

## **Instruction Sheet - Please Read Carefully**

### **Instructions and Information Regarding Submission of Updated Year 2000 Status Information for Non-Compliant Products**

Information is requested regarding the "Year 2000 Compliance Status" of biomedical equipment (medical devices and scientific laboratory equipment). Specifically, information is requested on all products (current and past production which are still in use) which are not compliant according to the definition provided below (and also contained in the January 21, 1998 letter from the Deputy Secretary, DHHS). This request is a special year 2000 data gathering request made pursuant to the Year 2000 Information and Readiness Disclosure Act.

**Definition:** For the purpose of this product status reporting, "Year 2000 Compliance" means, with respect to medical devices and scientific laboratory equipment, that the product accurately processes and stores date/time data (including, but not limited to calculating, comparing, displaying, recording and sequencing operations involving date/time data) during, from, into and between the twentieth and twenty-first centuries, and the years 1999 and 2000, including correct processing of leap year data.

This definition is compatible with the definition of Year 2000 Conformity contained in the British Standards Institute (BSI) published document PD2000-1:1998 and further described in BSI publication PD2000-4:1998. These publications may be obtained from the Internet at the web location <http://www.bsi.org.uk/bsi/disc/year2000.html>.

This definition is also the same as the definition of "Year 2000 Compliance" as used in the Federal Acquisition Regulations for information technology products (see 48 CFR Part 39.002), modified to address biomedical equipment. The intent is that for products to be Year 2000 compliant they must function as intended or expected, regardless of the date.

**Applicability:** A manufacturer's reporting of Year 2000 compliance status should include all products (units) produced which could still be in service. Submission of this data is a certification to the Government that the manufacturer has evaluated all such products and is reporting about all non-compliant products or products whose status is unknown. If there are obsolete or unsupported products that, to the knowledge of the manufacturer, might still be in use and which the manufacturer can not or will not assess, these products should be identified as potential non-compliant products and the lack of assessment stated as the problem description.

**Upgrades:** In addition, the Y2K status information provided should reflect the condition of each model as originally marketed or with any manufacturer provided upgrade that might have been applied. The existence of a Y2K "fix" or upgrade does not render the product model compliant for the purposes of this status reporting, unless the manufacturer can assure that the upgrade has been applied to all products. Healthcare facilities need to know of the non-compliant status of the original or interim products to adequately assess their product inventories.

**Clarification regarding date formats:** There has been concern and possible confusion on whether a product can meet this definition of "Year 2000 Compliance" if it uses only two digits to describe the year, either in a display of the date or in a printed record of the date (or otherwise correctly uses the year or date information). It is the position of the FDA that this definition of a compliant product can be met by products that use only two digits to indicate the year in displays or printed records, provided the displayed year is correct before and after January 1, 2000. A product also can meet the definition of compliance if only two digits for representation of the year are used in internal device operations or in external data communication. Such use is compliant provided it does not result in incorrect functioning of the device, such as incorrect sorting or information storage, or transmission of data which is incorrect or ambiguous when compared to the design specifications of the product and its data interface specifications. The

format of any date information presented to the user by the device or available at any interface should be clear from the context of the usage or described in the product labeling.

**Review of Information and Submission of Updates:** Manufacturers are requested to review the enclosed information and provide updated information where applicable, with specific emphasis on the following data elements:

1. *Type of Product* - Identify the generic product type by providing the FDA Product Classification Regulation number under which the product is classified. This number will be used to associate the product classification name with the device for regulated products. The definitions for each product classification may be found in Title 21 of the Code of Federal Regulations in Sections 862 through 892 and on the FDA web site at <http://www.fda.gov/cdrh/yr2000/classification.html>. For products that have not been classified by the FDA, provide a description of the generic product type, not a manufacturer-specific trade or brand name. (This is line 5a and 5b on the Form FDA 3469A.)

2. *Description of date-related problem* - Provide a narrative description of the date-related problem that contains sufficiently detailed information to permit the typical user to determine the impact of the date-related problem on the normal function or operation of the product, i.e., *What specifically will happen? How will the date-related problem affect the product's functioning as it relates to its intended use?* This description should permit an assessment of the risk from or impact of the failure of the product to meet the definition of Year 2000 compliance. Stating that the product is "obsolete" or that there is a "minor problem" or that there is a "date error" is not sufficient information. (This is line 11 on the Form FDA 3469A.) The response for this element should answer the question:

*Does the transition from Dec. 31, 1999 to Jan. 1, 2000, or between two other times, introduce unexpected or incorrect performance or functioning of the product? If so, describe this.*

3. *Description of any user action necessary* - Provide a description of any actions that must be taken by the user for continued use of the product. (This is line 14 on the Form FDA 3469A.) The response for this element should answer the question:

*Does the product require operator intervention such as reinitiating or manual date setting to function correctly after a given date? If so, describe this.*

**Product history:** Manufacturers are asked to provide information related to any mergers, acquisitions or divestments of product or product lines which have resulted in a manufacturer that is different from the manufacturer identified on the product label being the source of Y2K status information for a product currently in use. The purpose of this information is to aid users of these products to identify the manufacturer(s) currently able to provide Y2K status information. Information provided will be incorporated in the corporate history data portion of the Federal Y2K Biomedical Equipment Clearinghouse.

**Address for submission of revised information:** Please return all of the attached forms for non-compliant products whose Y2K status information requires revision to:

Y2K Coordinator (HFZ-Y2K)  
Center for Devices and Radiological Health, FDA  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Attachment: Listing of Product Classification Names  
Forms for Reporting Updated Data