DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702 Industry Information: www.fda.gov/oc/industry	06/01/2010 - 06/14/2010* FEI NUMBER 3002859814

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Joseph A. Vinhais, Senior Director Quality, Regulatory and Sustainability

FIRM NAME	STREET ADDRESS
Philips Medical Systems	3860 North First Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95134-1702	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, your complaint PR 287361 opened on 9/30/09 describes a patient ripping the fingernail off at the root of his left "pinky" finger and breaking the finger while pulling his finger from the space where the finger was caught between the table and the table cover of the CardioMD table during patient repositioning. An MDR was not submitted for this complaint.

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, complaints describing malfunctions similar to complaints of malfunctions that have already been submitted as MDRs have not been submitted as malfunction MDRs:

1. MDR 2916556-2009-00004 was submitted in response to Complaint 2009-02631 (later entered into your (b) (4) data base as PR 258133) which reported a BrightView SPECT detector falling and hitting the gantry during a collimator exchange. There was no patient on the table at the time. Your investigation of this event determined that during the assembly process of the lead screw there is a "potential of over-stressing the return finger inside the ball-nut" and that this failure could lead to "failure and the detector dropping". Although you had knowledge of the potential for the detector dropping with this type of ball-nut malfunction of the lead screw, you did not submit MDR reports for subsequent complaints of similar lead screw ball-nut malfunctions. These complaints are PR numbers: 254882, 269465, 352332, 308934, 310890 and 310891. For these complaints your MDR decision trees state that if the malfunction recurred it would not "lead to a death/serious injury".

2. MDR 2916556-2010-00001 was submitted in response to Complaint PR 330823 which reported a Transcam detector

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	Christine M Parmentier, Investigator Christine M. Parmentier	06/14/2010

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falling off and hitting the floor missing the technician's foot when the camera was being returned to the department after performing a scan in a patient's room. It was discovered during investigation that this camera which reached its end of life in 2009 was serviced by a third party vendor and that the screws holding the detector onto the camera had fallen to the floor or were not completely screwed in. Also it was noted that visual inspection could not detect if (b) (4) had been applied to the screws. A subsequent complaint PR 344760 that reported the screws holding the detector onto the support arm of a Transcam being stripped and voicing a concern that the detector could fall off was not reported as an MDR. This complaint's decision tree states that the device malfunctioned, but that a recurrence would not be likely to lead to a death/serious injury.

OBSERVATION 3

Document control procedures have not been adequately maintained.

Specifically, your procedure, "Complaint Handling Process", (b) (4) defines (b) (4) (b) (4) and states that (b) (4) (b) (4) Another procedure with the same title, "Complaint Handling Procedure", but a different document number, (b) (4), states in Section 4.12 that (b) (4) I was told that the (b) (4) database is not used currently for entering new complaints and that all complaints in this database were closed (b) (4) (b) (4) ago. Although the (b) (4) database can still be used to access complaint information, it is no longer being used for complaint documentation in the way (b) (4) describes.

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Observation Annotations

Observation 1: Promised to correct.

Observation 2: Promised to correct.

Observation 3: Promised to correct. CMP

*** DATES OF INSPECTION:**
06/01/2010(Tue), 06/03/2010(Thu), 06/04/2010(Fri), 06/07/2010(Mon), 06/08/2010(Tue), 06/09/2010(Wed), 06/10/2010(Thu), 06/11/2010(Fri), 06/14/2010(Mon)

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