Midwest Research Institute

January 26, 2011

Mr. Michael LaFranzo
Health Physicist
U.S. Nuclear Regulatory Commission
Region III
Division of Nuclear Materials Safety
2443 Warrenville Rd., Ste. 210
Lisle, IL 60532-4352

Dear. Mr. LaFranzo;

We appreciate your comments about MRI's bioassay program for carbon-14 radiosynthesis work during your recent compliance audit. It certainly initiated interesting discussions about our current procedures. Three issues emerged from the discussions; what event(s) should trigger a mandatory C-14 bioassay, what type(s) of bioassay sampling would be useful for estimating dose, and what exposure model(s) would be useful for estimating dose from the bioassay results. Many of the questions that you posed to us during your visit were directed at these very issues.

As you are well aware estimating dose from a bioassay result for C-14 is very complicated, as it is one of the main biological elements and you can find it in a number of different chemical compounds. The different chemical compounds will have a more determining effect on dose, based on target organs and biological half life, than just the effects of C-14. The process of determining dose is relatively straightforward if you are measuring just one compartment; however, depending on the chemical compound, there could easily be a half a dozen important compartments to determine before dose reconstruction could occur.

When reviewing our historical urinalysis data, we are confident that the engineering controls in the radiosynthesis laboratory are sufficient to protect the researcher from exposure to airborne labeled chemicals during normal operations. We are confident that the mandatory personnel protective equipment will protect the researchers from dermal contact during normal operations. We are also confident that the work practices and chemical hygiene measures used in this laboratory will protect against inadvertent ingestion. The researchers receive reoccurring training in all these procedures. Weekly bioassay sampling may not be necessary when the laboratory is operating normally and there has been no event that would cause inadvertent inhalation, ingestion, or dermal contact with C-14 labeled materials.

We intend to follow the bioassay program for C-14 as stated in the NRC license. Specifically, the trigger events for mandatory bioassays for C-14 will be as follows: *Urinalysis is required within 24 hours, if possible, but not later than 72 hours following ingestion, inhalation, or skin contamination of personnel that could, in the judgment of the RSO, lead to an exposure of one tenth of regulatory limits.* The circumstances that would trigger a bioassay would be a spill of C-14 labeled material outside of

engineering controls, a failure of the engineering controls during active use of labeled materials, or direct skin contact with a labeled chemical with physical properties that would allow dermal adsorption of the material.

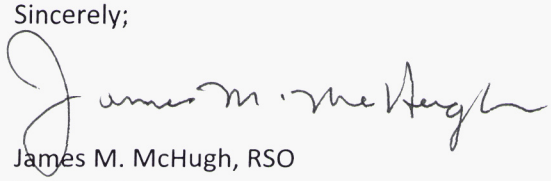
The type of bioassay sampling (e.g., urine, blood, exhaled breath) would be dependent on the physical and toxicological properties of the labeled chemical. We have toxicologists at MRI that can be consulted when a bioassay is deemed necessary by the RSO. A Certified Health Physicist will be consulted for dose reconstruction when necessary.

In summary, the following changes to the program will be made:

- Weekly bioassay monitoring of C-14, P-32 and other radionuclides on our license will be discontinued unless there is an upset condition within the lab
- If an upset condition occurs in the lab, urinalysis will be required within 24 hours
- A Certified Health Physicist will be consulted for dose reconstruction

The changes to the procedures are consistent with the current license and will not require an amendment. If you have any questions, please contact me at 816-360-5338 or Eric Jeppesen at 816-360-5378.

Sincerely;



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