agencies and to develop and implement a program which would satisfy the quality assurance needs of purchasing agencies within the mandate given to FDA. The overall approach included seven separate, but closely related action plans.

Work under the first action plan was completed with the establishment on December 10, 1974, of a managing unit for the program. The unit--known as the Medical Products Quality Assurance Staff--was placed in FDA's Office of the Associate Commissioner for Compliance and became operational--but not fully staffed--on February 2, 1975.

Another of FDA's action plans involved development of detailed procedures and resource and time estimates for each of the major elements identified as needed for FDA's assumption of the Government-wide quality assurance program. Each of the elements was studied on an in-depth basis by interagency working groups composed of representatives of FDA, DOD, VA and PHS. The task groups have completed their work and have submitted to FDA final reports which are now being reviewed. FDA, in consultation with the other involved agencies, will soon be making final decisions on procedures for implementing the task groups' recommendations.

In an April 1, 1975, memorandum to OMB, the Acting Assistant Secretary for Health stated that both HEW and FDA attach great importance to the carrying out of FDA's Government-wide quality assurance responsibilities. He stated also that