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D. Howe

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May 29, 1997

Hugh L. Thompson, Jr.,
Deputy Executive for
Regulatory Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Hugh:

On May 28, 1997, at 0730 hrs., I had a telephone meeting with Larry Camper, Kathy Haney, and Donna-Beth Howe to discuss problems or possible problems with DG-0009, the draft regulatory guide for nuclear medicine physicians. We discussed four issues:

1) FDA has amended its regulations for human research, permitting research without obtaining informed consent in certain highly limited situations in which such consent is impossible. In DG-0009, the absolute requirement for informed consent precludes compatibility with FDA's new policy. The NRC document must be changed to accept anything FDA accepts.

2) In DG-0009, there is a table which asks each medical licensee to list each radionuclide, its chemical and/or physical state, and its intended use.

   a) "Chemical state" means the actual chemical compound involved, e.g. "Tc-99m-dimercaptosuccinic acid".

   b) "Physical state" means "solid, liquid, or gas".

   c) "Intended use", to a medical licensee, means "clinical indication".

The need to fill out such information would essentially preclude medical practice, because a physician would have to make every single compound he uses, every radionuclide he uses, and each clinical indication into a license condition, and he could not vary his practice without amending his license. This is of course preposterous, renders the Radiopharmacy Rule meaningless, and has no basis in scientifically or medically valid thinking.

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Larry agrees, and stated that of course none of that information is actually required. The answer to "chemical and/or physical state" should be "unsealed", and the answer to "intended use" should be "any use in 35.100, 200, or 300". Research is not included here. Of what use is this information to NRC?

I pointed out to Larry that our byproduct material is not "unsealed"; we don't slosh buckets of it around the department, as that word might indicate. Xe-133 comes in sealed glass ampoules, most radiopharmaceuticals come in sealed single dose or multidose vials, and our generator columns are sealed by multiple valve systems. Radiochemicals come in sealed containers as well. They are just not sealed sources, but they are not "unsealed". Larry says that this use of the word "unsealed" comes from Jon Sharp, who used to be in the Texas program. Jon is now retired; he was actually an astronomer, not a nuclear physicist. In any case the wording is poor. I also questioned what is the use to NRC of merely seeing the word "unsealed" written over and over? Licensees could be asked to list "sealed source" and "non-sealed source" material, and that would be clear and our concerns would lessen. Our concern, of course, is that despite Larry and Donna-Beth's ardent denials, that there is intent from NRC to require exactly what it appears to require.

NRC is asking us to believe that "chemical state" doesn't mean "chemical state", that "physical state" does not mean "physical state", that "intended use" has nothing to do with "clinical indication", and that "unsealed" really means "sealed". Moreover, none of these strange definitions appear in writing. Donna-Beth says they have to be this way because of "Form 313". I am not an NRC licensee, I do not know what "Form 313" is, but maybe you should discard it if it dictates such confusion and abuse of language. Anyway, if you buy this scheme, I'd like to talk to you about a used car.....!

Larry and Donna-Beth are basically asking me and others to "trust NRC". That is not realistic.

Therefore, I ask that you order that the terms "chemical state", "physical state", "intended use", and "unsealed" be removed or replaced by crystal-clear English words and phrases with scientifically accurate meanings. Perhaps Dr. Pollycove or members of the ACMUI can help you out here. For example, "atomic no. 1-83 in any chemical or physical form for medically-related uses" should be fine.

Remember, you are licensing physicians whose education, training, and experience should be sufficient to enable them to use any radioactive material safely. At that point, licensing should not be exhaustively prescriptive or repetitious of that education, training, and experience. It should be broad, inclusive, simple, and short. It should assume the knowledge required for licensure in the first place. Physicians truly qualified in the basic nuclear and radiation sciences required for nuclear medicine competence are not well-loggers.

Your present licensing is a nightmare of unnecessary, prescriptive nitpicking. It has been optimized to justify large numbers of licensing personnel, who then write poor licenses to optimize the need for amendments, justifying their jobs and maximizing income from amendment fees. NRC's claims of simplifying the licensing process are going awry because it is in the hands of people who are not going to risk admitting that their job is unnecessary. I see no improvements in the present scheme.

I can practice any other medical specialty with a license 2 inches by 3 inches in size. I have a license from the DEA to prescribe narcotics and dangerous drugs that is 4 inches by 7 inches in size. My radionuclide license, all of which is for low risk diagnostic and therapeutic activities, has so much paper, including the supporting documents, that it weighs almost as much as a lead brick. The area of paper subsumed should probably be expressed in units of acres, not square inches.

In fact, none of this byproduct licensing is necessary. If you stamped "radionuclides" on the back of my medical license, and stated in 10 CFR Part 35 that physicians using radionuclides must practice in such a manner as to honor the standards, but not the prescriptive regulations, of 10 CFR Part 20, we could dispense completely with licensing and not sacrifice one iota of radiation safety. You could downsize substantially, cut the cost of nuclear medicine in the United States by about $1 billion/year, and replace the present 10 CFR Part 35 with little more than the qualifications needed to obtain the "radionuclide" stamp on a medical license. The recommendation to hold medical practitioners to the standards, but not the prescriptive requirements, of Part 20 was made by the NAS-IOM in its report of Dec., 1995. It is interesting that NRC has never mentioned this. The "take out" clause in Part 20 permits NRC to do this immediately. What have you got against saving $1 billion/year in nuclear medicine without sacrificing safety?

Therefore, in addition to fixing the four items previously discussed for DG-0009, I ask you to consider some long-overdue, basic changes in the entire licensing process. The present staff and management has an obvious conflict of interest and can never make the needed improvements.

Thank you for your attention and consideration.

Sincerely,

Carol

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and
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