



April 29, 1997

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Dear Hugh:

I should like to bring to your attention an apparent omission in Draft Regulatory Guide 0007 that appears staggering in its potential consequences. It appears to make it impossible for nuclear pharmacies and nuclear medicine physicians to purchase non-FDA-approved radiochemicals for compounding and many research purposes. While the "Radiopharmacy Rule" gives us the right to compound radiopharmaceuticals as needed for our patients, this right becomes a farce if we cannot obtain our raw materials.

There are many manufacturers of radiolabeled compounds who are not registered drug manufacturers with FDA or a state, and there are FDA-registered manufacturers who also sell radiolabeled compounds that are not FDA-approved.

Is there another draft regulatory guide for other manufacturers who are not FDA-approved? Is there a mechanism for us to purchase radiochemicals, as opposed to FDA-approved radiopharmaceuticals? Or did our absolute need to obtain radiochemicals disappear from NRC's radar screen?

Please clarify this issue as soon as possible. The analogous problem exists with sealed sources and devices.

There is also a requirement in DG-0007 that each manufacturer would have to have a separate license for distribution. As every manufacturer distributes, this seems counterproductive to NRC's commitment to streamlining the paperwork of licensing. About the only "usefulness" that this new requirement would appear to have is to cut off our radiochemical supplies from all suppliers at once, without openly calling attention to this apparent agenda ahead of time. Please explain the benefits of double licensing for the agency and for the nation. Why shouldn't any manufacturer be able to distribute to anyone licensed to receive the material, so long as DOT-type requirements are met?

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While the omission of radiochemicals could be explained as careless NRC oversight, the combination of the omission with this strange double licensing ploy suggests the possibility of a purposeful act.

DG-0007 is called "Guide for the Preparation of Applications for Licenses to Authorize Distribution of Various Items to Commercial Nuclear Pharmacies and Medical Use Licensees". It was issued in March, 1997. The contact persons listed are D. Howe and S. Jones.

Thank you for your attention and consideration.

Sincerely,



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and
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cc: Barry Siegel, M.D.
Myron Pollycove, M.D.
Carl Paperiello, Ph.D.
John Hoyle, Secretary, USNRC

CSM:sfd