BIOASSAY TESTS - THYROID COUNTS AUGUST 2019

According to DHS 157.22(4) and WISREG-1556 Vol. 9, Rev. 2 for purposes of assessing dose used to determine compliance with occupational dose equivalent limits, a licensee or registrant shall take suitable and timely measurements of all of quantities of radionuclides in the body.

Clarification

The bioassay protocol is currently limited and directed to I-131 NaI (unbound) and I-131 mIBG (bound). If it is determined other therapeutic radiopharmaceuticals have the potential of having measurable activity this protocol will be updated accordingly.

Preparation

Any radiopharmacist or radiopharmacy technician who routinely prepares I-131 will perform a bioassay at weekly intervals.

Any radiopharmacy observer will perform a bioassay as described below under Administration/I-131 Solution.

Administration

I-131 Capsule

Any Nuclear Medicine staff physician, resident, technologist, or student (and any other personnel involved) who are in the room for the administration(s) of I-131 capsules that total more than 100 mCi in one work day will perform a bioassay not less than 6 hours or more than 72 hours following administration.

I-131 Solution

Any Nuclear Medicine staff physician, resident, technologist, or student (and any other personnel involved) who administer any I-131 solution will perform a bioassay not less than 6 hours or more than 72 hours following administration. (This also includes radiopharmacy observers.)

The Capintec system will convert the activity in the thyroid to μ Ci using the calculated efficiency (efficiency is calculated with a Ba-133 source).

Evaluation Limit: 0.1 uCi Any thyroid bioassay results greater than 0.1 μ Ci shall be reported to both Radiation Safety (pager ID 1804) and the Nuclear Medicine or Nuclear Pharmacy Manager within the next working day

Investigational Limit: 0.5 uCi Any thyroid bioassay results greater than 0.5 uCi shall be reported to both Radiation Safety (pager ID 1804) and the Nuclear Medicine Manager or Nuclear Pharmacy Manager immediately.

Reporting will include your name, μ Ci, expected date of contamination/uptake and possible explanation. All bioassay information with be stored on the Capintec system and then archived on compact disc.

<u>Audit</u>

Preparation: Bioassays for Radiopharmacy personnel are checked off when completed and that check off is routinely reviewed.

Administration: All therapy administrations will be noted on the therapy log. This log will have a column to indicate when a bioassay is required/performed and another indicating the audit. The audit will include

- A frequency of every Monday, Wednesday and Friday.
- Validate the bioassay was or was not needed.
- Verification of the completed bioassay against the Thyroid Uptake Probe bioassay records on its' PC.
- Omissions found will be taken care of that day as it will still be within the 6 to 72-hour window.

References

NUREG/CR-4884 pg. B-103 NRC Reg Guide 8.9 "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"

Reviewed By:

Scott B. Perlman, MD, MS Chief, Nuclear Medicine Jason Timm Radiation Safety Officer

Derek Fuerbringer, CNMT Manager, Nuclear Medicine Scott Knishka, RPh, BCNP Radiopharmacist