

CASSANDRA F. FRAZIER
TRANSMITTAL
UNITED STATES

MATERIALS LICENSING BRANCH

TELECON & FAX

TO: _____ COMPANY: _____

NUCLEAR REGULATORY COMMISSION
REGION III

#PAGES: _____



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FAX #: _____

CONVERSATION RECORD

TIME

DATE

7/19/2011

NAME OF PERSON(S) CONTACTED

David Pellicciarini

ORGANIZATION

IBA Molecular North America, Inc.

TELEPHONE NO.

310-699-2584

SUBJECT

License Amendment for 45-25221-05

SUMMARY

Licensee is requesting to remodel their Kansas City, MO. Facility to allow IBA to better comply with US Food and Drug Administration's requirements. I requested clarification on Item 7 of the amendment request regarding the proposed exhaust system diagram. It states that the exhaust system is unchanged except for a new branch being added to pull from the new synthesis cells, target delivery chamber and pass-through box from the dispensing hot cell (DHC). It further states that the DHC will be operated at positive pressure. We discuss why the positive pressure and what would happen if there was a spill in this area.

Mr. Pellicciarini indicated that DHC needed to be at positive pressure to pass the Board of Pharmacy requirement for to have a "sterile injectable drug"; known as a Class 5 environment. They tried to get to a Class 5 with negative pressure, but was unable to do so. Therefore they decided to separate the target delivery chamber from the DHC. The DHC is then operated at positive pressure. However, from a radiation protection view, the pass-through box was added and is operated at negative pressure. All drugs are put through the pass-through box to prevent any spread of contamination.

I explained that upon approval of the amendment request, the RI ((45-25221-01MD) and RIII (45-25221-05) licenses will be issue concurrently.

ACTION REQUIRED

Requested that he be provided with a e-mail when the license is issued at
David.Pellicciarini@IBA-Group.com

NAME OF PERSON DOCUMENTING CONVERSATION

Cassandra F. Frazier

SIGNATURE

DATE

7/19/2011