

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 10/23/2017-11/7/2017* FEI NUMBER 2074359
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Blair W. Galbreath, Director Pharmaceutical Services

FIRM NAME Dignity Health - Northridge Hospital Medical Center	STREET ADDRESS 18300 Roscoe Blvd
CITY, STATE, ZIP CODE, COUNTRY Northridge, CA 91325-4105	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
OBSERVATION 1**

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically,

Your ISO 7 clean room is currently segregated from outside unclassified air using a plastic strip curtain. This clean room does not have a permanent door to ensure that air from an unclassified area does not enter the clean room. In addition, the absence of a permanent door does not allow the ISO 7 room to maintain an adequate pressure differential to the unclassified area. Within the ISO 7 clean room are ISO 5 classified areas where aseptic processing occurs. For example on 10/27/17, we observed the production of (b) (4) of potassium phosphate and (b) (4) of potassium chloride mixed into a 1000 mL IV bag of 0.9% sodium chloride. This drug had a beyond use date of "930" on "10/28/17".

THIS IS A REPEAT OBSERVATION FROM THE MARCH 2016 INSPECTION.

OBSERVATION 2

Sinks or drains were present in the cleanroom where the ISO 5 classified aseptic processing area was located.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Uttaniti Limchumroon, Investigator Andrew K Haack, Investigator Taichun Qin, Generic Drug User Fee Amendments (GDUFA)	DATE ISSUED 11/7/2017
	<div style="text-align: right;"> Uttaniti Limchumroon Investigator Signed By: Uttaniti Limchumroon - S X Date Signed: 11-07-2017 11:01:42 </div>	

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There is a sink present in the IV room classified as a ISO 7 clean room. This room contains a (b) (4) and (b) (4) where sterile drugs are produced. The sink is used by technicians to wash their hands prior to donning their gowning materials to prepare for aseptic processing. On 10/27/17, we observed technician (b) (6) use this sink to wash her hands prior to producing (b) (4) of potassium phosphate and (b) (4) of potassium chloride mixed into a 1000 mL IV bag of 0.9% sodium chloride. This drug had a beyond use date of "930" on "10/28/17".

THIS IS A REPEAT OBSERVATION FROM THE MARCH 2016 INSPECTION.

OBSERVATION 3

The ISO 5 classified aseptic processing area was located within a non-classified room (segregated production area).

Specifically,

Sterile, hazardous drugs are produced within a ISO 5-classified (b) (4) (model (b) (4)) this production occurs in an unclassified room, located on the 1st floor satellite pharmacy. For example, the following hazardous drugs are produced within this area: Eribulin mesylate 1mg/2mL and Azacitidine for injection, in a lyophilized 100mg vial.

OBSERVATION 4

Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically,

In the ISO 7 clean room identified as the IV room (b) (4) recessed sprinkler heads were observed. A visible gap between the sprinkler head and the ceiling were present (b) (4) sprinkler head is (b) (4) the (b) (4) used as a ISO 5 aseptic processing area (b) (4) sprinkler is (b) (4)

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(b) (4) the (b) (4) and (b) (4) laminar flow hood, both are maintained as a ISO 5 aseptic processing areas.

THIS IS A REPEAT OBSERVATION FROM THE MARCH 2016 INSPECTION.

OBSERVATION 5

Your facility was designed and/or operated in a way that permits poor flow of personnel.

Specifically,

Your firm does not have a designated anteroom for technicians to don their gowns prior to entering the ISO 7 clean room. Technicians enter the ISO 7 clean room wearing their street clothing and don their sterile gowns. In this room, on 10/27/17, we observed technician (b) (6) mix (b) (4) of potassium phosphate and (b) (4) of potassium chloride into a 1000 mL IV bag of 0.9% sodium chloride. This drug had a beyond use date of "930" on "10/28/17".

THIS IS A REPEAT OBSERVATION FROM THE MARCH 2016 INSPECTION.

OBSERVATION 6

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically,

On 10/27/17, as a part of your (b) (4) cleaning, we observed technician (b) (6) fail to apply the (b) (4) sporicidal solution to the interior surface of view screen while she was cleaning the interior surface

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of the (b) (4). When in operation, the view screen is an interior surface of the area that is maintained as ISO 5 and is where aseptic processing of drugs occurs.

OBSERVATION 7

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

On 10/24/17, we observed an IV bag of 5% Dextrose, (b) (4) vials of Heparin and a package of sterile presaturated wipes being moved into the pass-through chamber of the ISO 5 (b) (4) from the ISO 7 clean room without being disinfected. We observed the technician moving the items onto (b) (4) prior to disinfecting these items. These materials were used to produce 500 mL of Heparin, 500 units/mL with a BUD of "1030" on "10/25".

OBSERVATION 8

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

On 10/27/17, we observed technician (b) (6) use non-sterile lint-free wipes within the ISO 5 (b) (4) during cleaning.

THIS IS A REPEAT OBSERVATION FROM THE MARCH 2016 INSPECTION.

OBSERVATION 9

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Personnel engaged in aseptic processing were observed with exposed hair.

Specifically,

On 10/27/17, we observed technician (b) (6) to be wearing a non-sterile hair cover that did not completely cover the hair on the back of her head while she aseptically processed drug products inside the ISO 5 (b) (4) laminar flow hood. With hair exposed, she processed factor IX complex with a BUD of "1400" on "10/27".

In addition, we observed this same technician placing her head and body inside the ISO 5 (b) (4) and ISO 5 (b) (4) laminar flow hood while she was cleaning the ISO 5 areas.

OBSERVATION 10

The segregated production areas surrounding the ISO 5 classified aseptic processing area contained dust-collecting overhangs without adequate and frequent cleaning.

Specifically,

On 10/23/17 and on 10/27/17, we observed a ledge on the operator's right hand side, adjacent to the (b) (4) that contained a visible build-up of dust. This ledge is adjacent to the (b) (4) for cleaning. On 10/27/17, we observed (b) (4) of potassium chloride and (b) (4) of potassium phosphate mixed into a 1000 mL IV bag of 0.9% sodium chloride produced in this (b) (4). This drug had a beyond use date of "930" on "10/28/17".

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***DATES OF INSPECTION**

10/23/2017(Mon), 10/24/2017(Tue), 10/27/2017(Fri), 11/02/2017(Thu), 11/07/2017(Tue)

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