

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

December 17, 1999

NRC INFORMATION NOTICE 99-32: THE EFFECT OF THE YEAR 2000 ISSUE ON
MEDICAL LICENSEES

Addressees:

All U.S. Nuclear Regulatory Commission medical licensees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to remind all addressees of the potential problems their computer systems and software may encounter as a result of the change to the year 2000. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid potential problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

The Year 2000 (Y2K) problem pertains to the potential inability of computers to correctly recognize dates beyond December 31, 1999. This problem results from computer hardware and/or software that uses two-digit fields to represent the year. These systems may misread the year 2000 and cause the systems to fail, generate faulty data, or act in an incorrect manner. The Y2K problem has the potential to interfere with the proper operation of any computer system, hardware that is microprocessor-based (embedded software), software, or database.

As discussed in this Information Notice (IN), "Y2K Ready" is defined as a computer system or application that has been determined to be suitable for continued use into the year 2000, even though the computer system or application is not Y2K Compliant. A Y2K Readiness Program is a plan for a facility to become Y2K Ready. "Y2K Compliant" is defined as a computer system or application that accurately processes date/time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the years 1999 and 2000, and beyond, including leap-year calculations.

The Y2K problem is urgent because it has a fixed, non-negotiable deadline that is quickly approaching. This matter requires priority attention because of the limited time remaining to assess the magnitude of the problem, assess its associated risks, and implement programs that will achieve a satisfactory resolution of the Y2K problem.

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Existing reporting requirements under 10 CFR Part 21 provide for notification to NRC of deficiencies, non-conformances, and failures, such as the Y2K problem in safety-related systems

Examples of systems that may be affected by the Y2K problem include:

- Treatment planning systems
- Dose calibrators
- Embedded systems
- Decay programs
- Interlocks
- Radiation monitoring systems
- Dosimeters, dosimetry programs, and readers
- Communication systems
- Surveillance and maintenance tracking systems

To alert licensees and certificate holders to the Y2K problem, NRC issued several INs:

- IN 96-70, "Year 2000 Effect on Computer System Software," on December 24, 1996;
- IN 97-61, "U.S. Department of Health and Human Services Letter, to Medical Device Manufacturers, on the Year 2000 Problem," on August 6, 1997;
- IN 98-30, "Effect of The Year 2000 Computer Problem on NRC Licensees and Certificate Holders," on August 12, 1998;
- IN 99-18, "Update on NRC's Year 2000 Activities for Materials Licensees and Fuel Cycle Licensees and Certificate Holders," on June 14, 1999; and
- IN 99-20, "Contingency Planning for the Year 2000 Computer Problem," on June 25, 1999.

Discussion:

NRC is concerned with the effect that the Y2K computer problem may have on medical licensees. In particular we are concerned with treatment planning systems used in brachytherapy and teletherapy procedures. The Y2K problem may cause treatment planning systems to operate in an incorrect manner. For example, the treatment planning system may incorrectly calculate the activity of the source(s) used in brachytherapy or teletherapy procedure. This could cause an incorrect treatment time to be calculated and lead to a patient receiving an overdose or an underdose of radiation. Additionally, some dose calibrators have been found not to be Y2K Compliant by the manufacturer.

Addressees should contact their treatment planning system and dose calibrator vendors to determine if their systems are Y2K Ready. Further, addressees should verify that their

treatment planning systems and dose calibrators are Y2K Ready. The Y2K status of some medical equipment may be found at the U.S. Food and Drug Administration (FDA) website <<http://www.fda.gov/cdrh/yr2000/year2000.html>> or manufacture's website. In some cases, manufacturers have upgrades available to correct the Y2K problems for these systems, but licensees need to act to determine whether their systems have Y2K problems and obtain the upgrades.

After the transition to the year 2000, your systems should be tested for proper operation before treating a patient.

The list below contains the FDA's potentially high-risk device types that could be subject to Y2K problems. The list includes the section number in Title 21 of the U.S. Code of Federal Regulations where the generic device type is described. While all of the generic device types listed below are not subject to NRC jurisdiction, licensees should consider FDA's guidance that these radiation or radionuclide systems are potentially at risk for a Y2K problem.

892.5050* MEDICAL CHARGED-PARTICLE RADIATION THERAPY SYSTEM*
892.5300* MEDICAL NEUTRON RADIATION THERAPY SYSTEM*
892.5700* REMOTE CONTROLLED RADIONUCLIDE-APPLICATOR SYSTEM*
892.5750* RADIONUCLIDE RADIATION THERAPY SYSTEM*
892.5900* X-RAY RADIATION THERAPY SYSTEM*

FDA also has developed the MedWatch Reporting Database. FDA's MedWatch reporting requirements are stated below:

Mandatory Reports: Any device-related death or serious injury in your facility, you are required to report deaths to FDA and the manufacturer and injuries to the manufacturer only. Please report these problems through procedures established by your facility; identify the report as a Y2K problem.

Voluntary Reports: Any date-related problem that did not cause death or injury but caused unexpected performance, for example, a malfunction that could cause death or serious injury if the problem recurred. We encourage you to report any contradiction between your device findings and those findings claimed by the manufacturer. Please identify your report as a Y2K problem.

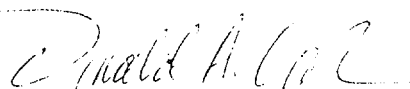
How to Report:

- By telephone to 1-800-FDA-1088
- By FAX, use Form 3500 to 1-800-FDA-0178
- By Mail, use Form 3500, to
MedWatch
Food and Drug Administration, HF-2
5600 Fishers Lane
Rockville, MD 20857-9787
- Electronically at: <<http://www.fda.gov/medwatch/index.html>>

* The device classifications specified above, flagged with an asterisk, include radiation treatment planning systems that are accessories to these device types.

For additional Y2K information, visit our website at <http://www.nrc.gov/NRC/Y2K/Y2KNMSS.html>. The site contains updates of NRC's Y2K activities and provides useful links for additional Y2K information.

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.



Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Contact: Gary Purdy, NMSS
(301) 415-7897
E-mail: gwp1@nrc.gov

Attachments:

1. Selected Year 2000 Web Sites
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

SELECTED YEAR 2000 WEBSITES

1. The American Hospital Association conducted a survey of hospital Year 2000 (Y2K) readiness status. The results of the survey can found at the American Hospital Association's website. <<http://www.aha.org/y2k>>
2. The American Medical Association website has Y2K information for the medical community. <<http://www.ama-assn.org/not-mo/y2k/index.htm>>
3. The Federal Communications Commission website provides information regarding the effects of Y2K on the communications and broadcasting industry. <<http://www.fcc.gov/year2000/>>
4. The Food and Drug Administration has placed reports of Y2K-compliant and non-compliant medical devices on its website. The reports are organized by manufacturer. <<http://www.fda.gov/cdrh/yr2000/year2000.html>>
5. The General Accounting Office has placed Y2K reports on assessment, testing, and contingency planning on its website. <<http://www.gao.gov/y2kr.htm>>
6. The Health Care Financing Administration has placed Y2K information for health care claim repayments for Medicare, Medicaid, and Child Health Insurance Programs on its website. The site also includes the Y2K status of health care facilities, Y2K activities, and Y2K help for health care facilities. <<http://www.hcfa.gov>>
7. The Institution of Electrical Engineers Y2K website provides information on embedded systems. The site explains the use of Y2K risk management techniques. <<http://www.iee.org.uk>>
8. The intraVision website provides links to Oncology/Radiology commercial sites. <<http://www.intravsn.com/vendors.shtml>>
9. The International Atomic Energy Agency website provides Y2K information for nuclear safety, waste management, medical facilities, and safeguards/physical protection. <<http://www.iaea.org/worldatom/program/y2k>>
10. The National Institute of Standards and Technology (NIST) Y2K webpage includes Y2K test programs for small businesses, free software, Y2K standards, Y2K compliance and testing, Y2K hotlines, and Y2K slide shows. <<http://www.nist.gov/y2k>> At the NIST website for small businesses, "The Conversion 2000: Y2K JumpStart Kit " for jump-starting a Y2K project is available. Also, action planning, assessment, and remediation project planning workshops are available. <<http://y2khelp.nist.gov>>

11. The North American Electric Reliability Council website provides information and guidance on the effect of the Year 2000 problem on the electricity supply for North America. <<http://www.nerc.com>>
12. The U.S. Nuclear Regulatory Commission (NRC) website provides the status and findings of NRC's Y2K program which includes nuclear power plant audits, Information Notices, Generic Letters, and Y2K links. <<http://www.nrc.gov/NRC/NEWS/year2000.html>>
13. The President's Council on Year 2000 Conversion website has information regarding Y2K and the Federal government's efforts to prepare its computer systems, links to information on Y2K compliance for critical sectors of the economy, and other Y2K resources. In addition, the Council has established a Y2K consumer information line at 1-888-USA-4-Y2K, which provides free Y2K information to the public. <<http://y2k.gov>>
14. The Radiation and Health Physics website provides links to radiation detection device manufacturers and dosimetry companies. <<http://www.sph.umich.edu/group/eih/UMSCHPS/commercial/>>
15. The Rx2000 website is devoted to Y2K medical issues. The site has a pay section and a free section. Information found in the free section includes a provider preparedness model and comparator, Rx2000 list server and discussion forum, health care Y2K articles and publications, Rx2000 downloadable presentations, links, and health care Y2K self-help materials. <<http://www.rx2000.org>>
16. The Small Business Administration website provides Y2K help for small businesses. The site includes Y2K materials, Y2K activities, and links to other sites. <<http://www.sba.gov/y2k>>
17. The United Kingdom Year 2000 website provides Y2K Information on software compliance. The reports are organized by manufacturer. <<http://www.open.gov.uk/bug2000.htm>>
18. The Department of Veterans Affairs (VA) website provides Y2K information and contingency planning for hospitals and the status of VA Y2K efforts. <<http://www.va.gov>>

Except for its own website, the U.S. Nuclear Regulatory Commission makes no claims regarding the accuracy of the information provided at these websites. The list of sites is provided for use by addressees as a possible source of Y2K information.

LIST OF RECENTLY ISSUED
 NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
99-31	Operational Controls to Guard Against Inadvertent Nuclear Critically	11/17/99	All NRC licensed fuel cycle conversion, enrichment and fabrication facilities
99-30	Failure of Double Contingency Based on Administrative Controls Involving Laboratory Sampling and Spectroscopic Analysis of Wet Uranium Waste	11/8/99	All fuel cycle licensees and certificates performing laboratory analysis to determine uranium content, in support of administrative criticality safety controls
99-29	Authorized Contents of Spent Fuel Casks	10/28/99	All power reactor licensees and spent fuel storage licensees and applicants
99-28	Recall of Star Brand Fire Protection Sprinkler Heads	9/30/99	All holders of licenses for nuclear power, research and test reactors, and fuel cycle facilities
99-27	Malfunction of Source Retraction Mechanism in Cobalt-60 Teletherapy Treatment Units	9/2/99	All medical licensees authorized to conduct teletherapy treatments
99-26	Safety and Economic Consequences of Misleading Marketing Information	8/24/99	All Distributors and/or Manufacturers of Generally Licensed Products
99-24	Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices	7/12/99	All medical licensees' of broad-scope and master materials licensees
99-23	Safety Concerns Related to Related Control Unit Failures of the Nucletron Classic Model High-Dose-Rate Remote Afterloading Brachytherapy Devices	7/6/99	All U. S. NRC medical licensees authorized to use brachytherapy sources in Nucletron Classic Model high-dose-rate remote afterloaders

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99-29	Authorized Contents of Spent Fuel Casks	10/28/99	All power reactor licensees and spent fuel storage licensees and applicants
99-01, Rev. 1	Degradation of Prestressing Tendon Systems in Prestressed Concrete Constrainments	10/7/99	All holders of operating licensees for nuclear power reactors
99-28	Recall of Star Brand Fire Protection Sprinkler Heads	9/30/99	All holders of licenses for nuclear power, research and test reactors, and fuel cycle facilities
99-27	Malfunction of Source Retraction Mechanism in Cobalt-60 Teletherapy Treatment Units	9/2/99	All medical licensees authorized to conduct teletherapy treatments
99-26	Safety and Economic Consequences of Misleading Marketing Information	8/24/99	All Distributors and/or Manufacturers of Generally Licensed Products
99-25	Year 2000 Contingency Planning Activities	8/10/99	All holders of OLs for nuclear power plants and fuel cycle facilities

* The device classifications specified above, flagged with an asterisk, include radiation treatment planning systems that are accessories to these device types.

For additional Y2K information, visit our website at <http://www.nrc.gov/NRC/Y2K/Y2KNMSS.html>. The site contains updates of NRC's Y2K activities and provides useful links for additional Y2K information.

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Donald A. Cool, Director
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

Contact: Gary Purdy, NMSS
 (301) 415-7897
 E-mail: gwp1@nrc.gov

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1. Selected Year 2000 Web Sites
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