

August 13, 2008

U.S. Nuclear Regulatory Commission, Region III
Nuclear Materials Safety Branch
2443 Warrenville Road
Ste. 210
Lisle, IL 60532-4352

RE: Material License #24-04206-12MD (Kansas City)

Please Expedite Licensing Action

Dear License Reviewer:

Please amend the above referenced material license to reflect the following modification:

1. Add an Iodine-131 automated dispensing system to the list of equipment in Item 9, "Facilities and Equipment" of the current license application. This dispensing system will be used to make Iodine-131 therapy products. The exhaust will be tied into the existing glove box exhaust line. Ventilation system parameters will be unchanged. A revised diagram, depicting the dispensing system addition, is provided in Attachment I and will replace Appendix E. The revised facility diagram depicting the location of the dispensing system within the restricted area is provided as Attachment II and will replace the facility diagram in Appendix D of the current license application.

The DRAXIMAGE Smart-Fill™ (patent pending) capsule-filling machine (photograph provided in Attachment III) is a computer-controlled dispensing unit which consists of: a shielded enclosure, manipulator and transfer arms, integrated dose calibrator, and a multi-well carousel for the preparation of custom I-131 capsules. The unit is shielded with an inch of lead on the front and sides and a half inch of lead on the back. The system allows for improved radiation protection and precise and reproducible dispensing. The computer interface allows personnel to generate a detailed report containing order information such as activity ordered, calibration date, volume dispensed, production date and operator name.

After receipt of the unit, a 2" PVC duct leading from the dispensing unit will be mechanically connected to the existing 6" ductwork and mechanically sealed. The 6" ductwork is part of the independent ventilation system which provides negative pressure to the current glove box and waste cabinet.

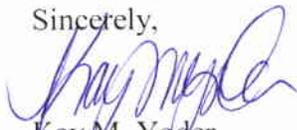
To ensure no leakage, the connection to the ventilation system will be mechanically sealed and silicone caulk applied to all sealing surfaces. The existing manometer will continue to monitor air flow at all times to ensure the system is at negative pressure to the environment. Breathing zone air samples will be collected and analyzed weekly at the dispensing unit, glove box, filter unit and waste cabinet and analyzed for I-131 airborne radioactivity

Prior to service, a representative from the vendor and who has previously installed the DRAXIMAGE Smart-Fill at other facilities, will setup and calibrate the dispensing unit and validate the test system using both water and Tc-99m product. All Covidien authorized nuclear pharmacists will be trained by the vendor to operate the dispensing unit.

The dispensing unit has been modified in two areas. One modification is to adjust an internal capping unit to meet the specifications of the vendor-supplied vial. The second modification is to adjust the vial shield holder to meet the specification of Covidien's custom made vial shield. These modifications will not affect the integrity of the lead shielding or air seals within the dispensing unit.

All other items relating to our established Radiation Safety Program remain unchanged at this time. Please contact April Chance, Manager, Radiological Affairs, at (314) 654-7960 for additional information to support this request. Thank you for your prompt assistance regarding this matter.

Sincerely,



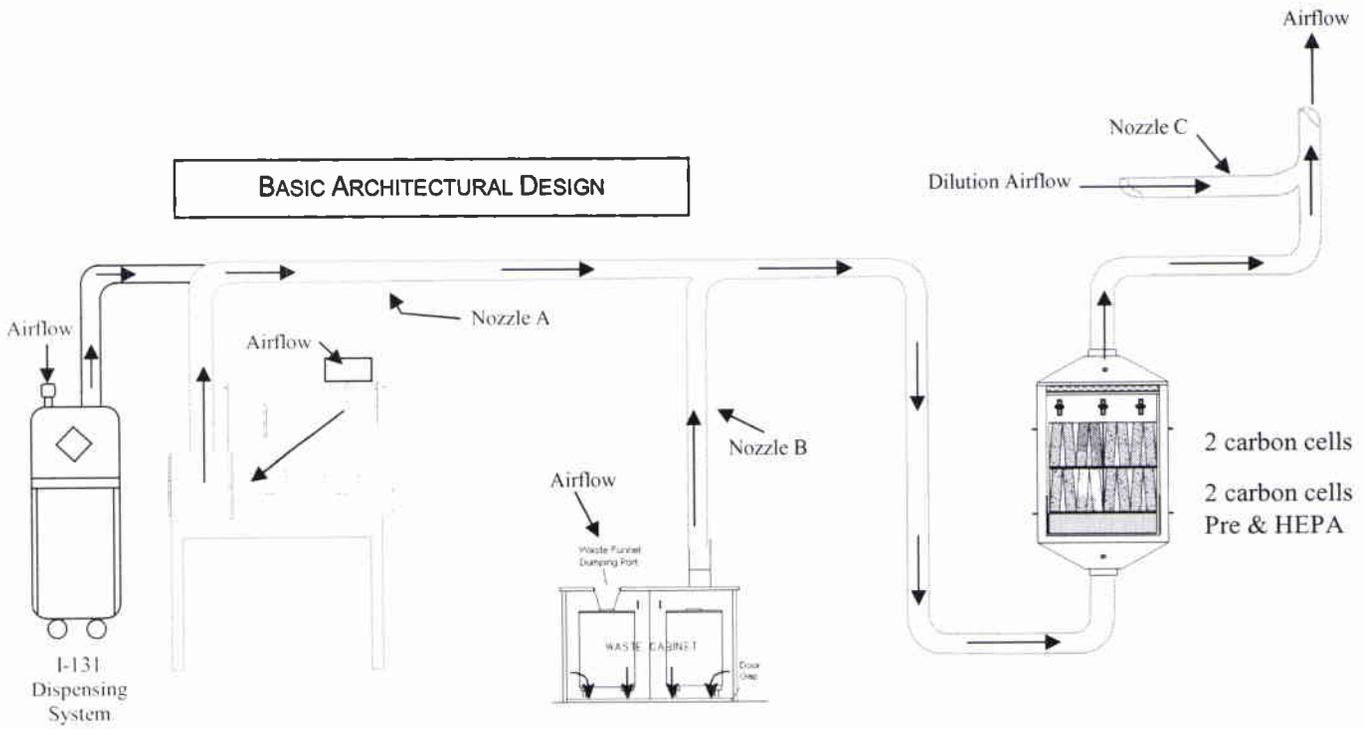
Kay M. Yoder

Director, Radiation, Environment, Safety & Health

Attachments

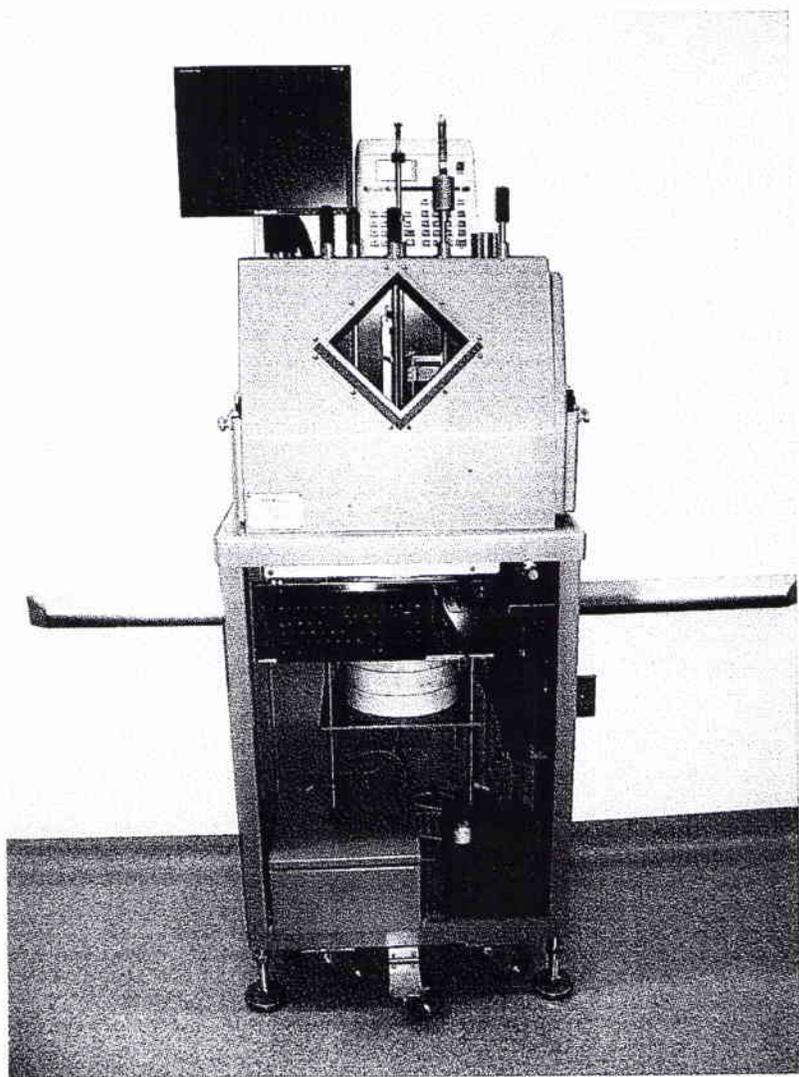
cc: D. Persinger, R.Ph., RSO (Kansas City, MO Nuclear Pharmacy)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)

ATTACHMENT I VENTILATION SYSTEM DIAGRAM



**ATTACHMENT II
FACILITY DIAGRAM**

ATTACHMENT III
DRAxIMAGE SMART-FILL™ DISPENSING UNIT PHOTOGRAPH



From: Origin ID: ALNA (314)654-7089
April Chance
Covidien
Earth City
675 McDonnell Blvd.
Hazelwood, MO 63042



CLS853888/2124

Ship Date: 15AUG08
ActWgt: 1 LB
System#: 3742267/NET8061
Account#: S *****

Delivery Address Bar Code

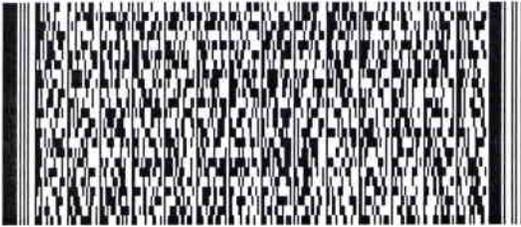


Ref # 0200032441076656
Invoice #
PO #
Dept #

SHIP TO: 6308299500

BILL SENDER

REGION III
U.S. NUCLEAR REGULATORY COMMISSION
NUCLEAR MATERIALS LICENSING SECTION
2443 WARRENVILLE RD STE 210
LISLE, IL 605324352

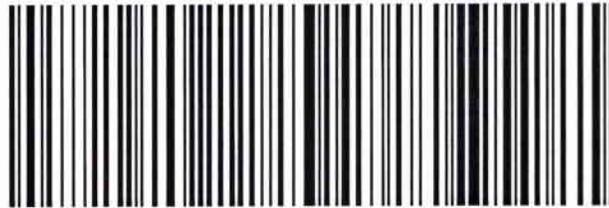


TRK# 7919 4107 7499
0201

MON - 18AUG A2
STANDARD OVERNIGHT

60532
IL-US
ORD

XH ENLA



After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.