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Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

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YEAR 2000 COMPUTING CRISIS

Compliance Status of Many Biomedical Equipment Items Still Unknown

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GAO

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The Honorable Terry Everett
Chairman, Subcommittee on Oversight
and Investigations
Committee on Veterans' Affairs
House of Representatives

Dear Mr. Chairman:

Biomedical equipment is important to the Veterans Health Administration's (VHA) role of providing health care services to the nation's veterans. This equipment includes medical devices, such as cardiac defibrillators, cardiac monitoring systems, and pacemakers, which can record, process, analyze, display, and/or transmit medical data, and some of which may be implanted in patients, as well as scientific and research instruments, such as blood gas and glucose analyzers. Biomedical equipment may employ computers or computer chips to operate and/or may be adversely affected by the Year 2000 problem.[1] In addition, the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) has responsibility for oversight and regulation of medical devices, including the impact of the Year 2000 problem.[2]

As you requested, and based on subsequent discussions with your office, we assessed the status of VHA's and FDA's Year 2000 biomedical equipment programs. Our assessments of other aspects of the Veterans Benefits Administrations' and VHA's Year 2000 programs, including their mission-critical systems, locally developed software applications, commercial off-the-shelf software products, and facility systems, were reported to you separately.[3]

[1]The Year 2000 problem is rooted in how dates are recorded and computed. For the past several decades, many existing computer systems have used a two-digit date field to represent the current year—such as "98" for 1998. However, such a format does not distinguish between 2000 and 1900. Computer programs that are not corrected to accommodate the 2000 date could process information incorrectly, possibly affecting the medical care and safety of patients.

[2]The Federal Food, Drug and Cosmetic Act grants FDA authority to regulate medical devices. The term medical "device" is defined in 21 U.S.C. section 321 (h). For purposes of this report the term biomedical equipment includes both medical devices subject to FDA regulation and scientific and research instruments which are not subject to FDA regulation.

[3]Year 2000 Computing Crisis: Progress Made in Compliance of VA Systems, But Concerns Remain (GAO/AIMD-98-237, August 1998).

Results in Brief

Since our September 1997 testimony,[4] VHA has made progress in implementing its Year 2000 strategy for biomedical equipment, which relies on compliance information from the manufacturers. As of July 29, 1998, VHA had received information on biomedical equipment compliance from 73 percent of the 1,490 manufacturers on its list of suppliers; 701, or 47 percent, of these manufacturers, reported that their products are Year 2000 compliant.

In spite of this, VHA does not yet know the full extent of the Year 2000 problem on its biomedical equipment and the associated costs to address this problem. This is because, as of July 29, 1998, it had not received compliance information from 27 percent of the manufacturers on its list of suppliers, as well as the nearly 100 additional manufacturers that VHA determined are no longer in business. Among the manufacturers that had yet to respond or complete their assessments is one that supplies high-dollar value equipment, such as radiology systems and electronic imaging systems equipment, to VHA.[5] Because VHA, like other health care providers, relies on the manufacturers to validate, test, and certify that their equipment is compliant, it is critical that they provide this information to VHA so that it may take prompt action on noncompliant equipment in its inventory.

According to VHA's Year 2000 Project Manager, most of the manufacturers reporting that they had noncompliant equipment cited incorrect display of date and/or time as problems. Date and/or time display problems should not present a risk to patient safety because health care providers can work around them. However, some manufacturers cited problems that could pose a risk to patient safety. For example, a radiation therapy planning computer may miscalculate the radiation source strength on or after January 1, 2000, and the resulting radiation dose may be hazardous or ineffective for the patient.

To the extent that noncompliant biomedical equipment has to be replaced or repaired, the cost estimate reported by the Department of Veterans Affairs (VA) to the Office of Management and Budget (OMB) is incomplete. This is because (1) the estimate is not based on updated cost information from the medical facilities, (2) some manufacturers have not provided compliance and cost information to VHA, and (3) nearly 100 manufacturers are no longer in business. Furthermore, VHA's medical facilities have not

[4]Veterans Affairs: Action Underway Yet Much Work Remains to Resolve Year 2000 Crisis (GAO/T-AIMD-97-174, September 25, 1997).

[5]High-dollar value equipment has a purchase price in excess of $250,000.

yet completed development of business continuity and contingency plans to help ensure the health and well-being of VHA patients in the event that some biomedical equipment items fail to operate at the turn of the century, which poses a risk to patient safety.

To assist health care facilities in the public and private sectors, HHS, on behalf of the Chief Information Officer (CIO) Council's Subcommittee on the Year 2000 for Biomedical Equipment, and FDA issued a letter in January 1998 to biomedical equipment manufacturers, requesting information on products affected by this computer problem. In contrast to VHA, as of July 30, 1998, FDA had only received responses from 1,975, or about 12 percent, of the approximately 16,000 biomedical equipment manufacturers[6] to which its letter was sent. According to an FDA official, many of these manufacturers do not produce any computerized products. He said most of these respondents indicated that there are no Year 2000 problems with their products, but about 100 indicated that at least one of their products is not compliant. FDA, like VHA and other health care providers, relies on the manufacturers to validate, test, and certify that their equipment is compliant. Accordingly, failure to obtain timely compliance information from the manufacturers increases the risk to health care providers and biomedical equipment users that their equipment may not operate properly on and after January 1, 2000.

FDA has made information from the biomedical equipment manufacturers available through an Internet World Wide Web site. VHA, however, has not yet done so because (1) when VHA requested the information from the manufacturers, VHA did not tell them that it intended to release the information outside the federal government and (2) VHA said it had concerns regarding whether it would be proper for it to release some of the information provided by the manufacturers because the information may be proprietary. VHA, on the advice of VA's Acting General Counsel, informed manufacturers in June 1998 that it plans to release information that VHA has determined is not confidential commercial information. This is an important step because compliance information from biomedical equipment manufacturers is of interest to all health care providers and users of biomedical equipment.

Background

Biomedical equipment, such as magnetic resonance imaging (MRI) systems, X-ray machines, cardiac monitoring systems, cardiac defibrillators, and

[6]Biomedical equipment refers to both medical devices regulated by FDA and scientific and research instruments not regulated by FDA.

various other tools for laboratory analysis, are critical to health and medical treatment and research in federal and private sector health care facilities. This equipment may use a computer for calibration or day-to-day operation. The computer could be either a personal computer that connects to the equipment remotely or a microprocessor chip embedded within the equipment. In either case, the controlling software may be susceptible to the Year 2000 problem if any type of date or time calculation is performed. This could range from the more benign—such as incorrect formatting of a printout—to the incorrect operation of the equipment with the potential to adversely affect patient care or safety. The degree of risk depends on the role of the biomedical equipment in the patient's care.

VHA manages health care delivery to veterans within 22 regional areas known as Veterans Integrated Service Networks (VISN). These VISNs encompass 172 VHA medical centers, 376 outpatient clinics, 133 nursing homes, and 30 domiciliaries—a total of 711 facilities. VHA's biomedical equipment inventory—with its acquisition cost valued at almost $3 billion—can be found at these facilities. As the largest centrally directed civilian health care system in the United States, VHA is a key stakeholder in determining the Year 2000 compliance of biomedical equipment. VHA's CIO has overall responsibility for planning and managing the Year 2000 compliance program. The CIO created a VHA Year 2000 Project Office, which directs and oversees the Year 2000 assessment and renovation activities in the VISNs.

Another key player in determining the Year 2000 compliance of biomedical equipment is FDA. Under provisions of the Federal Food, Drug, and Cosmetic Act,[7] as amended, FDA protects public health through oversight and regulation of medical devices. FDA regulates medical devices that use computers or software pursuant to applicable FDA medical device regulations.

In September 1997, we testified that both VHA and FDA had just begun efforts to assess biomedical equipment for Year 2000 compliance.[8] VHA had sent letters to approximately 1,600 biomedical equipment manufacturers that supply VHA, requesting compliance information for their products. We also testified that FDA had sent a letter to about 13,000 medical device manufacturers in July 1997, reminding them of their responsibility to ensure that their products will not be affected by the century change.

[7] 21 U.S.C. sections 301 et. seq.

[8] GAO/T-AIMD-97-174, September 25, 1997.

Objective, Scope, and Methodology

The objective of this review was to assess the status of VHA's and FDA's Year 2000 biomedical equipment programs. In performing this review, we applied criteria from our Year 2000 Assessment Guide[9] and Year 2000 Business Continuity and Contingency Planning Guide.[10] In assessing the status of VHA's Year 2000 biomedical equipment program, we reviewed and analyzed VHA documents, including the March 25, 1998, VISN Assessment Feedback Reports; the January 30, 1998, Assessment Phase Report; the July 1997 Year-2000 Product Risk Program; the April 30, 1997, and October 31, 1997, versions of the Year-2000 Compliance Plan; and the May 15, 1998, and August 15, 1998, quarterly reports to OMB. We did not independently verify data contained in these documents. We met with Year 2000 project teams in three VISNs—VISN 4, VISN 5, and VISN 12—and in VHA medical facilities in Pittsburgh; Philadelphia; Wilmington, Delaware; Washington, D.C.; Baltimore; Martinsburg, West Virginia; and Chicago. We also discussed VA biomedical equipment assessment and renovation plans and efforts with members of the Year 2000 Project Office at VHA headquarters in Washington, D.C.

To assess the status of FDA's Year 2000 biomedical equipment program, we reviewed FDA documents on this issue, including those on its Internet World Wide Web site. We met with HHS' Director of Policy and Evaluation in Washington, D.C., and the Director of FDA's Division of Electronics and Computer Science at the Center for Devices and Radiological Health, located in Rockville, Maryland.

We also met with biomedical engineers, who were attending the 1998 annual meeting of the Association for the Advancement of Medical Instrumentation. At this meeting, both VHA and FDA officials presented their respective Year 2000 biomedical equipment programs.

We performed our work from July 1997 through June 1998, in accordance with generally accepted government auditing standards. We requested written comments on a draft of this report from the Secretary of Veterans Affairs and the Secretary of Health and Human Services. These comments are reprinted in appendixes I and II.

[9] Year 2000 Computing Crisis: An Assessment Guide (GAO/AIMD-10.1.14, September 1997).

[10] Year 2000 Computing Crisis: Business Continuity and Contingency Planning (GAO/AIMD-10.1.19, August 1998).

VHA Has Made Progress in Implementing Its Year 2000 Strategy

Since our September 1997 testimony, VHA has made progress implementing its Year 2000 strategy for biomedical equipment. This strategy, which depends on compliance information from the manufacturers, consists of five steps. These are (1) increase awareness and continually educate VHA CIOs, VISNs, and health care facilities on biomedical issues, (2) establish an expert working group to provide guidance, (3) develop a database of biomedical equipment manufacturers that supply equipment to VHA, (4) survey these manufacturers to identify the compliance status of biomedical equipment and solutions for noncompliance, and (5) communicate survey results to the field for use in determining the compliance status of biomedical equipment at the medical facilities. Each month, these facilities are expected to report to the VHA Year 2000 Project Office their strategies for dealing with noncompliant and conditional-compliant equipment in their inventories and the cost to accomplish this.

To increase awareness, VHA has established an intranet web site containing compliance information from the manufacturers. This web site is also used to educate VHA CIOs, VISNs, and health care facilities on biomedical issues. VHA has also established an expert working group[11] to assist the Year 2000 Project Office in identifying, assessing, and evaluating biomedical equipment at risk from the Year 2000 problem.

VHA developed a database of biomedical equipment manufacturers by using an existing database, which tracks service manuals of both medical devices and scientific and research instruments purchased by its medical facilities. The expert working group reviewed the database to ensure that key manufacturers in specialty areas were included.

To survey biomedical equipment manufacturers, the VHA Year 2000 Project Office sent a series of letters to them requesting information on the Year 2000 compliance status of their products. The first letter was sent to approximately 1,600 manufacturers on September 9, 1997. Two follow-up letters were sent to those that did not respond on October 6, 1997, and November 12, 1997. Upon receipt of responses to these letters, VHA categorized the compliance status provided by the manufacturers for the equipment, as illustrated in table 1.

[11]This group consists of physicians and engineers from the fields of radiology, nuclear medicine, pathology and laboratory, cardiology, surgery, biomedical engineering, acquisition and materiel management, medical research, prosthetics, and the Year 2000 Project Office.

Table 1: VHA Biomedical Equipment Compliance Categories

Category	Explanation
Compliant	Equipment will function properly in all aspects upon the change to the year 2000 without any modification or revision.
Noncompliant	Equipment will not function properly upon the change to the year 2000, and no manufacturer remedy is available. In some cases, improper function involves an incorrect date-time stamp on the output of the equipment, but the equipment's clinical function is not impaired.
Conditional-compliant	Equipment requires some form of user intervention to function properly after the year 2000. Such intervention includes the installation of manufacturer-provided software or hardware or a one-time user action (such as turning the equipment on and off after the year 2000).
Pending	Manufacturers reported to VHA that they have not completed the Year 2000 assessment of their product line.

Source: Veterans Health Administration.

Of the nearly 1,600 manufacturers in VHA's initial mailing, VHA determined that about 100 were no longer in business. Accordingly, VHA revised its list of manufacturers to 1,504 as of June 1, 1998, and reported that it received compliance information from 1,070, or 71 percent, of these manufacturers. Just under half of the 1,504 manufacturers reported that all of their devices are Year 2000 compliant.

As shown in table 2, the manufacturers have provided VHA with compliance information on a wide range of biomedical equipment. VHA's data, as of June 1, 1998, indicated that for those manufacturers that reported, at least 80 percent of the equipment types are compliant. According to VHA's Year 2000 Project Manager, the expert working group reviews the information provided by the manufacturers for reasonableness. The Year 2000 Project Office has provided this information to its medical facilities through VHA's intranet web site, and the facilities are to use the information to assess the compliance status of their equipment.

Table 2: Reported Biomedical Equipment Year 2000 Compliance Categories, as of June 1, 1998, and Examples

Compliance category	Number of manufacturers	Number of equipment types within this category	Examples of equipment types within this category[a]
Compliant	694	3,873	Intra-aortic balloon pump, dialysis machine
Noncompliant	34	182	Defibrillator monitor, cardiology monitor
Conditional-compliant	102	673	Electrocardiograph machine, defibrillator
Pending	53	157	Ultrasound system, ventilator
Manufacturer merged or bought out	187	[b]	
Total	**1,070**	**4,885**	

[a]Inclusion of a specific type of biomedical equipment in the compliant, noncompliant, conditional-compliant, or pending category does not necessarily mean that all equipment of this type in VHA's inventory was reported by the manufacturer; similar equipment made by other manufacturers could fall into different categories.

[b]The biomedical equipment reported by these manufacturers have already been accounted for in one of the above compliance categories.

Source: Veterans Health Administration. We did not independently verify these data.

According to VHA officials, most of the manufacturers that reported one or more of their biomedical equipment products as noncompliant cited incorrect display of date and/or time as problems. For example, a noncompliant electrocardiograph machine, used to monitor heart signals, would print charts with two-digit dates, showing the year 2000 as "00." According to the Diagnostic Services Chief of VHA's Technology Division, these cases do not generally lead to the equipment failing to operate and do not present a risk to patient safety because health care providers, such as physicians and nurses, are able to work around this problem. For example, a physician or technician would note the correct year on the printout from the electrocardiograph machine when the equipment imprints "1900" on the printout.

However, VHA recognizes that incorrect date-time representation or use could pose a risk when the date is used in a calculation or when records generated by the equipment is sorted automatically to present a patient's condition, over a period of time, to a physician for diagnosis and treatment. Specifically, when records are sorted by date of recording, the

accuracy of such dates can be critical to a physician's monitoring of patient progress in, for example, the case of blood sugar readings. If readings were taken on December 25, 27, and 30, 1999, and again on January 1, 2000, for example, the ordering might appear with the last entry first, if it were abbreviated as "00" and read as January 1, 1900. If the physician or other clinician did not pay close attention, a faulty diagnosis or treatment decision could be made based on a misreading of the data.

VHA also recognizes that an equipment function that depends on a calculation involving a date and that is performed incorrectly as a result of a date problem, could present a risk to the patient. One example reported by a manufacturer is a product used for planning the delivery of radiation treatment using a radioactive isotope as the source. An error in the calculation of the radiation source's strength could result in inappropriate treatment—either too low or too high a dosage—and could have an adverse effect on the patient on or after January 1, 2000. This noncompliant equipment is currently in the inventory of several VHA medical facilities. In commenting on a draft of this report, VA noted that VHA has identified three facilities that use this specific equipment, and the noncompliant equipment will be taken out of service.

Given the above case scenarios, it is crucial that biomedical equipment manufacturers provide VHA with information on the compliance status of their equipment. This information is necessary for VHA medical facilities to formulate safe and effective solutions to address Year 2000 problems.

Between November 1997 and January 1998, VHA's medical facilities completed inventories of their biomedical equipment and reported the results to the Year 2000 Project Office. Using data on the facility's biomedical equipment inventory from VHA's equipment database, each facility was to conduct a physical inventory of its biomedical equipment and check this inventory against compliance information submitted by the manufacturers, which the Year 2000 Project Office had posted on the VHA intranet web site.

According to VHA's January 30, 1998, Year 2000 Assessment Phase Report, the medical facilities noted that based on the information from the manufacturers, some of the noncompliant biomedical equipment at VHA sites included defibrillator monitors, noninvasive blood pressure machines, vital signs monitors, and cardiology monitors. VHA officials have stressed that noncompliant equipment of one type reported by certain manufacturers does not indicate that all equipment of the same type in use

at its medical facilities is noncompliant. VHA officials told us that there are other manufacturers of this equipment type that have reported that their equipment is compliant.

The VHA Year 2000 Project Office has directed VHA medical facilities to regularly check the web site for updates on the compliance status of biomedical equipment reported by manufacturers. This is important for the medical facilities because, in some cases, the manufacturers have subsequently changed the compliance status of their equipment after their initial reports to VHA. The changes have ranged from some equipment previously reported as conditional-compliant that is now being reported as compliant to equipment previously reported as compliant that is now considered noncompliant. According to VHA's Year 2000 Project Manager, the project office monitors the medical facilities' Year 2000 activities through periodic reports and site visits.

VHA officials have informed us that they will be relying on the biomedical equipment manufacturers to validate, test, and certify that replacement equipment is Year 2000 compliant. This is because some manufacturers have informed them that VHA should not attempt to conduct in-depth testing by manipulating the software embedded inside the equipment. According to the Diagnostic Services Chief of VHA's Technology Division, such testing may void the manufacturer's certification to FDA that the equipment is safe for use on patients, thereby exposing VHA to legal liability in the event that a patient's health is harmed by equipment that malfunctions following VHA testing. VHA's Year 2000 Project Manager told us that the medical facilities will perform limited functional testing of replacement equipment and of manufacturer modifications to conditional-compliant equipment. He stated that the medical facilities will test equipment performance in accordance with locally established acceptance testing procedures for new equipment.[12]

Uncertainty Over Year 2000 Compliance Status Increases Risk

Despite VHA's progress in implementing its Year 2000 strategy, as of July 29, 1998, it still did not know the full extent of the Year 2000 problem on its biomedical equipment because it has not received compliance and cost information from 27 percent of the manufacturers on its list of suppliers, as well as from nearly 100 additional manufacturers that are no longer in business. This situation impedes VHA's medical facilities from promptly developing strategies to deal with equipment with potential

[12]These procedures generally prescribe that a systematic examination be performed to determine if the equipment meets the electrical safety requirements of the medical facility and the manufacturer's performance specifications for the equipment.

patient safety problems. In addition, the current cost estimate of $40 million[13] reported to OMB to replace or repair noncompliant equipment is incomplete. Also, given the uncertainties surrounding the compliance status of many VHA biomedical equipment items, it is critical that medical facilities develop contingency plans to ensure patient care in the event of Year 2000-related failures. However, the medical facilities have not completed such plans.

Some Manufacturers Have Not Provided Compliance Information on Their Equipment

VHA does not currently know how much of its biomedical equipment is Year 2000 compliant because, as shown in table 3, it has not yet received compliance information from 398 manufacturers. This information is critical to VHA because, like other health care providers, it relies on the manufacturers to validate, test, and certify that their equipment is compliant.

Table 3: Status of Manufacturer Responses as of July 29, 1998

Status of manufacturer response	Number of manufacturers
Compliant manufacturers[a]	701
Noncompliant manufacturers[b]	43
Conditional-compliant manufacturers[c]	106
Pending manufacturers[d]	47
Manufacturer merged or bought out	195
Nonresponsive manufacturers[e]	398
Total	**1,490**

[a]For inclusion in this category, 100 percent of a manufacturer's products had to be considered compliant.

[b]For inclusion in this category, only one of a manufacturer's products had to be considered noncompliant.

[c]For inclusion in this category, the manufacturer has no noncompliant equipment, no pending equipment, and at least one conditional-compliant equipment item.

[d]For inclusion in this category, the manufacturer has no noncompliant equipment and at least one equipment item that is pending.

[e]For inclusion in this category, VHA had not received compliance information from the manufacturer.

Source: Veterans Health Administration. We did not independently verify these data.

Letters sent to more than half of the nonresponsive manufacturers—227 out of 398—were returned to VHA by the U.S. Postal Service marked with no forwarding addresses. In addition, as noted in table 3, an additional 47

[13]We did not independently verify the $40 million cost estimate.

manufacturers that did respond are in the pending category because they reported that they had not completed their assessments, and, therefore, did not yet know if their products were compliant. Among the manufacturers that had not yet responded or completed their assessments as of July 29, 1998, is one that supplies high-dollar value equipment, such as radiology systems and electronic imaging systems equipment, to VHA.

According to the Year 2000 Project Manager, VHA will continue its efforts to obtain compliance information from nonresponding manufacturers. Consistent with this strategy, on June 24, 1998, VHA sent another letter to nonresponsive manufacturers requesting that they provide VHA with Year 2000 compliance information on their products. The Project Manager said VHA will continue to work through October 1998 to obtain compliance information from the manufacturers. Further, he said at that time, VHA's medical facilities must be ready to put contingency plans into effect for noncompliant and conditional-compliant equipment and for that equipment, the status of which is unknown.

Year 2000 Cost Estimate for Biomedical Equipment Is Incomplete

VHA's Year 2000 cost estimate for replacing and/or retiring noncompliant biomedical equipment is incomplete. In its August 15, 1998, quarterly report to OMB, VA estimated the Year 2000 cost to replace or repair this equipment at $40 million. It also reported that VA expects the costs to replace or repair noncompliant biomedical equipment to increase as manufacturers continue to disclose their compliance status. The VHA Year 2000 Project Manager told us that VHA expects to manage these costs within the department's budget. However, the $40 million estimate is not based on updated cost information from the medical facilities, and VHA does not know the replacement and repair cost for biomedical equipment for the manufacturers that have not reported compliance and cost information, as well as the nearly 100 manufacturers that are no longer in business.

VHA's Year 2000 Project Manager informed us that three quarters of the $40 million estimate was calculated based on cost information provided by the VISNs and medical facilities. Specifically, the VISNs and facilities reported to the Year 2000 Project Office the number of noncompliant and/or conditional-compliant equipment items in their inventories and the replacement or repair cost for this equipment using information provided to VHA by the manufacturers and posted on its intranet web site in January 1998. The remaining $10 million was calculated based on the VHA Year 2000 Project Office's estimate of the number of such equipment items

at VHA medical facilities and any cost information provided by manufacturers during the period February through April 1998.

VHA's Year 2000 Project Manager has acknowledged the shortcomings of the current cost estimate. Accordingly, the VISNs were to begin using a new reporting process, effective July 31, 1998. The new process will use a recently developed software package to track the status of noncompliant and conditional-compliant equipment at the medical facilities and the associated costs to replace, repair, or retire it. In commenting on a draft of this report, VA stated that this software was released on July 10, 1998, and the Under Secretary for Health signed an information letter, providing direction and instruction on the software to VHA medical facilities on July 20, 1998.

VHA Has Not Yet Completed Business Continuity and Contingency Plans for Biomedical Equipment

To assist agencies in their business continuity and contingency planning efforts, we have prepared a guide[14] that discusses the scope of the Year 2000 challenge and offers a step-by-step approach for reviewing an agency's risks and threats as well as how to develop backup strategies to minimize these risks. This business continuity and contingency planning process safeguards the agency's ability to produce a minimally acceptable level of outputs and services in the event of failures of internal or external mission-critical information systems and services. A business-level contingency plan would address how each VHA medical facility would handle various types of Year 2000 problems caused by business partner problems, such as nonresponsive manufacturers and the nearly 100 manufacturers that VHA determined were no longer in business.

Despite the uncertainties surrounding the compliance status of many of VHA's biomedical equipment and the potential health risks to patients of certain equipment, VHA medical facilities have not yet completed business continuity and contingency plans on actions they must take to address potential Year 2000-related failures. The Year 2000 Project Manager informed us that these plans need to be ready for implementation by October 31, 1998. He did not know the status of these plans because the project office had not reviewed them. The Project Manager told us that he expects to review these plans when Year 2000 Project Office representatives visit the VISNs and medical facilities later in 1998.

[14]GAO/AIMD-10.1.19, August 1998.

Our review of the March 25, 1998, VISN Assessment Feedback Reports[15] for the three VISNs we visited showed that these VISNs had reported that they did not have business continuity and contingency plans to deal with 76 of the 89 noncompliant biomedical equipment items identified in their inventories. The CIOs at two of these VISNs informed us that they are currently in the process of developing these plans. The third CIO said the VISN's medical facilities have prepared business continuity and contingency plans. However, our review of four of the five plans for this VISN disclosed that these plans did not specifically address Year 2000-related failures of biomedical equipment. Instead, they focused on preventative maintenance inspections and general system and equipment failures.

In light of the uncertainties surrounding the compliance status of VHA's biomedical equipment and their potential effect on patient health and safety, it is crucial that medical facilities be prepared in the event of Year 2000 failures. An official in VHA's Year 2000 Project Office told us that the office is in the process of developing a guidebook to assist the VISNs and medical facilities in addressing Year 2000 business continuity and contingency planning for biomedical equipment and other related issues. The Year 2000 Project Manager said the guidebook will discuss VHA's strategy for obtaining information from nonresponsive manufacturers and address issues such as replacing, repairing, and/or retiring noncompliant biomedical equipment and equipment produced by the nearly 100 manufacturers no longer in business; using the new reporting software for biomedical equipment; procuring compliant biomedical equipment; and having adequate facility staff available on the weekend of January 1, 2000. In commenting on a draft of this report, VA noted that a draft of the guidebook was completed on August 6, 1998, and it expects to issue a final guidebook by September 1998.

FDA Is Also Relying on Biomedical Equipment Manufacturers for Compliance Information

FDA, the agency with oversight and regulatory responsibility for domestic and imported medical devices, is also trying to determine the Year 2000 compliance status of these devices, as well as some scientific and research instruments. Its goal is to provide a comprehensive, centralized source of information on the Year 2000 compliance status of biomedical equipment used in the United States and make this information publicly available on an Internet World Wide Web site.

[15]These reports, prepared by VHA's Year 2000 Project Office, provide feedback to each VISN on its reported January 1998 assessment results and suggest actions that should be taken to enhance the Year 2000 assessment and renovation process at the facility and VISN level.

On January 21, 1998, HHS, on FDA's behalf, issued a letter to approximately 16,000 domestic and foreign biomedical equipment manufacturers[16] requesting information on the Year 2000 compliance of their complete product line.[17] The letter stated that all information received would be made available to the public through FDA's web site. Manufacturers were asked to identify any noncompliant products by type and model number and provide a brief description of the date-related problems and the solutions for mitigating the problems. If all the manufacturer's products were considered compliant, the manufacturer was asked to provide a statement certifying such compliance. In this case, the manufacturer did not have to provide information on the compliant device's make and model. Manufacturers were instructed to forward their responses in writing or electronically to FDA's Center for Devices and Radiological Health.

FDA acknowledges that the response rate to date to the January 1998 letter is disappointing. As of July 30, 1998, FDA had received 1,975 responses from biomedical equipment manufacturers and posted them on its web site. The Director of FDA's Division of Electronics and Computer Science cited several reasons for the low response rate, including manufacturers not yet completing their assessments and the manufacturers' responses to FDA's request being voluntary. He also indicated that the vast majority of manufacturers that received letters from FDA do not make products with any sort of electronic components, and he believed that many of these manufacturers chose not to respond because the request did not pertain to them.

On June 29, 1998, FDA sent a second request to 1,935 medical device manufacturers that had not previously responded to its inquiry and that FDA believes have products that might employ computers or embedded systems. According to the Director, as of July 30, 1998, 628 manufacturers reported that their products employ a date/time function. Of these, about 100 indicated that one or more of their products were not compliant.

[16]FDA developed its mailing list from the manufacturers that have registered their products with the FDA and also the mailing lists of two scientific and research instrument manufacturing associations. Accordingly, this list included manufacturers that do not employ computers or embedded systems in their products, e.g., products such as rubber gloves, tongue depressors, and eyeglasses.

[17]For FDA, compliance means that the product will accurately process and store date/time data (including but not limited to calculating, displaying, recording, and sequencing operations involving date/time data) during, from, into, and between the 20th and 21st centuries, including the correct processing of leap year data.

According to the Director of FDA's Division of Electronics and Computer Science, FDA does not perform technical evaluations of the manufacturers' responses to determine their adequacy. Rather, the Director, his secretary, and a biomedical engineer review the manufacturers' submissions to see if the responses included answers to the questions in the January 1998 letter. He said that FDA relies on the manufacturers to certify whether their products are Year 2000 compliant. FDA's web site includes the statement that

> "Inclusion of information in this database indicates that the manufacturer has certified that the data is complete and accurate. The Food and Drug Administration, however, cannot and does not make any independent assurances or guarantees as to the accuracy or completeness of this data."[18]

The Director informed us that except for diagnostic X-ray equipment, FDA does not test new medical devices entering the market. In addition, he said that FDA has performed about 8 to 10 tests per year involving forensic investigations of problem devices. In commenting on a draft of this report, HHS stated that FDA tests this equipment during the premarket review process to ensure that it is in compliance with a mandatory federal performance standard for X-ray equipment. It also indicated that the testing of this equipment does not include compliance with Year 2000 requirements.

According to the Director, FDA reviews the test results submitted by manufacturers requesting premarket approval of their medical devices to see if the manufacturers have demonstrated that products are safe and effective for intended use. When asked if FDA will request test reports from manufacturers that have renovated medical devices that are not Year 2000 compliant, the Director informed us that FDA will not. He said that correcting a date problem does not change the design of the device, and it is the manufacturers' responsibility to ensure proper device design. We disagree with the Director that the date change will not change the design of the device. Correcting the date problem will change the software design of the device and may alter the internal logic of the software. The Director also cited staff limitations as another reason for not requesting and reviewing test results from the manufacturers.

[18]Food and Drug Administration, Year 2000 Impact on Biomedical Equipment, (Washington, D.C., FDA), *http://www.fda.gov/cdrh/yr2000/y2kintro.html*, (cited March 19, 1998).

Some Users Question Usefulness of Current FDA Biomedical Equipment Web Site

While FDA is making an effort to assemble information on biomedical equipment compliance and making this information available to the public, some biomedical engineers attending a June 1998 meeting of the Association for the Advancement of Medical Instrumentation expressed concern that information on the FDA web site is not detailed enough to be useful. Specifically, as mentioned earlier, FDA's list of compliant equipment contains no information on the equipment's make and model. In contrast, VHA's list of compliant equipment generally contains such information.

Also, a review of the FDA database for noncompliant equipment disclosed that some manufacturers have reported that they will have solutions for their equipment in late 1999. Putting off solutions until this late date is risky. However, making this information publicly available does provide hospitals and other users of biomedical equipment with the opportunity to plan alternative solutions.

Further, the Year 2000 compliance information publicly available through FDA does not include responses from many of the manufacturers that have responded to VHA. For example, we selected, on a random basis, a sample of 53 manufacturers in VHA's database that reported their products to be Year 2000 compliant and found that 48 of them were not listed in the FDA database. We, likewise, selected a sample of 13 manufacturers in VHA's database that reported that their products are not Year 2000 compliant, and found that 12 of them were not listed in the FDA database. These manufacturers' products include cardiology equipment, defibrillator monitors, and ultrasound equipment.

The Director of FDA's Division of Electronics and Computer Science acknowledged that the manufacturers were more responsive to VHA's requests, and the VHA database, therefore, contains a higher percentage of responses. He said that he believed the primary reason for this was VHA's position as a large volume customer that could take future action toward the manufacturer if the information was not forthcoming. He also noted that FDA requested information on the complete product line of the manufacturers, while VA requested information from the manufacturers on its list of suppliers.

New Reporting Requirements Identify Medical Devices Posing Health Risk

FDA implemented a new rule[19] on May 18, 1998, requiring medical device manufacturers and importers to report promptly to FDA action to correct and remove devices that pose a health risk or that are in violation of the Federal Food, Drug, and Cosmetic Act.[20] This rule protects public health by ensuring that FDA has current and complete information regarding actions taken on medical devices. These reports are expected to improve FDA's ability to evaluate device-related problems, as well as enable it to take prompt action regarding devices, that pose a health risk. Under the new rule, the affected manufacturer is required to submit a report of action taken to correct the problem or remove the device from service.

According to the Director of the Center for Devices and Radiological Health, under the new rule, FDA has a better chance of learning what corrective actions, including those to address the Year 2000 computer problem, are taken by the manufacturers on medical devices that could pose health risks. The Director said that no manufacturers have yet submitted any reports under this new reporting requirement.

VHA Plans to Make Compliance Information Available to the Public

In contrast to FDA, VHA had not been making information obtained from biomedical equipment manufacturers on the Year 2000 compliance status of their products available to the public through an Internet World Wide Web site. VHA has not yet done so because (1) when VHA requested this information from the manufacturers, VHA did not tell them that it intended to release the information outside the federal government and (2) VHA said that it had concerns regarding whether it would be proper for it to release some of the information provided by the manufacturers because the information may be proprietary. The VHA Year 2000 Project Manager told us that VHA believed it would need the manufacturers' permission before it could share this information. He said that VHA is concerned about the proprietary nature of the products, potential legal issues, and manufacturers' price structure for Year 2000 compliant products. VHA had shared some of Year 2000 compliance status information provided by manufacturers with federal agencies, such as the Department of Defense and the National Institutes of Health (NIH), with the caveat that it was for federal use only. NIH then shared this information with FDA.

VHA, on the advice of the VA Acting General Counsel, has recently informed the manufacturers of its plans to make this information available to the

[19] 21 CFR part 806. The regulation implements provisions of the Safe Medical Devices Act of 1990 (P.L. 101-629).

[20] 21 U.S.C., sections 301 et seq.

public through an Internet World Wide Web site. Specifically, on June 17, 1998, VHA mailed letters to manufacturers that had responded to VHA's previous requests for compliance information. It informed the manufacturers that it intended to place information they provided to VHA on a publicly-available World Wide Web site unless the manufacturers informed it otherwise. VHA included similar language in a June 24, 1998, letter to manufacturers that had not yet provided compliance data. The VHA Year 2000 Project Manager said the response from the manufacturers as of June 30, 1998, has been positive. He added that two manufacturers objected to disclosing this information to the public, citing proprietary reasons. These responses have been referred to VA's legal department.

VA has not yet decided how and when a clearinghouse of compliance information provided to VHA from manufacturers will be made available to the public. According to VHA's Year 2000 Project Manager, the FDA web site is one of the options being considered for the clearinghouse. The Director of FDA's Division of Electronics and Computer Science informed us that FDA and VHA have discussed using FDA's web site as such a clearinghouse.

VA's Under Secretary of Health recognizes the importance of gathering compliance data and sharing them publicly. Specifically, in a July 9, 1998, press conference sponsored by the National Patient Safety Partnership,[21] he called on biomedical equipment manufacturers to identify and address potential patient safety problems resulting from the Year 2000 problem. On behalf of the partnership, he called for (1) all health care practitioners and medical treatment facilities to survey their equipment and seek information from their relevant biomedical equipment manufacturers about their products' Year 2000 compatibility, (2) all health care consumers who use biomedical equipment at home to check with their health care providers about the products' Year 2000 compatibility, (3) the medical equipment manufacturers to take immediate action to determine the compliance status of their equipment, and (4) the establishment of a single, national clearinghouse from which compliance information from manufacturers can be readily accessed by the public. The Under Secretary reiterated these four items in a July 23, 1998, hearing before the Senate Special Committee on Year 2000.

Conclusions

Prompt correction of the Year 2000 problem for biomedical equipment is critical to VHA's role as a health care provider. Although VHA has made

[21]The National Patient Safety Partnership is a coalition of public and private health care providers, including VA, the American Medical Association, the American Hospital Association, the American Nurses Association, and the Joint Commission on Accreditation of Healthcare Organizations.

progress in assessing its biomedical equipment, it does not yet know the full extent of the Year 2000 problem with this equipment and the associated costs to address this problem because it has not received compliance information from many of the manufacturers. This information is important because VHA relies on the manufacturers to validate, test, and certify that their equipment, including replacement equipment, is compliant. Despite these uncertainties, VHA medical facilities have not yet completed business continuity and contingency plans on actions they must take to address Year 2000-related failures. The Year 2000 Project Office also has not yet completed a Year 2000 contingency guidebook for biomedical equipment to assist the VISNs and medical facilities in their business continuity and contingency planning and other activities. Until these issues are resolved, VHA lacks adequate assurance that its delivery of medical care through the use of biomedical equipment will not be adversely affected by the Year 2000 problem.

FDA's goal is to provide a comprehensive, centralized source of information on the Year 2000 compliance status of biomedical equipment used in the United States, and make this information publicly available on an Internet World Wide Web site. FDA, like VHA, relies on the manufacturers to validate, test, and certify that the equipment is Year 2000 compliant. However, FDA has no assurance that the manufacturers have adequately addressed the Year 2000 problem for noncompliant equipment because it does not require manufacturers to submit test results to FDA certifying compliance. Also, FDA does not have as much information in its database on the compliance status of biomedical equipment as VHA.

Finally, VHA, which currently does not make compliance information obtained from the manufacturers available to the public, now plans to do this through an Internet World Wide Web site. The sharing of this information could greatly assist all health care providers and other users of biomedical equipment in identifying noncompliant and conditional-compliant equipment in their inventories and taking prompt action to make them compliant. Sharing also could provide users with a mechanism to overcome the deficiencies in the FDA database, such as the lack of detailed information on the make and model of compliant equipment and the disappointing response rate from manufacturers to FDA's request for compliance information.

Recommendations to the Secretary of Veterans Affairs

We recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to take prompt action to:

- Ensure that the VISNs and medical facilities use the new reporting system to provide the VHA Year 2000 Project Office with up-to-date and more complete information on the cost to replace and/or repair noncompliant and conditional-compliant biomedical equipment.
- Complete and issue as soon as possible to the VISNs and medical facilities a Year 2000 guidebook on how to address contingency planning and other related issues for biomedical equipment for incorporation in their individual Year 2000 plans.
- Require that each VISN director ensure that medical facilities within the VISN complete development of a Year 2000 business continuity and contingency plan for biomedical equipment in its inventory. This plan should address steps the facility will take on (1) biomedical equipment produced by the manufacturers from which VHA has not received compliance information and the nearly 100 manufacturers no longer in business, (2) noncompliant equipment that have date-time problems but can still be safely used on and after January 1, 2000, and (3) equipment that manufacturers have certified as compliant but that may cease to function or malfunction on and after January 1, 2000.

Recommendations to the Secretary of Veterans Affairs and the Secretary of Health and Human Services

We recommend that the Secretary of Veterans Affairs and the Secretary of Health and Human Services work jointly to develop immediately a single data clearinghouse that provides compliance information to all users of biomedical equipment. Development of this clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Health Affairs, American Hospital Association, American Medical Association, and Health Industry Manufacturers Association. At a minimum, the clearinghouse should contain (1) information on the compliance status of all biomedical equipment by make and model, (2) the identity of manufacturers that are no longer in business, including the types of equipment, makes, and models produced by these manufacturers, (3) the identity of manufacturers that have and have not provided VHA and/or FDA with test results certifying that their equipment is Year 2000 compliant, and (4) the identity of manufacturers that have not provided compliance information to VHA and/or FDA.

We also recommend that the Secretary of Veterans Affairs and the Secretary of Health and Human Services, in conjunction with VA's Under

Secretary for Health and the Commissioner of the Food and Drug Administration,

- determine what actions, if any, should be taken regarding biomedical equipment manufacturers that have not provided VHA and/or FDA with compliance information;
- determine what actions, if any, are needed to address biomedical equipment produced by manufacturers no longer in business;
- take prudent steps to review the test results for critical care/life support biomedical equipment, especially equipment once determined to be noncompliant but now deemed compliant, and that for which there are concerns about the determination of compliance, and make the results of these reviews publicly available through the single data clearinghouse; and
- determine what legislative, regulatory, or other changes are necessary to obtain assurances that the manufacturers' equipment is compliant, including performing independent verification and validation of the manufacturers' certification.

Agency Comments and Our Evaluation

In commenting on a draft of this report, VA generally concurred with our recommendations to the Secretary of Veterans Affairs and the first of two joint recommendations to the Secretary of Veterans Affairs and the Secretary of Health and Human Services to develop a single data clearinghouse. VA stated that VHA is working closely with other federal agencies, such as the Department of Defense and FDA, to address common problems with biomedical, clinical, and laboratory equipment and facilities. VA also noted that it has joined with the American Hospital Association, the American Nurses Association, and the Joint Commission on the Accreditation of Healthcare Organizations in calling for a joint effort to create a national clearinghouse for Year 2000 information.

VA stated that the percentage of manufacturers not responding to VHA's inquiries is now 14 percent, meaning an 86 percent response rate. However, VHA counted letters returned to VHA by the U.S. Postal Service marked with no forwarding address as responses. Because these manufacturers did not provide VHA with information on the compliance status of their products, the response rate from manufacturers, based on updated information provided to us by VA as of July 29, 1998, is 73 percent, only slightly above the 71 percent rate cited in our draft report.

VA also described actions taken and planned to implement our recommendations, as well as a number of suggested changes to this

report. These comments have been incorporated into the report as appropriate and are reprinted in appendix I.

Regarding our second joint recommendation to the Secretary of Veterans Affairs and the Secretary of Health and Human Services, VA stated that it has no legislative or regulatory authority to implement this recommendation and defers to HHS. VA, however, stated that it will provide consultation or other appropriate assistance to HHS in implementing this recommendation.

HHS, in commenting on a draft of this report, also concurred with the joint recommendation to the Secretary of Veterans Affairs and the Secretary of Health and Human Services to develop a single data clearinghouse. It stated that HHS and VA are merging their efforts to provide complete information to the health care community and the general public regarding the Year 2000 compliance of biomedical equipment. It also stated that FDA will post on the web site the names of manufacturers that have not provided compliance certification. However, HHS did not believe that it is necessary or cost-effective to list all compliant products. It believed that information at the individual model level is only needed for noncompliant products. We disagree with HHS. The make and model information will provide users with detailed data on the reported compliance status of their products, especially for those 195 manufacturers that VA has determined to have merged or been bought out by other manufacturers as of July 29, 1998.

In addition, HHS concurred with two of the three components of the second joint recommendation. Specifically, it concurred with the component of the recommendation to determine the actions that should be taken regarding manufacturers who fail to respond to requests for compliance information. HHS also stated that under current regulations, FDA does not have the authority to require all device manufacturers to submit reports on whether their devices are Year 2000 compliant.

HHS also concurred that the identity of defunct manufacturers, along with the known types, makes, and models of devices they manufactured should be included in the clearinghouse database. It further stated that it would explore possible approaches to acquiring additional information regarding defunct manufacturers' products.

HHS did not concur with the component of the recommendation to review test results supporting the medical device equipment manufacturers'

certifications that their equipment is compliant. It believed that the submission of appropriate certifications of compliance is sufficient to ensure that the certifying manufacturers are in compliance. We disagree that this is sufficient. Through independent reviews of the manufacturers' test results, users of the medical devices are provided with a level of confidence that the devices are Year 2000 compliant. HHS also stated that it did not have the resources to undertake such a review, and there is insufficient time to complete a review of this nature. In this regard, if HHS lacks sufficient resources to review the manufacturers' test results, it may want to solicit those of federal health care providers and professional associations, such as VA and the National Patient Safety Partnership. Additionally, to make effective use of limited resources, FDA and the health care community, at a minimum, should focus their review efforts on critical care/life support biomedical equipment that was determined to be noncompliant but is now deemed compliant and that for which there are concerns about the determination of compliance.

Regarding our recommendation on legislative or regulatory changes necessary to obtain assurances that manufacturers' biomedical equipment is compliant, HHS believed that the solutions to the Year 2000 problems can be reached through approaches such as the clearinghouse. HHS also clarified FDA's testing of diagnostic X-ray equipment. We have revised the report to reflect this.

Finally, HHS described actions it has taken and planned to implement our recommendations, and these are reprinted in appendix II. HHS also provided a number of technical suggestions to this report, and these comments have been incorporated into the report as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. We will then send copies to the Ranking Minority Member of the Subcommittee on Oversight and Investigations, House Committee on Veterans' Affairs, and the Chairmen and Ranking Minority Members of the Subcommittee on Benefits, House Committee on Veterans' Affairs, and the Subcommittee on Health, House Committee on Veterans' Affairs. We will also provide copies to the Chairmen and Ranking Minority Members of the Senate and House Committees on Veterans' Affairs; the Senate Committee on Appropriations; the Senate and House Subcommittees on VA, HUD and Independent Agencies, Senate and House Committees on Appropriations; the Subcommittee on Labor, Health and

Human Services, Education and Related Agencies, Senate Committee on Appropriations; the Senate Committee on Labor and Human Services; the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs; the Subcommittee on Public Health and Safety, Senate Committee on Labor and Human Resources; House Committee on Appropriations; the Subcommittee on Labor, Health and Human Services, and Education, House Committee on Appropriations; the House Committee on Government Reform and Oversight; the Subcommittee on Human Resources, House Committee on Government Reform and Oversight; and the Subcommittee on Oversight and Investigations, House Committee on Commerce; and the Secretary of Veterans Affairs; the Acting Commissioner of the Food and Drug Administration; the Director of the Office of Management and Budget; and the Chair of the President's Council on Year 2000 Conversion. Copies will also be made available to others upon request.

Please contact me at (202) 512-6253 or by e-mail at *willemssenj.aimd@gao.gov* if you have any questions concerning this report. Major contributors to this report are listed in appendix III.

Sincerely yours,

Joel C. Willemssen
Director, Civil Agencies Information Systems

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Abbreviations

CIO	chief information officer
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MRI	magnetic resonance imaging
NIH	National Institutes of Health
OMB	Office of Management and Budget
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Comments From the Department of Veterans Affairs

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF VETERANS AFFAIRS
ASSISTANT SECRETARY FOR POLICY AND PLANNING
WASHINGTON DC 20420

AUG 25 1998

Mr. Gene Dodaro
Assistant Comptroller General
Accounting and Information Management Division
U. S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dodaro:

This is in response to your draft report, ***YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown*** (GAO/AIMD-98-240). We are pleased that GAO recognizes the progress the Department of Veterans Affairs is making in implementing its Year 2000 (Y2K) strategy for biomedical devices. However, although it is not GAO's intent, the draft report infers that Y2K compliance issues with biomedical equipment are unique to VA when in fact, they are industry-wide problems. Moreover, the Veterans Health Administration (VHA) has used its own resources to gather more information than anyone else in the healthcare industry has on biomedical devices. VHA is also ensuring that this information is available to other healthcare providers and consumers. We concur in the recommendations, and have several comments, many of which serve to update information presented in the draft report.

See comment 1.

VA, like the Food and Drug Administration and many private hospitals and other hospital organizations, bases its Y2K strategy for biomedical devices on obtaining compliance information from the original equipment manufacturers (OEMs) of the devices. This is because the OEMs are the only parties with full access to all design and operating parameters that may have Y2K implications and are, therefore, the most reliable sources of information. VHA has aggressively pursued OEM compliance information, and, although it is still tracking manufacturers who have not responded to its inquiries, of the 55 OEMs with extensive representation at VA facilities with high cost ($250,000 or more), high volume (multiple pieces of equipment at a site) or critical care/life support equipment, only 1 manufacturer remains unresponsive, not the 19 cited in the report. GAO correctly notes that VHA has found only one device posing a serious risk to patient safety. We hasten to add that VHA has already notified the three facilities with this device of its Y2K problem. In addition, the percentage of manufacturers not responding to VHA's inquiries is now 14 percent, not the 29 percent cited in the report. This raises VHA's total response rate to 86 percent. The enclosure presents a table that provides the most recent data on the status of VHA's efforts.

See comment 2.

See comment 1.

2. Mr. Gene Dodaro

See comment 1.

As stated in our response to your recent report, ***YEAR 2000 COMPUTING CRISIS: Progress Made in Compliance of VA Systems, But Concerns Remain*** (GAO/AIMD-98-237), VHA is working closely with the Department of Defense (DoD), the National Institutes of Health, Centers for Disease Control and Prevention, and the Food and Drug Administration to address common problems with biomedical, clinical and laboratory equipment and facilities. VHA is also working with the National Patient Safety Partnership to increase awareness of compliance problems and has joined the American Medical Association, the American Hospital Association, the American Nurses Association, and the Joint Commission on the Accreditation of Healthcare Organizations in calling for a joint effort to create a national clearinghouse for Year 2000 information. This clearinghouse is intended to meet the needs of health care providers and consumers who face the same set of issues for medical devices that VA faces.

Finally, as we previously stated in the above cited Y2K report, the reluctance by business entities to disclose compliance information may be resolved by the Administration's proposed "Good Samaritan" law. This law will encourage vendors to disclose their compliance activities.

The enclosure describes our actions taken and planned to implement your recommendations. It also contains recommended corrections to the draft. I appreciate the opportunity to review the draft of your report.

Sincerely,

Dennis Duffy

Enclosure

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown
(GAO/AIMD-98-240)

GAO recommends that the Secretary of Veterans Affairs direct the Under Secretary for Health to take prompt action to

- **Ensure that the VISNs and medical facilities use the new reporting system to provide the VHA Year 2000 Project Office with up-to-date and more complete information on the cost to replace and/or repair noncompliant and conditional-complaint biomedical devices**

Concur - With input from field-based Biomedical Engineers, VHA has developed software to enhance its equipment tracking module AEMS/MERS (Automated Engineering Management System/Medical Equipment Reporting System) to provide for Y2K tracking, documentation and reporting. VHA released this module on July 10, 1998. To provide direction and instruction, the Under Secretary for Health signed an Information Letter, "VISTA Patch for Year 2000 Tracking and Reporting" (IL 10-98-17). VHA released the information letter to all its medical facilities on July 20, 1998.

- **Complete and issue as soon as possible to the VISNs and medical facilities a Year 2000 guidebook on how to address contingency planning and other related issues for biomedical devices for incorporation in their individual Year 2000 plans.**

Concur - A special task group of Biomedical Engineers completed a draft of a "VHA Year 2000 Guidebook for Medical Equipment" on August 6, 1998. The guidebook illustrates available tools and resources within VHA for use by medical facility staff to address Year 2000 compliance for medical devices. The topics include Awareness, Assessment, Renovation/Implementation, and Validation (which addresses contingency planning and testing principles).

- **Require that each VISN Director ensure that their medical facilities complete development of a Year 2000 business continuity and contingency plan for the biomedical devices in its inventory. This plan should address steps the facility will take on (1) biomedical devices produced by the 29 percent of the manufacturers from whom VHA has not received compliance information and the nearly 100 manufacturers no longer in business; (2) noncompliant devices with a date-time**

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown
(GAO/AIMD-98-240)
(Continued)

problem, which can still be safely used on and after January 1, 2000; and (3) devices that manufacturers have certified as compliant but which may cease to function or malfunction on and after January 1, 2000.

Concur with modification - The publication of the guidebook (discussed above) will enable facilities to develop local contingency plans tailored to their needs and their unique Y2K compliance position. The book discusses scenarios to be considered for contingencies, should specific vulnerabilities materialize. This GAO recommendation is based on developing contingency plans, in part, based on "the 29 percent of the manufacturers from whom VHA has not received compliance information..." As discussed earlier in this response, the percent of manufacturers has been reduced to 14 percent. We expect this trend to continue as we aggressively pursue manufacturer compliance information. The recommendation should reflect this change.

GAO also recommends that the Secretary of Veterans Affairs and the Secretary of Health and Human Services work jointly to develop immediately a single data clearinghouse that provides compliance information to all users of biomedical equipment. Development of this clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Health Affairs, American Hospital Association, American Medical Association, and the Health Industry Manufacturers Association. At a minimum, the clearinghouse should contain: (1) information on the compliance status of all biomedical equipment by make and model; (2) the identity of manufacturers who are no longer in business, including the types of devices, make and model produced by these manufacturers; (3) the identity of manufacturers who have and have not provided VHA and/or FDA with test results certifying that their equipment is Year 2000 compliant; and (4) the identity of manufacturers who have not provided compliance information to VHA and/or FDA.

Concur - VA is addressing this recommendation. Representatives from both VA and Health and Human Services met to plan a common database to serve the needs of the public. We developed a draft charter for the federal partners in this effort, which will include the Department of Defense (DoD). We expect our weekly meetings to continue

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
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(Continued)

until the working group adequately identifies resources, database definition, and database integrity, among other details. The final product is intended to meet the needs of all healthcare providers and consumers who face the same set of issues for medical devices and the Year 2000 problem.

GAO also recommends that the Secretary of Veterans Affairs and the Secretary of Health and Human Services, in conjunction with VA's Under Secretary for Health and the Acting Commissioner of the Food and Drug Administration:

- **determine what actions, if any, should be taken toward biomedical equipment manufacturers who have not provided VHA and/or FDA with compliance information;**
- **take prudent steps to review the test results supporting the biomedical equipment manufacturers' certifications that their equipment is compliant, and make the results of these reviews publicly available through the single data clearinghouse; and**
- **determine what legislative or regulatory changes are necessary to obtain assurances that the manufacturers' equipment is compliant, including performing independent verification and validation of the manufacturer's certification, similar to the current process for reviewing radiological equipment.**

See comment 1.

VA has no legislative or regulatory authority to implement this recommendation and defers to the Department of Health and Human Services. We will, however, provide consultation or other appropriate assistance to HHS in implementing this recommendation.

Specific Comments:

See comment 3.
Now on pp. 2 and 9.

1. GAO makes several references (page 3 and page 15) to a radiation therapy planning computer that is noncompliant. GAO should note in the report that VHA has already identified the three VHA facilities that use this specific device and the noncompliant device will be taken out of service at these facilities.

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown
(GAO/AIMD-98-240)
(Continued)

2. On page 3, paragraph 1, and page 4 paragraph 2:

Now on pp. 2 and 3.
See comment 3.

We suggest inserting the words "like other health care providers" when referring to VHA's reliance on manufacturers to validate, test and certify that their devices are compliant. This recommended change is consistent with the report's language on page 18.

3. On page 5, paragraph 1:

Now on page 3.
See comment 3.

Suggest changing the second and third sentences to read:

> VHA, however, has not yet done so because (1) when VHA requested the information from the manufacturers, VHA did not tell them that it intended to release the information outside the Federal government, and (2) as a result, VHA believes that some of the information provided by the manufacturers may be proprietary information, which VHA could not legally release to the public. In order to resolve this issue, on advice of the Acting General Counsel, VHA recently asked manufacturers to advise the agency if they considered any of the information provided to VHA to be confidential commercial information. VHA will then consider the response of each manufacturer in light of all the information available to VHA to determine whether the information provided by that manufacturer is confidential commercial information. If VHA determines that the information is not confidential commercial information, subject to notice to the manufacturer in indicated instances, VHA will release the information. If VHA determines that the information is confidential commercial information, absent consent from the manufacturer, VHA legally may not release the information.

4. On page 7, paragraph 1:

Now on page 4.
See comment 3.

Suggest changing sentence to "...to approximately 1,600 device manufacturers who supply VHA..."

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
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(GAO/AIMD-98-240)
(Continued)

Now on pp. 11 and 12.
See comment 3.

5. On page 18, paragraph 1 and page 21, paragraph 1:

In our May Year 2000 quarterly report to OMB, VA noted that we expect costs to replace or repair non-compliant biomedical equipment to increase as manufacturers continue to disclose their compliance status.

Now on page 14.
See comment 3.

6. On page 24, paragraph 2:

A special task group of biomedical engineers completed a draft "VHA Year 2000 Guidebook for Medical Equipment" on August 6, 1998. The final guidebook will be released by September 1998.

Now on page 18.
See comment 7.

7. On page 30, paragraph 3:

The language should be modified to be consistent with the new language we suggested for page 5, the first paragraph.

Now on page 18.
See comment 3.

8. On page 31, paragraph 1:

Change end of last sentence from "internal use" to "Federal use."

Updating Information:

Original Equipment Manufacturer's Response to Year 2000 Compliance Inquiry by Category

See comment 3.

June 1, 1998	July 29, 1998	Category	Difference
694	701	Compliant	+7
34	43	Non-Compliant	+9
102	106	Conditionally Compliant	+4
53	47	Pending	-6
187	195	Mergers/Buyout	+8

The following are GAO's comments on the Department of Veterans Affairs' letter dated August 25, 1998.

GAO Comments

1. Discussed in "Agency Comments and Our Evaluation" section of report.

2. Report updated to reflect that only 1 of 19 manufacturers remains unresponsive.

3. Report changed to reflect agency comments.

Comments From the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP - 2 1998

Mr. Gene L. Dodaro
Assistant Comptroller General
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Dodaro:

Enclosed are the Department's comments on your draft report entitled, "Year 2000 Computing Crisis: Compliance Status of Many Biomedical Devices Still Unknown." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided extensive technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

June Gibbs Brown
Inspector General

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Comments of the Department of Health and Human Services on the General Accounting Office Draft Report Entitled, YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown GAO/AIMD-98-240

We are grateful for the visibility that the Congress and this General Accounting Office (GAO) report have provided on behalf of the Department of Health and Human Services' Food and Drug Administration's (FDA) national clearinghouse on biomedical equipment (includes medical devices regulated by FDA as well as other computerized equipment used in the medical field). We share your concerns and will do our utmost to protect the uninterrupted provision of safe and effective patient care by the health care community, and continuation of our Nation's medical research activities.

General Comments

Because it is imperative to ensure that biomedical equipment systems with embedded microchips function properly in the next century, the Department of Health and Human Services (the Department or HHS) has been involved in an effort to ensure the compliance of biomedical equipment for over a year. As noted in the report, on January 21, 1998, the Department issued a letter to 13,000 manufacturers of medical devices and, working through professional associations, approximately 3,000 manufacturers of scientific laboratory equipment. This letter asked the manufacturers to provide information concerning the compliance status of their products.

See comment 1.

As also noted in the report, on June 29, 1998, FDA issued a follow-up letter to 1,935 manufacturers. In considering this follow-up strategy, FDA targeted particular manufacturers that, based on their FDA registration information, appeared to produce medical devices that could have a date problem. The follow-up letter has resulted in a number of new submissions from manufacturers, but the Department believes more efforts are needed to ensure the compliance of biomedical equipment.

See comment 2.

To improve our ability to provide complete information to the health care community and to the general public regarding the Year 2000 compliance of medical devices and biomedical equipment, the Department and the Department of Veterans Affairs (VA) are merging our efforts on biomedical equipment. We have convened a steering committee to develop a charter, action milestones, and funding mechanisms. The charter and a collaborative agreement are in the final stages of development, and a high level action plan, along with a funding estimate, has been drafted. We will work through the Health Care Sector Outreach Committee and the White House Year 2000 Conversion Council to enhance our ability to make more information available to the public. We also will take steps to include additional data elements as mutually decided by the participating Departments. In addition, FDA has requested a supplemental appropriation in order to fund the collection, verification, and posting of information by the biomedical equipment clearinghouse.

The Departments' objective remains the uninterrupted provision of safe and effective patient care and the continuation of our Nation's medical research activities through the provision of a comprehensive, centralized national source of information on the Year 2000 compliance status of medical devices used in the United States and making this information publicly available through our web site. Our joint efforts with the VA are designed to better leverage our collective information and influence. As noted above, we already are working together to enhance the existing website to be the national biomedical equipment clearinghouse by adding equipment inventories from other organizations and by conducting additional follow-up activities.

The National Institutes of Health (NIH) works directly with grantees on the Year 2000 compliance issue, which is critical for accomplishing the NIH medical research mission. The grantees will greatly benefit if, by joining together with the other agencies, we are able to gather sufficient, publicly available data to inform them of the compliance status of medical devices and scientific laboratory equipment. The Department is working with NIH to assure that their needs are met, as well as those of the other government agency and the general public.

These activities include checking whether a medical devices manufacturer has met a planned date for availability of a compliant product version and inspecting records relating to the Year 2000 compliance of computerized medical devices during FDA inspections. Additional enhancements are also under consideration. For example, we are considering how to provide the ability for manufacturers to update their product information when the compliance status of the product changes, without eliminating the existing information, as well as many of the changes recommended by GAO.

See comment 3.

There are several areas of concern regarding the text of the report, its conclusions and recommendations that we wish to bring to GAO's attention. First, the report's premise regarding how FDA tests diagnostic x-ray equipment (*only* diagnostic x-ray equipment, *not* "radiological equipment") is not correct. This premise appears to be the basis for much of the report and the recommendations, and therefore, needs to be corrected. The tests FDA conducts on diagnostic x-ray equipment are very limited and are the only routine tests of medical devices by FDA. FDA tests these systems during the premarket review process only to ensure that they are in compliance with a mandatory Federal performance standard for x-ray equipment. The tests are run on a single piece of new equipment that is provided by the manufacturer just for the purpose of being tested. The testing is limited to well-defined tests that are measured against well-defined criteria set by the Federal Performance Standard. The testing of equipment for compliance with Year 2000 requirements would require testing most, if not all, devices currently in use. Furthermore, there are no broadly applicable tests and criteria for determining Year 2000 compliance; every product would require its own unique testing regimen to reflect the unique characteristics and operating environment of the particular device. Contrary to the draft report, testing devices for compliance with Year 2000 requirements is not "similar" to any current FDA practice, and would create a very significant additional burden on FDA's resources.

See comment 4.

The report sometimes refers to biomedical devices and sometimes to biomedical equipment. GAO needs to distinguish between "medical devices", which FDA regulates, and "biomedical equipment" which includes not only medical devices, but also many other products (for example,

laboratory equipment) that FDA does not regulate, and indeed has no authority to regulate. FDA can take action only where there is statutory authority to do so. The report should be precise in its discussion and in the final recommendation to avoid confusing the reader regarding the extent of FDA's authority. If GAO believes FDA needs additional authority to take action with regard to the Year 2000 problem, their recommendation should be directed to Congress.

Finally, the report should explicitly acknowledge that Federal Government action, including legislative or regulatory action, cannot be expected to resolve all Year 2000 concerns with medical devices or other biomedical equipment and that manufacturers and users must accept responsibility for addressing the specific concerns that arise in their facilities.

GAO Recommendation

We recommend that the Secretary of Veterans Affairs and the Secretary of Health and Human Services work jointly to develop immediately a single data clearinghouse that provides compliance information to all users of biomedical equipment. Development of this clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Health Affairs, American Hospital Association, American Medical Association, and the Health Industry Manufacturers Association. At a minimum, the clearinghouse should contain: (1) information on the compliance status of all biomedical equipment by make and model; (2) the identity of manufacturers who are no longer in business, including the types of devices, make and model produced through by these manufacturers; (3) the identity of manufacturers who have and have not provided VHA and/or FDA with test results certifying that their equipment is Year 2000 compliant; and (4) the identity of manufacturers who have not provided compliance information to VHA and/or FDA.

Department Comment

See comment 2.

We concur. The Department and VA already are working as a Federal partnership to develop a single data clearinghouse. Our private sector associates, mostly professional associations such as the American Medical Association, the American Hospital Association, and the Joint Commission on Health Care Accreditation, will provide advice and assistance as requested. We also agree that it would be useful to provide an indication of whether a particular manufacturer has or has not provided information on Year 2000 compliance for manufacturers of electronic products that are susceptible to Year 2000 concerns. To that end, FDA will post on the web site the identity of manufacturers who have not provided compliance certification.

See comment 2.

We do not believe, however, that listing all compliant products is either necessary or cost-effective. The FDA web site already includes a certification statement assuring total compliance from those manufacturers who report that all of their products are compliant. Information at the individual model level is needed for noncompliant products only. If a manufacturer's entire product line is compliant, users of the clearinghouse would receive no additional benefit from the model-level information, which would be quite expensive to obtain and enter into the database. Furthermore, manufacturers could be expected to cooperate more fully with the clearinghouse if reporting burdens are kept to a minimum and only essential information is requested.

Because we believe there is redundancy between this recommendation and those that follow, we will address the remaining elements of this recommendation in our responses below.

GAO Recommendation

We also recommend that the Secretary of Veterans Affairs and the Secretary of Health and Human Services, in conjunction with VA's Under Secretary for Health and the Acting Commissioner of the Food and Drug Administration:

> determine what actions, if any, should be taken toward biomedical equipment manufacturers who have not provided VHA and/or FDA with compliance information;

Department Comment

See comment 2.

The Department concurs that it will be necessary to determine what further action should be taken regarding manufacturers which fail to respond. FDA already notes on its web site that there is no assurance that manufacturers which have not responded to FDA's survey request are Year 2000 compliant. Under current regulations, FDA does not have the authority to require all device manufacturers to submit reports on whether their devices are Year 2000 compliant, although FDA can communicate with firms and encourage cooperation with the clearinghouse.

GAO Recommendation

> determine what actions, if any, are needed to address biomedical equipment produced by manufacturers no longer in business;

Department Comment

See comment 2.

We concur that the identity of manufacturers known to be defunct, along with the known types, makes, and models of devices they manufactured should be included in the clearinghouse database, and will explore possible approaches to acquiring additional information regarding defunct manufacturers' products. At this time, however, appears that obtaining this information would be very difficult and costly, and might not be possible for the majority of the defunct manufacturers. When a corporate entity goes out of existence, usually there remains no legally responsible party to whom a request for information could be addressed, nor is there any assurance that such detailed information would still exist. One approach that should be considered is to advise hospitals and other users of devices manufactured by a defunct firm that they will need to develop alternative strategies for assuring their equipment will continue to function appropriately after the Year 2000 problems. These alternative strategies could include examination of the device and any manuals or other documents, testing by internal staff or a consultant, or replacing the device with one known to be Year 2000 compliant.

GAO Recommendation

> take prudent steps to review the test results supporting the biomedical equipment manufacturers' certifications that their equipment is compliant, and make the results of these reviews publicly available through the single data clearinghouse; and

Department Comment

See comment 2.

We do not concur. Resources to undertake such a review are not available, and there is insufficient time before the Year 2000 to complete a review of this nature.

We believe that submission of appropriate certifications of compliance is sufficient to assure that the certifying manufacturers are in compliance. Certifications submitted to any Federal agency must be truthful. Certifiers are subject to criminal prosecution under 18 USC 1001 if they submit false information. Furthermore, the responsibility for truthfully assuring the compliance of medical devices must rest primarily with those who manufacture and market such devices, and are best able to assess and correct Year 2000 problems.

GAO Recommendation

> determine what legislative or regulatory changes are necessary to obtain assurances that the manufacturers' equipment is compliant, including performing independent verification and validation of the manufacturer's certification, similar to the current process for reviewing radiological equipment.

Department Comment

See comment 2.

While we would welcome any assistance the Congress could give, the Department believes that the solutions to Year 2000 problems relating to medical devices can be achieved through other approaches, such as the clearinghouse and other educational efforts that are already underway. Also, as noted in the general comments above, GAO appears to have misunderstood FDA's role in approving new medical devices. FDA does not independently verify and validate test data provided by manufacturers except in the one instance cited above. As noted above, we do not have the resources to undertake such a program at this time.

The following are GAO's comments on the Department of Health and Human Services' letter dated September 2, 1998.

GAO Comments

1. Report modified to include "1,935 manufacturers."

2. Discussed in "Agency Comments and Our Evaluation" section of report.

3. Report revised to reflect agency comments.

4. Report revised to clarify the terms "biomedical equipment" and "medical devices." The term biomedical equipment includes both medical devices subject to FDA regulation and scientific and research instruments which are not subject to FDA regulation.

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