NOTE relating to letter from Carol S. Marcus, ACNP, dated October 18, 1996
Subject: Comments on NRC's Strategic Assessment and Rebaselining Project: Materials/Medical Document No. 7

The predecisional material referenced in the Addenda on page 14, item 3, has been removed from this package.

Marie, 10/25/96

Please see me on the Marcus letter. Sam Jones came over and indicated that the page is still pre-decisional. I will tell you more when I see you. Emile

the diagnostic test, but this would add expense, inconvenience, and delay to an otherwise straight-forward procedure.

This alternative serves as the base case from which the other alternatives are evaluated.

Alternative 2 - Grant the petition via an exemption to permit physicians who are not "authorized users" to receive and use capsules containing 1 μCi of ^{14}C-urea

This alternative would permit the receipt and medical use of capsules containing 1 μCi ^{14}C-urea by physicians who are not authorized users.

However, manufacture and distribution of exempt materials can only be made by NRC licensees; Agreement States licensees who intend to manufacture or distribute such capsules would need to obtain an NRC manufacture and distribution license in addition to their Agreement State license (10 CFR 150.15(a)(6)). Therefore, this alternative is not recommended.

Alternative 3 - Grant the petition via a general license to permit physicians who are not "authorized users" to receive and use capsules containing 1 μCi of ^{14}C-urea

This alternative would permit physicians who are not authorized users to receive and use capsules containing 1 μCi ^{14}C-urea for medical use under a general license.[1]

This alternative is preferred over the base case (Alternative 1) for the following reasons:

o Health and Safety

As noted earlier, a detailed safety analysis was performed that analyzed public, worker, and patient radiation safety hazards associated with

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[1] The concept of a general license for medical use is not new. Prior to 1987, Part 35 regulations permitted the medical use of certain radioactive drugs under a general license to physicians who were registered. Registration certificates would not be necessary for ^{14}C because, as discussed in the SAFETY ANALYSIS section, radiation safety concerns associated with the use of these capsules are insignificant. The general license was deleted from Part 35 because of the low level of use.

Ann Jones 1/15-6198

From: Marie Slater
To: TWD2.TWP9.SZJ
Date: 10/23/96 3:45pm
Subject: Predecisional: Tri-Med C-14 urea petition

Sam--
I left a message for you on voice mail earlier today, but I need to get a response to this ASAP.

I have received a comment on NRC's Strategic Issues Paper No. 7 re Material/Medical Oversight from Carol Marcus of the American College of Nuclear Physicians. One of her attachments is an excerpt from an NRC document she identifies as Pre-decisional - for Limited Distribution - NRC material on Tri-Med C-14-urea petition that discusses NRC alternatives 2 and 3.

Emile Julian of the Docketing and Service Branch, SECY believes the material that Marcus submitted as predecisional is now in the public domain. Is there any way you can verify that this material is now publicly available. I would like to delete these markings before I send the document to the Public Document Room and NRC's RIDS Distribution System.

I'll walk it over if you need to see the document.

Thanks,
Marie Slater
SECY 415-1675, MDS

CC: elj