Attachment 5 (reference: Question #2)

QA/QC PROCEDURES FOR GENERALLY LICENSED DEVICES

The following procedure shall be complete for each generally licensed device or specifically licensed device being change to a generally licensed device prior to installation.

PROCEDURE:

1. Prior to installation, choose the proper Quality Control checklist as identified below. These checklists are to ensure all devices are properly labeled and all required information is provided to the customer.

    a) Checklist for Generally licensed device.
    b) Checklist for changing a Specific licensed device to a Generally licensed device.

2. Checklist for Generally Licensed Devices:

    a) Complete the customer information.
    b) Complete the device information.
    c) Are all labels for generally licensed devices attached to the device?
    d) Are collimator fasteners of a tamper-proof type?
    e) Is the operations manual for the generally licensed device provided?
    f) Date and sign.
    g) This document must be placed in the customer's file.

Checklist for changing a Specific Licensed Device:

a) Complete the customer information.
b) Complete the device information.
c) Have the labels been changed to the general licensed device as required?
d) Have the collimator fasteners been changed to a tamper-proof type?
e) Has the customer been provided the amendment to the operations manual for generally licensed devices?
f) Date and sign.
g) This document must be placed in the customer's file.

CHECKLIST FOR GENERALLY LICENSED DEVICES

Date of Installation: _____

CUSTOMER INFORMATION:

Name: _____

Address: _____

City, State, Zip: _____

Contact Person: _____Telephone No.: _____

DEVICE INFORMATION:

Isotope: _____ Activity: _____mCi

Device Model #: _____ Device Serial #: _____

Date of Assembly: _____

LABELS:

1. The "Caution Radioactive Material" level with isotope, activity, date of assay is attached? (Check one) Yes _____ No _____

   If no, explain corrective action: _____

2. The general licensed label is attached? Yes _____ No _____

   If no, explain corrective action: _____

FASTENERS:

Tamper-proof fasteners are installed on the collimator plate? Yes ____ No ____

If no, explain corrective action: _____

OPERATIONS MANUAL:

The operations manual for this general licensed device has been provided to the customer. Yes _____ No _____

If no, explain corrective action: _____

Signature of Technician _____Date _____

CHECKLIST FOR CHANGING A SPECIFIC LICENSED DEVICE TO A GENERALLY LICENSED DEVICE

Date of Change/Installation: _____

CUSTOMER INFORMATION:

Name: _____

Address: _____

City, State, Zip: _____

Contact Person: _____Telephone No.: _____

DEVICE INFORMATION:

Isotope: _____ Activity: _____mCi

Device Model #: _____ Device Serial #: _____

Date of Assembly: _____

LABELS:

1. The "Caution Radioactive Material" level with isotope, activity, date of assay is attached and legible. The specific licensed device label is adequate? (Check one) Yes _____ No _____

   If no, explain corrective action: _____

2. The general licensed label is attached to the device? Yes _____ No _____

   If no, explain corrective action: _____

FASTENERS:

Tamper-proof fasteners have been installed on the collimator plate?
Yes ____ No ____

If no, explain corrective action: _____

OPERATIONS MANUAL:

The customer was provided a copy of the amendment to the operations manual for generally licensed devices. Yes _____ No _____

If no, explain corrective action: _____

Signature of Technician _____Date _____