



AUG -9 2000

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

William A. Gibson - FSCT 2529 '00 AUG 16 P2:28  
General Electric Medical Systems  
N25 W23255 Paul Road  
Pewaukee, Wisconsin 53072

FDA Docket No. 98V-1233

Dear Mr. Gibson:

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) has reviewed your letter of June 28, 2000, concerning an extension of the General Electric Medical Systems (GEMS) variance 98V-1233 which extended the original variance 96P0306. CDRH has allowed GEMS to electronically submit records to the designated FDA receiving unit for form FDA-2579. This variance should provide GEMS with relief from reporting on the prescribed form and provide for a suitable means of assuring radiation safety and protection.

Included in the conditions under which this variance is granted, is a provision that reports of assembly, must still be submitted (via paper media) to the purchaser and to the State agency responsible for radiation protection, however, this paper submission may be an approved alternative format to the current form FDA-2579. The format and content of the approved alternative paper submission (see attachment C) must be substantially equivalent to the format and content of the current form FDA-2579. In addition, the approved alternative paper submission needs to include a variance statement that identifies the FDA variance number (98V-1233) and informs the recipient that the approved alternative paper submission is only authorized for GEMS employees that are in conformance with GEMS internal computer security procedures for electronic signatures.

The items of the variance are:

**A. Variance Number**

98V-1233

**B. Effective Date**

This variance shall become effective on the date of this letter, in accordance with 21 CFR 1010.4(c)(1).

**C. Termination Date**

This variance, unless renewed, shall terminate on

98V-1233

VRA/

December 31, 2001, or when the CDRH announces an electronic submission protocol that all manufacturers must follow for electronic submissions.

**D. Product for Which Variance is Granted**

This variance is applicable to all certified components of diagnostic x-ray systems assembled by GEMS unless the product is exempted by 21 CFR 1020.30(d)(2).

**E. Provisions From Which Variance is Granted**

A variance is granted from certain provisions of 21 CFR 1020.30(d)(1) requiring that all assemblers who install certified components shall file a report of assembly of a diagnostic x-ray system on a prescribed form. This form (FDA 2579) is the assembler's written affirmation that the manufacturer's instructions were followed in the assembly or that the certified components meet all applicable requirements of 21 CFR 1020.30 through 21 CFR 1020.33. This variance, which will allow the assembler to use an electronic method to file a report of assembly to FDA, will continue to require the assembler to affirm that the manufacturer's instructions were followed in the assembly of the diagnostic x-ray equipment. By filing the electronic version the assembler will also affirm that the certified components meet all applicable requirements of 21 CFR 1020.30 through 21 CFR 1020.33. This method of filing electronically with FDA is conditioned on the restrictions listed below in section F. The assembler will continue to provide the user and the state with a paper copy version of the report of assembly. All other provisions of the performance standard for diagnostic x-ray systems and their major components remain applicable to the product.

**F. Conditions Under Which Variance is Granted**

In lieu of the requirements referred to in section E above, the following conditions shall apply to reports of assembly filed by GEMS under this variance

1. The use of the electronic submission method of filing the report of assembly to FDA remains voluntary.
2. All electronic reports of assembly must be submitted in the format (attachment A) prescribed by the FDA unit assigned to receive the submission. Such format may be changed by FDA upon notice to GEMS.

3. Each electronic submission must be uniquely identified with a control letter/number combination. The letter for GEMS would be a "G" followed by a six digit number not less than 100000 and not greater than 999999. Amended submissions must also be uniquely identified with a suffix.
4. Completed reports of assembly must be submitted to CDRH using telecommunications methods (attachment B) prescribed by the FDA unit assigned to receive the submission.
5. Completed reports of assembly, must still be submitted (via paper media) to the purchaser and to the State agency responsible for radiation protection, however, this paper submission may be an approved alternative format to the current form FDA-2579. The format and content of the approved alternative paper submission must be substantially equivalent to the format and content of the current form FDA-2579. In addition, the approved alternative paper submission needs to include a variance statement that identifies the variance number (98V-1233) and informs the recipient that the approved alternative paper submission is only authorized for GEMS employees that are in conformance with GEMS internal computer security procedures for electronic signatures.

**G. Basis for Approval of Variance**

In accordance with 21 CFR 1010.4(a), the CDRH has determined that granting this variance, with the conditions listed in item F above, is in keeping with the purposes of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V of the Federal Food, Drug and Cosmetic Act (Act), and there is not sufficient time for promulgation of an amendment to the standard.

**H. Certification Label**

The variance shall not require any modifications to the electronic product certification label required by 21 CFR 1010.2

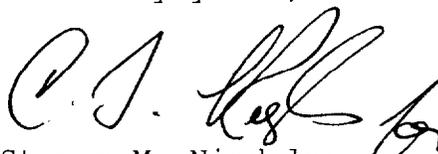
Except for the confidential material, this variance action is available for public disclosure in the Dockets Management Branch, Food and Drug Administration. The variance will apply to products assembled on or after the effective date, and will

Page 4 - Mr. Gibson

remain in effect until the termination date, unless a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

If you have any questions concerning this variance, you may contact Mr. Henry H. Knox, Diagnostic Devices Branch (HFZ-322), Division of Enforcement I, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850, by phone at (301) 594-4591, or by FAX at (301) 594-4636.

Sincerely yours,

A handwritten signature in black ink, appearing to read "S.M. Niedelman". The signature is fluid and cursive, with a large initial "S" and "M".

Steven M. Niedelman  
Acting Director,  
Office of Compliance  
Center for Devices and  
Radiological Health

## **Attachment A**

Format of Electronic Submission  
for the information of form FDA-2579  
July 27, 2000

The electronic submissions will be formatted in an XCEL data base with 80 columns using the field names as provided to GEMS. The data will be separated into two categories of those that are system installations (new or re-assembly) and those that are replacement or additions to existing systems. CDRH will notify GEMS of any changes to this format upon review of the submitted records.

**Attachment B**

Telecommunication Method of Electronic Submission  
for the information of form FDA-2579  
July 27, 2000

Please use the following method

Send all electronic records to the Internet Email account  
ddbo@cdrh.fda.gov

The subject should be "Form FDA 2579 data (date of submission)"

**Attachment C**

Approved Alternative Format of Paper Submission  
for the information of form FDA-2579  
July 27, 2000

(this submission would be sent to the purchaser  
and to the State agency responsible for radiation protection)

The printed version must have all of the information contained on the FORM FDA 2579 in the same arranged order of format. The variance statement for use of the alternative format will be printed on the form. This format may be used until or unless FDA provides an imaged version of Form FDA 2579 for electronic transfer to paper copy at which time the electronic information must be provided on the prescribed image in the appropriate spaces provided. FDA may from time to time require certain modifications in the format and will notify GEMS concerning such changes.

G #####.##

98V-1233

REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM

GENERAL ELECTRIC MEDICAL SYSTEMS (GEMS) EMPLOYEES HAVE BEEN AUTHORIZED TO USE THIS FDA APPROVED ALTERNATIVE FORMAT BY FDA VARIANCE NUMBER 96P-0306 CFI WHICH TERMINATES ON DEC. 31, 1998. THE VARIANCE PERMITS GEMS EMPLOYEES TO USE ELECTRONIC SIGNATURES. FOR INFORMATION CONCERNING THIS VARIANCE, PLEASE CONTACT THE DIAGNOSTIC DEVICES BRANCH (HFZ-322), DIVISION OF ENFORCEMENT I, OFFICE OF COMPLIANCE, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, 2098 GAITHER ROAD ROCKVILLE, MD 20850 (PHONE 301-594-4591).

CUSTOMER NAME: ##### ASSEMBLER : #####
ADDRESS : ##### ADDRESS : #####
CITY : ##### CITY : #####
ST/ZIP CODE : ## #####-#### ST/ZIP CODE : ## #####-####
TELEPHONE : ###-###-#### TELEPHONE : ###-###-####

# NEW ASSEMBLY # REASSEMBLY ALL CERT. # REASSEMBLY MIXED # REPLACEMENT # ADDITION TO EXISTING SYSTEM
# GENERAL PURPOSE RADIOLOGY # PODIATRY # CT HEADSCANNER # DENTAL - PANORAMIC
# GENERAL PURPOSE FLUOROSCOPY # UROLOGICAL # CT WHOLE BODY SCANNER # RADIATION THERAPY SIMULATOR)
# TOMOGRAPHY (OTHER THAN CT) # MAMMOGRAPHY # HEAD / NECK (MEDICAL) # C-ARM FLUOROSCOPIC
# ANGIOGRAPHY # CHEST # DENTAL-INTRAORAL # DIGITAL
# CHIROPRACTIC # DENTAL-CEPHALOMETRIC # OTHER (SPECIFY IN COMMENTS)

# STATIONARY # MOBILE ROOM NAME : ##### ASSEMBLY DATE : MM/DD/YY

# NEW INSTALLATION CONTROL MFR #####
# EXISTING CERTIFIED CONTROL MODEL ##### CT SYSTEM NAME #####
# NON-CERTIFIED CONTROL SERIAL ##### MANUFACTURE DATE : MM/YY

COMPONENTS MANUFACTURER MODEL NO MFR DATE INDICATE QUANTITY OF EACH ITEM
BLD ##### MM/YY # X-RAY CONTROL # CRADLE
BLD ##### MM/YY # HIGH VOLTAGE GENERATOR # FILM CHANGER
TABLE/TOP ##### MM/YY # VERTICAL CASSETTE HOLDER # IMAGE INTENSIFIER
TABLE/TOP ##### MM/YY # TUBE HOUSING ASSEMBLY # SPOT FILM DEVICE
CT GANTRY ##### MM/YY # DENTAL TUBE HEAD # OTHER (SPECIFY IN COMMENTS)

EMPLOYEE ID : ##### COMMENTS:
ASSEMBLER : #####
SIGN DATE : MM/DD/YY
DATE SENT TO FDA : MM/DD/YY

ASSEMBLER CERTIFICATION : I AFFIRM THAT ALL CERTIFIED COMPONENTS ASSEMBLED OR INSTALLED BY ME FOR WHICH THIS REPORT IS BEING MADE, WERE ADJUSTED AND TESTED BY ME ACCORDING TO THE INSTRUCTIONS PROVIDED BY THE MANUFACTURER(S) , WERE OF THE TYPE REQUIRED BY THE MANUFACTURER(S) WERE OF THE TYPE REQUIRED BY THE DIAGNOSTIC X-RAY PERFORMANCE STANDARD (21 CFR PART 1020), WERE NOT MODIFIED ADVERSELY TO AFFECT PERFORMANCE, AND WERE INSTALLED IN ACCORDANCE WITH PROVISIONS OF 21 CFR PART 1020. I ALSO AFFIRM THAT ALL INSTRUCTION MANUALS AND OTHER INFORMATION REQUIRED BY 21 CFR PART 1020 FOR THIS ASSEMBLY HAVE BEEN FURNISHED TO THE PURCHASER AND WITHIN 15 DAYS FROM THE DATE OF ASSEMBLY, COPIES OF THIS DOCUMENT WILL BE DISTRIBUTED AS PRESCRIBED BY 21 CFR PART 1020.

DRAFT HKNOX/7/28/00 REDRAFT:8/7/00  
Rev: TMJ 7/28/00  
Final:jap 8/7/00

AK 8/8/00

CC:  
BOARD  
MFR GECO  
HFR-MW300  
HFR-MW350  
HFZ-100  
HFZ-200  
HFZ-300  
HFZ-320  
HFZ-322 (KNOX)  
HFZ-400  
HFZ-500  
HFZ-80  
HFZ-84  
HFA-305  
HFA-224  
VARIANCE

*SHJ 8/9/00*  
*TMJ*  
*8/12/00*

TRACK 83955 &84298  
FILE; J:\DOE1\DDB\HHK\CASE\GE2579VAR.DOC