Ms. S. Kimberly Belshe[´], Director Department of Health Services 714/744 P Street P.O. Box 942732 Sacramento, California 94234-7320

Dear Ms. Belshe:

I am responding to your December 23, 1994, letter to Chairman Selin. We thank you for the suggestion that, from a California Agreement State Program review standpoint, we start with a clean slate and a new review that would reflect the current status of your program. As described below, I believe that with the completion of a few additional actions, the California program will likely be adequate and compatible and the equivalent of a clean slate will be established.

As you know, the report documenting our January 18 through February 1, 1994 follow-up review and the March 1-3, 1994, special sealed source and device review was mailed to you on December 23, 1994. Except for the addition of a pharmacy supplement to inspection forms and regulation compatibility issues, that report documents that recommendations from the January 1993 routine program review have been satisfactorily resolved and are considered closed. Upon receipt of a confirmation from your staff that the pharmacy supplement has been added to the inspection forms, that item will be closed. Our December 23, 1994, letter transmitting the 1994 report indicated that we will reevaluate the withholding of adequacy upon receipt of your plan to address the comments and recommendations applicable to your sealed source and device evaluation program. We will remove the adequacy withholding when we determine your plan satisfactorily addresses the Likewise, we will remove the compatibility comments and recommendations. withholding once we have received notice that you have promulgated all regulations, in a form that is compatible with NRC's equivalent regulations, that have not been adopted within the three-year period required by the NRC.

With the completion of the three actions identified above, we will have a basis to find your program adequate and compatible and the status of your program will be current. Finally, for tentative planning purposes, please note that we are currently forecasting that the next routine review of the California Agreement State Program should be conducted during December 1995. At that time, all findings from previous reviews will likely be closed. By that time, we may be conducting program reviews using the new Integrated Materials Performance Evaluation Program process, which will also contribute to the sense of a clean slate approach which you describe.

We continue to welcome your suggestions and recommendations that will improve the effectiveness of the Agreement States program.

Sincerely,

Richard L. Bangart, Director Office of State Programs

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