



Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

June 26, 2008

FMI 15085

To: Hospital Administrator; Radiology Administrator

Subject: Product Issues:

Possible missing collimator filter on some GE OEC 9600 C-arms

Affected Product: GE OEC 9600 C-arm

Our records indicate that your facility has one or more of the following GEHC OEC products:

- GE OEC 9600

GE Healthcare has discovered that GE OEC 9600 C-arms that had collimators replaced may not have had the secondary collimator filter re-installed during collimator replacement. GE OEC 9600 C-arms that do not have the secondary collimator filter installed may exceed maximum Entrance Exposure rates (EER) as regulated by 21CFR 1020.32(d). The Half Value Layer filtration remains compliant to 21CFR 1020.30 (m).

This may cause additional X-ray dose to patient and/or operator.

Interim Solution:

The GE OEC 9600 C-arm should have the Maximum EER assessed if the collimator has been replaced since the last periodic compliance verification. If the GE OEC 9600 is found to exceed the Maximum EER limits, the use of the 9600 should be discontinued and GE Healthcare Service should be contacted to mitigate this issue.

Permanent Solution:

A GEHC OEC Representative will contact you to schedule an inspection of your GE OEC 9600 for the proper installation of the secondary collimator filter. If the filter is missing, your GEHC OEC representative will install and verify compliance. This corrective action will be performed at no cost.

If you have any questions or concerns regarding this issue, please do not hesitate to contact the service team for further information at 800-874-7378 option #8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

A handwritten signature in cursive script that reads "Pete McCabe".

Pete McCabe
President and CEO

A handwritten signature in cursive script that reads "Maria Frame".

Maria Frame
Vice President Quality and Regulatory Affairs