

3-3. What procedures were used for determining the vendor's readiness status?
Were Y2K web pages reviewed?
If so, did you retain copies of those pages?
Did you conduct specific tests on your own?
Did you analyze product specs?
Did you use another techniques?

3-4. What were the results of the vendor readiness assessment?
What vendor products were not compliant?
What impact, if any, does that have on the compliance of your products?

3-5. What are the expected horizon dates (date of first impact)?
Have any "horizon dates" already been encountered?
Were you ready in time?
Are there any upcoming horizon dates
Will you be ready?

3-6. Have your physical facilities been assessed for Y2K compliance?
How did you evaluate facility compliance?
What statements, web pages, etc were available to document the compliance status of facilities?
What assurances do you have from power companies, phone companies, etc.

3-7. What were the results of the physical facilities assessment?
Are there concerns about your ability to function through the Y2K window?

Section 4 –Remediation, Repair, Replace, Retire Phase

4-1. Are Remediation standards defined and documented?
Are these specific Y2K standards or have they been in use as part of your standard product development and maintenance methodology?

4-2. What Remediation process and methods are used?
Are automated code review tools used?
Do you have a tool to make, or suggest fixes to be made?

4-3. Are the standards being followed?
Do you have peer review standards?
What approvals are required for the implementation of a change?
If you use contractors for parts of the work, are, or were, they required to follow the same standards?
If not, what standards did they follow?

4-4. Have you had to take corrective action for any specific product? If so, for what product and what action was taken?

Section 5 –Year 2000 Application Testing

5-1. Is the Y2K testing approach, process and strategy documented (types of tests, techniques to be used, test participants)?
What groups participated in the definition of the process?

5-2. Have detailed test plans/directions been developed?
Who developed the plans?
Who approved the plans?
Were specific Y2K tests used or were normal test procedures deemed sufficient to cover the Y2K situation?

5-3. Have date definitions been defined?

5-4. Have resource requirements been identified and allocated?
Were separate testbeds used?
What steps were taken to protect normal processes when clocks were reset for Y2K testing and returned to the actual date?

5-5. Has a detailed test schedule been established?
When was it established?
What was the schedule (general start – end dates)?
Was the schedule met?
How much is left to be done?
Do you expect to stay on schedule?

5-6. Has a trouble resolution procedure been defined? What does it include?

5-7. Have acceptance criteria been defined?
What groups defined them?
If not, how was the accuracy of the results determined or documented?

5-8. What were your test results?

5-9. Have the test results been archived for future reference?
Have any printouts, etc been saved in either paper or digital form?
Have audit/reviewer annotations been saved to allow confirmation of the review?
Have test inputs been saved so that the test can be repeated?

Section 6 – Integration Testing

6-1. Are internal and external system interfaces understood and coordinated?

- Internal interfaces are interfaces completely inside the company
- External interfaces involve entities outside of the company.
- Includes both inputs and outputs.

How was the analysis done?
Are the interfaces documented?

6-2. Has your supply chain been verified for Y2K compliance?
Has there been a test with the supply chain?
If not, what verification process was used?

6-3. What were the results of your supply chain test?

6-4. Are Test Reports and data available for review?

6-5. Are all the applications undergoing Y2K testing in production?

6-6. How did you accept and certify the Y2K integration test?
Who developed the test?
Who performed the test?
Who validated the test?
Was there a review or audit of the test by a third party?

Section 7 –Contingency Planning

7-1. Are the business unit manager(s) aware of year 2000 risks and issues?
How were they made aware?
How have you verified that they understand the problem and the potential impact in their areas of responsibility?
Are there meetings, etc.?

7-2. Have business units examined key business processes for year 2000 risks and potential implications?

7-3. Has a risk inventory been compiled?
Who compiled it?
Were the results documented?

7-4. If you know that you will have problems with Y2K, what work-arounds have you put into place?
For each problem,
What was the problem?
What is the potential impact?
What is the work-around?

7-5. Have you established Contingency plans in the event something unexpected goes wrong? If so, what does the plan address and what is the actual plan? Who has authority to declare a problem? Are there plans to rapidly bring in resources?
7-6. What do the plans address and what is the actual plan?
7-7 Has the contingency plan been tested?
7-8 How was the contingency plan validated?

Attachment E – Survey Results

Table E1 – Y2K Readiness Survey Report - Question #1 (All Manufacturers)

Y2K Readiness Survey Status Report for All Manufacturers as of November 5, 1999			
Y2K Readiness Survey Response Information			
			2,160 responses/3,070 surveys
(a) Number of Surveys Analyzed and Processed		1,837	
Number of manufacturers that have reported that they **DO NOT** manufacturer essential medical supplies.	368		
Number of "completed" surveys.	1,469		
(b) Number of Surveys That Require Analysis and/or Follow-up.		170	
(c) Number of Surveys That Were "Return to Sender/Unknown Address"		153	
Y2K Readiness Survey Results (Based on 1,469 "completed" surveys.)			
Question #1 - Developed a comprehensive plan and are taking the appropriate steps.			
Yes	1,444		
No	20		
(a) 11 Manufacturers answered "No" but have stated that one or more of the Y2K Program phase(s) is completed, underway, or not started.			
(b) 9 Manufacturers answered "No" and have stated that none of the Y2K Program phases are part of their plan.			
Did not answer	5		

Question #1a-e - Number of Manufacturers Who Are/Will Be "Done" With Their Y2K Program Phases, by Completion Date[1]

Projected Completion Date	Number Completed	Percent Complete, %	Cumulative Percent Complete, %
Currently "Done"	763	52.8%	52.8%
by 5/31	2	0.1%	53.0%
6/1 to 6/30	4	0.3%	53.3%
7/1 to 7/31	20	1.4%	54.6%
8/1 to 8/31	45	3.1%	57.8%
9/1 to 9/30	200	13.9%	71.6%
10/1 to 10/31	198	13.7%	85.3%
11/1 to 11/30	92	6.4%	91.7%
12/1 to 12/31	118	8.2%	99.9%
Incomplete	2	0.3%	100.0%
	1,444	Based on the number of manufacturers that answered Yes to Question #1.	

[1] *A manufacturer is designated as being "Done" when all of the Y2K program phases (1a-e) are fully completed or are not part of their plan.*

Table E2 – Y2K Readiness Survey Report - Question #1(a-e) (All Manufacturers)

Y2K Readiness Survey Status Report for All Manufacturers as of November 5, 1999

Question #1a-e – Summary of Y2K Program Phase Responses, by Reported Status

	Y2K Program Phase				
	Awareness (1a.)	Renovation (1b.)	Testing (1c.)	Implementation (1d.)	Contingency Plans (1e.)
Number of manufacturers that have included the phase as part of their Y2K plan.	1,454	1,292	1,298	1,323	1,197
Percentage of manufacturer that has included the phase as part of their Y2K plan.	99.0%	88.0%	88.4%	90.1%	81.5%
Number of manufacturers that state the phase as being Completed.	1,321	953	805	803	716
Number of manufacturers that state the phase as being Underway.	125	329	462	486	444
Number of manufacturers that state the phase as being Not Started.	8	10	31	34	37
Number of manufacturers that state the phase as not being part of the plan.	14	177	170	144	271
Number of manufacturers that did not answer.	1	0	1	2	1

Table E3 – Y2K Readiness Survey Report - Question #1 (Few-source Manufacturers)

Y2K Readiness Survey Status Report for Few-Source Manufacturers as of November 5, 1999

Y2K Readiness Survey Response Information

		199 responses/225 surveys[1]
(a) Number of Surveys Analyzed and Processed		180
Number of manufacturers that have reported that they **DO NOT** manufacturer essential medical supplies.	17	
Number of "completed" surveys.	163	
(b) Number of Surveys That Require Analysis and/or Follow-up.		14
(c) Number of Surveys That Were "Return to Sender/Unknown Address"		5

[1] The total number of few source manufacturers (225) represents a subset of the total number of manufacturers (3070).

Few source manufacturers are defined as those manufacturers of consumable devices where there are three (3) or fewer manufacturers of those devices.

Y2K Readiness Survey Results (Based on 163 "completed" surveys.)

Question #1 - Developed a comprehensive plan and are taking the appropriate steps.

Yes	158
No	3

(a) 1 Manufacturers answered "No" but have stated that one or more of the Y2K Program phase(s) is completed, underway, or not started.

(b) 2 Manufacturers answered "No" and have stated that none of the Y2K Program phases are part of their plan.

Did not answer	2

Question #1a-e - Number of Manufacturers Who Are/Will Be "Done" With Their Y2K Program Phases, by Completion Date[2]

Projected Completion Date	Number Complete	Percent Complete, %	Cumulative Percent Complete, %
Currently "Done"	50	31.6%	31.6%
by 5/31	0	0.0%	31.6%
6/1 to 6/30	1	0.6%	32.3%
7/1 to 7/31	2	1.3%	33.5%
8/1 to 8/31	4	2.5%	36.1%
9/1 to 9/30	34	21.5%	57.6%
10/1 to 10/31	30	19.0%	76.6%
11/1 to 11/30	19	12.0%	88.6%
12/1 to 12/31	18	11.4%	100.0%
Incomplete	0	0.3%	100.0%
	158	Based on the number of manufacturers that answered Yes to Question #1.	

[2] A manufacturer is designated as being "Done" when all of the Y2K program phases (1a-e) are fully completed or are not part of their plan.

Table E4 – Y2K Readiness Survey Report - Question #1(a-e) (Few-source Manufacturers)

Y2K Readiness Survey Status Report for Few-Source Manufacturers as of November 5, 1999

Question #1a-e – Summary of Y2K Program Phase Responses, by Reported Status

	Y2K Program Phase				
	Awareness (1a.)	Renovation (1b.)	Testing (1c.)	Implementation (1d.)	Contingency Plans (1e.)
Number of manufacturers that have included the phase as part of their Y2K plan.	160	142	147	147	136
Percentage of manufacturer that has included the phase as part of their Y2K plan.	98.2%	87.1%	90.2%	90.2%	83.4%
Number of manufacturers that state the phase as being Completed.	144	81	63	66	59
Number of manufacturers that state the phase as being Underway.	14	59	82	77	71
Number of manufacturers that state the phase as being Not Started.	2	2	2	4	6
Number of manufacturers that state the phase as not being part of the plan.	3	21	16	16	27
Number of manufacturers that did not answer.	0	0	0	0	0

Table E5 – Y2K Readiness Survey Report - Question #1 (Single-source Manufacturers)

Y2K Readiness Survey Status Report for Single-Source Manufacturers as of November 5, 1999			
Y2K Readiness Survey Response Information			
			50 Responses/57 Surveys[1]
(a) Number of Surveys Analyzed and Processed		46	
Number of manufacturers that have reported that they **DO NOT** manufacturer essential medical supplies.	4		
Number of "completed" surveys.	42		
(b) Number of Surveys That Require Analysis and/or Follow-up.		3	
(c) Number of Surveys That Were "Return to Sender/Unknown Address"		1	

[1] The total number of single source manufacturers (57) represents a subset of the total number of sole source manufacturers (225).

Single source manufacturers are defined as those manufacturers of consumable devices where there is only a single manufacturer of those devices.

Y2K Readiness Survey Results (Based on 42 "completed" surveys.)

Question #1 - Developed a comprehensive plan and are taking the appropriate steps.

Yes	40
No	1

(a) 0 Manufacturers answered "No" but have stated that one or more of the Y2K Program phase(s) is completed, underway, or not started.

(b) 1 Manufacturers answered "No" and have stated that none of the Y2K Program phases are part of their plan.

Did not answer	1

Question #1a-e - Number of Manufacturers Who Are/Will Be "Done" With Their Y2K Program Phases, by Completion Date[2]

Projected Completion Date	Number Complete	Percent Complete, %	Cumulative Percent Complete, %
Currently "Done"	13	32.5%	32.5%
by 5/31	0	0.0%	32.5%
6/1 to 6/30	1	2.5%	35.0%
7/1 to 7/31	0	0.0%	35.0%
8/1 to 8/31	0	0.0%	35.0%
9/1 to 9/30	13	32.5%	67.5%
10/1 to 10/31	3	7.5%	75.0%
11/1 to 11/30	4	10.0%	85.0%
12/1 to 12/31	6	15.0%	100.0%
Incomplete	0	0.3%	100.0%
	40	Based on the number of manufacturers that answered Yes to Question #1.	

[2] A manufacturer is designated as being "Done" when all of the Y2K program phases (1a-e) are fully completed or are not part of their plan.

Table E6 – Y2K Readiness Survey Report - Question #1(a-e) (Single-Source Manufacturers)

Y2K Readiness Survey Status Report for Single-Source Manufacturers as of November 5, 1999

Question #1a-e – Summary of Y2K Program Phase Responses, by Reported Status

	Y2K Program Phase				
	Awareness (1a.)	Renovation (1b.)	Testing (1c.)	Implementation (1d.)	Contingency Plans (1e.)
Number of manufacturers that have included the phase as part of their Y2K plan.	40	37	37	37	34
Percentage of manufacturer that has included the phase as part of their Y2K plan.	95.2%	88.1%	88.1%	88.1%	81.0%
Number of manufacturers that state the phase as being Completed.	36	20	14	16	12
Number of manufacturers that state the phase as being Underway.	4	17	23	20	20
Number of manufacturers that state the phase as being Not Started.	0	0	0	1	2
Number of manufacturers that state the phase as not being part of the plan.	2	5	5	5	8
Number of manufacturers that did not answer.	0	0	0	0	0

Table E7 – Y2K Readiness Survey Response Report – Question #2

As of November 5, 1999

Y2K Readiness Survey Response Report – Question #2

Question #2 – Do you plan on having an independent organization review all or portions of your Y2K preparation activities?[1]

All Manufacturers			Few Source			Single Source		
Responses	**Number**	**%**	**Responses**	**Number**	**%**	**Responses**	**Number**	**%**
Yes	374	28.8%	Yes	50	34.0%	Yes	16	43.2%
No	919	70.8%	No	97	66.0%	No	21	56.8%
Did Not Answer	5	0.4%	Did Not Answer	0	0.0%	Did Not Answer	0	0.0%
Totals:	1298	100.0%	**Totals:**	147	100.0%	**Totals:**	37	100.0%

Number of manufacturers that will be done with their independent review by completion date

All Manufacturers				Few Source				Single Source			
By 5/31	92	24.6%	24.6%	By 5/31	8	16.0%	16.0%	By 5/31	2	12.5%	12.5%
6/1 to 6/30	51	13.6%	38.2%	6/1 to 6/30	10	20.0%	36.0%	6/1 to 6/30	5	31.3%	43.8%
7/1 to 7/31	29	7.8%	46.0%	7/1 to 7/31	2	4.0%	40.0%	7/1 to 7/31	1	6.3%	50.0%
8/1 to 8/31	26	7.0%	52.9%	8/1 to 8/31	4	8.0%	48.0%	8/1 to 8/31	1	6.3%	56.3%
9/1 to 9/30	62	16.6%	69.5%	9/1 to 9/30	3	6.0%	54.0%	9/1 to 9/30	0	0.0%	56.3%
10/1 to 10/31	62	16.6%	86.1%	10/1 to 10/31	14	28.0%	82.0%	10/1 to 10/31	4	25.0%	81.3%
11/1 to 11/30	19	5.1%	91.2%	11/1 to 11/30	1	2.0%	84.0%	11/1 to 11/30	1	6.3%	87.5%
12/1 to 12/31	33	8.8%	100.0%	12/1 to 12/31	8	16.0%	100.0%	12/1 to 12/31	2	12.5%	100.0%
Totals:	374			**Totals:**	50			**Totals:**	16		

[1]Based on those manufacturers that have stated that testing is part of their Y2K plan (Reference Question 1c).

Table E8 – Y2K Readiness Survey Response Report – Question #3
As of November 5, 1999

Y2K Readiness Survey Response Report – Question #3

Question #3 – Do you have foreign suppliers of essential materials or components used in the manufacture of your products sold in the United States?[1]

All Manufacturers			Few Source			Single Source		
Responses	**Number**	**%**	**Responses**	**Number**	**%**	**Responses**	**Number**	**%**
Yes	801	54.5%	Yes	108	66.3%	Yes	25	59.5%
No	667	45.4%	No	55	33.7%	No	17	40.5%
Did Not Answer	1	0.1%	Did Not Answer	0	0.0%	Did Not Answer	0	0.0%
Totals:	1469	100.0%	**Totals:**	163	100.0%	**Totals:**	42	100.0%

Question 3a – If the answer to the above is "yes", have you asked these foreign suppliers about their Y2K readiness?[2]

All Manufacturers			Few Source			Single Source		
Responses	**Number**	**%**	**Responses**	**Number**	**%**	**Responses**	**Number**	**%**
Yes	736	91.9%	Yes	97	89.9%	Yes	22	88.0%
No	61	7.6%	No	10	9.3%	No	3	12.0%
Did Not Answer	4	0.5%	Did Not Answer	1	0.9%	Did Not Answer	0	0.0%
Totals:	801	100.0%	**Totals:**	108	100.0%	**Totals:**	25	100.0%

[1]Based on those manufacturers that have stated that testing is part of their Y2K plan (Reference Question 1c).

[2]Based on those manufacturers that have foreign suppliers of essential materials used in the manufacture of their products (Reference Question 3).

Table E9 – Y2K Readiness Survey Response Report – Question #3, Completion Dates
As of November 5, 1999

Y2K Readiness Survey Response Report – Question #3											
Of those that stated that they have not completed reviewing their foreign suppliers, when will this task be completed?											
All Manufacturers				**Few Source**				**Single Source**			
By 5/31	0	0.0%	0.0%	By 5/31	0	0.0%	0.0%	By 5/31	0	0.0%	0.0%
6/1 to 6/30	0	0.0%	0.0%	6/1 to 6/30	0	0.0%	0.0%	6/1 to 6/30	0	0.0%	0.0%
7/1 to 7/31	7	11.5%	11.5%	7/1 to 7/31	0	0.0%	0.0%	7/1 to 7/31	0	0.0%	0.0%
8/1 to 8/31	11	18.0%	29.5%	8/1 to 8/31	1	10.0%	10.0%	8/1 to 8/31	1	33.3%	33.3%
9/1 to 9/30	18	29.5%	59.0%	9/1 to 9/30	5	50.0%	60.0%	9/1 to 9/30	2	66.7%	100.0%
10/1 to 10/31	18	29.5%	88.5%	10/1 to 10/31	3	30.0%	90.0%	10/1 to 10/31	0	0.0%	100.0%
11/1 to 11/30	1	1.6%	90.2%	11/1 to 11/30	0	0.0%	90.0%	11/1 to 11/30	0	0.0%	100.0%
12/1 to 12/31	6	9.8%	100.0%	12/1 to 12/31	8	10.0%	100.0%	12/1 to 12/31	0	0.0%	100.0%
Totals:	61			**Totals:**	10			**Totals:**	3		

Table E10 – Y2K Readiness Survey Response Report – Question #4a

As of November 5, 1999

Y2K Readiness Survey Response Report – Question #4

Question #4a – If you have substantially completed the development of contingency plans (as indicated in 1e): Have the contingency plans been tested where feasible? [1]

All Manufacturers			Few Source			Single Source		
Responses	**Number**	**%**	**Responses**	**Number**	**%**	**Responses**	**Number**	**%**
Yes	585	48.9%	Yes	53	39.0%	Yes	14	41.2%
No	264	22.1%	No	44	32.4%	No	9	26.5%
Not Planned[2]	257	21.5%	Not Planned[2]	25	18.4%	Not Planned[2]	4	11.8%
Did Not Answer	91	7.6%	Did Not Answer	14	7.6%	Did Not Answer	7	20.6%
Totals:	1197	100.1%	**Totals:**	136	100.1%	**Totals:**	34	100.1%

Number of manufacturers that will be done with their independent review by completion date

All Manufacturers				Few Source				Single Source			
By 5/31	1	0.4%	0.4%	By 5/31	0	0.0%	0.0%	By 5/31	0	0.0%	0.0%
6/1 to 6/30	0	0.0%	0.4%	6/1 to 6/30	0	0.0%	0.0%	6/1 to 6/30	0	0.0%	0.0%
7/1 to 7/31	5	1.9%	2.3%	7/1 to 7/31	1	2.3%	2.3%	7/1 to 7/31	1	11.1%	11.1%
8/1 to 8/31	17	6.4%	8.7%	8/1 to 8/31	1	2.3%	4.5%	8/1 to 8/31	1	11.1%	22.2%
9/1 to 9/30	107	40.5%	49.2%	9/1 to 9/30	17	38.6%	43.2%	9/1 to 9/30	3	33.3%	55.6%
10/1 to 10/31	63	23.9%	73.1%	10/1 to 10/31	15	34.1%	43.2%	10/1 to 10/31	1	11.1%	66.7%
11/1 to 11/30	43	16.3%	89.4%	11/1 to 11/30	5	11.4%	88.6%	11/1 to 11/30	2	22.2%	88.9%
12/1 to 12/31	28	10.6%	100.0%	12/1 to 12/31	5	11.4%	100.0%	12/1 to 12/31	1	11.1%	100.0%
Totals:	264			**Totals:**	44			**Totals:**	19		

[1] Based on those manufacturers that have stated that testing is part of their Y2K plan (Reference Question 1c).

[2] Manufacturer indicated that testing of contingency plans is not planned.

Table E11 – Y2K Readiness Survey Response Report – Question #4b and #4c
As of November 5, 1999

Y2K Readiness Survey Response Report – Question #4

Question #4b – If you have substantially completed the development of contingency plans (as indicated in 1e): Do the contingency plans address potential problems with your key business partners (utilities, service providers, suppliers, vendors, distributors)? [1]

All Manufacturers			Few Source			Single Source		
Responses	**Number**	**%**	**Responses**	**Number**	**%**	**Responses**	**Number**	**%**
Yes	965	80.6%	Yes	110	80.9%	Yes	27	79.4%
No	133	11.1%	No	12	8.8%	No	0	0.0%
Did Not Answer	99	8.3%	Did Not Answer	14	10.3%	Did Not Answer	7	20.6%
Totals:	1197	100.0%	**Totals:**	136	100.0%	**Totals:**	34	100.0%

Question #4c – If you have substantially completed the development of contingency plans (as indicated in 1e): Do the contingency plans address potential problems with foreign suppliers (e.g., establishment of alternative suppliers)? [1]

All Manufacturers			Few Source			Single Source		
Responses	**Number**	**%**	**Responses**	**Number**	**%**	**Responses**	**Number**	**%**
Yes	699	58.4%	Yes	89	65.4%	Yes	21	61.8%
No	308	25.7%	No	23	16.9%	No	3	8.8%
Did Not Answer	190	15.9%	Did Not Answer	24	17.6%	Did Not Answer	10	29.4%
Totals:	1197	100.0%	**Totals:**	136	100.1%	**Totals:**	34	100.0%

[1]Based on those manufacturers that have stated that testing is part of their Y2K plan (Reference Question 1c).

Table E12 – Y2K Readiness Response Report - Question #5

As of November 5, 1999

Y2K Readiness Survey Response Report – Question #5

Question #5 – In the event of an unexpected increase in demand for products essential for healthcare due to Y2K concerns on the part of customers or in response to actual production or supp1y problems encountered by other suppliers of similar products, is an increase in your products feasible? [1]

All Manufacturers			Few Source			Single Source		
Responses	**Number**	**%**	**Responses**	**Number**	**%**	**Responses**	**Number**	**%**
Yes	1340	91.2%	Yes	148	90.8%	Yes	36	85.7%
No	119	8.1%	No	15	9.2%	No	6	14.3%
Did Not Answer	10	0.7%	Did Not Answer	0	0.0%	Did Not Answer	0	0.0%
Totals:	1469	100.0%	**Totals:**	163	100.0%	**Totals:**	42	100.0%

Question #5a – Do you have plans to increase production of any of your products, which could be considered essential to the delivery of healthcare, due to an anticipated increase in customer demand as a result of Y2K concerns

All Manufacturers			Few Source			Single Source		
Responses	**Number**	**%**	**Responses**	**Number**	**%**	**Responses**	**Number**	**%**
Yes	617	42.0%	Yes	68	41.7%	Yes	21	50.0%
No	843	54.7%	No	95	58.3%	No	21	50.0%
Did Not Answer	9	0.6%	Did Not Answer	0	0.0%	Did Not Answer	0	0.0%
Totals:	1469	100.0%	**Totals:**	163	100.0%	**Totals:**	42	100.0%

[1]Based on those manufacturers that have stated that testing is part of their Y2K plan (Reference Question 1c).

Attachment F - Audit Results

Table F1 – Summary of Audit Results
As of November 5, 1999

	Single-Source Manufacturers	Few-Source Manufacturers	Non-priority Manufacturers	Total
Green	32	90	70	192
Via Telephone	24	67	60	151
Via Site Visit	8	23	10	41
Green w/Caution	3	4	6	13
Via Telephone	2	1	5	8
Via Site Visit	1	3	1	5
Watch	1	2	2	5
Via Telephone	0	1	1	2
Via Site Visit	1	1	1	3
Yellow	0	0	0	0
Via Telephone	0	0	0	0
Via Site Visit	0	0	0	0
Red	0	0	1	1
Via Telephone	0	0	1	1
Via Site Visit	0	0	0	0
Complete – Not Rated	0	0	1	1
Via Telephone	0	0	1	1
Via Site Visit	0	0	0	0
Scheduled	0	0	0	0
Via Telephone	0	0	0	0
Via Site Visit	0	0	0	0
Refused	2	6	11	19
Via Telephone	1	5	10	16
Via Site Visit	1	1	1	3
Remaining to be Scheduled	15	5	26	46
Via Telephone	14	5	21	40
Via Site Visit	1	0	5	6
Not required	0	2*	0	2
Total	53	109	117	279

* Determined not to produce essential medical supplies.

Green: Item on track, issues known and appropriate actions planned (with Caution: Minor Issues)
Watch: Potential major issues (no known problems, but there may be trouble lurking)
Yellow: Critical issue impacting success (trouble identified)
Red: Item is behind, out of control, or well over budget (serious difficulty that will likely prohibit success