The GAO report on the two projects, issued in August 1971, confirmed but did not comment on, this train of events. Several researchers at Idaho, including two who had reviewed a draft version of the report, said that the final, public version omitted serious criticisms of the AEC's management of the LOFT and PBF projects. One of those who had read the draft said that, They attributed these deletions to pressure exerted by the commission, which customarily reviews GAO reports of AEC affairs before they are made public.

In an interview, Shaw was asked whether he thought it was fair to blame Phillips for delays in construction when they lacked full authority over contracts. "If they didn't have it, who did?" he said. The AEC, it was suggested. "Well, let's be fair. *Neither* Phillips nor the AEC out there had the necessary competence."

Perhaps the bitterest conflict of all at Idaho developed around Washington's efforts to institute stringent new quality standards in the construction of reactors—not only for commercial nuclear power plants, but for the AEC's own test reactors as well. These two parallel efforts—one internal, one aimed at the industry—commingled to a large extent, and, in the view of a number of safety program staff, with disastrous results. An administrator at Oak Ridge National Laboratory who watched the battle at Idaho from afar says:

> You have to give Shaw credit for pushing the industry to adopt tougher standards. They were urgently needed, and some elements of the industry—and I refer to Westinghouse and General Electric [the two leading reactor manufacturers]—fought it all the way. The question is whether these or similar standards are appropriate for research facilities. We think they are not.

The critics in Idaho charge that in late 1966 Shaw co-opted the LOFT project for use as a "showcase" for standards, to prove to a reluctant industry that they really were feasible. The problem, says an engineer involved in the affair, was that some of the standards, in their initial form, turned out not to be feasible:

> The whole philosophy became one of using LOFT to develop standards and check them out, rather than producing the safety information we desperately needed. And some of them were a bit extreme, requiring that metals be traceable back to the mine. . . . The overall effect was to drive up costs of some com-

FDA to Regulate All Blood Banks

Federal regulations will soon be extended to cover all blood-banking and plasma-collecting operations nationwide, regardless of whether they are engaged in interstate transactions, the Food and Drug Administration (FDA) announced on 26 August.

The new federal directive comes only a month after the Division of Biologics Standards (DBS), now known as the Bureau of Biologics (BOB), was transferred from the National Institutes of Health to the FDA.

The changes are scheduled to go into effect after a 60-day comment period. The FDA action is merely one step in what can be expected to be a series of federal initiatives relating to the nation's blood collection and distribution systems. The next move will probably come following the completion this fall of a massive NIH-sponsored blood study.

The BOB is already responsible for registration and inspection of some 530 large blood banks that collect about 85 percent of the nation's supply of blood for medical use. With its expanded purview, BOB will also oversee more than 3000 small community- and hospital-based facilities that collect the remaining 15 percent.

Plasmapheresis Centers Covered

The new regulations also apply to some 200 plasma-collecting and processing stations that hitherto have escaped federal regulation because they are engaged in collecting products declared in "short supply." These centers have only been required to conform to the requirements of their customers, the federally licensed manufacturers of plasma fraction products.

The legal justification for the new move is a provision Congress added in 1962 to the Food, Drug, and Cosmetic Act. The provision requires registration and inspection of all establishments that manufacture, prepare, or process drugs. All biologics (including blood) are regarded by the FDA as "drugs"—defined as "articles" used in the diagnosis, treatment, and cure of disease.

The new director of the BOB, Harry M. Meyer, offered no particular explanation as to why the regulations hadn't been changed long ago. It is known, though, that the previous leadership of the biologics bureau resisted making use of the food and drug law for fear the DBS would be ensnared by the FDA.

Some Blood Bankers Concerned

The American Association of Blood Banks (AABB), a voluntary organization to which most non–Red Cross banks belong, expressed some trepidation about the new ruling. President-elect Robert Langdell said that the AABB didn't want the government to be "superimposing" its authority on AABB banks, and that the regulations would result in a great deal of duplication of effort and costly paperwork. The duplication would only be partial. Government regulations are concerned with collection, storage, and distribution of blood, while AABB standards also cover the medical area, which includes processing, cross matching, handling, and infusion into the patient.

The Red Cross—which, together with the AABB, draws almost 90 percent of blood used by the nation's medical establishment—seemed happy with the FDA initiative. Medical director Tibor Greenwalt said he always welcomed outside inspection.

The recommended change in regulations will have little effect on a problem that has caused a good deal of public hue and cry of late: the high incidence of hepatitis in the blood of paid donors. Commercial blood banks are responsible for a large portion of hepatitis-contaminated blood (nonprofit banks also pay some donors), and most of these are already federally licensed.

—C.H.