Food and Drug Administration
Center for Devices and Radiological Health

Report on the Evaluation of Manufacturers' Activities to Assess the Year 2000 Compliance Status of Their Medical Devices

November 9, 1999

Prepared for the FDA by Battelle Memorial Institute
Under Contract # 223-97-5511/TO16

FDA Project Officer:
E. Stewart Crumpler
Office of Compliance
Center for Devices and Radiological Health

Evaluation of Manufacturers' Activities to Assess the Year 2000 Compliance Status of Their Medical Devices

Healthcare facilities need accurate, comprehensive and reliable information on the Year 2000 compliance status of their medical devices in order to know which devices can continue to be used safely, and which need to be upgraded or taken out of service. For the past two years, the Food and Drug Administration (FDA) has been working with the device industry and the healthcare community to develop such information and make it available.

What Has Been Learned?

The vast majority of medical devices are not affected by the Year 2000 problem because they do not use or depend on computers or embedded microprocessors. Moreover, most devices that are computerized are not dependent on any date-related function. Even for those devices that are vulnerable to a Year 2000 problem, most do not depend on date-related information for any of their critical functions. Record-keeping or date display functions that are adversely affected by a date problem present little chance of any significant risk to patients. However, there are a few devices for which a Year 2000 problem could pose a risk, and these deserve special attention.

Availability of Year 2000 Compliance Information

To help healthcare facilities screen their medical devices, it is valuable to have reliable information in a single, searchable location. Comprehensive information on the Year 2000 compliance status of computerized medical devices has been made available through the efforts of medical device manufacturers and the establishment of the Federal Year 2000 Biomedical Equipment Clearinghouse. In addition, FDA has published a list of computer-controlled, potentially high-risk devices (PHRDs) that are critical to patient care and whose unexpected failure or malfunction could present significant risks to patients. FDA has suggested that healthcare facilities pay particular attention to the Year 2000 compliance status of these types of devices.

Is Information in the Clearinghouse and on Manufacturers' Websites Reliable?

To provide additional confidence in the Clearinghouse, and an independent verification of the reliability of the information provided by manufacturers, the FDA contracted with Battelle Memorial Institute for a study of manufacturers of PHRDs to assess their efforts to address the Year 2000 issue. A randomly selected sample of 80 manufacturers were visited on-site to examine their Year 2000 procedures and records. The results of that study are described in the contractor's attached report. The study examined the extent of activities undertaken by manufacturers of PHRDs to assure that the Year 2000 status of these types of medical devices was known and appropriately addressed. The contractor assessed the processes and procedures used by the manufacturers to determine whether their computerized medical devices had any Year 2000 compliance problems. The

contractor also assessed the procedures used to design, develop and test upgrades or modifications to correct any Year 2000 non-compliant devices, and the actions taken by the manufacturers to communicate relevant information to users of their products.

What Do We Now Know About Computer-Controlled, Potentially High-Risk Devices?

Based on the results of the assessments, as described in the attached report, FDA has a high level of confidence that manufacturers have taken appropriate steps, in conformance with FDA regulations, to carefully evaluate their computerized medical devices for vulnerabilities to Year 2000 problems. In addition, when devices were identified with Year 2000-related problems, manufacturers have taken the appropriate steps, in conformance with FDA regulations, to advise users of potential problems, to develop and validate upgrades or to describe devices as obsolete and warn against their continued use.

The FDA has reviewed the results of each assessment and those areas of moderate or high levels of concern identified and described by the contractor. In FDA's judgment, the contractor assessments have revealed no issues or conditions at the firms assessed that raise significant concerns regarding the adequacy of manufacturers' programs to assure the safe functioning of their medical devices. FDA has reviewed the areas of concern identified during the very thorough and detailed review by the examiners and the agency has concluded that none of these issues raise fundamental questions about the safety of the medical devices. On the basis of this statistical sample, one can conclude with a high level of confidence that the remaining firms in the population of manufacturers of computer-controlled, potentially high-risk devices have taken similar and equally appropriate actions.

The results of this study provide the FDA and the public with confidence that information in the Federal Year 2000 Biomedical Equipment Clearinghouse is reliable. The vast majority of manufacturers of computer-controlled medical devices have assessed their products for Year 2000-related problems and, when upgrades were required, have used appropriate processes and procedures to design and test these upgrades in conformance with FDA regulations.

Attachment: PHRD Study Final Report

Unisys

Food and Drug Administration

CDRH Year 2000 Medical Device Assessment

Final Report

Summary of Medical Device Assessments

Battelle/Unisys/LGS

Table of Contents

Executive Summary

The Food and Drug Administration (FDA) has chosen to address concerns about the adequacy of the Medical Device Industry's manufacturers' actions taken to avoid serious Year 2000 problems by independently validating manufacturers' Year 2000 self-assessments. The FDA has identified a list of 90 device types that could pose a risk to patients if a date-related failure affects the function or operation of the device, and has designated these as computer-controlled potentially high-risk devices (PHRDs)

A study designated as a "Special Year 2000 Data Gathering Request" was initiated by the FDA to examine the Year 2000 programs at a random sample of manufacturers of PHRDs. The goals of the study were as follows:

- To provide a high level of assurance that manufacturers have properly assessed the Year 2000 status of their computer–controlled medical devices
- To verify that the manufacturers have developed and properly validated appropriate upgrades to correct any Year 2000 problems for these devices
- To confirm the information provided by manufacturers for the Federal Year 2000 Biomedical Equipment Clearinghouse by examining the supporting documentation of the manufacturers.

From the population of 803 PHRD manufacturers that market their devices in the United States a group of companies was chosen based on random selection. A screening process to ensure that computer-controlled PHRDs were part of the companies' product lines followed that selection. Participation was solicited on a voluntary basis.

Battelle contacted 325 manufacturing companies about the study. Eighty agreed to participate. Of the remainder, 197 (60.6 percent) did not manufacture a PHRD at that location; 29 (8.9 percent) declined to participate in the study; and 5 (1.5 percent) were non-responsive (callers were unable to contact them by telephone).

During the 80 on-site visits, the Examiners assessed six critical areas. Those assessment areas were Executive Leadership and Control, Risk Management, Corrective and Preventative Action, Test Planning and Procedures, Communication with Consignee, and Implementation and Contingency Planning. Only one company received a rating at the high level of concern in any of the six assessment areas. The overwhelming majority of ratings received were at the Low Concern level (91.3 percent of all ratings given). Medium Concerns were given for 8.3 percent of all ratings. High Concern ratings constituted only 0.4 percent of all ratings for the entire study. The medium concerns were spread across all the assessment areas. The high concerns were received by the same company in the areas of (1) Executive Leadership and Control and (2) Test Planning and Procedures.

Based on the results of the assessments of the 80 medical device manufacturers' Year 2000 programs, Battelle finds that the selected manufacturers have quality systems that are adequate to deal with the Year 2000 issue for their devices. Those firms have systematically applied quality processes and procedures to determine the Year 2000 compliance of their products. Moreover, where Year 2000 compliance problems existed, the companies have taken the necessary corrective actions to remedy the problems. Since these results were obtained from a representative, statistical sample of manufacturers, Battelle believes that further assessments

would produce similar results and the additional results obtained would not offer any substantial benefit to the FDA.

1 Introduction

1.1 Overview

The US Food and Drug Administration (FDA) has identified a list of 90 device types that could pose a risk to patients if a date-related failure affects the function or operation of the device, and has designated these as computer-controlled potentially high-risk devices (PHRDs). The FDA initiated a study designated as a "Special Year 2000 Data Gathering Request" for the examination of the Year 2000 programs at a random sample of manufacturers of PHRDs. Battelle contracted with the FDA to perform all tasks necessary to carry out assessments at 80 foreign and domestic manufacturers. This report presents the results of that study.

1.2 Background

The Food and Drug Administration (FDA) chose to address concerns about the adequacy of the Medical Device Industry's manufacturers' actions taken to avoid serious Year 2000 problems by independently validating manufacturers' Year 2000 self-assessments.

The general approach was as follows:

- Battelle, and its subcontractors, Unisys Corporation and LGS Group, Inc., with the assistance of the FDA, identified the objectives for the assessments of participant manufacturers' Year 2000 programs.
- An Examiner's Guideline was developed to ensure that the same questions were asked of all manufacturers. Six areas of concern were identified in the guideline.
- Battelle selected a random sample from the population of manufacturers who have distributed computer-controlled, potentially high-risk devices and obtained agreement of the companies to participate in the study. Participation was solicited on a voluntary basis.
- LGS Group, Inc. provided experienced software quality engineers (or persons with similar qualifications) to examine the design records of each participating manufacturer, examine the adequacy of the manufacturers' procedures for Year 2000 assessments and, if applicable, Year 2000 corrective actions. The examinations also provided reasonable assurance that a Year 2000 assessment and, if applicable, remediation procedures had been consistently applied to all currently produced or previously manufactured PHRDs. This was done through an examination of a random sample of PHRDs. The examination was not intended to be exhaustive, but was intended to cover a representative sample of the manufacturers' PHRDs, sustaining confidence in the general accuracy of the manufacturers' claims in the Federal Year 2000 Biomedical Equipment Clearinghouse.
- A report was prepared on each manufacturer and a level of concern (Low, Medium, or High) was assigned to each of the six assessment areas. These reports were submitted to the FDA.

These assessments were designated a Special Year 2000 Data Gathering Request under the Year 2000 Information and Readiness Disclosure Act. Under this law, the FDA will not use the results of this study for any civil action, and the FDA will not publicly release specific study results without the prior consent of the subject companies. Each Examiner, and any other

contractor or subcontractor personnel that handled confidential trade secret information, signed non-disclosure agreements that are on file at the FDA.

2 Preparation for Assessments

2.1 Assessment Plan Development

The first task in the project was to develop an overall project plan, including all tasks to be completed, the schedule for completion of the tasks, and the staffing, resources, and training plans for the project. The project plan had to identify all government-provided information, materials, and personnel needed for successful completion of the project. The project plan also had to include or reference a specific assessment plan for how Y2K assessments would be conducted, and detailed assessment procedures for Examiners in conducting their Y2K assessments of potentially high risk medical device manufacturers (referenced henceforth as the Examiner's Guideline).

The project plan, assessment plan, Examiner's Guideline, assessment checklists, draft assessment report format, training plan and any subsequent changes to these plans and procedures had to be reviewed and approved by the FDA project officer prior to implementation. Given the very short deadline for completion of this project, very close coordination between the contractor's project manager and the FDA project officer was required.

To meet the tight deadlines imposed by the project, immediately after the award of the contract, the Battelle team conducted a two day "Groupware" workshop with the staff of the three contractors on the task along with the FDA project officer and other FDA personnel. The purpose of the workshop was to create the methodology and tools needed for the assessments. The objectives for the team to reach at the end of the two days were as follows:

- Define team roles and responsibilities.
- Create the assessment processes.
- Create the assessment tools.
- Define the assessment products (the site assessments and final reports).
- Determine the assessment plan.
- Develop the training curriculum and plan.

"Groupware" was chosen for its ability to speed up the process of obtaining consensus on managing each part of the project. Each participant in the meeting had use of a personal computer to input and respond simultaneously to structured activities designed to meet the objectives. "Groupware" also allows each participant an equal amount of time to discuss or provide input on the issues. The "Groupware" workshop addressed all the deliverables: project plan, training plan and proposed training site, assessment plan, specific assessment procedures, assessment checklists, and draft assessment report format.

At the end of the two-day workshop, all participants had agreed to the following:
a firm assessment plan, a well-developed list of questions for the Examiners in draft form, decisions on report content and format, Examiners' training course content, and team roles and responsibilities.

2.2 Examiners' Training

The Examiners participated in a training program conducted jointly by the Battelle team and the FDA. This training was intended to ensure consistency in assessment performance, data collection and reporting. The FDA portion of the training was videotaped during the first training session so that all Examiners would receive the same instructions. The Battelle team provided the instructors and curriculum on Y2K technical issues and on assessment and reporting procedures.

Training was held over a two-week period in three separate locations. Initial train the trainer sessions were held at Battelle facilities in Arlington, Virginia. The second training session was held at LGS Group, Inc. facilities in Ottowa, Ontario, Canada, from July 26 – 28, 1999. The third training session was held at LGS Group, Inc. facilites in Vancouver, British Columbia, Canada, from July 28 – 30, 1999.

The FDA project officer attended the initial training session and was available to answer questions from participants. FDA personnel covered the following topics and assisted in conducting Examiner training regarding:

- Types of devices to be covered
- Types of Y2K problems already seen or anticipated by FDA
- FDA procedures, rules, special concerns
- FDA quality system requirements
- Types of manufacturer records available
- Manufacturer sensitivities
- Manufacturer internal assessment issues
- Non-availability / access to independent validation & verification results
- Gaining voluntary access to the company
- Ethics, integrity and confidentiality issues
- Non-disclosure agreement
- FDA contacts if Examiner has problems
- Frequently asked questions
- FDA guidance documents and other references
- Any clearances needed from foreign governments prior to foreign assessments

2.3 Random Selection Methodology

The FDA requested that Battelle assess the Year 2000 programs at 80 manufacturing facilities. A population of 803 facilities was provided to Battelle in a database for use in selecting the manufacturers to assess. It should be noted that many manufacturers have multiple facilities. Therefore, it was anticipated that in a random sampling, these manufacturers could have more than one facility identified as a candidate for an assessment. The results were as anticipated.

Therefore, though 80 visits were conducted, only 68 unique companies were involved in the assessments.

Preliminary estimates of possible responses to a request to participate were as follows:

- 10 percent of the manufacturers would not actually manufacture a computer-controlled PHRD. These manufacturers would be considered to "fall out" of the study because their devices presented no danger to the public due to Year 2000 problems.
- 10 percent of the manufacturers would decline to participate for various reasons.
- 80 percent of the manufacturers would agree to participate.

However, an analysis of the project indicated the possibility that a single, random sample of manufacturers might fail to provide an adequate number of manufacturers for the study and additional samples might be required to obtain the necessary data. Therefore, the methodology used to generate the sample from the population had to support sequential extraction of multiple samples.

Two methods for extracting samples from a population were considered. One method involved ordering the population, then selecting entries at random. Samples thus generated would have to be statistically tested against the population as a whole to ensure they were properly representative. Generating additional samples would require that the entire process be repeated. Further, the process by which random entries were selected would have to be checked against previous iterations to ensure that additional samples were random relative to one another as well as to the population as a whole.

A second sampling method involved randomizing the entire population, then selecting records at regular intervals as a sample. As samples are taken, the remaining population retains its random order, which ensures that all samples are random relative to one another. This method requires careful attention to and proper testing of the randomizing process, but once this is accomplished extraction of multiple samples becomes trivial.

The second sample generation method was selected. Randomizing of the FDA-supplied database was accomplished by appending a random number to each record, then sorting against that number. The random nature of the sequence was then checked both by subjective review and by statistical testing of the sequence of numbers used.

Creation of the random numbers was accomplished using the RANUNI random number generator (uniform distribution) by SAS Institute, Inc. Experience with this software indicates that it is a reliable source for sequences of statistically random numbers. A simple program loop produced 1,000 random numbers within the range zero to one with seven decimal places. Each number was then multiplied by 1,000,000 to adjust the magnitude. Finally, 0.5 was added prior to conversion to integer value to eliminate any remaining fractional parts without uniform truncation (which might skew the results).

The list of numbers was tested for statistical validity and both the standard deviation and the distribution appeared random. The list was then tested again by dividing it in half and comparing the standard deviations of the two parts. This test disclosed no significant variation in statistical parameters between the first 500 numbers and the second or between the parts and the whole.

The 803 PHRD facilities identified by the FDA were stored in a Microsoft Access database. At the request of the FDA project officer, 102 of the facilities were removed from the sample (their records were deleted from the database) because the FDA had already planned visits to those facilities. Random numbers were then appended to the remaining 701 records and the database was sorted according to the random number assigned to each record. This effectively randomized the database. Multiple samples could now be extracted by selecting records at regular intervals. Sampled records were then marked as "used."

The first sample was extracted by the selection of every 6th record. This sample was provided to Battelle's Statistician for review. His analysis showed a uniform distribution with no statistical anomalies, confirming its random character. Additionally, FDA personnel with knowledge of the manufacturers involved reviewed the list and subjectively judged it to be random.

Ultimately nine samples totaling 325 manufacturing facilities were extracted from the database. The number of facilities that "fall out," that is, that did not actually manufacture a "computer-controlled" PHRD and thus posed no danger to the public, was much higher than estimated (60.6 percent). This necessitated a much larger sample than initially estimated in order to secure the 80 visits required for the study. The actual responses to the request to participate in the assessment are summarized in a table in Attachment 1. Manufacturers were categorized as "Fall Out," "Visit Scheduled," "NO's," "No Response," or "Duplicate." "No Response" was used to refer to manufacturers that could not be contacted. "Duplicate" was used to refer to manufacturers with multiple locations that had agreed to assessments at two or more locations, and which had additional locations identified in the latter samples. The FDA decided that additional assessments of previously assessed companies would not contribute to the value of the project.

2.4 Identification of Participants

The assessment plan required first contact telephone calls by contractors from the Battelle team to determine if companies would agree to a voluntary site assessment. Using a sample of 103 firms drawn according to the random selection methodology, the callers began working the week of July 19. Site visits were to begin during the week of August 2, 1999, and to end during the last week of September 1999. All 103 companies on the first sample received a letter from the FDA Commissioner explaining the nature of this unique study and asking for their voluntary participation.

The first task of the caller was to research the companies to become familiar with the FDA-identified products and to verify the address, telephone number, and point of contact. The caller researched the FDA Clearinghouse database for a website address and to verify the address and telephone number of the companies. Most companies' websites provided sufficient information for the caller to judge the kind of device and the reported status of the Year 2000 compliance of the cited device on the selected sample.

Callers used a prepared script to identify themselves, to explain the purpose of the call to this particular company, and to ask a standard set of questions in order to determine the companies' suitability for a site visit. When the caller talked to the appropriate point of contact, the main points to determine were if the companies had received the FDA Commissioner's letter and if the product(s) identified by the FDA met the definition of computer controlled potentially high risk medical devices. If the companies had not received the letter or needed the official definition of

a PHRD, the caller had to fax the information before the discussion could continue. Once the companies had the required information, the caller asked for permission to make a site visit to conduct an assessment.

Every company on the samples received calls, many of them receiving multiple calls. All of the results of the calls were documented. Companies were considered "outstanding" (meaning not finished with this process) until a letter of invitation was received or for some reason the firm was removed from the study. The calling document was used to provide weekly updates and status to the FDA project officer with the number of fallout firms, number of visits scheduled, visits completed, firms saying "no," firms still undecided saying "maybe," and those firms that were not reachable or that provided "no response."

When a company agreed to a visit, the caller asked for a letter of invitation to be sent to the Battelle team. Usually, the company asked to review the Examiner's Guidelines, which were sent upon request. When the invitation letter was received by Battelle, the company was added to a calendar of scheduled visits and it was noted that the letter of invitation had been received. The information about the firm was provided to LGS Group, Inc. for use in making the pre-examination call.

When the first sample of 103 firms yielded a 64.1 percent fallout rate, and only 28 of the 80 required visits had been scheduled, another random sample was pulled. Since none of the firms in this second sample had been sent the FDA Commissioner's letter, the callers had to adjust the calling procedure to explain the study, fax the FDA letter, and wait for responses. In all, nine samples were pulled for a total of 325 companies that were to be called. The final calls were made the week of September 20, 1999. Attachment 1 summarizes the results of the calls to all 325 companies.

For various reasons firms were determined to "fall out" of the realm of possible site visits. Many of these reasons were not anticipated, resulting in a reevaluation of the calling process and the use of the random selection methodology to identify potential candidates. Fortunately, the process was adaptable to these unforeseen contingencies. Of the 325 firms called, 197, or 60.6 percent did not meet the requirements for the site visit. Either the product listed on the sample was <u>not</u> computerized, did not meet the FDA definition of a potentially high-risk medical device, or had been transferred or sold to another manufacturer. All of these reasons were acceptable reasons for not scheduling a visit.

Callers encountered difficulties in getting the firms onto the schedule. The main problems include the following:

- In many cases either the appropriate decision-maker had not been identified or was not available to make decisions. This resulted in callers being required to make many attempts to reach the appropriate personnel.
- The period of performance for the study was an issue. Many European companies schedule vacations in August. Thus many key staff members were not available during the period of time allocated for this study.
- Few Asian companies could not be contacted during normal Eastern Time Zone business hours. LGS staff in Vancouver, British Columbia attempted to reach the companies during their business hours.

- Many foreign companies do not have voice mail, and a few did not have personnel who spoke English.
- Companies were reluctant to commit time and resources for various reasons and questioned if the study was actually "voluntary."

Only 29 (8.9 percent) of the companies called actually declined to participate in the study. The reasons given fall into distinct categories that are summarized in the following table.

Reason for Declining	**Number of Firms**
Audited recently by FDA	3
Not available during period of study	3
Device manufactured in another location	2
Device not affected by the date function	1
Information already given to FDA	1
No reason	1
No resources or too time-consuming	11
Reorganization in progress	2
Timing wrong - can only accommodate a visit after the end of the study	5
Total	29

Only 5 or 1.5 percent of companies were categorized as providing "no response." Companies were categorized in this manner if they could not be reached by telephone or facsimile transmission (numbers provided were incorrect or out of service), if the telephone was not answered, or if no response was received to messages left on an answering machine or to facsimile transmissions.

2.5 Preparation for Examinations

Once a manufacturer voluntarily agreed to the examination, a pre-visit contact was made with the manufacturer to confirm the types and models of PHRDs that were actually manufactured at a specific site. The manufacturer was notified (by documented telephone call) of the intent to perform an examination, given an explanation of the approach and the name of the Examiner who would perform the examination. A request was made that the manufacturer have available the personnel responsible for the Year 2000 project at the site and that adequate meeting and communications facilities be provided for the Examiner. The Examiner's Guideline that had been provided to the manufacturer was discussed to ensure an understanding of the assessment process. Any logistical problems that existed were discussed and resolved in the telephone call.

2.6 Problems Encountered

During the course of this study, Battelle experienced difficulty in achieving the target of scheduling 80 assessments of manufacturing facilities of PHRDs. Preliminary estimates from the FDA indicated that 80 percent of the companies would agree to participate, 10 percent of the devices classified as PHRDs would not actually be PHRDs and would fall out of the sample, and 10 percent of the companies would decline to participate in this voluntary study. Actually 24.6 percent agreed to participate, 60.6 percent fell out and 8.9 percent of the companies declined to

39 participate. The remaining companies in the random sample either could not be contacted or were subsidiaries of large corporations that had already had three or more manufacturing facilities assessed. In this latter situation a decision was made by the FDA to exclude duplicates from the study since there would be no benefit gained from additional assessments of large companies with standardized procedures. A significant increase in the number of samples was necessary in order to obtain the required level of participation. The time required for performing research on each company, identifying and contacting the companies' Year 2000 points of contact, determining if the companies really manufactured computer-controlled PHRDs, and then scheduling visits exceeded preliminary estimates. This pushed some site visits into late September and early October, and the project was not completed in September 1999, as originally planned.

3 Execution and Reporting of the Assessments

3.1 Execution of the Assessment

The assessments were conducted using an Examiner's Guideline developed by Battelle, Unisys, LGS and the FDA. The Office of Management and Budget (OMB) reviewed and approved this guideline prior to its use by the Examiners and assigned a control number to the document. All participant companies were given a copy of the guideline prior to the start of the site visit.

The review was conducted in five steps:

- Incoming Briefing: introduction and development of mutual understanding with the company representatives; description of the overall terms of reference, scope, assessment process, constraints, schedule, etc., of the examination;
- Facilities Tour: development of appreciation of size and scope of the operation, the physical process including all phases of design, manufacturing and control;
- Interviews and Information/Documentation Gathering: scheduled and/or extemporaneous meetings with key managers to glean the necessary Year 2000 compliance process information and documentation;
- Exit Briefing: summary of information, facts and preliminary findings (without conclusions or recommendations) conducted with key company representatives. Objective is to assure agreement with company representatives that the information, facts and preliminary findings are accurately and completely portrayed;
- Analysis and Report Writing: analysis of the information obtained, development of the findings and conclusions and writing the final site report.

The examinations were structured around six Assessment Areas that were identified during the Assessment Plan Development phase as important to the success of Year 2000 projects. The individual assessment reports discussed strengths and concerns in each area and summarized the findings by applying a high, medium or low concern rating to each assessment area. The concern ratings were based on the identification of the most severe of the following observed characteristics:

High Late, no plan, or inadequate plan
Inadequate or incomplete resources
Incomplete or inaccurate deliverables
Unable to validate results - due diligence inadequate

Medium Somewhat late, or incomplete plan
Insufficient or incomplete resources
Deficiencies in deliverables
Incomplete validation of results

Low On schedule
Adequate resources
Completed

Through interviews of knowledgeable staff and review of available documentation, the Examiners evaluated the adequacy of the manufacturers' Year 2000 self-assessment process for PHRDs. To support the concern ratings given, the Examiner's Guideline required consideration of the following:

- Evidence of a systematic approach to assessments of all devices including PHRDs
- Manufacturers' logic process for Year 2000 assessments
- The nature of Year 2000 functional problems in devices
- Risk analysis documentation, both before and after any Year 2000 correction
- Design change documents
- Changed parts
- Validation / verification / testing protocols
- Comprehensiveness of testing to determine the exact nature of the Year 2000 problem
- Year 2000 test reports (not to include test results unless offered by the manufacturer)
- Any Independent Validation and Verifications (IV&V) reports
- Confirmation that those IV&V procedures were followed and actions taken in response to IV&V findings
- Contingency planning for any problems that have not or cannot be corrected
- Communications to customers (consignees) regarding the up-to-date status of Year 2000 readiness of manufactured PHRDs

If a company declared a device to be obsolete and did not provide a Year 2000 correction, the Examiners collected information regarding that decision, including:

- Specific details of the nature of a Year 2000 failure (if known)
- Information regarding the date functionality of the device
- The basis of the decision to declare the device obsolete
- How that decision was communicated to customers (consignees)
- Current status of removing all obsolete devices from use (if known)
- Contingency planning if users refuse to discontinue use of the device

Using the information gathered from the personnel interviews, review of participant companies' related documentation and project reports, and the comparison with the guidelines, the Examiners were able to assess the manufacturers' Year 2000 programs and report on those findings.

3.2 Reporting of Assessment Results

Direct feedback was provided to each manufacturer regarding findings of the examination of their facility. The Examiners conducted a debriefing with each company's management at the

conclusion of the examination. A draft report was submitted to the Battelle team for a quality review and consistency check. Any discrepancies were analyzed and FDA direction was requested for any issues that could not be resolved by the review team. Subsequent to completion of each draft report an additional technical review was conducted. Use of these independent reviews and a standard reporting template helped to ensure that all Examiners were basing their judgments on the same criteria. All site visit reports were forwarded to the companies involved and to the FDA. Any responses received from the companies were reviewed by the Examiners and forwarded to the FDA along with the Examiner's agreement or disagreement to the responses. The results of the individual assessments have been incorporated in this summary report.

4 Summary of Findings

The following sections address the six assessment areas. A summary of the assessment of all areas for all sites is provided as Attachment 2.

4.1 Executive Leadership and Control

Ratings

Assessment Area	Concern		
	HIGH	MED	LOW
Executive Leadership and Control:	**1**	**8**	**71**

Seventy-one of the eighty companies assessed (88.8 percent) received a Low Concern rating for this assessment area. Of the 71 companies with low concern ratings, 50 had no specific concerns identified for any of the three rating criteria. The remaining 21 companies had minor concerns identified, primarily due to informality in the record keeping processes and failure to have formal definitions of Year 2000 compliance. In all cases these minor concerns were alleviated by the overall familiarity that the companies had with the compliance status of their products.

One company did receive a High Concern rating. That company did not follow the processes specified in the various guidelines of the FDA, did not have a structure with which to effectively manage their Year 2000 project, did not have a Year 2000 compliance definition, did not have a repository for the documentation necessary to meet due diligence requirements, did not have a formalized strategy or plan to assess or define the scope of remediation for its device, and did not have any provisions in place in the event of system failure.

The remaining eight companies received Medium Concern ratings. The main reasons cited for this rating was the absence of formal project organizations and funding, informal recording keeping, and poorly defined processes for Year 2000 remediations.

4.1.1 Management Chain

Strengths

The Examiners found that 74 of the 80 companies (92.5 percent) had established Year 2000 projects, generally with separate, clearly defined budgets. Activities were typically undertaken through a matrix of shared responsibilities between line and program managers, or through cross-disciplinary project teams. There was regular contact between the participants and reports were submitted to corporate executive management. In many cases job performance ratings took into account performance against Year 2000 objectives.

Concerns

High Concern – None observed.

Medium Concern

The primary concern for three of the eight companies that received a medium rating centered on the fact that they did not have a Year 2000 project in existence with separate, clearly defined budgets, resources, and plans. However, in all three cases, the companies were very small and upper management was very aware of all activities concerning Year 2000 compliance. One larger company had a very loose management structure, resulting in somewhat unclear lines of responsibility for remediation and implementation. One of the reasons for this structure involved the recent integration of an acquired company into the organization. In addition, two of the eight companies were very informal in the manner in which reporting occurred. One provided reports on an irregular schedule to the President of the company and the other had no written records of results and no indication that the President was made aware of the results. Still, despite the absence of records, the Examiners were reassured by the companies' Year 2000 program coordinators that in both cases the companies' upper management was very aware of all Year 2000 activities and results. Finally, one company lacked strong Senior Management oversight of its Year 2000 efforts, with no evidence of management quality audits and infrequent status reports. Also, the processes used to make key Year 2000 project decisions have not been documented and existing documentation was not centrally filed. This situation was mitigated by strong efforts by departmental managers and the recent appointment of a strong Year 2000 Program Manager.

Low Concern

The Examiners identified minor issues in the management area for nine of the companies reviewed. One of the nine did not have a separately established Year 2000 project, instead using a matrix approach to management, linking line management to a parallel Year 2000 Program with executive accountability for performance management objectives. Other low risk concerns pertained to informal documentation of authority and reports on Year 2000 activities and results. Only one company was identified as being unaware of potential issues with real-time operating systems, compilers, and embedded systems. When advised of the issues, management of that company promised to immediately initiate an investigation of the issues and stated that remedial actions would be taken as needed.

4.1.2 Planning

Strengths

Generally, the Examiners found that planning activities were well organized; detailed procedures for achieving compliance were in place; documentation of compliance activities was available; and design reviews and any design changes required were tracked, validated, and communicated to users.

Concerns

High Concern

The one firm with a High Concern rating did not have a clear Year 2000 compliance definition, no schedules or budget information, and no provisions for defining activities that would identify operations or processes potentially affected by Year 2000 problems. Their plans did not make provisions to raise the level of awareness in the organization such that staff would know and understand the magnitude of the Year 2000 impact.

Medium Concern

For three companies receiving a medium concern rating in this category, separate project plans and timelines had not been established. For these companies compliance activities were conducted as part of regular duties and tended to be relatively informal and on an irregular schedule. Therefore, progress could not be tracked. However, both companies were relatively small with a fairly flat management structure that resulted in speedy communication of issues to top management. A fourth company to receive a medium concern rating did not record its Year 2000 compliance definition and did not keep records on devices with no date functionality to document that testing was not required. In addition, this one company did not have any records to document that devices with a date function successfully passed Year 2000 compliance tests. The fifth company lacked a formal plan featuring a Gantt chart to plot the project time line and manage task interrelationships. The final three companies had two separate Year 2000 compliance statements in existence, which could create some ambiguity as to the meaning of results presented to individuals or organizations.

Low Concern

At nine companies, there were specific concerns about the lack of formality in the documentation of meetings and discussion on Year 2000 and the absence of design control process flow documents, action plans, and written results of Year 2000 testing. However, these concerns were determined to be relatively minor based on the overall awareness and familiarity of the respective companies' management with Year 2000 compliance requirements and activities. In addition two companies did not have a formal definition of Year 2000 compliance though technical staff did have an adequate level of understanding of relevant issues.

4.1.3 Design Control and Configuration Management

Strengths

Overwhelmingly, the manufacturers' Year 2000 Project Methodologies were well-defined and included project reporting, compliance definition, outside-vendor contact, testing, remediation/validation, de-commissioning, qualifications of required personnel, and adherence to due diligence standards.

Concerns

High Concern

The one firm that received a High Concern rating did not have a well-defined Year 2000 Project Methodology compliance definition. Documentation regarding application software development did not have a clearly stated purpose, had inadequate internal control, and provided guidance that is open to interpretation by the user. The company also did not have a repository for the documentation necessary to meet due diligence requirements, did not have a formalized strategy or plan to assess or define the scope of remediation for its device, and did not have any provisions in place in the event of system failure.

Medium Concern

Only four medium level concerns were identified in the category of Design Control and Configuration Management. One company did not have an overall design control process flow document. However, that company did have established standard operating procedures, pertaining to design control and specifically mandated that Year 2000 compliance was required for new products and product changes. Another did not address Year 2000 compliance as a special requirement. The third company did have a process, but the application of the process to Year 2000 remediations was not clearly defined and documented. The last had key configuration status accounting information split between two sites, a situation that would complicate compliance documentation.

Low Concern

For eight companies, the Examiners identified minor concerns, including inventory records issues, compliance statements and software quality manuals.

4.2 Risk Management

The objective of the risk management assessment area was to verify that the manufacturers' risk analysis procedures were logical and adequate. The Examiners used the following definitions when assessing the risk management area.

- Risk is the combination of the probability of occurrence of harm and the severity of that harm (ISO/DIS 14971).
- Risk management is the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, and controlling risk (ISO/DIS 14971).

Looking at both risk analysis and risk control, the Examiners focused on hazard analysis and risk estimation as well as the intent to eliminate the hazard and to mitigate the estimated risk to an acceptable level. Additionally, the assessment required viewing the firm's risk management documentation, which included the description of the hazard, the severity of the risk, the specific software cause, the risk control method, the test or verification method, and the severity level after mitigation.

In the risk analysis review, Examiners had to confirm that the manufacturers assessed the probability of the occurrence of a Year 2000 event and the level of risk to a patient. Examiners

identified devices currently in service that were not Year 2000 compliant or potentially not Year 2000 compliant. The Examiners also assessed the process and testing methodologies used by the manufacturers to determine vendor compliance for third party components.

Ratings

Assessment Area	Concern		
	HIGH	MED	LOW
Risk Management:	**0**	**8**	**72**

Strengths

Examiners stated that 69 of 80 (86.3 percent) of the companies examined either followed standard operating procedures suggested by the FDA/CDRH or their own internal standard operating procedures in evaluating and documenting risk to patients. Guidance from FDA may be found in the document "Information Paper on FDA Activities Related to the Year 2000 Date Problem and Medical Devices," dated December 18, 1997, page 3, in the paragraph entitled "Corrective Actions by Manufacturers." Examiners specifically reported on, and found acceptable mappings between, hazard severity and the probability of occurrence.

Risk management considerations included patient care, technical, business risks, and costs. To eliminate the key risk for medical devices, one manufacturer actually designed devices with Year 2000 compliance in mind. Most manufacturers conducted a risk analysis for all their computer-controlled devices to identify any date-related functionality and then documented the potential risk exposure to operators and patients. Triage codes to determine the needs for fixes from essential to lowest were instituted by four companies. Some manufacturers whose medical devices have been assessed for Year 2000 compliance have the status and compliance level posted on the company web site.

Many manufacturers initiated software revisions to remedy non-compliant devices. Where software revisions were not available, workarounds were identified and communicated for products requiring user intervention.

As in other assessment areas, the discovery of no date-related events critical to the functioning of the devices or that no remediation or modification was necessary for the devices made the concern for risk management very low at 21 of the companies visited (26.3 percent). Some companies conducted a very informal Year 2000 compliance process outside of their rigorous risk analysis due to these very reasons as well as the fact there was no identified risk to patients.

Examiners noted that device manufacturers made contacts with third party vendors to obtain information on Year 2000 readiness of their components with embedded clock chips.

Concerns

High Concern: None observed.

Medium Concern

A medium level of concern was noted for eight companies in the sample. Four of these companies had not conducted a separate risk assessment of Year 2000 failures. The others had done so, but had not separately documented the results.

Low Concern

Specific issues were identified at 15 of the 72 firms that were rated as Low Concern. Those issues were:

1. Remediation planning and associated risk analyses were not conducted or were not documented by 13 companies for devices that tested Year 2000 compliant.
2. The Year 2000 was not actually listed as a "hazard."
3. Risk analyses were not conducted on devices no longer being manufactured.

4.3 Corrective and Preventative Actions

This assessment area encompasses the practices used in the company to ensure the manufacturer has comprehensive procedures for dealing with customer interaction regarding changes in devices and/or warnings regarding uses with the devices. Whether the company performed Year 2000 compliance checks, determined if devices were obsolete, and communicated this information to customers is part of this assessment area as well. This area includes any processes for logging, addressing and tracking customer complaints and incident reports. The company may also use customer communications to support corrective and preventative actions and the Examiner was looking for evidence of such communications during the site visit. Evidence of any remediation documentation or planning for devices, rollback procedures, and/or contingency planning based upon risk are part of this assessment area also.

Ratings

Assessment Area	Concern		
	HIGH	MED	LOW
Corrective and Preventative Actions:	**0**	**1**	**79**

This was the single strongest area found in this study. All but one company received a Low Concern rating for this assessment area.

Strengths

Examiners specifically mentioned reviewing a standard operating procedure for handling all customer requests for corrective and preventative action in 63 companies (78.8 percent). Responsibility for planning and implementation usually was at the senior manager level. Most companies have extensive manuals outlining what actions and responses are required regarding reported problems with devices, whether discovered internally or through customers. Corrective

Action Requests and/or Engineering Change Proposals are standard practices in 17 of the companies visited. Some Examiners cited the fact that companies follow the FDA Guidelines to include the Quality System Regulation.

Many companies did use specific testing protocols exclusively for Year 2000 compliance on the devices. Devices with date-related functions at 19 companies had specific remediation plans created for tracking and change verification/validation. Year 2000 project activities were well documented, tracked, and monitored by specific managers at eight companies. Twelve companies decided to use existing corrective and preventative action processes that are well established rather than creating specific Year 2000 procedures.

Remediation and validation plans were identified, designed, validated, and documented for products that tested Year 2000 non-compliant in 35 of the companies visited. Examiners identified 11 companies where specified design controls and changes to the design are checked to determine if they comply with design controls, including change verification and validation. Four companies do not have remediation processes because date-related functions are only convenience features and not integral to the operation of their devices.

Communication on device events related to Year 2000 compliance are commonly related through a website, a central phone number, technical support services, and/or a specific e-mail address at 22 companies.

Concerns

High Concern – None observed.

Medium Concern

Only one company, where remediation and validation plans have not been identified, designed, validated or documented and no service levels defined, received a Medium Concern in this assessment area.

Low Concern

Overall, the Examiners cited specific issues at only twelve of the 79 companies that were rated as a Low Concern. The issues raised were considered minor and many companies acknowledged the weaknesses and began working to correct the problems.

Although not all companies identify remediation planning and documentation specific to Year 2000, the documentation available was excellent for actions taken on their devices. Two companies had not specifically identified that remediation actions taken were actually Year 2000 compliance actions. One of those two companies also did not provide any Year 2000 compliance information on its website. However, both companies received Low Concern ratings because of the way they handled compliance within their overall quality system.

Examiners noted that one company did not complete formal change requests, but stated that the company was working on that issue. Two companies did not have contingency plans based upon risk defined.

4.4 Test Planning and Procedures

This assessment area focused on the ability of the manufacturer to ensure the adequacy of test plans and procedures.

Ratings

Assessment Area	Concern		
	HIGH	MED	LOW
Test Planning and Procedures:	**1**	**11**	**68**

4.4.1 Vendor Related

This sub-category of the assessment area focused on the manufacturers' procedures for assessing the components purchased from their vendors. A concern was the consideration of all of the components of the companies' microprocessor-based devices. Examiners sought to determine if an assessment of components had been carried out and documented. Part of the review involved the examination of statements of compliance solicited and received from suppliers. Also, the Examiners determined if a single, consistent compliance definition was used on correspondence with suppliers. Examiners did discover that not all companies assessed use components from outside vendors.

Strengths

Examiners reviewed files of vendor related materials and sampled for quality and completeness. The sizes of companies, the number of products marketed, and the relationships with vendors ranged from small to very large, few to many, and simple to complex. Sixty-eight companies (85 percent) receive supplies from outside vendors and had valid, well-established processes in place. The processes included standard contact methods, a means to qualify information and an on-going review process to maintain the latest updated information. Generally, statements from all vendors of critical components were on file. Examiners found that after written notices were sent to suppliers, many companies followed up with telephone calls to make sure the suppliers were aware of compliance issues.

There were some companies that did not have typical vendor relationships and had developed distinctive processes to deal with the vendor products they are using. Seven companies had no date criticality in their vendor products so supplier assessment issues focused mostly on software compliance. Three companies, to ensure the software components were compliant, took a unique approach by testing all the software components internally and giving them compliance ratings. Most companies adapted their purchasing processes to specify that all vendor supplied products must be Year 2000 compliant. Statements of compliance for vendor products were available at 55 of the firms assessed (68.8 percent). These compliance statements were required to provide vendor contact information, an information source, the date of the vendor statement, model version or revision numbers, device associations, device failure modes, suggested remediation for identified problems, and the status (complete/incomplete) of the vendor review process for each item.

Concerns

High Concern: None observed.

Medium Concern

The Examiners found at three sites (all for the same firm) that the process to upgrade Year 2000 non-compliant computers was unclear. The firm considered such an upgrade to be the customer's responsibility when the computer was not under a service contract. One company did not have a well-developed vendor compliance process with standard contact methods, qualification of information, and an on-going review process to maintain the most up-to-date information. Five companies did not have a consistent compliance definition to use in correspondence with vendors. Two companies relied heavily on verbal reports of compliance from their vendors. One company had a questionnaire for vendors that was too brief and general to permit the identification of specific Year 2000 compliance or possible failure modes for specific devices. One company did not solicit specific statements of compliance, but instead obtained information from their suppliers' websites. That same company did not inspect purchased items for Year 2000 compliance. One company had not documented the decision model used to designate vendors as being critical, and there is no certainty that all vendors have been rated consistently. This is a fairly important part of the due diligence documentation.

Low Concern

Of the 68 firms that received Low Concern ratings, fifteen firms did not have structured vendor test plans, special procedures for assessing the compliance of vendor-supplied components, or had not completed their reviews of the products supplied by critical vendors. Four companies did not define a consistent compliance definition to use in correspondence with vendors. In one company a very minor concern existed due to the lack of a structured vendor test plan, although much of the critical software was developed in-house. In two companies some original test results were missing. Subsequent to the assessment one of these two companies initiated additional testing to correct the loss. Special procedures for assessing Y2K compliance of components received from vendors, on incoming inspection, were not in place in one company, but the Examiner determined it was not significant due to strict supplier approval procedures.

There were other, isolated concerns identified. One company was thought to maintain vendor certifications for critical components at corporate headquarters, but the site visited did not produce any documentation to support the belief. In another company, although compliance definitions from the vendor were relied upon for Year 2000 compliance, the compliance statements were pulled from the vendors' websites rather than from communications with the vendors. Finally, the vendor compliance process at one company did not include an on-going review procedure to maintain the latest updated information on the vendors.

4.4.2 Test Planning

In this sub-category assessment area, Examiners focused on the steps involved in the review and approval to a test protocol, test results, and the documentation required by the test plan. If any data and test scripts were used to test devices for Y2K compliance, the Examiners related those to risk management as well.

Part of the concern in this sub-category dealt with the dates examined for Y2K vulnerability as well as the list of products that were to be tested for Y2K. The focus was on the criteria, process, and approval for eliminating devices from the list. Examiners also sought documentation of the reasons required for removing specific devices from the list.

Strengths

In sixty-nine of the companies (86.3 percent) testing was indicated for the medical devices and Examiners found test plans were well developed. Testing documentation is based upon a standard template. The Examiners reviewed all documents in the templates. Typically, these documents contain test procedures addressing each of the major risks that were identified during the hazard analysis activity. The person running the test signed each step in the test procedures, ensuring full accountability for the test results. Examiners found generally that all high risk devices were Year 2000 tested with the exception of those with no date/time function, those with no recording of date/time, or those not being manufactured, but used only for concept exploration. Examiners specifically cited 26 companies that used test planning from existing software testing, while definitely making sure the Year 2000 critical dates were addressed. Results for the devices tested were confirmed.

Concerns

High Concern

Only one company received a High Concern. The Examiner was concerned with the types of testing and their definitions, the fact that some of the tests failed, and that the errors noted on the tests were not typical for acceptance testing. This was a major concern because this level of testing is not acceptable for a mission critical application or a PHRD. Further concerns were raised because unit testing, integration testing, and system testing were not performed by a qualified person. Also the planning of test cases did not include complete test scenarios to encompass all possible conditions. Another item of concern was that the Design Specifications used were outdated. Finally, the Examiner found that a thorough testing methodology was not implemented.

Medium Concern

Although test procedures existed for all non-compliant devices, explicit documentation of one or more "standard" Year 2000 test planning or procedures documents or templates was not in evidence in four sites visited. For another three companies the test results were not verified and reviewed by an independent third party. Two companies had no formal test planning, only a verbal request which did not encompass all the Year 2000 possible failures. In one company an overall Year 2000 test plan covering all devices was not identified; procedures for Year 2000 testing did not go through the normal Test Design Process and test scripts were recorded and tracked elsewhere.

Low Concern

Of the 68 firms that received Low Concern ratings, Examiners noted specific issues at only three companies. At two firms, there were no plans for an independent verification/validation check on the testing results. At the third firm, rollover testing had not been planned.

4.4.3 Execution of the Testing

For this sub-category assessment area, the focus was on the actual conduct of the Y2K evaluation of devices through selection of a specific PHRD device as an example. Examiners were looking at the detailed testing in accordance with approved methodology, with or without user groups or by proxy.

Documentation of test results, a list of Y2K problems that have been identified in the devices, and a list available of the Y2K fixes that have been implemented are sought in this area. Examiners also looked for documentation of testing after fixes were complete, a regression test analysis following the fix, and any independent verification and validation.

Strengths

Testing performed by qualified personnel was completed on high-risk devices and documented very well by the subject companies. Test results were on file along with the remediation plans. For 71 of the companies visited (88.8 percent), the testing for Year 2000 according to a testing plan was successfully completed. Companies whose devices were Year 2000 compliant required no remediation or subsequent testing of upgrades. Test results varied from 100 percent pass of devices showing no Y2K problems to various problems identified for remediation. Examiners found only one High and four Medium Concerns in this area.

Concerns

High Concern

The one company to receive a High Concern did not address critical dates. Also, only tests that failed were retested after remediation efforts. All test cases should have been re-tested to ensure that changes made did not affect other areas or create new problems.

Medium Concern

At one company the Examiner was concerned that the testing was not controlled enough to take into account all Year 2000 potential failures. In another company, some test results were incomplete or were missing signatures. No additional Year 2000 documentation above and beyond the regular Engineering Change Order (ECO) process documentation had been created to document the Year 2000 testing process in the third company. At a fourth company a fix was still required for one PHRD.

Low Concern

Of the 68 firms rated as Low Concern, Examiners identified specific issues for only one company. This company had no single document that captured all the results of the Y2K tests.

4.4.4 Independent Verification and Validation

This sub-category of the assessment area is concerned with any work groups outside the immediately responsible work group that reviewed the Y2K assessment plan and participated in the Y2K testing. If there was an external Independent Verification and Validation (IV&V) completed to assist the company's internal audit process, the Examiner was interested in confirming whether appropriate actions were taken and completed in response to the findings and any recommendations from the internal or external IV&V.

Strengths

Where no date-related functions were found and no testing actually required, no IV&V was performed. Therefore the number of companies assessed in this area depended on the types of device manufactured by the company. For 61 companies (76 percent of the total) that identified Year 2000 problems, internal audits were conducted. In addition, many companies practice internal quality audits in accordance with ISO 9001 procedures. The Examiners reviewed the schedule of audits to be done, saw documentary evidence that such audits had been done in the past, that written reports had been produced and reviewed by management, and that appropriate actions were taken. Twenty-four manufacturers (30 percent of the firms) have, in addition to internal corporate auditors and audit procedures, obtained external audits by a third party company.

Concerns

High Concern: None observed.

Medium

Five of the sites did not identify specific requirements or explicit procedures for IV&V, did not specifically audit the Year 2000 readiness of products or devices, and did not participate in the Year 2000 test planning or testing per se. Three of the companies (4 percent) had no outside verification that the products were Year 2000 ready with one company being dependent on another company's testing. Despite the existence of a strong Quality Assurance department, no independent verification and validation (IV&V) was performed at one company but with their strong test planning, the assessment merited only a medium risk.

Low

Of those firms that were rated as Low Concern, fourteen companies did not conduct an external Independent Verification and Validation (IV&V) of their Year 2000 project. One company permitted part of their development group to validate their process, so there was no truly independent validation. One company received a Low Concern rating because of the absence of IV&V in areas of code review and actual testing.

4.5 Communications with Consignee

This assessment area examined the types of programs and services that companies have provided to facilitate communication with consignees regarding changes, notices, updates, and software upgrades for medical devices. Examiners reviewed the methods used by the companies to communicate the Year 2000 status of their devices, including those that were obsolete, to the consignees of those devices. If an obsolete, potentially high-risk device had a Year 2000 problem that posed a risk to a patient, the Examiners determined if there were fixes and the

methods by which consignees could obtain the fixes. Included in the review were the communications acknowledging receipt by consignees of device status reports.

This assessment area also considered the companies' ability to support requests for assistance in upgrading devices and in the verification that fixes were applied correctly. Examiners checked for documentation of efforts made to encourage the removal of obsolete PHRD devices from the user community. Responses from PHRD users were reviewed to determine the adequacy of the companies' efforts.

Ratings

Assessment Area	Concern		
	HIGH	MED	LOW
Communications with Consignee:	**0**	**4**	**76**

Seventy-six (or 95 percent) of the companies assessed received a Low concern evaluation in this area. Most companies have strong programs in place to permit effective communication with their consignees. Some minor concerns were noted, but only four of the companies visited received a Medium concern rating. Overall, this was the second strongest assessment area for all companies. The medical device manufacturers appear to have addressed the issue of communicating with their customers very seriously.

Strengths

The Customer Contact Process is well established in all the companies visited. One Examiner noted that the most efficient method of communicating status to concerned parties appeared to be through the Internet. Most companies have established websites that list Year 2000 information for the public to access. In addition, other, more traditional means of communication are in existence and are working well.

Most sites have a standard procedure and process in place to deal with customer inquiries or concerns and an on-going process to distribute the most current updates. Some of the following standard contact methods and procedures were found at the companies visited:

- A Year 2000 web site maintained with regular updates of the latest information, one even providing private access for clients.
- Hotline and/or call center.
- Mass mailing of an informational letter(s).
- Questionnaire seeking information from consignees with respect to instruments in use and follow-up phone calls.
- Technical support services with 1-800 numbers for assistance.
- Informational newsletter.
- Letter responses to inquiries.
- Registered mass mailings with tracking for receipt and follow-up.

- Shipped free upgrade software to customers as follow-up to non-responses.
- Incentives for non-respondent customers.
- Printed materials describing company's response to Year 2000 issues.
- Letters of Year 2000 compliance for products, the company's internal business processes, and ability to deliver products to customers.
- Distribution of an informational CD/ROM.
- Postings on the FDA Clearinghouse.
- Database of all consignees for all products worldwide.
- Major advertisement campaign
- Presentations to users' group.

Concerns

High Concern – None observed.

Medium Concern

The companies that were assigned a Medium Concern rating needed to develop Customer Contact Processes and to implement them rapidly. Due to the short amount of time remaining until the Year 2000, it was felt that these companies would experience difficulty in contacting consignees and completing the installation of upgrades. Nevertheless, the companies involved had limited numbers of consignees and also were relatively small, with agile organizations that could response as required.

Low Concern

The Examiners identified specific issues at only 13 of the 76 companies that were rated as Low Concern. Most of these issues pertained to the amount and accuracy of information available to consignees and the methods through which it could be obtained. A very few companies did not have a Customer Contact Process in place, one even relying on its customers to make contact regarding upgrades. One company uses Field Service Engineer visits to provide customers with Year 2000 compliance information. Another company did not have a single source for information for its customers, instead, maintaining the information in separate departments.

Three companies visited do not have Year 2000 compliance information for their products on their websites and one company's website was undergoing modification, thus their Year 2000 compliance information could not be accessed.

4.6 Implementation and Contingency Planning

This assessment area focused on the manufacturers' ability to ensure that the necessary Year 2000 planning has been or will be successfully executed. For intended Year 2000 upgrades, Examiners were looking to the completed development of all upgrades according to an identified schedule. If the company has not completed upgrades, the Examiners were to ask for the plan

for addressing the issue in sufficient time and for communicating options to its customers. When a company has upgrades, the Examiner needed to know if the company made the upgrades available to its customers and how that company communicated the availability of those upgrades.

Obsolete devices were also included in this assessment area. Of specific concern were the plans that companies have to address the problem of users who decide to continue to use an obsolete device. A more thorough discussion of obsolete devices may be found in section 4.7 of this document.

Finally, companies were expected to have plans in place for unexpected Year 2000 contingencies and emergencies regarding their devices. The Examiners sought evidence that those plans had been tested or rehearsed. Specifically, in conjunction with the risk analysis, manufacturers should have a plan for reacting quickly and efficiently to unexpected problems reported by end users. Also, since many problems arising during the century change timeframe potentially could be inaccurately attributed to a perceived Year 2000 bug, the Examiners asked if the companies would have additional trained staff available to respond to reported problems. Any such staff would be expected to be able to correctly identify bona fide issues and quickly respond to crises by communications, directions, and actions.

Ratings

Assessment Area	Concern		
	HIGH	MED	LOW
Implementation and Contingency Planning:	**0**	**8**	**72**

Strengths

The Examiners found no reason for concern in this assessment area at 50 of 80 companies. Twenty-three other companies received a low concern rating, eight received a medium concern rating, and none received a high concern rating. It was found that, in general, companies have completed upgrades and tested them according to schedule. They have also provided remediation solutions for their date/time sensitive PHRDs. All but four of the companies have an inventory of devices that is kept current on an ongoing basis as items are added, moved, modified, or taken out of service (becoming obsolete). These databases are used as the repository for electronic documentation of information related to the Year 2000 inventory items. The information from these databases is available on some of the companies' web sites. In many cases, companies have developed comprehensive steps on a corporate-wide scale to address business continuity during the transition phase.

Concerns

High Concern: None observed.

Medium Concern

The primary concern for all eight companies that received a medium rating is the absence of a formal plan to address unexpected Year 2000 emergencies. Special plans have not been put in place to train personnel, assign additional staff to work or otherwise prepare for emergencies during the transition period.

Low Concern

The Examiners expressed specific concerns about eight companies that had no contingency plans and seven that were still planning contingency work, because of the need to confirm that operational issues are resolved before the end of the year. The Examiners had other concerns about the absence of any planned post-Year 2000 support at four sites; about the absence of plans at four sites to discourage the use of obsolete devices by customers; and about plans at five sites to use routine customer support and escalation procedures for unforeseen Year 2000 problems. One company had potential problems with support of products released as late as September 1999 and another had not addressed external dependency issues.

4.7 Obsolete PHRD Devices

Products become obsolete as a result of technology changes, customer requirements for additional features, and the company's inability to support it because of the lack of available parts. Product retirement is driven by a business decision to move to a more advanced product with improved functionality. Retired products are usually supported for a lengthy period of time before they are officially obsolete as they continue to consume disposable supplies. Some obsolete products are Year 2000 compliant. Companies perform a general risk assessment on affected models and make a determination of the risk to patients. Consignees of record are advised of the status of the devices. Compliance status and remediation solutions, including upgrade replacement incentives are provided to users.

Companies with no obsolete devices
Examiners found 22 companies that have no obsolete devices in service.

Companies with no devices made obsolete
In 38 companies no devices have been made obsolete because of Year 2000 non-compliance.

Companies with obsolete devices
Examiners found 20 companies with obsolete devices in service – some compliant, others non-compliant, and others not affected by the date rollover. There were three companies with obsolete devices that are Year 2000 compliant found in this study. Companies with obsolete devices demonstrated that they have communicated any Year 2000 issues associated with non-compliant products to their customers. Examiner cited nine companies that have posted all of their obsolete products on their Year 2000 web sites.

4.8 Federal Year 2000 Biomedical Equipment Clearinghouse

The examination confirmed the accuracy of the Federal Year 2000 Biomedical Equipment Clearinghouse for 54 of the 80 sites visited (67.5 percent). An additional 16 Clearinghouse entries referred to a page at the corporate web site which contained accurate and timely information. Clearinghouse entries for two companies needed review but contained no errors of substance and two others had some data missing. Three companies had inconsistencies between the data presented on their web pages and the data in the Clearinghouse. The Clearinghouse entries for two companies lack data on at least one major product, and one restricts access to its Year 2000 data to clients and internal users.

4.9 Conclusions

Based on the results of the assessments of the 80 medical device manufacturers' Year 2000 programs, Battelle finds that the selected manufacturers have quality systems that are adequate to deal with the Year 2000 issue for their devices. Those firms have systematically applied quality processes and procedures to determine the Year 2000 compliance of their products. Moreover, where Year 2000 compliance problems existed, the companies have taken the necessary corrective actions to remedy the problems. Since these results were obtained from a representative, statistical sample of manufacturers, Battelle believes that further assessments would produce similar results and the additional results obtained would not offer any substantial benefit to the FDA.

Attachments

Attachment 1

Results of Telephone Calls

Sample Number	TOTAL	FALL OUT	% of Total	VISITS SCHED	% of Total	NO'S	% of Total	No Response	% of Total	Dup Sites		Check
1	103	66	64.1%	28	27.2%	8	7.8%	1	1.0%	0	0.0%	103
2	13	6	46.2%	5	38.5%	2	15.4%	0	0.0%	0	0.0%	13
3	43	28	65.1%	13	30.2%	1	2.3%	1	2.3%	0	0.0%	43
4	10	5	50.0%	4	40.0%	0	0.0%	0	0.0%	1	10.0%	10
5	44	28	63.6%	9	20.5%	6	13.6%	0	0.0%	1	2.3%	44
6	36	26	72.2%	7	19.4%	2	5.6%	0	0.0%	1	2.8%	36
7	16	5	31.3%	3	18.8%	5	31.3%	0	0.0%	3	18.8%	16
8	40	24	60.0%	6	15.0%	1	2.5%	3	7.5%	6	15.0%	40
9	20	9	45.0%	5	25.0%	4	20.0%	0	0.0%	2	10.0%	20
TOTAL	325	197	60.6%	80	24.6%	29	8.9%	5	1.5%	14	4.3%	325

Attachment 2

Summary of Assessment Area Results

Assessment Area	High	Medium	Low
Executive Leadership and Control	1	8	71
Risk Management	0	8	72
Corrective and Preventative Action	0	1	79
Test Planning and Procedures	1	11	68
Communication with Consignee	0	4	76
Implementation and Contingency Planning	0	8	72
Totals	2	40	438