

Medical Devices and The Year 2000: One Hospital's Approach

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CORRESPONDENCE AND REPRINTS

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ABSTRACT

As the medical device experts of the hospital, many clinical engineering departments have been shouldered with the responsibility of ensuring that all medical devices will not be adversely affected by the year 2000 century rollover issue. At Yale-New Haven Hospital, experience has shown that the solution is more than just a technical one, it is a management one. This article discusses the development and implementation of the strategy adopted by the hospital to deal with the issue, and presents the emerging results.

INDEX UNDER:

Clinical Engineering; Year 2000

INTRODUCTION

As the year 2000 approaches, more and more hospitals are becoming concerned about what has been colloquially termed the “millennium bug.” Simply stated, the issue is as follows: when designing their equipment, some device manufacturers chose to represent the date in a two-digit format, i.e. “99” for 1999. The problem is that the device may not correctly interpret the “00” once the year 2000 occurs. Instead, the device may interpret the “00” as 1900, or as some other year. In addition, some designers did not correctly program their devices to recognize the year 2000 as a leap year. These incorrect date rollovers could impact the functionality of the device. For instance, an ultrasound unit may miscalculate an estimated due date, affecting the physician’s diagnosis. The potential risks such computations raise make the year 2000 problem an important one to hospitals.

THE STRATEGY

At Yale-New Haven Hospital, the year 2000 project grew out of the Management Information Systems (MIS) Department. In late 1997, a hospital year 2000 steering committee was formed, headed by a representative from MIS. Committee members included representatives from all facets of the hospital, including Purchasing, Materials Management, Facilities, Legal, Human Resources, Clinical Engineering,

MIS, and Internal Audit. The function of this committee was to develop remediation plans, review progress, create contingency plans, and discuss any problem areas.

One of the initial tasks of the committee was to define a strategy for dealing with the over 14,000 medical devices in the hospital. At the time, it was unclear what, if any, potential compliance issues existed. Therefore, to assist with the development and implementation of the project, Clinical Engineering retained the services of CIRACET Corporation. Together, a plan was developed which divided the project into three main portions: review of work scope, vendor communication, and remediation.

Review of Work Scope

Verifying the hospital's inventory was the first step. Using the department's medical equipment management database, a list of equipment was compiled. It included all electronic medical equipment located in both patient care and support areas, including Diagnostic Imaging and Laboratory Medicine. In total, over 14,000 pieces of equipment were identified, ranging from simple examination lamps to complex radiography systems.

Vendor Communication

Beginning in February 1998, Clinical Engineering contacted approximately nine hundred manufacturers via mail, phone, and Internet in order to request compliance statements.

- To date, 450 manufacturers have provided year 2000 information, whose devices represent 83% of total inventory.
- 404 individual devices, or 3% of total inventory, were identified as having known year 2000 issues.
- 25 individual devices were not tested by the manufacturer for year 2000 compliance.

The statements obtained were filed alphabetically by manufacturer, and entered into a Microsoft Access database. Compliance statements are continually updated and perused for changes, especially when the statements are posted on the Internet. In addition, work is ongoing to contact manufacturers who have not yet responded to year 2000 inquiries.

Remediation

The testing phase was the most crucial step of the year 2000 project. In December 1997, ECRI published one of the first articles on testing medical equipment for compliance (ECRI, 1997). ECRI recommended testing equipment when manufacturer compliance statements were not available; however, they did not state a position on testing equipment when manufacturer compliance statements were provided. Later, in December 1998, ECRI issued another article, in which stated that testing was not necessary for equipment when year 2000 compliance statements were provided by the manufacturer (ECRI, 1998).

However, on the advice of the legal counsel on the steering committee, Yale-New Haven Hospital chose to remediate all medical equipment. Remediation was defined as (1) year 2000 compliance statements from medical equipment manufacturers would be obtained and filed, and (2) compliance statements would be verified by rolling dates on equipment whenever possible. The testing protocol reproduced the user environment on the dates of interest (see Figure 1). A networked device would be tested as an individual device and also as part of the system. For devices where the dates could not be physically changed, the hospital would rely solely on the manufacturer's compliance statement.

In order to streamline the remediation process, the over 14,000 pieces of equipment in the hospital database were prioritized into three classes using the method recommended by ECRI (ECRI, 1997):

- Class 1** Equipment in this category is used for life support, resuscitation, or critical monitoring, or is likely to seriously harm a patient if it fails. (Examples include ventilators and imaging equipment.)

- Class 2** Equipment in this category could have a significant impact on patient care if it fails, but its failure does not pose immediate harm to patients. (Examples include ultrasound units and most laboratory analyzers.)

Class 3 Equipment in this category does not have any serious impact on patients. (Examples include video printers and examination lamps.)

These classes categorized the equipment according to their potential to harm patients. Class 1, or “mission critical” devices were remediated first, followed by classes 2 and 3.

Each of the three classes were then further subdivided into testing levels, based on the equipment design and manufacturer year 2000 compliance statement.

Level A Equipment in this category is capable of being physically tested. All equipment in this category will be tested.

Level B Equipment in this category cannot be physically tested. There is no access to the equipment clock. All equipment in this category will be thoroughly documented. Copies of the vendor year 2000 position letter, test plans, and results will be obtained and filed. Vendor representatives will be contacted and consulted as necessary.

Level C Equipment in this category does not include date sensitive software or embedded systems. Equipment in this category will not be tested.

To indicate remediated equipment, a “Year 2000” sticker was affixed to devices. The steering committee decided that stickering devices would raise awareness in the end users and calm fears. In addition, stickering would provide an easy way for the end user to determine whether a device has been assessed for year 2000 compliance.

EMERGING RESULTS

Reporting

Reporting was accomplished using a Microsoft Access database (See Figure 2). This allowed the greatest flexibility in creating custom reports for both the administration and Clinical Engineering staff. Using the database, both compliance and remediation information was tracked for each individual device.

Remediation progress as of April 1999 is depicted in Figure 3. The classification of the equipment into risk classes allowed Clinical Engineering to target all Class 1, or “mission critical”, devices first. Following that, Classes 2 and 3 were tackled. From the report’s statistics, it becomes apparent that the remediation process was faced with some hurdles.

Hurdles

During the initial months of the project, remediation progressed rather quickly. Devices were easily found, remediated, and stickered by the Clinical Engineering staff. However, as the amount of remediated equipment grew, it became more difficult to find equipment that was not remediated. Two main hurdles were faced: (1) gaining access to heavily trafficked areas; and (2) locating mobile equipment.

In order to gain access to constantly busy areas (such as the Intensive Care Units), Clinical Engineering staff provided unit secretaries with room lists. As patients were discharged, unit secretaries contacted Clinical Engineering staff, who remediated the devices in the room. Once remediation was complete, the room was crossed off the list. In this way, devices were remediated with no effect on patient care.

Locating mobile equipment was a more challenging task. As Yale-New Haven Hospital has no central repository for mobile equipment, it was especially difficult to locate devices for remediation. Fortunately, as part of the preparation for an upcoming JCAHO inspection, nursing coordinators collected all mobile equipment for cleaning and tagging. During this time, missed devices were remediated.

Most important in battling remediation hurdles was education. All hospital staff were instructed to inform Clinical Engineering if devices without year 2000 stickers were found. Furthermore, they were further instructed not to use devices without a year 2000 sticker once the new year begins.

Due to the time and resources involved in overcoming the above hurdles, many hospital systems chose not to perform in-house year 2000 compliance testing (United States Senate, 1999). However, anecdotal information has shown that compliance verification was a good investment for Yale-New Haven Hospital:

- Several manufacturers changed their statements from non-compliance to compliance and vice versa. These manufacturers did not notify the hospital of the changes in their statement. The remediation process caught such instances.
- In one case, a service representative upgraded devices in the hospital. The remediation process found two of these devices that failed the year 2000 test. In essence, the devices were not properly upgraded.
- Since the remediation process involved all testable equipment and not just a sampling, software variations in otherwise identical devices were identified.

Equipment with Year 2000 Issues

As expected in a large institution, some equipment was identified which had year 2000 issues. In total, 429 individual devices (3% of total inventory) were found to have problems transitioning to the year 2000. The issues ranged from simple date display problems to actual errors in operation. The devices spanned all three risk classes and test levels. It is significant to note that to date, no Class 1, or “mission critical” equipment, was found whose Year 2000 issue affected functionality.

In order to most efficiently deal with these devices, the equipment was categorized into different status levels. The following questions were considered when classifying the equipment:

- How crucial is this piece of equipment to the functionality of the unit/laboratory? Is it used often?
Rarely?
- Are any printouts made which are saved in the patient medical record?
- Where available, is the workaround acceptable to the unit/laboratory?
- Would it be more cost effective to replace the device rather than upgrade it?
- Will there be any changes in protocols which will make the device unnecessary by December 1999?

- Is it possible to exchange the device with an equivalent model that has no year 2000 issue?

Using the answers to the above questions, the following categories were devised.

Equipment Needing Replacement or Upgrades. 68% of the equipment with year 2000 issues fell into this category. In general, the date in these devices were important for functionality and/or patient medical records. The manufacturer's recommendation and a technology assessment by Clinical Engineering determined whether the devices were replaced or upgraded.

Equipment With Operational Notes. 25% of the equipment with year 2000 issues were classified here. For some devices, following a certain protocol on the affected date would resolve their year 2000 issue. For instance, resetting internal clocks at the start of the new year allow some devices to function normally. In other cases, the equipment's year 2000 issue affected an unused function, or date display only. End users were instructed of the issue, and the device was labeled with the issue noted.

Equipment No Longer in Use. 2% of the equipment with year 2000 issues were no longer used in the hospital. These devices identified in this category will be removed prior to the year rollover.

Equipment Not Tested by the Manufacturer. 5% of the devices classified with year 2000 issues were not tested by the manufacturer for compliance. These devices were no longer supported by the manufacturer, due to their age. Rather than performing a compliance test, the hospital adopted the policy that these devices will be replaced or removed before the year 2000.

The inventory in the above four categories was not static. As more information became available from the manufacturer or as protocols changed in the hospital departments, devices were often reclassified. In July 1999, the hospital will enact a freeze on all equipment upgrades. This will prevent any changes to equipment that may affect year 2000 compliance. At this time, it is expected that all year 2000 issues will be resolved.

CONCLUSION

The Year 2000 project has been a challenging one for Clinical Engineering. It has drawn on both the managerial and technical expertise of the staff, and has required the cooperation of all departments in the hospital. As the hospital focus shifts from device remediation to business continuity strategies, both administration and the Clinical Engineering Department feel confident that their medical devices will function properly well into the year 2000.

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BIOGRAPHY

Rachel C. Mercado received her BSE degree in Bioengineering in 1995 from the University of Pennsylvania, and her MS degree in Biomedical Engineering in 1997 from Rensselaer Polytechnic Institute at Hartford (formerly Hartford Graduate Center). She completed a two-year clinical engineering internship at the University of Connecticut Health Center, and most recently worked as a Clinical Engineering Manager at New York Presbyterian Hospital (Columbia-Presbyterian campus). She is currently a clinical engineer for CIRACET Corporation, and is managing the Year 2000 medical device remediation project at Yale-New Haven Hospital.

FIGURE 1. Testing protocol developed by Yale-New Haven Hospital to verify manufacturer compliance statements.

FIGURE 2. Data fields included in in-house Year 2000 medical device database.

FIGURE 3. Remediation progress report generated April 30, 1999. Equipment is classified by risk class and test level, and percentages documented and remediated are listed. "Remediated" includes devices with filed compliance statements, in-house testing results (if possible), and affixed "Year 2000" labels.

Y2K Medical Devices Compliance Program

-Generic Testing Protocol-

1. Confirm proper operation at current time and date. Record observations.
2. Set time to 11:59:00 PM and date to 12/31/99.
3. Allow clock to roll over to 01/01/00. (January 1, 2000 – New year)
4. Confirm proper operation on 01/01/00. Record observations.
5. Turn unit off.
6. Wait 5 seconds.
7. Turn power on.
8. Confirm proper operation on 01/01/00. Record observations.
9. Advance clock to 11:59:00 PM and set date to 02/28/00. (February 28, 2000 – Leap year)
10. Allow clock to roll over to 02/29/00. (February 29, 2000)
11. Confirm proper operation on 02/29/00. Record observations.
12. Turn unit off.
13. Wait 5 seconds.
14. Turn power on.
15. Confirm proper operation on 02/29/00. Record observations.
16. Re-set clock to current time and date.
17. Confirm proper operation on current time and date. Record observations.
18. Turn unit off.
19. Wait 5 seconds.
20. Turn power on.
21. Confirm proper operation on current time and date. Record observations.

- On networked areas only the central monitors will be down. Estimated time: **4 minutes**
- For stand alone devices the estimated time for a Y2K test is: **10 – 15 minutes**
- For a network of devices the estimated time for a Y2K test is: **25 - 50 minutes**

Year 2000 Medical Device Database Fields

Hospital Control Number

Equipment Class

Manufacturer

Model

Location

Documentation (Y/N)

Remediation (Y/N)

Date Remediated

Initials

Year 2000 Sticker Number

Risk Class

Test Level

Compliance Notes

Date of Manufacturer Response
