DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	1/26/2016-1/29/2016* FEI NUMBER 3003684822

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Robert J. Panser , Chief Quality Officer

FIRM NAME	STREET ADDRESS
University Of Rochester Medical Center	601 Elmwood Ave, Box 608
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rochester, NY 14642-0001	Hospital

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

The written MDR procedure does not include documentation and recordkeeping requirements for systems that ensure access to information that facilitates timely follow-up and inspection by FDA.

Specifically, your MDR procedures for collection of information to determine if an event is reportable includes an internal incident reporting and risk management application system, along with concurrent and retrospective reviews. Events reviewed under this inspection were found to be incomplete; for example there was no contact with Clinical Engineering for event numbers b(6), b(6), and b(6). A user error for an incident that occurred on 5/16/15 under event number b(6) was still listed as an equipment error, and event # b(6) that occurred on b(6) involved an ankle tag, and event # b(6) found that the equipment necessary for review had not been sequestered.

Specifically, your MDR reportable event files are listed under the New York State Department of Health (NYPORTS), detail code 938 with occurrence ID numbers b(3) and b(3).

Annotations to Observations

Observation 1: Promised to correct

*DATES OF INSPECTION

1/26/2016(Tue),1/27/2016(Wed),1/29/2016(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Harry J Brewer, Investigator Invalid signature X Harry J Brewer Harry J Brewer Investigator Signed by: Harry J. Brewer -S	1/29/2016

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EMPLOYEE(S) SIGNATURE

Harry J Brewer, Investigator

Invalid signature

X Harry J Brewer

Harry J Brewer
Investigator
Signed by: Harry J. Brewer -S

DATE ISSUED

1/29/2016

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."