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

not mean the end of the radioactive release problem. "It's a step in the right direction," says Dr. Arthur R. Tamplin, a leading critic of present-day levels. However, the Lawrence Radiation Laboratory scientist adds, to solve the problem the releases from fuel reprocessing plants will have to be cleaned up as well.

There is also the matter of boiling water reactors, which produce more radioactive waste. Because most do not have the middleman, or heat exchange system, of the pressurized water reactors, steam goes directly into generating electrical energy and so radioactivity is less amenable to control. There are ways to reduce releases, though, such as by increasing the waste storage capacity of the system. And General Electric, which makes boiling water reactors, is expected to come out with its answer to Westinghouse shortly. □

SUPERSONIC TRANSPORT

Ready for metal cutting

President Nixon breathed new life into the American supersonic transport program last year when he requested $1.3 billion for the construction of two prototype models (SN: 9/27, p. 265). This week the SST met its first major hurdle when the House Appropriations Committee voted on a $290 million bill to begin the actual metal cutting work on the prototypes. The bill is still to be debated on the House floor, where approval is expected.

The big battle, though, will come in the Senate, where a close, hard fight is expected. Debate will revolve around environmental, technical and financial issues, and all three overlap at times.

The chief environmental concern is noise: airport noise and sonic boom. Though the SST as presently conceived cannot meet existing airport noise limits or ones proposed by the Federal Aviation Administration for the aircraft, there is a technical solution: noise suppressors. But these mufflers, not yet developed, would also reduce thrust.

"Take-off field length would thus become 12,000 to 12,500 feet, well beyond even the 11,000-foot length to which the principal international airports are expected to build their runways," says IBM industrial physicist Dr. Richard L. Garwin, a member of the President's Science Advisory Committee.

Runway extension would create problems with the environs, and estimates for redeveloping the land around airports run into the billions of dollars.

Sonic boom is another matter. At present, there is no way to control it except by reducing speed or prohibiting flights over land. The SST's supporters point to a proposed FAA rule that would do just that, but critics point out that the language leaves too many loopholes.

On the technical front, says Boeing's William Clothier, "We don't see anything like a showstopper." He says that there is still some major developmental work, such as manufacturing and testing of the large panels of brazed (soldered with an aluminum alloy) titanium structures on the wing and developing the proper fuel tank sealant. But these, he is sure, will be overcome by 1973, well before the scheduled commercial service date in 1978.

The loudest objections that will be raised to the SST will be its financing. As originally envisioned, the Government would support only prototype development and then step out of the picture when commercial production was ready to begin. But that situation has changed. H. W. Withington, vice president of Boeing's SST division, estimates that another $1.5 to $2 billion will be needed. Without Federal assistance, "It's hard to see how we can get that kind of money up," he admits.

The Senate is not expected to take kindly to the alternative. □

Boeing

Full-scale mockup of the SST nears completion; prototypes still to come.

MANSFIELD AMENDMENT

Future in doubt

Last year's Mansfield Amendment, restricting Defense Department support of basic research (SN: 12/13, p. 550), has been drawing increasing fire from academic scientists caught in the current budget squeeze. Even those who agree with its intent, to lessen the dependence of science on the military, are now concerned over its effects: a further shrinkage of sources for support of fundamental science. The expectations that the National Science Foundation would be able to pick up the tab for most of the basic science dumped by Defense have not been fulfilled.

Rep. Emilio Q. Daddario (D-Conn.) and his House Subcommittee on Science, Research and Development oppose the measure. Dr. Philip Handler, president of the National Academy of Sciences, says scientists may end up paying a high price for their silence when it was proposed.

A recent potshot came from President Nixon's science policy task force (SN: 5/16, p. 478). "It would be a great mistake for the Defense Department to avoid the bolder or imaginative and longer-range research efforts because of a myopic interpretation of their bearing on its problems," the task force said.

The House Armed Services Committee this year showed a sympathetic ear to the complaints. After hearings that saw Defense science head John S. Foster Jr. and the research chiefs for the Navy and Air Force oppose the measure, the committee has reported out and the House has passed a bill devoid of Section 203, as it is known. "This seemingly innocuous provision now appears to be fraught with danger," the committee said, "for it adversely affects research efforts involving the security of the nation 5 to 10 years from now."

Dr. Foster estimates that the total value of the projects disqualified under the measure is $8.25 million of the $368.5 million made available in 1970; nevertheless it is regarded as an important symbol of research support.

The real test of the effort to keep the Mansfield Amendment out of 1971 legislation will come in the Senate. The measure originated there, and in addition to its author, Majority Leader Michael J. Mansfield (D-Mont.), it has the strong support of such influential Senators as J. W. Fulbright (D-Ark.), Richard Russell (D-Ga.) and John Stennis (D-Miss.).

Mansfield maintains his opposition to Defense primacy in basic research funding. He is preparing testimony on the subject to submit to hearings of the Senate Armed Services Committee in June. □