The Year 2000 Medical Device Assessment:

Guidebook

Department of Veterans Affairs
Veterans Health Administration
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Acknowledgements

Prologue

Health care today depends on a vast array of high-technology devices and systems. Located in hospitals, outpatient clinics, physician offices, laboratories, pharmacies, and patients' homes, many of these devices and systems are highly dependent on embedded microprocessors and/or computers. This technology includes not only medical devices used in the diagnosis, treatment or monitoring of patients, but also building systems that support the clinical environment and information technology to manage and track critical patient information and business functions.

This Guidebook was developed to assist health care facilities as well as community organizers in managing the complex Year 2000 problem. The ultimate goal is to encourage health care organizations to conduct a thorough review of their biomedical equipment and share findings within and across organizations. The strategized approach will carefully lead individual facilities through assessment and compliance conversion of their medical devices and systems. Implementation should not be limited to the suggestions in this Guidebook; additional tools and resources have been provided to further explore possible disruption posed by the Millennium Bug. Time is of the essence. As health care providers, we have a duty to ensure that our patients are safe from Year 2000 risks when the clock ticks forward to the 21st century.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health, Department of Veterans Affairs

Executive Summary

This guidebook describes practical approaches to managing Year 2000 compliance issues for medical equipment used in your health care organization. It is organized into four major chapters:

- ***Awareness*** – describes and communicates the scope of the Year 2000 compliance issues for medical devices to facility staff.
- ***Assessment*** – combines available compliance information with the local medical equipment inventory and tracks required action.
- ***Renovation/Implementation*** – describes action(s) necessary to correct identified Year 2000 problems for medical devices.
- ***Validation*** – describes action(s) necessary to assure implementation is effective, including contingency planning.

These chapters, plus the detailed Appendices, will lead individual facilities through a thorough assessment of their medical device inventory and provide an ongoing means of tracking and insuring that corrective actions are taken when required.

For consistency of application, each chapter is divided into three sections:

- ***Objective*** – describes the intent of the subject chapter as it applies to Year 2000.
- ***Strategy*** – describes what approaches may be employed to implementing the objective.
- ***Tools and Resources*** – describes the tools and resources available to accomplish the objective.

This guidebook was developed by Veterans Health Administration (VHA) biomedical engineers and Year 2000 project staff, who have successfully used existing resources and their inventory system to assess their facility's medical equipment inventory and plan corrective actions, including replacement equipment and contingency planning.

Currently, the situation is encouraging, with trends showing that most medical devices are Year 2000 compliant. These devices are expected to function properly with the change in the millennium. There are, however, still a significant number of devices that must

be identified, prior to the Year 2000, because they will require corrective action. Although the technical issue may not be as significant as first envisioned, the management challenge is now paramount and requires health care organizations to thoroughly identify, document, and track Year 2000 compliance status for medical equipment inventories. It is anticipated that this guidebook and the references included will assist with accomplishing this task.

Introduction

Introduction

Objectives

This guidebook will focus on strategies and tools for managing Year 2000 compliance for medical equipment in your health care organization. It has been developed by the Veterans Health Administration (VHA), which seeks to make available its experience so as to assist other health care organizations.

The intent of the guidebook is twofold: first, to provide current information for health care managers to properly present the problem; second, to define tools and resources that technical staff in health care organizations will require to address the Year 2000 problem. Technical staff alone cannot solve the Year 2000 problem.

In many ways the Year 2000 problem, with respect to biomedical devices, is more a management challenge than a technical issue.

The Problem

It is ironic that the same technology so instrumental in many advances of modern health care now threatens patient care at the start of the 21st century. High-speed computers make possible such devices as Computerized Tomography (CT) and Magnetic Resonance Imaging (MRI) systems, both of which have been readily adopted as standards of care. Furthermore, embedded microprocessors are found in a variety of critical devices such as implanted pacemakers or emergency defibrillators. There is an increasingly heightened concern from caregivers, patients, and the business organizations with whom they interact for the continued and safe operation of modern medical equipment upon the change of the calendar to January 1, 2000.

Like other types of devices with software dependencies, many medical devices have inherited design features that result in two digit representations for the current year - i.e., 98 for 1998. This is a holdover from previous design strategies when data storage was a premium and design measures were implemented to maximize limited memory.

The Year 2000 concern is that a device may not correctly recognize 00 as representing the Year 2000, instead interpreting the date as 1900 or some other year, such as the year the device was originally designed. These unexpected dates can cause the device to operate incorrectly, to provide incorrect

printouts, or to cease to function. The problem can affect computations that calculate age, sort by date, compare dates, or perform other specialized date-related tasks. For example, an incorrect sequence in the output of a blood gas analyzer could cause confusion in diagnosis and treatment planning. An incorrect age calculation, which is then stamped on an automated chest X-ray, could cause a misdiagnosis. Many health care systems are subject to the Year 2000 problem including: 1) information systems; 2) building systems such as elevators, heating, ventilation and air conditioning, and security control systems; and 3) billing and accounting systems. These systems must be thoroughly checked, repaired or replaced as required.

The Year 2000 problem poses significant challenges for all federal, state, and local health care organizations and the direct patient care they provide. Health care organizations own and operate sophisticated facilities and equipment that rely on embedded microprocessors and/or other software dependencies. All such equipment items are potential candidates for failure or other operating errors when the date changes from December 31, 1999 to January 1, 2000. Each organization's inventory is diverse and ranges from relatively simple devices, such as suction machines and sphygmomanometers, to complex systems such as cardiac catheterization laboratories.

It is also important to note that the majority of issues identified for non-compliant devices involve an incorrect date stamp on a hard copy printout. Many times, the wrong date in the stamp or printout does not pose a serious impact to patient health and safety.

The trend in VHA for medical equipment and Year 2000 implications is consistent with findings from other outside health care entities. "Most devices will be unaffected by the Year 2000 problem and will operate properly including tracking of times and dates, with the change to the year 2000. This is because general-purpose microprocessors and most medical device-specific application software or instruction sets are not likely to incorporate a date field. And many time tracking microprocessors use duration, rather than date, for their calculations. In addition, more recent equipment will have been designed to avoid the Year 2000 problem."[1]

As a result of continued public pressure through public hearings and congressional interest, manufacturers' compliance numbers are continually changing. In recent months, the number of non-responsive manufacturers has decreased because manufacturers have been more willing to release this information to the Food and Drug Administration (FDA) website.

The Year 2000 problem for medical equipment is beginning to be recognized as more of a management challenge than a purely technical issue. There must be a well documented and supported effort to assure patients that all prudent actions have been taken. It is anticipated that this guidebook and other resources referenced will be useful in achieving this goal.

Determining Compliance Status

To determine the compliance status of a medical equipment inventory, it is important to communicate with manufacturers and solicit data as early as possible. Follow-up with manufacturers is essential to ensure that the manufacturers assert the Year 2000 compliance of their products. The following are some scenarios that could occur once a manufacturer is contacted:

- A manufacturer could reply that all of its products are Year 2000 compliant, meaning there should be no problems because the device does not rely on date coding or the issue has already been addressed;

[1] *ECRI, "Medical Devices and the Year 2000 Problem", Health Devices, December 1997, Vol. 26, No.12.*

- A manufacturer could report that some models of equipment or devices are not Year 2000 compliant and are no longer supported by the manufacturer. These models could be considered obsolete and not able to be fixed by the manufacturer, even though in many cases the device is still functional and commonly used;

- A manufacturer could state that its devices are not currently Year 2000 compliant, but that it intends to repair or otherwise fix the device. In these cases, the manufacturer usually does not reveal how the Year 2000 compliance will affect the function of the device or how to fix the device, since the manner in which the manufacturer will provide the fix varies widely; or;

- A manufacturer could report that it is still performing analyses of its products and does not know if its product is Year 2000 compliant.

Beware that some manufacturers may have gone out of business, have been acquired by another company, return requests back labeled “return to sender,” or simply not respond to requests for information. When this occurs, look to the FDA website or other comparable websites to see if the manufacturer has provided product information to other organizations.

Ten Questions Hospital and Health System Management Should Be Asking

1. Are we one of the health care organizations that have not started their Year 2000 assessment?

- At this document's printing, there are less than 400 days until the Year 2000. Calculate the exact number of days left on the day you read this message.
  - *A tight timetable is required for a thorough compliance workplan – the workplan will be affected by updates/upgrades and must be flexible enough to accommodate necessary schedule delays*
  - *Resources are going to be harder to find as Year 2000 approaches*
- No systems are immune – even new systems:
  - *Only 50% of computer equipment sold in 1997 was compliant*
  - *Only 75% of computer equipment sold in 1998 will be compliant*
  - *Even some common programs are not fully compliant*
  - *Even a computer that has been carefully prepared for the Year 2000 can be undone if it electronically exchanges data with one that isn't "bug" free*

2. Is our assessment enterprise-wide, or just focused on information technology?

- Identify alternate sources for non-compliant and conditionally compliant devices whose status has not been identified
- Establish a correspondent relationship with another local hospital; this anticipates a potential supplier in the event that the normal suppliers are incapacitated
- Examples of possible Year 2000 vulnerabilities:
  - *Telecommunications*
  - *HVAC systems*
  - *Elevators*
  - *Medical devices*
  - *Automobiles/Ambulances*

3. How are our key vendors dealing with compliance issues?

- Beware of the ripple effect. The problem may appear to have been solved, but have the following companies been contacted:
  - *Utility companies*
  - *Banks*
  - *Payroll companies*
  - *Key suppliers (blood, food, pharmaceuticals, medical and surgical devices, utility companies)*

4. Will our key players be affected by Year 2000 compliance?

- Year 2000 issues could cause an interruption of payments or change previously standardized forms
- Electronic Data Interchange (electronic commerce)

Ten Questions Hospital and Health System Management Should Be Asking (continued)

5. Have we budgeted enough to solve the problem?

- When was the last IT project that came in under budget?
- Federal Express – a company that is very up-to-date technologically – spent half a billion dollars on solving its Year 2000 problems
- Costs will increase dramatically as the Year 2000 approaches:
  - *Analysts indicate programmers salaries will double every six months between now and the Year 2000*
  - *The Financing Accounting Standards Board (FASB) has stated that the cost to create a Year 2000 Solution will have to be expensed in the year such changes are incurred – and not capitalized*
- Year 2000 spending per health care organization ranged from $158 thousand to $45 million in 1997 alone
- Average 1997 Year 2000 budget for health care organizations was $4.7 million

6. How will we obtain/retain key Year 2000 compliance staff?

- Expect turnover before Year 2000 - given that the typical Chief Information Officer (CIO) remains only two years
- Key compliance staff could be recruited to ensure adequate staffing needs are met

7. How are we communicating our compliance status to our community and using public?

- Community and users need to be reassured that the health care organization will comply
- Expect media inquiries on compliance status

8. Is Year 2000 compliance a requirement on all purchases?

- Document the requirement on all potentially vulnerable new purchases

9. How can we minimize legal liability?

- Keep your board informed, create a steering committee, show due diligence on solving the problem
- Take advantage of the free flow of information on data collection and testing made available as a result of the Year 2000 Information and Readiness Disclosure Act (P.L. 105-271) recently signed by President Clinton

10. What is your backup plan?

- The U.S. General Accounting Office (GAO) has produced guidebooks on contingency planning. For more information, see GAO's website at www.gao.gov
- Assume what you believe to work will partially fail
- Test your contingency plans

The above information was modified from the American Hospital Association's "Year 2000: Mission Critical" Ten Questions List (June 1998)

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Awareness

Awareness

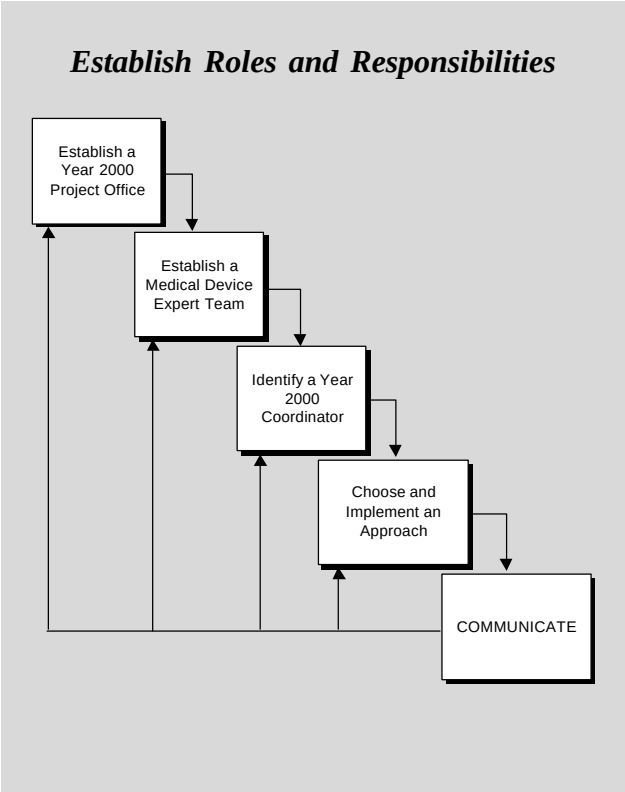
Objectives and Strategy

The objective of this section is to describe and communicate the scope of the Year 2000 problem for medical equipment and to define an effective approach to tackle the problem. Critical to the success of this project is management support, team organization, and assignment of roles and responsibilities. A sustained effort will be essential through the Year 2000 to ensure the continued delivery of health care and the continuity of business.

Some equipment may operate erroneously or not operate at all after December 31, 1999. Widespread failure of critical care and life support equipment clearly poses a significant risk to public health and safety and would be catastrophic. This is the worst case scenario, however, action must be taken to identify equipment at risk to determine the necessary corrective actions and/or required contingency planning.

Other devices will experience operating errors that are not critical, but nevertheless must be addressed. For example, it is possible for some ECG machines to operate correctly in representing and interpreting electrocardiograms, but not print the correct date on a hard copy printout. While work-around solutions to this can be implemented, it clearly does not pose the same kind of risk to public health and safety.

Approaches



Establish a Year 2000 Project Office

The Project Office should prepare a *Year 2000 Compliance Plan*. The Plan should be periodically updated and include a structured compliance strategy for all categories of the health care organization systems and equipment. The responsibility for Year 2000 compliance could/ should be assigned to the health care organization/ system's Chief Information Officer.

Establish a Medical Device Expert Team

Form a Medical Device Integrated Product Team to address Year 2000 plans for medical equipment. One recommendation is to form an expert team responsible to the Year 2000 Project Office with, the needed expertise, for example:

- Year 2000 Coordinator
- Millennium Engineer
- Radiology Staff
- Nuclear Medicine Staff
- Pathology and Laboratory Medicine Staff
- Medicine (Cardiology & Surgery) Staff
- Medical Research
- Biomedical (or Clinical) Engineering Staff
- Acquisition & Materiel Management Staff
- Facility Engineers

It is recommended that this expert team meet on a regular basis to monitor the progress of your facility/ system and to provide additional guidance. Contingency plans could also be developed by this group.

Identify a Year 2000 Coordinator

Each health care organization should have a Year 2000 coordinator, responsible for overall management of the Year 2000 project within their purview. At the individual facility level, biomedical engineers can provide key oversight and technical implementation of the medical device Year 2000 guidelines. Designate an engineer as the "Millennium Engineer" or similar title.

Choose and Implement an Approach

— *VHA* —

The following is the model approach used by the the Veterans Health Administration (VHA). It can be used by health care organizations to address medical device equipment compliance. This is the categorization scheme used throughout this guidebook.

1. Gather compliance data from original equipment manufacturers (OEM).
   (See Assessment section, page 11.)

2. Organize compliance data into defined categories.

Categories have been created to track and manage Year 2000 progress. They are defined as:

- *Fully Compliant* – a medical device that functions properly in all aspects upon the change to the Year 2000 without requiring user intervention.

- *Conditionally Compliant* – a medical device that requires user intervention to function in all aspects upon the change to the Year 2000. This may include a manufacturer software and/ or hardware update or other one-time user action.

- *Non-compliant* – a medical device that will not function properly in all aspects upon the change to the Year 2000 and no manufacturer remedy is available.

- *Not Applicable* – a medical device with no Year 2000 implications.

- *Pending* – Manufacturers have responded but their medical device compliance status is still unknown.

3. Make data readily available across the oranization/ system and continue to provide updates.

4. Manage compliance issues for medical equipment inventory. (See Renovation section, page 19.)

— *FDA* —

The Food and Drug Administration's (FDA) approach to medical device equipment compliance can be found on their website. (See Appendix A, page 29.)

Solutions can be offered by manufacturers to mitigate the problem. One of the following codes can be used to indicate solution to be provided for the product:

- SU/date – Upgrade to software will be available by (date) at no cost to purchaser.
- SU-C/date – Upgrade to software will be made available by (date) at a cost to purchaser.
- HU/date – Upgrade to product (hardware and software) will be made available by (date) at no cost.
- HU-C/date – Upgrade to product (hardware and software) will be made available by (date) at a cost to purchaser.
- M – Minor date-related problem with product, presenting no adverse health impact on product function and for which manufacturer will not provide a correction/upgrade.
- O – Product is obsolete or beyond reasonable useful service life and no upgrade will be provided.
- AI/date – Assessment of compliance status is currently incomplete but is underway and information will be made available by (date).

Communicate

Establish channels for communicating device information. This can be executed through memoranda, e-mail, meetings and presentations, posting and updating information on the internet, and training sessions. An organization-wide meeting and/or, for multi-organization system, conference call on Year 2000 issues could be conducted monthly to share national efforts, guidelines, deadlines, and reporting requirements.

In addition, some organizations have communication strategies such as video teleconferencing, audio conference calls, and face-to-face meetings that can prove useful.

Tools and Resources

- Websites (See Appendix A, page 29.)
- Educational Programs (Appendix A)
- Conference calls
- Safety committee
- Expert groups
- Year 2000 publications (Appendix A)
- Peer networking with other hospitals
- Emergency preparedness drills
- Biomedical engineer expert group

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Assessment

Assessment

Objectives

The assessment process combines available, confirmed compliance information with the local equipment inventory to provide the organization with a list of the medical equipment and its compliance status. A chart depicting the recommended Year 2000 assessment actions for medical equipment is provided in Figure1.

Biomedical or clinical engineers have experience in managing potential hazards identified with medical devices. The Year 2000 problem is just another potential hazard.

Every electronic item in the medical equipment inventory poses a potential hazard until assessment is complete.

The assessment process will provide a means to measure the size of the Year 2000 problem, and will give an idea of the magnitude of the required remediation efforts.

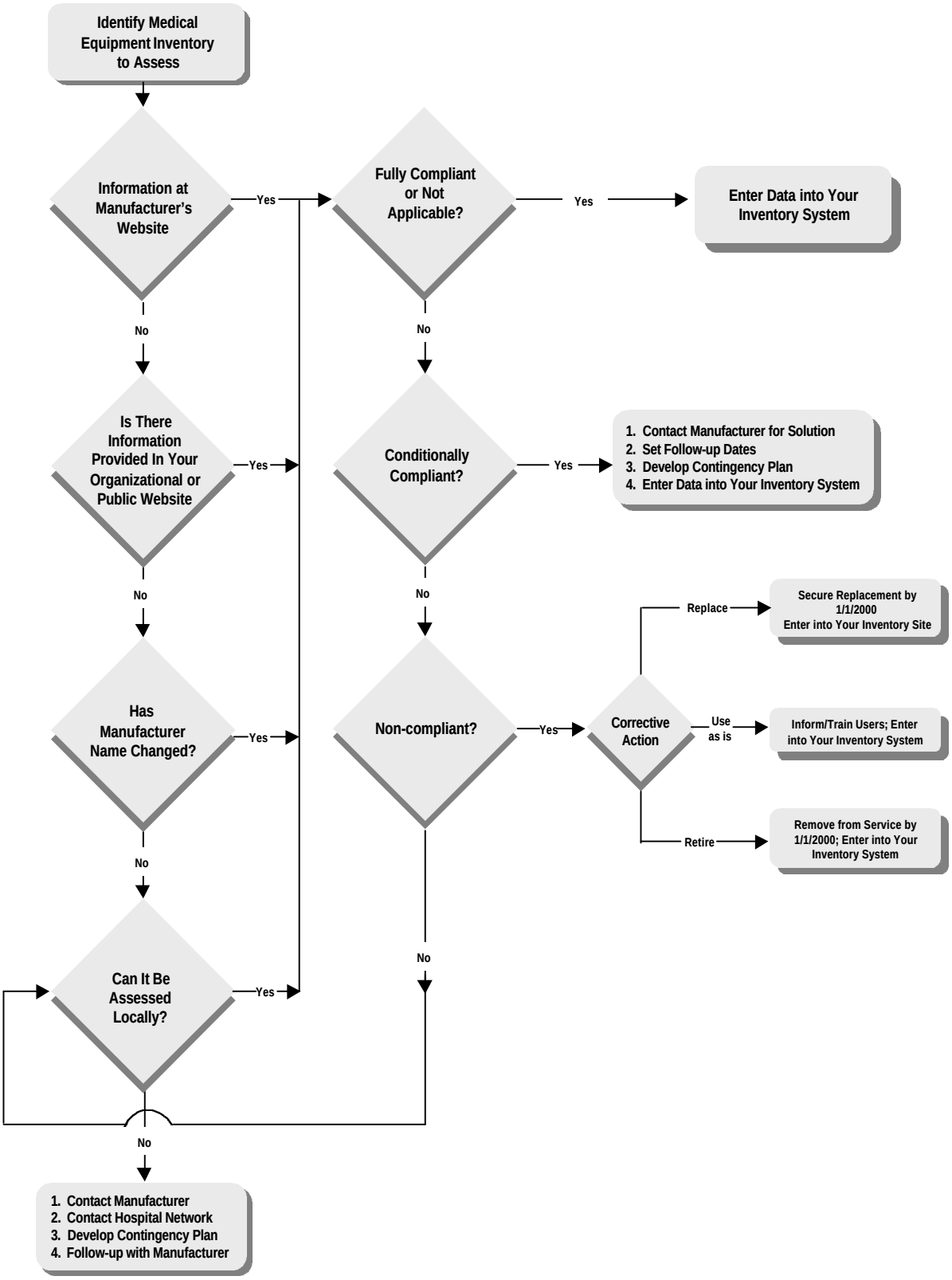
The Federal Government has established an internet site to provide information regarding the Year 2000 compliance of medical devices and scientific laboratory equipment. The general public and the health care and research communities have access to this website, the FDA's "Center for Devices and Radiological Health Care." It can be found at www.fda.gov/cdrh/yr2000/year2000.html Manufacturers of biomedical equipment are urged by FDA and the National Patient Safety Partnership (NPSP) to provide information regarding the Year 2000 compliance status of their products, including both current and previously manufactured products, for placement at this website. Other sources of information include letters, direct information from the manufacturer (including OEM websites), or written information from the equipment distributor.

Local assessment should be substituted for written compliance information only as a last resort.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires that all accredited hospitals maintain an active inventory of medical devices in their Equipment Management Program.

Neither medical device compliance information nor the inventory is static. Manufacturers continually update compliance data, including corrections (changing Fully Compliant to Non-compliant or

Figure 1
Recommended Year 2000 Medical Equipment Assessment Activities



changing the available date of a Year 2000 fix, as examples). As better information becomes available, Year 2000 efforts and activities continue to increase. The equipment inventory at individual sites is also subject to change as new items are added through normal acquisition. A single review of the inventory is not sufficient for ensuring complete Year 2000 assessment. Responsible medical equipment management requires that the assessment process continue past January 1, 2000, since not all systems will be compliant by this date.

The Year 2000 process also provides an opportunity to update and validate the facility's medical equipment inventory.

January 1, 2000, is not a moveable deadline. It will occur, whether or not you are ready.

Strategy

The primary source of compliance information should be determined by the OEM.

No other source, or combination of sources, can provide device-specific information while simultaneously ensuring proper and thorough testing. The manufacturer is the only source of design data regarding time and date usage; this proprietary information is unavailable to end users including biomedical engineering staff. Testing these devices can easily be incomplete, destructive, or inaccurate through no fault of the tester or its devised protocol. Testing has the potential to harm patients through inadvertent changes in internal settings that are not viewable or easily reset by a biomedical technician.

Medical Device Compliance Page on the FDA Year 2000 Compliance Project Website

The FDA merged medical device compliance data from the FDA and VHA into a national clearinghouse. These data are updated on a regular basis and can help you determine which systems the manufacturer deems compliant. It is important to remember that the information on the FDA website is dynamic. Certain manufacturers have yet to provide compliance information (the "pending" list), and other manufacturers have changed their compliance status. Regular updates, as listed by manufacturer changes, are posted regularly to the FDA and other websites.

Medical Equipment Inventory

Each health care organization is responsible for maintenance of its medical equipment inventory for quality assurance purposes, including requirements from JCAHO, the National Fire Protection Association (NFPA). Each organization's inventory also needs to meet the statutory requirements outlined in the Safe Medical Devices Act of 1990. The inventory should include manufacturer and model information that can be referenced against the information in the web pages.

You may want to consider changes to the format on the inventory file to allow for the inclusion of Year 2000 compliance information with the other inventory information. Changes can be designed to provide easy data entry and control modeled on the preventive maintenance routines already widely used.

Strategies for Assessing the Local Inventory

There are a number of approaches to identify equipment in local equipment inventories based on manufacturer-supplied information found on the FDA website. Approaches include the following:
1) Criticality of Equipment, 2) One Manufacturer/One Model at a Time, 3) Empirical Knowledge, 4) Divide and Conquer, and 5) a combination of these strategies. There are pros and cons to each of these approaches, the most important of which are outlined below.

1. Criticality of Equipment

Facilities should identify equipment that is most critical and requires preventive maintenance and/or performance testing for JCAHO accreditation. Identify the critical equipment first, and deal with the rest later. Such an approach obtains a maximum

result with minimal time. However, such an approach still leaves a large group of equipment for identification at a later time.

If time and resources are at a premium, this is the appropriate assessment strategy. It will minimize the risks presented by life-support and mission-critical equipment items. High volume and high dollar value equipment has a similarly high profile, and should be approached in the same way. (See Appendix B.)

2. One Manufacturer/One Model at a Time
This is a list of manufacturers and models. An alphabetical list of manufacturers and models can be found on the FDA website, and can be created in local equipment inventories. Methodically compare and match these two lists. Such an approach is time consuming, but thorough.

3. Empirical Knowledge
This is based on staff knowledge of the local inventory. A monthly scan of the non-compliant lists on the FDA website can identify the affected equipment in the local inventory. Everything else is either compliant or not applicable. Such an approach is quick, but can easily miss manufacturers that have changed names or use model designations on the website that are unfamiliar to staff members. This approach greatly depends upon the accuracy and completeness of staff memory.

4. "Divide and Conquer"
Staff with appropriate expertise, such as biomedical engineers, can be assigned to review compliance data when given preventive maintenance lists and to provide Year 2000 information for input into the inventory. Such an approach may require wide access to the FDA website and training of all team members to properly identify manufacturers and models.

5. Combination of Strategies
Selecting a combination of these approaches could be most useful. The objective is to narrow down the list of devices requiring assessment as quickly and as thoroughly as possible. One possible scenario is presented.

- An empirical or visual first pass through the list of conditionally compliant and non-compliant lists will quickly identify at-risk equipment in the inventory and make staff members familiar with the FDA website and its organization. Comparison to a list of critical equipment provides additional practice and familiarity with cross referencing to changed or unresponsive manufacturers. This practice sets up a methodical pass through the local equipment inventory.

- Training biomedical engineering staff in the identification process makes them stakeholders and adds observers to catch equipment that might otherwise be missed. Also, it will help them realize they have a real role in solving the Year 2000 problem.

- An alphabetical listing of manufacturers is provided on the FDA website. A status of non-compliant, pending assessment, compliant, and not applicable is associated with each manufacturer. Multiple statuses may be associated with a particular manufacturer. Certain manufacturers have a single status of either compliant or not applicable for their entire product line. This information can be used to quickly identify a large number of devices.

- Some manufacturers have developed their own internet sites as a means to pass on assessment information. Local reference to these sites could be necessary to identify equipment in your inventory that is not listed on the FDA website.

- Continuous referral between the website and your local equipment inventory is possible without printing out the entire contents. However, printed material can serve to identify work already completed.

Regardless of the approach chosen, communication about the Year 2000 objectives strategy and tools to the team is important.

Medical Equipment Related Systems Analysis

Medical equipment is becoming increasingly complex and dependent on multiple systems for advanced operations. Often, medical devices must receive communications, data, or accessories from other systems within the facility to function. The following guidelines are provided to assist with the assessment of those systems interfaced to medical equipment.

1. Medical Equipment Systems and Utilities

During assessment of medical equipment systems, a review of the utility delivery systems integral to the operation of the equipment should be performed. This may include water treatment systems, air coolant systems built into the equipment, smoke evacuation systems, medical gas supply systems, etc. Contingency plans should provide for operation of these ancillary utilities in the event of a Year 2000-related interruption in service. An example is the evaluation of a reverse osmosis water treatment system for the delivery of dialysate in a hemodialysis unit.

2. Medical Equipment and Data Processing Interfaces

Assessment of medical equipment systems should include any interconnection to network computing systems. This could include bidirectional interfaces, network hub connections, image management systems, and QA data collection systems. An example of such a system is a blood gas analyzer connected to a personal computer running quality assurance software routines and all bidirectional interface systems for analytical laboratory systems. An analysis of the network components is essential for assuring Year 2000 compliance for the complete medical equipment system.

3. Medical Equipment and Other Miscellaneous Systems

Some medical equipment systems will involve interfaces of communications systems, heating and cooling environmental control systems, steam supplies, EtO gas delivery systems, etc. For these systems, it is imperative that delivery of all necessary components be in Year 2000 compliance. For example, an electronic control valve for the delivery of nitrogen gas to a nitrogen-powered surgical tool could be Year 2000 sensitive and interfere with the delivery of gas flow during a surgical case.

4. Examples of Additional Systems

The above outline of medical equipment related systematic analysis is not exhaustive. However, a systematic approach to all medical equipment Year 2000 assessments will ensure a comprehensive review of the proper operation of the equipment. The following are examples of a few representative systems to scrutinize during Year 2000 assessments.

- Steam distribution for sterilizers
- Water treatment systems for delivery to dialysis, analytical laboratory devices, water cooled systems such as lasers, x-ray tubes, dental air supplies, medical air and vacuum supplies
- Data interfaces to analytical laboratory systems (bidirectional interfaces)
- Image management systems, picture archiving systems, network hubs, and personal computers for storage and forwarding images
- Network components of an electrocardiograph storage and retrieval system
- Smoke evacuation systems for laser plumes

- Waste anesthetic gas evacuation systems
- Clinical patient monitoring systems interfaced to network hubs, clinical information systems, or 24-hour full disclosure systems
- Telemedicine applications using modem or network interfaces, scanners, print networks, etc.
- Radiology print networks
- Alarm systems with interlocks for discontinuing operation of medical equipment until alarm situation is corrected
- Nurse call systems

Undetermined Year 2000 Response
If a medical device could incur an adverse Year 2000 problem, but compliance can not be assessed (i.e., the manufacturer is unresponsive or out of business), the facility must locally determine the risk of continued use of the device and formulate a proper response.

Many authorities consider that no knowledge about an item's Year 2000 compliance renders it "non-compliant" on January 1, 2000, until proven otherwise. This is probably the safest approach, and minimizes the risk to patients and staff. In any event, Year 2000 contingency plans should address this issue. The plan must consider the intended use of the device and the associated level of risk.

Reporting
The key to reporting is communication. Ultimately, success or failure will depend not only on your efforts but on the support received from your internal customers. The Year 2000 Project Office and its staff do not "own" the equipment affected by the Millennium Bug and should not be in the position of independently acquiring replacement equipment. Along the same line, coordination of updates or upgrades may require equipment to be out of service or require user retraining. Certain planned upgrades may be coordinated with a Year 2000 fix.

Health care facility management staff (e.g., CEO, COO, medical director, nursing director) need to be kept informed of Year 2000 efforts and progress. It is their responsibility to provide the resources needed to successfully complete Year 2000 tasks. Without current and accurate information they cannot provide support or accurate information.

Assessment sources and estimated costs should be included as part of your inventory system.

The report validation should be performed electronically by facility inventory managers. If electronic reporting is not used at your site, written monthly reports should be completed. Appendix C shows an example of an electronic spreadsheet VHA uses to track medical device compliance inventory and cost analysis.

Tools and Resources

Year 2000 Medical Equipment Management Plans
See Appendix D for a sample developed to meet JCAHO Environment of Care policy agenda and various VHA Year 2000 contingency/readiness plans.

Project Binder/Resource File
A locally-developed binder containing the latest compliance and inventory assessment information can also serve as a reference point to the Year 2000 Project Team. Such a tool would contain copies of the spreadsheets from the FDA website, vendor letters, local inventory data, expected completion information for conditionally compliant devices, and similar information. A log of additions and changes to the binder's contents will help speed access to the most relevant material and improve efficiency.

A central file of Year 2000 resources can be invaluable in providing information and stimulating discussion. Facility libraries may be able to help in this area.

Hospital Network Resources
Utilize available facility, biomedical engineering, and information technology networks to share information and ideas. Conference calls, video teleconferences, and attendance at professional meetings can be useful and provide validation of strategies, assessments, and implementation schemes.

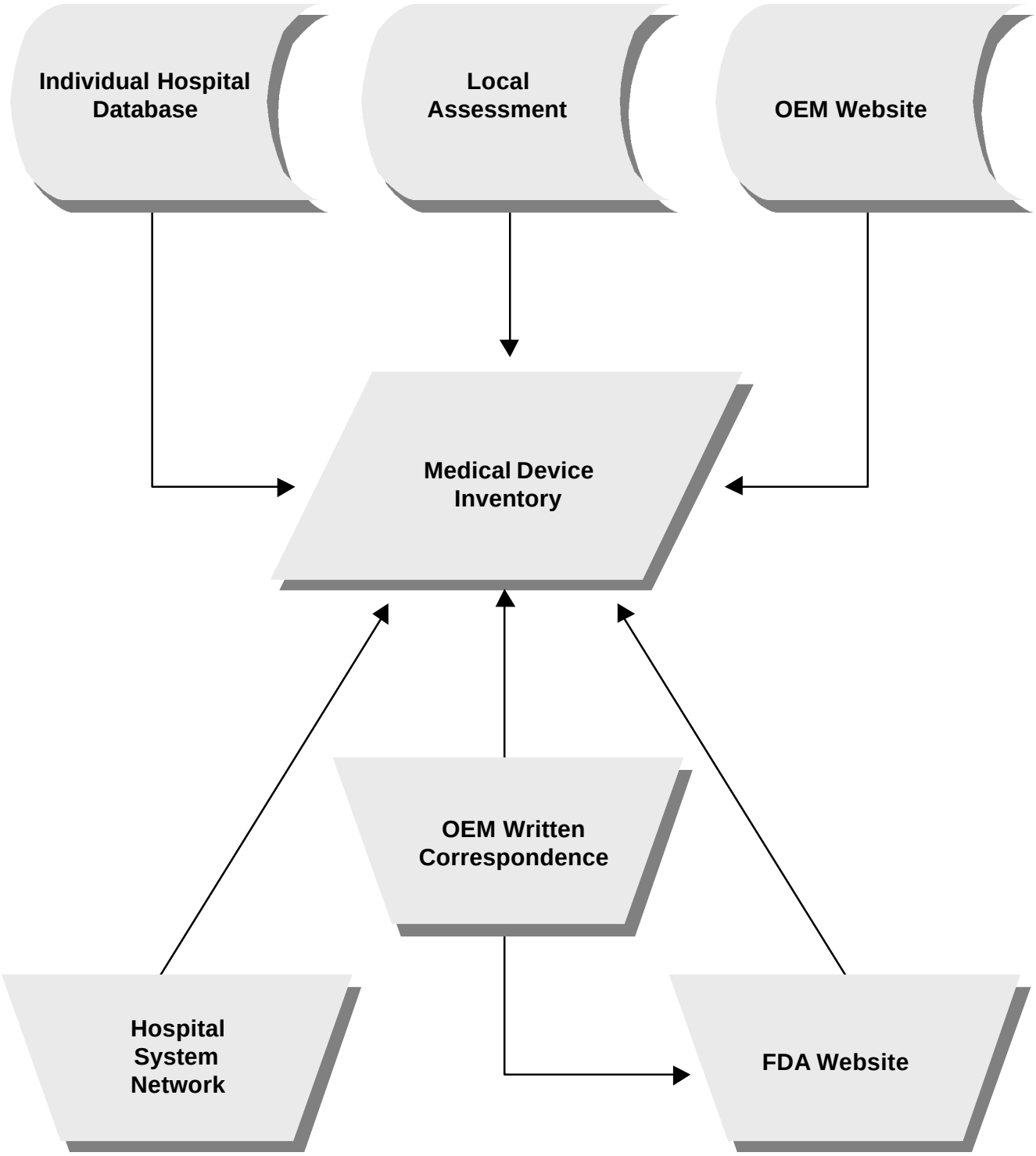
Websites for Medical Device Compliance Information
FDA's website is a useful resource for determining a device's compliance status. The medical device compliance section is the most in depth of all the areas on the site. It has both viewable and download-capable listings in each of the three compliance states: Compliant, Non-compliant, and Pending. In addition, there are listings of companies that have been bought out or merged and a new section on devices whose status has changed (from pending to compliant, for instance) as more detailed information has become available.

Manufacturers are beginning to revise some compliance data as they do more testing. To ensure that status changes are not missed, check the FDA website regularly. Note that manufacturers regularly undergo mergers and acquisitions. Changes are, however, reflected on the FDA website.

Manufacturers' Websites
A list of known manufacturers' websites can be found in FDA's website.

Manufacturers' Written Communication
Facilities might receive written communication from a manufacturer relating to their Year 2000 compliance. It is strongly suggested that this information be cross referenced against the FDA website as a precaution. A copy of the manufacturer's information should be kept as a permanent part of all equipment maintenance histories. If the data are not present in the FDA website, facility data are more recent, or there is a conflict between what the website and written correspondence indicates, please contact the FDA via the e-mail link in the website. This information will aid other users and helps to amplify the compliance effort in this area.
(See Figure 2 on page 18.)

Figure 2
Data Resources for Year 2000 Assessment



Renovation/ Implementation

Renovation/ Implementation

Objectives

The terms, renovation and implementation, address the actions necessary to correct identified Year 2000 problems and place the equipment back into service. Renovation is a task completed by the OEM. Implementing the renovation strategy is typically accomplished by the end user. Each Conditionally Compliant and Non-compliant device will require a strategy for bringing the device into full compliance.

Strategy

Renovation and implementation activities should be prioritized based on information gathered during the assessment phase. To ensure renovation strategies are implemented, facilities must continually track the progress of vendor-provided remedies. It is not uncommon to experience slippage of projected dates promised by the OEM for renovation solutions. Your inventory system software package could provide a mechanism for tracking promised renovation remedies from equipment manufacturers.

The implementation strategy for non-compliant medical devices will include one of the following:

- ***Retire*** – Take the non-compliant device out of service.
- ***Replace*** – Acquire a new compliant device that performs the same function as the non-compliant device and address in-service training needs.
- ***Use as is*** – Continue to use the device if it does not present an unreasonable risk or burden and train clinical staff.

The only Year 2000 renovation activity for conditionally compliant devices is to update those devices based on vendor-provided remedies. These remedies can include hardware updates, software updates, or a one-time user action.

Some conditionally compliant devices have a “latent” design defect and remedies should therefore be provided at no charge from the manufacturer. An update is generally considered a no charge remedy to correct an operating error, and an upgrade includes additional options and features provided at some cost. However, reasonable consideration must be applied since many devices older than ten years typically are no longer supported by equipment manufacturers. This is based on past experience and practice that makes use of Internal Revenue Service tables to determine the useful financial life for this type of equipment.

Monitor assessment phase cost estimates against actual renovation cost to determine the required resources. Resource planning for replacement of non-compliant devices may be addressed by whatever local committee handles medical device decisions.

Finally, it is critical to continually keep management informed of renovation and cost information for budgetary purposes. Identify a list of all unknown compliant devices and project anticipated costs to make these devices compliant or provide alternate strategies.

It is important to note that the Year 2000 is a leap year and necessary precautions should be taken.

Tools and Resources

Year 2000 Inventory System
Facility or system Year 2000 tracking systems should assist in scheduling work requests to perform necessary renovations to non-compliant and conditionally compliant devices.

Document Results
See Appendix C for a sample format of reporting.

Local Procurement Process
All new procurements should include documentation to guarantee the Year 2000 compatibility of the device. (See Appendix E.)

Validation

Validation

Objectives

The validation phase will ensure that actions taken during the Renovation/Implementation phase are effective. This includes both evaluation of identified compliance remedies and the formulation of contingency plans to provide guidance for continued operation of critical medical devices in case of unanticipated, adverse Year 2000 events.

Strategy

Verify the effectiveness of all actions taken on conditionally compliant and non-compliant devices. Make sure that all conditionally compliant equipment that required vendor updates are installed properly and documentation is available. Equipment operation should be checked to assure that functionality has not changed (i.e., in-service may be needed). Also make sure that all non-compliant equipment to be replaced or retired is done so in a timely manner.

Contingency Plans

Develop contingency plans addressing the following events:

1. Medical devices that cannot be renovated successfully to adhere to Year 2000 compliance and are required to remain in use. This includes those devices in which there are no life threatening implications associated with the use, e.g., when only the date output may be in error.

2. Medical devices for which the manufacturer's Year 2000 response is undetermined.

3. Medical devices that exhibit an unanticipated Year 2000 deficiency after December 31, 1999.

A contingency plan should be in effect for each device until the device in question is considered compliant or has been removed from service.

Maintenance of Compliance Status

Although not common, there are instances when the published compliance status of a device is changed from one category to another. After additional testing or other input, manufacturers could need to change the status from compliant to non-compliant or vice versa. When FDA makes changes to its website reflecting the more current information, the issue is raised as to how medical facilities can keep current with new information on a device for which they may already have assessed and tracked in one category or another. Rather than review the entire equipment

inventory on a regular basis, this issue may be addressed through the existing QA program that includes regularly scheduled preventive maintenance (PM) testing. Most devices, and certainly all critical devices, will be reviewed by biomedical engineering staff more than once in calendar year 1999. Before a PM work order is closed out, it is recommended that standard operating procedures be modified to require that the classes of devices for which PM has been accomplished be reviewed for current Year 2000 compliance status. This provides a more manageable means to validate the compliance status by breaking up the workload among staff throughout the year.

Functional Verification

Verify the correct operation for critical equipment items at the time of the change from December 31, 1999 to January 1, 2000.

During this period the Biomedical Engineering Department (or its equivalent) and clinical staff should closely monitor life support devices such as defibrillators, ventilators, critical care monitoring, anesthesia units, dialysis units, etc.

If a conditionally compliant device requires only a date change or other user intervention (such as on/off cycling) after December 31, 1999, to operate according to the manufacturer's original specifications, the device should be discontinued from use on or prior to December 31, 1999. After January 1, 2000, the date can be correctly reprogrammed; the device should be thoroughly tested by qualified personnel, and upon successful testing, returned to service. Once a device has received corrective action to bring it to full Year 2000 compliance and is tested to verify compliance, no further action should be required.

Staffing

Determine the staffing level requirements during the millennium rollover.

Additional staff should be on site at the millennium change to respond to unanticipated failures of critical equipment. These response teams should consist of individuals who are capable of responding to emergency medical equipment failures and they must include biomedical engineers. The facility should provide clinical staff with appropriate "refresher" training in such areas as manual IV drip counting, use of ambu-bags, etc. in the case of unanticipated medical device failure.

Additional biomedical engineering staff on-site at the rollover can be utilized to make the necessary changes for devices requiring a date change and validation.

Scheduling of elective clinical procedures should be avoided during the December 31, 1999/January1, 2000 weekend. In addition, follow-up teams should perform operational verifications on devices not scheduled for use at that time, such as CT scanners, MRI units, Special Procedure rooms, etc., sometime prior to the next business day in 2000.

Year 2000 Readiness

All health care facilities should take the following additional precautions to ensure their respective Year 2000 readiness:

1. Establish a cooperative relationship with another local hospital. This may assist in provision of necessary supplies in the event that the normal suppliers are incapacitated.

2. Implement contingency plans in a timely manner. If time frames for updates/upgrades are repeatedly delayed, it may be an indication that a contingency plan should be developed and implemented promptly for that device. Special care to scrutinize established time frames would minimize these occurrences and their respective impact.

3. Communicate all contingency plans with appropriate clinical and administrative personnel. Where clinical intervention is identified for immediate action, "dry" runs should be

performed. This may involve emergency disaster planning that simulates equipment failure. This will enable each site to:

a. Assess personnel levels necessary to implement these contingency plans,

b. Insure that sufficient materials are in place, and

c. Determine the efficiency of the action.

4. Assume operating ancillary systems for medical devices that rely on them. This can include uninterruptible power, medical gas, water, equipment supplies, etc. To fully ensure complete contingency planning, proper scrutiny of all system support items must be performed. This will require a multidisciplinary approach. It is recommended that all health care organizations involve all disciplines to ensure full Year 2000 Compliance.

Tools and Resources

Year 2000 Sticker Program

Some sites have implemented a program of placing a series of stickers on the equipment that identifies the compliance status (i.e., fully compliant, conditionally compliant, or non-compliant). This not only assists tracking of the compliance of individual equipment items, but it also helps keep clinical staff informed and aware of the Year 2000 status. In fact, this is considered a contingency planning action, since stickers affixed to non-compliant devices that are retained in use provides a reminder to the operator that alternative action is required – e.g., the operator is required to annotate the correct date directly on the device output.

Medical Equipment Contingency Plans

See sample in Appendix D.

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Conclusion

Conclusion

The Year 2000 Problem must be addressed in a timely manner using a systematic approach. The nine steps outlined below are critical. Some of these steps should occur simultaneously.

Step 1 – Develop Awareness: Each organization should establish a project office, assign project responsibility to an office or officer, define needed project support, define product categories, and outline a compliance plan.

Step 2 – Assign Management Responsibility: Each organization should assign management and oversight responsibility at appropriate levels throughout the organization (i.e., corporate, networks, health care facilities). Work groups should be responsible to the Year 2000 project office and could consist of multidisciplinary oversight teams (e.g., radiology, nuclear medicine, pathology, laboratory, cardiology, surgery, biomedical engineering, procurement, medical research, and prosthetics). Other work groups could include biomedical engineers, facilities engineers, and information resource management staff.

Step 3 – Develop Inventory: Develop an accurate accounting of potentially affected medical devices. Establish a repository for data and tools for data collection.

Step 4 – Assign Prioritization/Risk Management: Prioritize and develop a system to manage risk. Define medical device categories and devices at risk within each category. Suggested categories are: life support/ critical care (devices that are likely to seriously harm a patient if they fail), diagnostic, and therapeutic. In addition, identify high profile manufacturers whose products include life support/critical care medical devices, high dollar value, and high volume.

Step 5 – Assess: Identify original equipment manufacturer Year 2000 problems. Develop a manufacturer database, assessment tools, correspondence with manufacturer, track manufacturer responses grouped into categories of compliance, and validate manufacture responses. Develop categories of compliance. For example: *Fully Compliant* – medical device functions properly in all aspects at change

to Year 2000 without requiring user intervention; *Conditionally Compliant* – medical device requires user intervention to function properly in all aspects at change to Year 2000 (manufacturer software and/or hardware update or other one-time user action); *Non-compliant* – medical device will not function properly in all aspects at change to Year 2000 and no manufacturer remedy is available; *Not applicable* – medical device with no Year 2000 implications. Follow up on compliance data and disseminate information throughout the system.

Step 6 – Renovate/Implement: Develop a Year 2000 medical devices implementation guide and use it to monitor manufacturers' schedules and solutions for compliance. Monitor non-responsive manufacturers. Develop medical device contingency plans for non-compliant devices. Provide training to appropriate staff. Ensure that communication is perpetually occurring amongst system staff. Develop a mechanism to track manufacturer Year 2000 repairs.

Step 7 – Validate: Verify that all renovations have been properly implemented. Test each renovated system to ensure that it is actually Year 2000 compliant. Keep a running list of all systems that do not function properly after implementation and take the necessary steps to ensure proper renovation.

Step 8 – Communicate: Establish channels for communicating device information and use them regularly. This can be executed through conference calls, memoranda, electronic mail, meetings and presentations, posting and updating information on the internet, and training sessions.

Step 9 – Prepare Contingency Plans: Contingency plans should be written for all medical devices that are non-compliant, conditionally compliant, loaned/shared, and for those systems where the manufacturer is non-responsive. For facility-related systems and equipment, the following systems should have contingency plans: emergency management systems (utility systems, e.g., emergency generators, fuel in storage tanks, oxygen tanks with valves and holders, and emergency water supply), security systems, alarm systems, fire detection and control, environmental control systems, people movers, and other non-IT systems. With regard to scheduling, contingency plans should be written for operating rooms, dialysis, etc. With regard to staffing, contingency plans should be written for critical care areas of nursing, respiratory therapy, facilities maintenance (engineering), information systems, and biomedical engineering. Contingency plans should also be developed for devices in patients' homes.

Now that you have a handle on the magnitude of the Year 2000 problem and are aware of the necessary actions that should be taken, the process for achieving Year 2000 compliance for your hospital can begin. This guidebook provides a realistic step-by-step approach, which if followed, should enable your medical devices, and facility systems to safely operate at the turn of the century. It is not necessary to tackle this challenge on your own. Many resources have been made available to the public through the internet as well as through other publications by medical device manufacturers as well as both public and private health care organizations and their professional representatives. Take advantage of the progress made by federal agencies, such as VHA and FDA, as well as advances made by large private health care organizations throughout the country through inter-hospital networking.

It is not too late to begin this process NOW. Time is of the essence. Patients' lives are at risk. Make Year 2000 compliance an opportunity for your organization or system to continue preserving the patient care that you have provided throughout this century.

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Appendix A

Appendix A

*Resources**

Government Websites

www.fda.gov/cdrh/yr2000/y2krp298.html
The **U.S. Food and Drug Administration**, Center for Devices and Radiologic Health, status report of product Year 2000 compliance.

www.fda.gov/cdrh/yr2000/year2000.html
The **U.S. Food and Drug Administration**, Center for Devices and Radiologic Health, Site on Year 2000. Contains information on FDA and VHA activities as well as information sent to manufacturers requiring assessment of medical device operability.

www.gao.gov
The **U.S. General Accounting Office (GAO)** is the investigative arm of Congress. A wealth of GAO reports are available on its website regarding Year 2000 government program readiness.

www.senate.gov/~y2k/index.html
The **Special Committee on the Year 2000 Technology Problem** provides detailed information on the Commitee's Year 2000 proceedings.

www.itpolicy.gsa.gov/mks/yr2000/y201toc1.html
This home page, sponsored by the **General Services Administration** and the **Chief Information Officers Council Committee on Year 2000**, is designed to help government and other interested organizations in addressing the Year 2000 problem.

**This is not an all inclusive list. Please note that some of the websites are commercially owned and may charge for use of information.*

www.y2k.gov
The **President's Council on Year 2000 Conversion**. The Year 2000 Information and Readiness Disclosure Act (P.L.105-271) can be found on this site.

www.pccip.gov/info.html
The **President's Commission on Critical Infrastructure Protection (PCCIP)** advises and assists the President by recommending a strategy for protecting critical infrastructures from physical and cyber threats. The Year 2000 is one of the issues discussed and addressed on this website.

www.cdc.gov/y2k/y2khome.html
The **U.S. Centers for Disease Control and Prevention's (CDC)** website on Year 2000 issues — CDC and the Year 2000.

www.nist.gov/y2k/index.html
Information from the **U.S. National Institute of Standards and Technology** on the Year 2000.

Other Websites

www.millennia-bcs.com/CASRFAME.HTML
The Cassandra Project: Year 2000 and the Risks to Public Health and Safety raises public awareness and alerts public sector organizations of potential Year 2000-related health and safety risks and possible interruptions of basic and essential services. Provides Year 2000 links to health and safety issues.

www.easyon.com/users/simmonsp/YEAR2000.html
Summarizes a Hot Topic session on the Year 2000 date problems in health care that was attended by about 200 health care systems people. Summary was written by Paul Simmons of the **Cleveland Clinic Foundation**.

www.gartner.com
The Gartner Group website offers "research and analyses of significant information technology industry developments and trends," including Year 2000.

www.ggtech.com/hospital.html
Website from **Gordon & Glickson P.C.**, an information technology law firm. The firm's Third and Fourth Annual Healthcare Survey revealed that many hospitals have not addressed the computer problem issues expected to accompany the date change to the Year 2000. Survey results are available.

www.healthcare-informatics.com
Website for ***Healthcare Informatics***. Includes the current and back issues of the journal, vendor information, and a review of Information Systems products and services.

www.himss.org
Web site for **Healthcare Information and Management Systems Society**, a non-profit organization dedicated to promoting a better understanding of health care information and management systems. HIMSS represents over 9,000 health care professionals. The website includes information on HIMSS, its resources and publications, education programs, and advocacy. Year 2000 information is included.

**This is not an all inclusive list. Please note that some of the websites are commercially owned and may charge for use of information.*

www.itaa.org
The **Information Technology Association of America** contains analytical papers and information on ITAA's Year 2000 Certification Program.

www.mmue.com/year2000/index.html
The Metro Detroit Healthcare Year 2000 User Group website contains many links to articles and other organizations.

www.y2k.gov.au/biomed/index.html
The Year 2000 Biomedical Engineering Database is produced with the assistance of the **New South Wales Department of Health** and reports compliance status of biomedical equipment. Equipment is listed by manufacturer, model number, and description. They are actively seeking additional information for the database.

www.orhs.org/year2000/index.html
Sponsored by the **Orlando Regional Healthcare System (FL)**, contains links to other health care related Year 2000 sites and also provides information for its electronic mailing list.

www.rx2000.org
Rx2000 Solutions Institute is developing a number of resource and services specifically for the health care industry. Includes articles and publications, links to other sites, a PowerPoint presentation on Year 2000 issues, listing of local/regional executive briefings, and other information.

www.simnet.org
The **Society for Information Management** Year 2000 Working Group has online discussions about Year 2000 infrastructure problems, including embedded systems and medical equipment.

www.ttuhsc.edu/pages/year2000
Year 2000 site is maintained by **Texas Tech University Health Sciences Center**. Includes vendor listings, resources, web links, and other resources.

www.y2klinks.com
The **Year 2000 Links Database** site provides links and an informational database. Year 2000 Links is also the hub of the Year 2000 Millennium Resource Site Ring, a group of websites dedicated to the Year 2000 problem, which combined are the largest Year 2000 resource on the internet.

www.year2000.com
This **Year 2000** site is a forum for distributing information and discussing solutions. Includes articles and white papers on copyright and legal perspectives, as well as press clippings, user discussion groups, and related links. A section exists for frequently asked questions, an independent assessment of tools for testing PCs, and a directory of vendors.

**This is not an all inclusive list. Please note that some of the websites are commercially owned and may charge for use of information.*

Congressional Hearings and Publications on Year 2000 Issues

Year 2000 Special Committee

The Year 2000 Special Committee was created:
1) to study the impact of the Year 2000 technology problem on the Executive and Judicial Branches of the Federal Government, State governments, and private sector operations in the United States and abroad;
2) to make such findings of fact as are warranted and appropriate; and
3) to make such recommendations, including recommendations for new legislation and amendments to existing laws and any administrative or other actions, as the Special Committee may determine to be necessary or desirable.

For more information on the Special Committee on the Year 2000 Technology problem, see the Committee's website at: www.senate.gov/~Y2K/index.html

House of Representatives Hearings Held

The hearings listed below pertain only to the Department of Veterans Affairs. Other hearings can be found at www.house.gov/va/issues/year2000/y2k.html

House Committee on Veterans Affairs hearings on VA Year 2000 issues

1998
1. Oversight and Investigations Subcommittee Reviews VA Department's Readiness for Year 2000, September 24, 1998

1997
1. Year 2000 (Y2K) computer compliance issues and their impact on the Department of Veterans Affairs, September 25, 1997

2. Department of Veterans Affairs' efforts to achieve computer compliance with Year 2000 Requirements, June 26, 1997

Senate Hearings Held

Other hearings can be found at www.senate.gov/~y2k/index.html

1. Utilities
Lead Committee Member: Chairman Bennett, June 12, 1998, Washington, D.C.
Hearing to Discuss *Chances the Millennium Bug Will Cause the Nation's Power Grid to Fail*

2. Health Care Services
Lead Committee Member: Vice-Chairman Dodd, July 23, 1998, Washington, D.C.
Hearing: *Will the Health Care Industry Be Prepared for the Year 2000?*

GAO Testimony, Reports, and Publications

Information can be obtained from GAO's website at www.gao.gov

A Testing Guide — November 1988 (GAO/T-AIMD-10.1.21)

Actions Needed on Electronic Data Exchanges — July 1, 1998 (GAO/T-AIMD-98-124)

An Assessment Guide — September 1997 (GAO/AIMD-10.1.14)

Avoiding Major Disruptions will Require Strong Leadership and Effective Partnerships — August 19, 1988 (GAO/T-AIMD-98-267)

Business Continuity and Contingency Planning — August 1998 (GAO/T-AIMD-10.1.19)

Compliance Status of Many Biomedical Equipment Items Still Unknown — September 18, 1998 (GAO/AIMD-98-240)

Leadership Needed to Collect Disseminate Critical Biomedical Equipment Information — September 24, 1988 (GAO/T-AIMD-98-310)

Potential for Widespread Disruption Calls for Strong Leadership and Partnerships — April 30, 1998 (GAO/T-AIMD-98-85)

Severity of Problem Calls for Strong Leadership and Effective Partnerships — September 3, 1998 (GAO/T-AIMD-98-278)

Strong Leadership and Partnerships Needed to Address Risk of Major Disruptions — August 17, 1998 (GAO/T-AIMD-98-266)

Strong Leadership needed to Avoid Disruption of Essential Services — March 24, 1998 (GAO/T-AIMD-98-117)

Strong Leadership and Effective Partnerships Needed to Mitigate Risks — September 1, 1988 (GAO/T-AIMD-98-276)

Strong Leadership and Effective Partnership Needed to Reduce Likelihood to Adverse Impact — September 2, 1998 (GAO/T-AIMD-98-277)

Telecommunications Readiness Critical, Yet Overall Status Largely Unknown — June 16, 1998 (GAO/T-AIMD-98-212)

Testing and Other Challenges Confronting Federal Agencies — June 22,1998 (GAO/T-AIMD-98-218)

U.S. General Accounting Office. *Medicare Transaction System: Serious Managerial and Technical Weaknesses Threaten Modernization*. Washington, D.C. — 1997.

U.S. General Accounting Office. *Veterans Benefits Computer System*: *Uninterupted Delivery of Benefits Depends on Timely Correction of Year-2000 Problems*. Washington, D.C. — 1997.

U.S. General Accounting Office. *Veterans Health Administration Facility Systems: Some Progress Made in Ensuring Year 2000 Compliance, But Challenges Remain*. Washington, D.C. — 1997.

Articles and Publications

Hospital Computers Not Prepared for Next Century, Survey Finds.
Health Care Strategic Management. Apr. 1997.

McCormick, J. Beyond the Hype: Proved Strategies for Fixing the Year 2000 Problem.
Health Data Management. Jan. 1998.

McCormack, J. 2000: How Are Vendors Fixing Their Year 2000 Problems?
Health Data Management. Jun. 1998.

Patient Care at Risk from Millennium Bug. *Computer Weekly*. Aug. 5, 1997.

Quayle, C. Year 2000: Bug or Bugaboo? Either Way, Start Upgrading Your Facility's Equipment for the New Millennium. *Health Facilities Management*. Feb. 1998.

Shimkus, J. Millennium Meltdown: Code Blue 2000. *Trustee*. April 1998.

Vowler, J. How Lethal Is the Millennium Bug? *Computer Weekly*. June 11, 1997.

Year 2000: Hospitals Diagnose Themselves in Critical Condition. *Computerworld*. Mar. 2, 1998.

You Don't Have to Go it Alone. *Materials Management in Health Care*. Nov. 1997.

This is not an all inclusive list. Many other courses were available.

1998 Educational Programs*

Below is a list of organizations where conferences have already occured. Proceedings are available from sponsoring organizations. Similar workshops may be added in 1999. Contact the sponsoring organizations directly for more information.

Date: June 3
Program: ***Ensuring High Standards of Patient Care***
Location: Teleconference
Host: Georgia Hospital Association

Date: June 5
Program: ***The Year 2000 Problem: What Every Lawyer Needs to Know*** (part of Ninth Annual Advanced Computer Law Seminar)
Location: Dayton Convention Center, Dayton, OH
Host: The University of Dayton School of Law

Date: June 9
Program: ***Year 2000 Issues*** (session at Kansas Hospital Association's Summer Educational Seminar)
Location: Salina Holiday Inn, Salina, KS
Host: Kansas Hospital Association

Date: June 10
Program: ***Developing a Solid Contingency Plan***
Location: Teleconference
Host: Georgia Hospital Association

Date: June 18-19
Program: ***Year 2000 Computer Crisis: The Litigation Summit***
Location: Hyatt Regency, Atlanta, GA
Host Fulcrum Information Services, Inc.

Date: June 22-23
Program: ***Year 2000 Millennium Bug: Legal Liability & Risk Avoidance***
Location: Watergate Hotel, Washington, D.C.
Host: National Professional Communications Company

Date: July 13-17
Program: ***American Society Healthcare Engineering Annual Conference*** (various Year 2000 sessions offered)
Location: Denver, CO
Host: American Society of Healthcare Engineering

This is not an all inclusive list. Many other courses were available.

Date: July 30-31
Program: ***Year 2000 Computer Crisis: The Litigation Summit***
Location: Hyatt Regency, San Francisco, CA
Host: Fulcrum Information Services, Inc.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is providing a series of educational programs on the Year 2000 entitled, "Preparing Your Healthcare Organization for the Year 2000." The programs are offered in cooperation with sponsors from around the country and include the following dates:

November 16, 1998	Lincoln, NE
December 7, 1998	Roanoke, VA
January 25, 1999	Boston, MA
March 5, 1999	Dallas, TX
April 9, 1999	Greensboro, NC
April 21, 1999	Columbus, OH
May 3, 1999	Oklahoma City, OK
September 23, 1999	Northbrook, IL

For further information, please contact the customer service department at (630) 792-5800, or look for the program on JCAHO's website: www.jcaho.org

Appendix B

Prioritization of Medical Devices

The following table provides an example of how one organization prioritized its medical devices based on three categories: High Dollar Value (over $250,000 per product), High Volume (multiples at each site), and Critical Care/Life Support. A similar approach could be taken by any health care organization.

Manufacturer	Device	High $ Value	High Volume	Critical Care/ Life Support
Abbott Lab			X	
Acuson			X	
ADAC		X		
AMSCO (See Steris Corp)			X	
ATL (Adv Tech Lab, 9-19-97)			X	
Baxter	Rx Dispensing Systems		X	
Bayer Corp (Technicon)		X		
Biotronik				X
Bird			X	X
Cardiac Pace (See Guidant)	Pacemakers			X
Cemax-Icon		X		
Circon				X
CMS (Comp. Med. Sys.)	Radiation Planning	X		
Cobe				X
Cordis (Pacesetter St. Jude Medical Co)	Pacemakers			X
Diasonics Ultrasound		X		
ELA Medical				X
Elscint		X		
Fresenius				X
Fuji		X		
Gambro (See COBE)				X
General Electric		X		
Guidant	Pacemakers			X
Hewlett Packard		X	X	X
IMED (See ALARIS)			X	
Intermedics				X
IVAC (See ALARIS)			X	
Kodak		X		
Liebel-Flarsheim		X		
Marquette (CGE)		X	X	X
Medtronic				X
Mennen				X
Nellcor Puritan Bennet			X	X
North American Draeger				X
Ohmeda				X
Pacesetter St. Jude Medical Co.	Pacemakers			X
Philips Medical Sys		X		
Physio Control	Defibrillators		X	X
Picker	CT, MRI	X		
Sharplan				X
Siemens		X	X	X
Siemens-Elma (See Pacesetter St. Jude Medical Co)	Pacemakers			X
Spacelabs		X	X	X
Steris Corporation			X	
Sterling Diagnostics		X		
Teletronics (See Pacesetter St. Jude Medical Co)	Pacemakers			X
Theratronics		X		
Toshiba		X		
Valley Lab				X
Varian		X		
Ventritex (See Pacesetter St. Jude Medical Co)	Pacemakers			X
Viatron (See Medtronic)				X
Zoll			X	X

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Appendix C

Tracking Medical Device Compliance Inventories and Cost Data

This is a sample spread sheet used for tracking medical device compliance inventories and cost data.

Year 2000 Project Progress Report – Medical Devices

See Instructions Below

Health Care System:
Health Care Facility:
Report Month and Year:
Originator Name:
Originator Phone:

		Compliant	Non-compliant								Conditional Compliant			Others		
	Total Qty. in Inventory	Qty. Fully Compliant (FC)	Qty. Non-compliant (NC)	Qty. to Replace	Qty. Replaced to Date	Qty. to Retire	Qty. Retired to Date	Qty. to Use As Is	Qty. Unknown Strategy	Estimated Total Renovation Cost for NC, $	Qty. Conditional Compliant (CC)	Qty. Repaired to Date	Estimated Total Renovation Cost for CC, $	Qty. Not Applicable (NA)	Qty. Null or Yet to Be Assessed	Estimated Completion Date
Entry Type	Num	Num	Num	Num	Num	Num	Num	Num	Num	Num	Num	Num	Num	Num	Num	Date
Entry Size	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	Unltd.	mm/dd/yyyy
Medical Devices																

Unltd. = Unlimited Field Length

Instructions for Medical Devices report
Total quantity in inventory: Enter the total number of medical devices in the inventory.

Fully Compliant
Quantity fully compliant (FC): Enter the total (cumulative) number of devices that have been assessed as Year 2000 compliant.

Non-compliant
Quantity non-compliant (NC): Enter the total (cumulative) number of devices that have been assessed as Year 2000 non-compliant.
Quantity to replace: Enter the total number of non-compliant devices that will be replaced with compliant devices to solve the Year 2000 problem.
Quantity replaced to date: Enter the cumulative number of on-compliant devices that have actually been replaced to date.
Quantity retired to date: Enter the cumulative number of non-compliant devices that have actually been retired to date.
Quantity to use as is: Enter the total number of non-compliant devices that will be used as is.
Quantity unknown strategy: enter the total number of non-compliant devices for which a renovation strategy has not been established.
Estimated total renovation cost for NC: Enter the estimated total cost to renovate non-compliant devices, without regard to strategy.

Conditional Compliant
Quantity conditional compliant (C): Enter the total (cumulative) number of devices that have been assessed as Year 2000 conditional compliant.
Quantity repaired to date: Enter the total (cumulative) number of conditional compliant devices that have been repaired to solve the Year 2000 problem, to date.
Estimated total renovation cost for CC: the estimated total cost to renovate conditional compliant devices.

Others
Quantity not applicable (NA): Enter the total number of devices that do not have any computerized function.
Quantity null or yet to be assessed: Enter the number of devices that have yet to be assessed.

Estimated completion date: Enter the estimated date on which the entire Year 2000 process of assessment, renovation, and returning to service affected devices will be completed.

Appendix D

Sample
Developed to Meet JCAHO Environment of Care Policy Agenda for the Year 2000
Contingency Plan Medical Equipment Management Program Addendum — 6/22/98

Year 2000 Readiness

Introduction: The Year 2000 (Y2K) millennium change will present certain challenges to the operation of computer-based Medical Equipment throughout the Medical Center. All microprocessor based equipment that utilize a two-digit code to represent the year will be affected. This addendum will summarize the [Medical Center] VA Biomedical Engineering Department's response to managing risks associated with the Year 2000 issue as it pertains to all diagnostic, therapeutic, and monitoring equipment throughout the hospital.

The facility has formulated a Year 2000 response team consisting of the Chief, Biomedical Engineer as coordinator, the Chief, IRM and the Research Administrator. A reporting structure through the Medical Center Director to the hospital network has been established. All reports go through the Medical Center Director to the Chief Information Officer, hospital network. The hospital network holds monthly video teleconferences on the subject of Year 2000 for the Medical Center representatives.

Responsibility: The Biomedical Engineering Department has complete responsibility of managing the clinical and physical risks associated with the use of medical equipment. For the purpose of this addendum, medical equipment will pertain to all diagnostic, therapeutic, and/or monitoring equipment utilized within the facility.

Action: Biomedical Engineering will take the following action to minimize the risk of Year 2000 on medical equipment:

A. Inventory all Medical Equipment. The Biomedical Engineering Department utilizes the inventory system for tracking all medical equipment. This inventory is maintained to track any and all actions associated with medical equipment. Year 2000 assessments, reports, updates, and costs will be recorded in the inventory system and transmitted to the hospital network office for tracking.

B. Assessment. All medical equipment will be assessed for Year 2000 compliance status based upon the following categories :

Fully Compliant (FC) – A medical device that functions properly in all aspects upon the change to the Year 2000 without requiring user intervention.

Conditionally Compliant (CC) – A medical device that requires user intervention to function properly in all aspects upon the change to the Year 2000. This may include a manufacturer software and/or hardware update or other one-time user action.

Non-compliant (NC) – A medical device that will not function properly in all aspects upon the change to the Year 2000 and no manufacturer remedy or support is available.

Not Applicable (NA) - A device for which there are no electronic components and therefore no Year 2000 implications.

C. Documentation. As stated, the inventory system software will be used for all medical equipment Year 2000 documentation. Sources of confirmed Year 2000 status communication will be :

FDA Website – www.fda.gov/cdrh/yr2000/year2000.htm
Manufacturer letter or website
Local assessment

Local assessments will only be performed on those devices that are clearly Year 2000 compliant or Not Applicable. These will be defined as devices for which there is a low criticality and no microprocessor involvement and those devices that have no electronic components.

D. Reporting Structure. The hospital network requires monthly reporting of time associated with Year 2000 issues. This time will be transmitted by the Chief, Biomedical Engineer to the hospital network Year 2000 coordinator through the use of electronic e-mail (MS Exchange). In addition, the hospital network requires quarterly updates on Medical Equipment Year 2000 assessments. Again, these will be transmitted electronically through the use of MS Exchange.

Internal reporting will utilize the local VistA DHCP e-mail system and an e-mail group consisting of: Associate Medical Center Director, Chief, IRM, Chief FMS, Chief, Biomedical Engineering, Chief, MAS, Research Administrator, and MAS representative for Telecommunications.

E. Renovation. All medical devices classified as Conditionally Compliant or Non-compliant will require one of the following actions:

- Replacement
- Software Upgrade
- Hardware Upgrade
- Software and Hardware Upgrade
- Decommission

Biomedical Engineering will be responsible for initiating the above actions for any devices in those categories. A report to the Chief, A&MM for Equipment Committee review will be prepared to address budgeting forecasts. Coordination of upgrades and replacement will be supervised by Biomedical Engineering.

F. Contingency Planning.

Medical Equipment Contingency Plan Objectives: The objective for contingency planning is to provide guidance for continued operation of mission critical devices in the event of adverse Year 2000 compliance issues.

Criteria for Invoking the Plan: The following plans should be implemented in the event that :

1. A medical device can not be renovated successfully to adhere to Year 2000 compliance and the device remains in use and is mission critical.
2. A medical device exhibits an unanticipated Year 2000 deficiency after 12/31/1999.

Expected Life of the Plan: This plan should be implemented with adequate time for implementation (as deemed appropriate by the organization) and continue in effect until a suitable permanent solution is identified and implemented.

Responsibility: Appoint an individual(s) who will be responsible for implementing Year 2000 medical device contingency plans. All responsibility lies with the (specify — e.g., Biomedical Engineering Department).

Procedures for Invoking Contingency Planning:

Non-compliant Devices

Prior to 12/31/1999, contingency planning must be developed by each organization for those devices that have been assessed as Year 2000 Non-compliant. The contingency plan should take into account whether the device is mission critical or not, and could take one of the following forms:

1. Device is not mission critical, is no longer necessary, and is retired prior to 12/31/1999.

2. The non-compliance for the particular device requires only a date change after 12/31/1999 to operate according to the manufacturer's original specifications. In these cases, the device will be discontinued from use on or prior to 12/31/1999. After 1/1/2000, the date will be correctly programmed, the device will be thoroughly tested by qualified personnel and, upon successful testing, returned to use.

3. Device will be removed from service prior to 12/31/1999. A suitable replacement will be identified, purchased, and placed into use prior to 1/1/2000.

Conditionally Compliant Devices

For those devices that have been assessed as Conditionally Compliant, based upon a corrective action required, the contingency plan can be as follows:

1. Each device will be inventoried and coded "Conditionally Compliant". A date of estimated compliance completion will be recorded. The inventory will allow for tracking and reporting all conditionally compliant devices listed with date of anticipated correction.

2. If a conditionally compliant device has not received corrective action to bring the device to full Year 2000 compliance prior to 12/31/1999, the device will be treated as a non-compliant device and the contingency plan can follow the appropriate plan as outlined above.

3. Once a device has received corrective action to bring to full Year 2000 compliance and is tested to verify compliance, no further action will be required.

G. General Guidelines.

To ensure Year 2000 readiness, health care organizations should take the following additional precautions.

1. Identify alternate sources for non-compliant and conditionally compliant devices that have not received one of the aforementioned contingencies. These sources must be capable of delivering a suitable replacement device that is fully Year 2000 compliant. Verify availability and ensure that cost mechanisms are in place for immediate need.

2. A Year 2000 response team should be in place 12/31/1999 through 1/1/2000. This team will consist of individuals who are capable of responding to emergency medical equipment failures. The responsibility of the team would include unanticipated emergency response to critical equipment failure.

3. The [health care organization] should establish a correspondent relationship with another local hospital. This may assist in provision of necessary supplies in the event that the normal suppliers are incapacitated.

4. Implementation of contingency plans in a timely manner is critical to success. If time frames for updates/ upgrades experience repeated delays, it may be an indication that a contingency plan should be developed and implemented promptly. Special care to scrutinize established time frames will minimize these occurrences and their respective impact.

5. Communication of all contingency plans with the proper clinical and administrative personnel is essential. Where clinical intervention is identified for immediate action, “dry” runs should be performed. This may involve emergency disaster planning and will enable each site to assess personnel levels necessary to implement, sufficient materials, and efficiency of action.

Appendix E

Procurement Guidelines*

Objectives

Procurement departments play a major role in Year 2000 projects. Acquisition and Materiel Management (A&MM) departments are responsible for all vendor contracts. They are responsible for the initial negotiation of new contracts, review and extension of existing contracts, and resolution of performance issues with vendors. Thus, they have considerable leverage over vendors and are an important checkpoint in the compliance process.

Local Acquisition and Materiel Management departments must ensure that all existing and new contracts have Year 2000 language in place. It is also recommended that facility equipment committees be reminded of purchasing equipment that is compliant. VA uses an example utilizing Federal Acquisition Requirements (FAR) language. This language can be modified for individual contracting purposes.

In accordance with FAR 39.106, all items under this contract that contain information technology that performs date/time processing, shall be Year 2000 compliant, or must be upgraded to become Year 2000 compliant prior to the earlier of the following:

a) The earliest date on which the information technology may be required to perform date/time processing involving dates later than December 31, 1999, or on December 31, 1999.

b) Software for operation of the system; image acquisition, manipulation, reconstruction, analysis, and display; and maintenance of the system shall be provided by the contractor. The software updates compatible with the offered system's hardware shall be kept current at no cost to the Government as long as the equipment is in use in the VA or other Government agency health facility.

c) For the purpose of this clause, updates are defined as all modifications to correct or improve system operation and current functions. Upgrades, defined as providing additional functions, will be made available for purchase. Software revisions or modifications, which include both updates and upgrades, must be provided at no cost. The contractor may restrict added functions if restriction does not limit existing functions.

** This is an example of procurement guidelines sent out to VA medical centers. It was recommended that a similar document be produced for each department within the network.*

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Year 2000 and Related Terms

Year 2000 and Related Terms

Acceptance Test – Formal tests conducted on a product to determine whether a system satisfies its acceptance criteria. Acceptance testing enables the customer to determine whether to accept a system.

Assessment Phase – The interval in the Year 2000 lifecycle when efforts center on determining the size, scope and approach required to renovate the portfolio of applications and products so that they will continue to function correctly regardless of date changes. The application portfolio is partitioned into upgrade units and project plans are developed for each upgrade unit. A pilot project is sometimes executed as a part of this effort to help determine metrics used to refine the estimates for the upgrade units.

Awareness Phase – Period in the Year 2000 lifecycle when efforts focus on promoting Year 2000 awareness at all levels across the enterprise. The Awareness phase identifies key points of contact throughout the enterprise; during this period, points of communication are established and information is made available, laying the groundwork for the later phases in the Year 2000 lifecycle.

Bridge – Interface routines between applications, databases, and/or external interfaces that support date expansion or contraction to reconcile date format differences between applications and data sets. These bridges are used to convert dates to the proper format (e.g. converting two-digit year dates to four digits, or vice versa) depending on the requirements of/for an application, a database, or an external interface.

Business Plan – An action plan that the enterprise will follow on a short-term and/or long-term basis. It specifies the strategic and tactical objectives of the company over a period of time. The plan, therefore, is time dependent; it will change with the enterprise. Although a business plan is usually written in a style unique to a specific enterprise, it should concisely describe “what” is planned, “why” it is planned, “when” it will be implemented, by “who” and “how” it will be gauged. The architects of the plan are typically the principals of the enterprise.

Certification – For a product, it is the sign-off by a recognized authority that a particular product has passed successfully through the validation/testing phase and is Year 2000 compliant. Certification is also the process that is used to determine Year 2000 compliance for a product. Certification is the final step in the validation/ testing phase for migrating the renovated systems to the implementation phase.

Compliance – Year 2000 compliant application systems are capable of correct identification, manipulation, and calculation into the next century (i.e., using dates outside the 1900-1999 year range) and have been tested as such. This definition allows for short-term compliance using procedural approaches and long term compliance utilizing data approaches. VHA uses FAR 39.002 as the statement of compliance.

Compliance Strategy – The approach to storing, exchanging, and processing date information that a system or group of systems will use to mitigate Year 2000 impacts. See Redevelopment, Renovation, and Replacement.

Component – A single resource with defined characteristics. The component concept is used in defining precise specifications for testing the validity of various resources. These components are also defined by their relationship to other components.

Conditionally Compliant – A medical device that requires user invervention to function in all aspects upon the change to the Year 2000. This may include a manufacturer software and/or hardware update or other one-time user action.

Configuration Management – The continuous control of changes made to a system's hardware, software, and documentation throughout the development and operational life of the system.

Contingency Plan – In the context of the Year 2000 program, a plan for responding to the loss of a system due to a Year 2000 problem. In general, a contingency plan describes the steps the enterprise would take — including the activation of manual or contract processes — to ensure the continuity of its core business processes in the event of a Year 2000 induced system failure.

Date Expansion – A physical solution that uses four digits everywhere to represent the year. During the renovation phase all dataset/database year dates are expanded to four digits, and data types for date references for the year in applications are converted to handle four digits. Usually, all screens and reports must be modified to accept four digit years. For example, see Window.

Detailed Analysis – Provide detailed information about system exposure to aid in selecting a renovation approach and establishing system priorities. Requires use of "analysis" tools designed to identify complexity (use of embedded logic, literals, date fields within record keys, inconsistent naming, mixed formats, etc.). Analysis includes source code, files, databases, sorts, reports, screens, call modules, and copy members.

Debug – With software, to detect, locate, and correct logical or syntactical errors in a computer program.

Embedded System – Generally weapons, navigational, security, warning, guidance, medical devices, safety equipment, HVAC systems, and other real time systems that employ computing in performing their functions. An embedded system will usually have a microprocessor or micro-controller that is a component of some larger device that performs real-time operations.

Encoding – A renovation technique that allows additional century information to be packed into existing application parameters and data fields, leaving existing dataset fields and application date references unchanged. Encoding and decoding routines are developed to pack and unpack (store/retrieve) date information from these encoded dataset parameters and fields. An alternative to date expansion or windowing for remediation of systems.

FDA – U.S. Food and Drug Administration

Functional Testing – The process of verifying that a product's functions perform as specified.

GAO – U.S. General Accounting Office

IEEE – Institute of Electrical and Electronics Engineers, Inc.

Impact Assessment – That portion of the Year 2000 lifecycle that identifies the at-risk products, describes their attributes in a library, and determines their status. An order of magnitude of the size, scope, and complexity of the Year 2000 problem is established based on this inventory of information on the attributes of the at-risk products. The skill sets, resources, and amount of effort required to bring the products into Year 2000 compliance are estimated.

Implementation Phase – The final portion of the Year 2000 lifecycle in which effort is focused on moving the Year 2000 compliant systems into production mode with minimal impact to production.

Implementation Strategy – Systematic approach designed to place certified Year 2000 compliant systems into production; addresses resources to be used and how each will be utilized.

Integrated Product Team (IPT) – A multidisciplinary team led by the Program Manager. An IPT is in charge of acquisition of a product or service throughout the product's lifecycle; team members represent those functions with a major interest in the project; member disciplines should include technical, business, project, schedule, procurement, finance, etc., as appropriate to the product under acquisition.

Integration Testing – The orderly progression of testing in which software elements, hardware elements, or both, are brought together, combined, and tested until all interface/communication links have been integrated. Brings renovated product components or software units together, and determines if there are problems or faults in their interactions. Integration is usually employed as a bottom-up method, and is a key element of testing both internal and external interfaces.

Interface – The informational boundary between two products, components, elements, or modules. Interfaces are usually classified into "internal" and "external" interfaces.

Inventory – The process of collecting system product data in a database, and reporting it to appropriate enterprise personnel. Inventories are critical to the sizing and scoping of the Year 2000 effort, and the inventory data of products and their attributes is used to support and justify cost estimates, system status, interface status, and certification information.

IRM – Information Resources Management

ISO 8601 – This date standard has been adopted by the Federal Information Processing Standard and is the recommended format to be used in interfaces that exchange date formats with external agencies and organizations. The ISO 8601 format is: CCYYMMDD where:

CC =century
YY = year
MM = month
DD = date

Leap Year – There are three factors used to determine which years are leap years. Leap years occur every four years. If the year is divisible by four (4), it is a leap year, unless the year is divisible by 100 (then it is not a leap year). However, if the year is also divisible by 400, then it is a leap year. The year 1900 was not a leap year; the year 2000 is a leap year.

Lifecycle – Period of time beginning when a software product is conceived and ending when the product is no longer available for use. The Year 2000 lifecycle is typically broken into phases, such as, 1) Awareness, 2) Impact Analysis, 3) Renovation, 4) Validation/testing, 5) Implementation, and 6) Operation and Maintenance.

Line of Code (LOC) – Usually a number representing the total count of all lines of code (code statements in a module, application, or system), including executable code, declarative statements, comments, and blank lines.

Management Information Systems (MIS) – Generally support related systems such as payroll, personnel, and inventory control systems. Also referred to as Automated Information Systems (AIS).

Metrics – A rule for the conduct of some measurement of some characteristic. The results of performing the rule of measurement. Common software measurements include LOC, and quality measures.

Millennium – A thousand-year period marked at the end by a particular event.

Millennium Bug – Term also used to describe the Year 2000 problem.

Mission Critical – A product or system essential to the successful operation of an enterprise. Failure of a mission critical system cannot be tolerated by the enterprise.

Module – A module is a separately invoked element of a system.

OEM – Original Equipment Manufacturer

Operating System – The software which schedule tasks, allocates storage, handles the interface to peripheral hardware, and presents a default interface to the user when no application program is running.

Platform – The foundation technology of a computer system. Typically, a specific combination of hardware and operating system.

Potential Problems Resulting from Year 2000 – Ambiguous or erroneous calculations, erroneous sorts, spurious data selection criteria. archived data problems, data file corruption, dates as parts of names or security passwords, leap year related problems, and non-date functions using system date fields for hashing, generating random numbers, or recycling tapes.

Process – The sequence of steps that are performed in accomplishing some task, procedure or operation. Examples are the workflow processes that an organization uses in developing a software product, system, upgrade, or system validation/testing. Processes usually involve multiple stages, multiple types of activities, and often, performing them in parallel may optimize some of the activity's processes.

Project Management Plan (PMP) – Defines the organization's overall strategy in detail. Addresses Year 2000 goals and supporting objectives. Essential to Year 2000 management efforts at the and development/ maintenance levels. Documents acquisition and resolution strategies, certification and accreditation processes, cost/benefit analyses, performance measures, management approaches, responsibilities, configuration management, etc.

Quality Assurance (QA) – All the planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Redevelopment – Current application/system is reengineered using a new technology such as client server or an existing technology prior to its event horizon.

Regression Testing – Rerunning test cases that a program has previously executed correctly to detect errors created during renovation or modification activities. Testing that is performed after making a functional improvement or repair of an application. Regression testing is used to determine if a change has affected the correct operation of the system.

Reliability – The probability that a given product will satisfactorily meet its specifications in the performance of a required task or mission for a given time period.

Remediation – Describes the fix or conversion of at-risk Year 2000 code or data to achieve Year 2000 compliance. See Date Expansion, Encoding, Window.

Renovation – Modifying an applicant/system to meet the year 2000 compliance requirement (usually transparent to the user). Includes short term "survival" approaches along with long-term approaches.

Renovation Phase – Period in which efforts focus on making non-compliant systems compliant.

Renovation Strategy – Systematic approach designed to ensure Year 2000 compliant systems are made compliant using either the data approach, procedural approach, or both; addresses resources to be used and how each will be utilized.

Replacement – The current application/system is replaced by another application/system prior to its event horizon.

Requirement – A condition, capability, or other specified factor that a product must possess to satisfactorily solve a problem, satisfy a user, or otherwise achieve an objective.

Risk Assessment – A continuous process performed during all phases of system development to provide an estimate of the damage, loss, or harm that could result from a failure to successfully develop individual system components.

Risk Management – A management approach designed to reduce risks inherent to system development.

Software – Computer programs, procedures, rules, other files and associated documentation and data necessary to the operation of a computer system.

Strategic IRM Plan – A long-term, high-level plan that defines a systematic way of how the agency will use information technology to effectively accomplish the agency's missions, goals, and objectives.

System – By necessity, a very general "context sensitive" term. The IEEE Standard Glossary of Software Engineering Terminology defines system as a "collection of components organized to accomplish a specific function or set of functions." It also defines a subsystem as "a secondary or subordinate system with a larger system." MIL-STD-498 (5 December 1994) tries to deal with the potential ambiguity as follows:

a. The term "system," as used in this standard, may mean: 1) a hardware-software system (e.g., a radar system) for which this standard covers only the software portion, or; 2) a software system (e.g., a payroll system) for which this standard governs overall development.

b. If a system consists of subsystems, all requirements in this standard concerning system apply to the subsystems as well. If a contract is based on alternatives to systems and subsystems, such as complex items, the requirements in this standard concerning the system and its specification apply to these alternatives and their specifications.

Test – The examination and analysis of a product or a product component to determine that it is working or performing correctly.

Testing – The execution of a system product in a real or simulated environment to identify defects and/or determine that requirement specifications are met. The measurement and evaluation of a product's attributes and capabilities.

Unit Testing – Unit testing is used by the developers to expose faults on each software unit as the unit is coded or modified. The module is tested as it becomes available and is evaluated against its design specifications, ensuring coverage of the modules functions and capabilities.

Utilities – Computer programs designed to perform maintenance work on the system or on system components — e.g., a storage backup program, a disk or file recovery program, or a resource editor.

Validation Phase – Period in the Year 2000 lifecycle during which efforts are focused on the testing of the renovated product, the certification process, and the accreditation of systems for Year 2000 compliance. Determination of the correctness of the final program or software produced from a development project with respect to the user needs and requirements.

Verification – The process of determining that a product in a given phase of the Year 2000 lifecycle satisfies the input criteria for that step, and that the evaluation or analysis in that step can be traced to the incoming objectives established during the previous phase. Techniques used for verification include testing, inspection, and reviewing.

VHA – Veterans Health Administration

Window – VHA procedural remediation technique (a logical approach as opposed to a data solution (physical solution)) for converting dates to and from applications or datasets that usually leaves existing two-digit applications and data sets largely unchanged. Windowing will work for dates that span at most 100 years. There are two major forms of windowing. The windowing solution normally involves fewer changes to the applications code and data set, since the date references and data are not expanded. However, the windowing solution introduces the possibility of ambiguity in interpreting date data (both on input and output to screens and reports), adds processing to the code, and is more complex to maintain than a date expansion solution.

Year 2000 Compliant – A system that has been validated and shown to perform properly on dates that span both the 1900s and 2000s, and does not burden the user with limitations or constraints that would be imposed by a Year 2000 ready product.

Year 2000 Life Cycle – A conversion model comprised of five phases, each representing a major Year 2000 activity for bringing a system product into Year 2000 compliance. The five phases are:

a. Awareness - The definition and understanding of the year 2000 problem as it pertains to an enterprise. The gaining of executive level support and sponsorship, and staff appreciation of the potential Year 2000 impacts to the enterprise.

b. Assessment - Inventory of at-risk products and valuation of the year 2000 impact on the enterprise; development of a risk program and identification of contingency plans to handle data exchange issues; triage (prioritize) systems by identifying those that are mission critical.

c. Renovation - The remediation of the at-risk products to bring them into Year 2000 compliance. The conversion, replacement, or elimination of selected products, platforms, systems, or applications, including the modification of internal and external interfaces to remove date ambiguities.

d. Validation - The testing, validation, and certification of the converted or replaced product.

e. Implementation - The cutover of the validated system into production.

Year 2000 Project Office – The core information technology (IT) team responsible for coordinating Year 2000 renovation efforts and Year 2000 compliance for all at-risk products across the enterprise. Responsibilities include communication, cooperation across organizations, skills transfer, tool management, third-party relationships, and resolution of infrastructure issues.

Year 2000 Safe – An application or product that is prevented from causing or setting detrimental courses of action in motion when it fails.

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