

From: Woods, Susanne
Sent: Friday, July 01, 2011 3:39 PM
To: Mattsen, Catherine
Cc: Starkey, Doug; Hasan, Nasreen; Furst, David; Comfort, Gary; Hilton, Nick
Subject: OE review of Final Rule

Re: FSME request for review and concurrence on rule package

Final Rule: Requirements for Distribution of Byproduct Material, Parts 30, 31,32, 40, and 70.

OE is ready to concur on the rule language provided. However, my understanding is that 32.210(c) wording is to be revised, per our discussions, but appears to be missing from this package. Please provide the missing rule text to me and I will review it when I return to the office on 7/11 (one day after your return to the office). This date appears to still meet the 20 day deadline requested in your transmittal memorandum for the rule.

We offer the following comment on 32.211(1):

Consider revising the following wording: "However, if the certificate holder determines that an initial transfer was in fact the last initial transfer..."

Specifically, there is nothing to prompt the certificate holder to make such a determination as a matter of compliance. Removing the wording, "if the certificate holder determines..." and leaving the rest of the sentence will require the certificate holder to continuously monitor for such conditions where the initial transfer was in fact the last initial transfer..." Otherwise, it appears as if the certificate holder can claim that nothing caused them to make such a determination so compliance with the requirement was not applicable.

-Susanne Woods, Senior Enforcement Specialist, OE