ADMINISTRATION PROBLEM

Regulating medical devices

There was a time when stethoscopes, thermometers, tongue depressors and bone-conduction hearing aids were just about the only medical devices of any consequence. But a profusion of devices ranging from sophisticated operating-room and patient-monitoring equipment to artificial organs and parts has changed the picture dramatically.

None is guaranteed safe or effective, and devices that save lives can also kill. U.S. Food and Drug Administration records hold that pacemaker failures have killed 89 individuals and injured 186 others, while inadequate anesthesia machines are known to have killed 47 patients. X-ray equipment, according to FDA records, has been implicated in more than 2,000 injuries. There is no reason to presume that its data regarding any device are complete; there is no mandatory reporting system.

At the Downstate Medical Center in Brooklyn, Seymour Ben-Zvi, an electrical engineer, evaluates all medical devices used in the hospital. He finds that about 40 percent are defective. Problems also arise when insufficiently trained personnel use sophisticated equipment improperly.

One long-standing and controversial approach to the issue is to empower the FDA to test and preclear medical devices much the way it regulates the marketing of new drugs. In his October consumer message, President Richard Nixon said, "Certain minimum standards should be established for medical devices . . . (and for) premarketing clearance in certain areas."

Dr. Theodore Cooper, director of the National Heart and Lung Institute, was subsequently named to head a committee to look into the matter, and a draft report is being reviewed. It is Dr. Cooper's own view that while there is a need to clarify regulations, it is essential that any new legislation provide a highly flexible framework to accommodate the wide variation in types of devices. "Regulations," he says, "should not necessarily be patterned after the rules for new drugs in which every step is prescribed."

It is likely that, on the basis of the Cooper report, the Administration will propose medical-device legislation that will join more than a dozen bills now pending before House and Senate committees. Despite the concern of some about the problem, pressure has not built up for passage. Hearings are not anticipated on existing bills.

At the present time, medical devices are regulated, to the moderate extent that they are, by the FDA, which is empowered to act only when a device already on the market is mislabeled. FDA handles about 100 such cases a year, says Dr. Joseph Davis, of the agency's medical devices section.

The FDA has neither the manpower, money, or knowledge to evaluate and clear existing or new devices on a broad scale. But others are already moving to fill the vacuum.

At the National Heart and Lung Institute, Dr. Frank Hastings, director of the artificial heart program, has decreed that no heart parts developed with NIH funds can be tested in human beings until they have been evaluated by scientists at one of two new Test and Evaluation Facilities (SN: 4/11, p. 375). One, at the Illinois Institute of Technology Research Institute, is already in operation and testing an intra-aortic balloon pump designed by scientists at Johns Hopkins University. The other, scheduled to go into full operation in about a year, is at the University of Utah in Salt Lake City.

Each has a multidisciplinary staff of engineers, chemists and medical personnel and is expected to operate on a budget of $1 million to $2 million a year. After T&E scientists conclude their study of a device, their judgment will be reviewed by a panel of independent experts.

Says Dr. Allen Ream of the artificial heart program, "We are hoping that these facilities will set an example for the FDA if it moves firmly into the device field." Already, NHLI authorities are discussing their procedures with FDA officials even though the FDA has no direct legal control over the marketing of devices. In fact, the NHLI's control is limited to its own researchers. While it prohibits the clinical trials of the Hopkins balloon pump, for example, another, developed by Dr. Adrian Kantrowitz of Maimonides Hospital in Brooklyn, is available.

Dr. Ream believes that as control of medical devices emerges, the T&E facilities could evolve as the focal point of regulatory evaluation, first taking on studies of heart devices designed outside of the NIH and eventually setting a pattern for all types of devices.

The possibility of a network of T&E facilities is by no means a foregone conclusion. "We still have to prove the validity of the T&E concept," says Dr. Ream, who acknowledges that it does not by any means have the unanimous support of the scientific community. Clearly, there will be a repetition, if not exact duplication, of work. And the concept imposes yet one more step in the process of taking a device from experimental stages to application, a step some researchers feel will cause undue delay. □

RADIOACTIVITY

Close to zero

Present nuclear power plants operate with radioactive releases at less than one percent of the allowable limits set by the Atomic Energy Commission. Despite this there is a great deal of public dissatisfaction and pressure for futher reduction. In Minnesota, for example, the state and a power company are going to court because the state is unhappy with AEC limits and wants to use its own, which are much lower (SN: 4/25, p. 406).

The Westinghouse Electric Corp., which makes pressurized water reactors, has now announced a nuclear power plant system that is as close to zero discharge of radioactivity as possible with conventional technology.

"The experience gained from operating and maintaining the nine plants we have already placed in operation, plus recent technological developments, now makes it possible for Westinghouse to offer what is essentially a zero release plant under normal operating conditions," says Joseph C. Rengel, executive vice president of nuclear energy systems.

Present-day plants get rid of small amounts of low-level radioactive effluents by releasing them into rivers or lakes, where they are diluted, or into air, where they are dispersed. The Westinghouse facility would concentrate, contain and recycle the wastes.

The Westinghouse system works by concentrating gases and then collecting them in tanks, about five pressurized cylinders a year, it is estimated. The new system is able to achieve this concentration through its low level of gas production. To get this level it uses an ion exchange method, instead of the usual evaporation technique, to control power production. The result is that a reduced amount of liquid has to be processed, and this smaller volume means less gases of all kinds will be stripped off. Hence, it becomes feasible to concentrate and contain just the krypton and then move it off site.

As for tritium, its levels are low enough and the pressurized reactor operation such that tritiated wastes can be recirculated into the main coolant system instead of being discharged from the plant. To remove the tritiated water, the system needs to be bled, or siphoned, only once or twice every 40 years, the lifetime of a nuclear plant.

Besides these gases, there are other low-level wastes: nongaseous fission products—cesium, barium, strontium and others—and corrosion products. These are treated conventionally, concentrated into a slurry and carted off site. The small amount that remains is recycled into the coolant system.

The Westinghouse development does