J. McKnight

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

August 6, 1997

NRC INFORMATION NOTICE 97-61: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES LETTER, TO MEDICAL DEVICE MANUFACTURERS, ON THE YEAR 2000 PROBLEM

Addressees

All U.S. Nuclear Regulatory Commission medical licensees, veterinarians, and manufacturers/ distributors of medical devices.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to inform licensees of a letter from the U.S. Department of Health and Human Services, Food and Drug Administration (FDA), to medical device manufacturers, about the Year 2000 problem. 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 NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

In a letter dated June 25, 1997 (attached), the FDA reminded medical device manufacturers that some computer systems and software applications currently used in medical devices, including embedded microprocessors, may experience problems as a result of the turn to the new century. In addition, the letter indicated that computer-controlled design, production, or quality control processes could be adversely affected.

Discussion

The FDA requires the manufacturers it regulates to investigate and correct problems with medical devices that present a significant risk to public health. To ensure the continued safety and effectiveness of medical devices, the FDA recommended that manufacturers take the following actions: (1) ensure that medical devices submitted for premarket approval can perform date recording and computations that will not be affected by the Year 2000 problem; (2) conduct hazard and safety analyses on currently manufactured devices to determine whether device performance could be affected by the Year 2000 problem, and, if so, take appropriate steps to correct production and help customers who have purchased such devices; and (3) check design,

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production, and quality control processes to ensure year 2000 compliance. This letter also applies to those manufacturers that use radioactive material in their medical devices.

If there are any questions about medical device manufacturers' responsibilities regarding the Year 2000 problem, contact the FDA's Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, by phone, at 1-800-638-2041 or fax, at 301-443-8818. Also, an electronic copy of the letter is available on the FDA's World Wide Web home page at http://www.fda.gov/cdrh.

Related Generic Communications

NRC Information Notice 96-70, "Year 2000 Effect on Computer System Software," issued on December 24, 1996, addressed the Year 2000 problem and its applicability to NRC licensed programs.

This information notice requires no specific action nor 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

Technical contact: Patricia K. Holahan, NMSS
301-415-8125
E-mail: pkh@nrc.gov

Attachments:
1. FDA Letter to Medical Device Manufacturers
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

List filed in Jacket.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

June 25,1997

Dear Medical Device Manufacturer:

This is to remind you that some computer systems and software applications currently used in medical devices, including embedded microprocessors, may experience problems beginning January 1, 2000 due to their use of two-digit fields for date representation. In addition to adversely affecting the functioning of some devices, the two-digit date format could also affect computer-controlled design, production or quality control processes.

To ensure the continued safety and effectiveness of these devices, we are recommending the following actions:

- For <u>future</u> medical device premarket submissions, manufacturers should assure that the products can perform date recording and computations that will be unaffected by the year-2000 date change.

- For <u>currently manufactured</u> medical devices, manufacturers should conduct hazard and safety analyses to determine whether device performance could be affected by the year-2000 date change. If these analyses show that device safety or effectiveness could be affected, then appropriate steps should be taken to correct current production and to assist customers who have purchased such devices.

- For computer-controlled <u>design, production and quality control processes</u>, manufacturers should assure that two-digit date formats or computations do not cause problems beginning January 1, 2000.

The following information should help answer questions about premarket submission requirements relating to year-2000 changes:

- Manufacturers need not submit Premarket Approval Application Supplements for Class III devices to document that they have addressed year-2000 problems, provided that the modifications made in the device do not change other aspects of its performance.

- Manufacturers need not submit a new 510(k) (premarket notification) for year-2000 changes to an existing device, provided that the changes do not affect safety and effectiveness. This is in keeping with the information provided in the Office of Device Evaluation guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" available from the Division of Small Manufacturers Assistance and the FDA/CDRH World Wide Web home page. (Note that year-2000 changes should be included in any future 510(k) submission for a significant change to the device.)

Manufacturers should also note that under the previous GMP regulation and the current Quality System Regulation, effective June 1, 1997, they must investigate and correct problems with medical devices that present a significant risk to public health. This includes devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. Section 518 of the Food, Drug and Cosmetic Act requires notification of users or purchasers when a device presents an unreasonable risk of substantial harm to public health.

If you have questions regarding these issues, please contact the CDRH Division of Small Manufacturers Assistance by phone at 800-638-2041, or by fax at 301-443-8818. In addition, information concerning medical device regulatory issues may be found on the CDRH home page, at http://www.fda.gov/cdrh.

Sincerely yours,

D. Bruce Burlington, M.D.
Director,
Center for Devices and
Radiological Health

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
97-58	Mechanical Integrity of In-Situ Leach Injection Wells and Piping	07/31/97	Holders of and Applicants for Licenses for In-Situ Leach Facilities
97-57	Leak Testing of Packaging Used in the Transport of Radioactive Material	07/30/97	Suppliers and users of packaging for the transportation of radioactive material required to perform packaging leak tests
97-56	Possession Limits for Special Nuclear Material at the Environcare of Utah Low-Level Radioactive Waste Disposal Facility	07/28/97	All licensees authorized to possess special nuclear material
97-55	Calculation of Surface Activity for Contaminated Equipment and Materials	07/23/97	All Uranium Recovery Licensees
97-51	Problems Experienced with Loading and Unloading Spent Nuclear Fuel Storage and Transportation Casks	07/11/97	All holders of OLs or CPs for nuclear power reactors Designers and fabricators of independent spent fuel storage installations All holders of or applicants for licenses to operate ISFSIs
97-50	Contaminated Lead Products	07/10/97	All U.S. Nuclear Regulatory Commission licensees
97-47	Inadequate Puncture Tests for Type B Packages Under 10 CFR 71.73(c)(3)	06/27/97	All "users and fabricators" of type B transportation packages [as defined in 10 CFR 171.16(10(B)]

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
97-60	Incorrect Unreviewed Safety Question Determination Related to Emergency Core Cooling System Swapover from the Injection Mode to the Recirculation Mode	08/01/97	All holders of OLs or CPs for pressurized-water reactors
97-59	Fire Endurance Test Results of Versawrap Fire Barriers	08/01/97	All holders of OLs or CPs for nuclear power reactors
97-58	Mechanical Integrity of In-Situ Leach Injection Wells and Piping	07/31/97	Holders of and Applicants for Licenses for In-Situ Leach Facilities
97-57	Leak Testing of Packaging Used in the Transport of Radioactive Material	07/30/97	Suppliers and users of packaging for the transportation of radioactive material required to perform packaging leak tests
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97-55	Calculation of Surface Activity for Contaminated Equipment and Materials	07/23/97	All Uranium Recovery Licensees

OL = Operating License
CP = Construction Permit

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DOCUMENT NAME: 97-61.IN *SEE PREVIOUS CONCURRENCE

OFC	IMOB	Tech Editor	IMOB	IMAB	IMNS
NAME	MASitek*	EKraus*	JMPiccone*	LWCamper*	DACool*
DATE	7/11/97	7/11/97	7/16/97	7/19/97	7/25/97

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DOCUMENT NAME: imns5850.mas *SEE PREVIOUS CONCURRENCE

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NAME	MASitek*	EKraus*	JMPiccone*	LWCamper	DACool
DATE	7/11/97	7/11/97	7/16/97	7/18/97	7/21/97

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7/21/97

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