Variance from Manufacturer Report Number Format [MDR letter]

DATE: July 16, 1996

TO: Medical Device Manufacturers

FROM: Director, Office of Surveillance and Biometrics
Center for Devices and Radiological Health, FDA

SUBJECT: VARIANCE FROM MANUFACTURER REPORT NUMBER FORMAT

CDRH has become aware of several problems or issues related to use of the proscribed format for the manufacturer report number that is to be used in submission of reports using FDA Form 3500A when the new MDR regulation becomes effective on July 31, 1996. The number consists of the FDA registration number of the manufacturing site, the four digit calendar year and a five digit sequence number that is to begin with 00001 for the first report submitted during a calendar year (Ref. 21 CFR 803.3(o)). The following types of problems have been noted:

1. Several reporting sites share the same registration number and also share that number with a manufacturing site at the same location that makes devices for the reporting sites. The registration number does not allow each reporting site to be uniquely identified and the reporting sites have difficulty coordinating assignment of sequence numbers since they report on events involving devices made at the same manufacturing site.
2. Reporting sites have different registration numbers but share the same manufacturing site. They have difficulty coordinating sequence number assignment.
3. Multiple manufacturing sites at the same location share the same registration number. Therefore, the manufacturer report number will not distinguish between manufacturing sites.
4. A device is manufactured at more than one site. Information sufficient to determine the actual manufacturing site of a device involved in an event can not be obtained. The reporting site can not create the manufacturer report number since the manufacturing site is unknown.

The Office of Surveillance and Biometrics, CDRH, is issuing separate variances under the authority of 21 CFR 803.19(c) which are intended to deal with these problems.

VARIANCE NO 1:

Effective July 31, 1996, manufacturers having multiple reporting sites at the same location that share the same registration number as a manufacturing site at that location may request and will be granted an FDA assigned reporting number for each additional reporting site at that location. One reporting site will continue to use the official registration number assigned to the site. The FDA assigned reporting number, which will contain the same number of digits as a registration number, is to be used in creating the manufacturer report number in lieu of the official registration number of the manufacturing site for devices manufactured at that site. The FDA assigned reporting number must also be used in lieu of the reporting site registration number in completion of any forms or submission of any information requiring use of the reporting site registration number.

In order to take advantage of this option, reporting sites at the same location and sharing the same registration number must jointly submit a single letter requesting assignment of FDA assigned reporting numbers. The letter must provide the current registration number and the complete name and address of each reporting site and the name, address and telephone number of the official MDR contact for the reporting site. A unique name or other unique identifier and mail address for each organization, division or group that will be submitting reports (reporting site) must be provided. The organization, division or group that will be using the official registration number assigned to the site must also be identified. The letter should reference this variance and be addressed to the reporting address specified by 21 CFR 803.12(a). The outside of the mailing envelope should contain the statement: "Request for FDA assigned reporting numbers for reporting sites."

CDRH will assign a number to each separate organization, division or group listed in the letter and will inform them of this number.

VARIANCE NO 2:

Effective July 31, 1996, manufacturers who have one or more manufacturing sites that make devices for multiple reporting sites may apply for and will be granted an FDA assigned reporting number for each manufacturing/reporting site combination. The FDA assigned reporting number will be used in lieu of the official manufacturing site registration number by the reporting site assigned to use that particular FDA assigned reporting number. That is, each reporting site will be assigned a unique number for each manufacturing site that makes devices for the reporting site so that the reporting site can control reporting sequence number assignments.

If devices are manufactured in stages at different manufacturing sites, then the request for an FDA assigned reporting number should be made for the manufacturing site that is considered the principal manufacturing site. This site should also be listed in Part 2, item 1 of the baseline report as the principal manufacturing site.

To implement this variance, a manufacturer must submit a letter to CDRH requesting the assignment of FDA assigned reporting numbers for manufacturing sites that multiple reporting sites will be sharing. The letter must provide for each reporting site/manufacturing site combination for

which an FDA assigned reporting number is being requested, the name, address and registration number of the reporting site and the name, address and registration number of the corresponding manufacturing site. The reporting site/manufacturing site combination that will use the existing official manufacturing site registration number must also be identified so that only FDA assigned reporting numbers actually needed will be assigned. The letter should also reference this variance and be addressed to the reporting address specified by 21 CFR 803.12(a). The outside of the mailing envelope should contain the statement: "Request for FDA assigned reporting numbers for manufacturing sites."

CDRH will assign a number for each separate reporting site/manufacturing site combination listed in the letter and will inform the manufacturer of these numbers which will then be used in constructing the manufacturer report number when submitting reports using FDA Form 3500A.

VARIANCE NO 3:

Effective July 31, 1996, manufacturers who have multiple manufacturing sites that share the same registration number may apply for and will be granted an FDA assigned reporting number for each manufacturing site needing a number. One manufacturing site will use the existing official registration number.

To implement this variance, a manufacturer must submit a letter to CDRH that requests the assignment of FDA assigned reporting numbers. The letter must provide a unique name or other unique identifier and address for each manufacturing site and the common registration number that each shares. The site that will use the official registration number for medical device reports must also be identified. The letter must also reference this variance and be addressed to the reporting address specified by 21 CFR 803.12(a). The outside of the mailing envelope should contain the statement: "Request for FDA assigned reporting numbers for manufacturing sites with same registration number."

CDRH will assign a number for each manufacturing site listed in the letter that will need an FDA assigned reporting number and inform the manufacturer of these numbers which will then be used in constructing the manufacturer report number when submitting reports using FDA Form 3500A.

VARIANCE NO 4:

Effective July 31, 1996, manufacturers who manufacture a device at more than one site and who can not determine which site manufactured the device involved in an event may arbitrarily assign a manufacturing site using any method of assignment. For example, they may (1) use one of the manufacturing sites as the default manufacturing site, (2) randomly choose a manufacturing site to designate as the manufacturing site, or (3) choose, on a rotating basis, a manufacturing site to designate as the manufacturing site. However, the manufacturer must state in item H10 of Form 3500A that the actual place of manufacture could not be determined.

If you have any questions concerning these variances, please contact the Reporting Systems Monitoring Team, HFZ-533, CDRH, OSB, DSS, 1350 Piccard Drive, Rockville, MD 20850 (telephone number (301) 594-2735 or Fax number (301) 827-0038).

Email: **rsmb@cdrh.fda.gov (mailto:rsmb@cdrh.fda.gov)**

/s/

Larry Kessler

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)