

(October) to the subject "What Went Wrong?" It's an intriguing series of case studies of technological failure. Or if not total failure, at least less than total success.

It's all in the constructive spirit of learning from errors, epitomized by inventor Peter Goldmark, who says: "Above all, somehow you must have the guts to admit to yourself—and to others—that you made a mistake and you have to make a fresh start, a change in direction." Goldmark, as the journal rightly says, is one of the United States' great inventors. Yet one of the failures described is Goldmark's EVR, electronic video recording for classroom use, a project abandoned by CBS in 1972 because of the complexity and expense of the system.

Nine other subjects—ranging from entire technological systems to single gadgets—are examined in case studies: The U.S. Postal Service's difficulty-plagued automated ZIP-code-reading equipment. 3-D radar for air-traffic control. The Browns Ferry nuclear power plant fire. The superpowerful computer Illiac IV. The implantable cardiac pacemaker (its now remarkable success came 15 years later than expected). The NASA decision to get out of the communications satellite business (a decision now being reevaluated as Japan and Europe make big strides in the field). The Great Blackout of 1965. The U.S. Navy Big Dish project in the late 1950s to build the world's largest steerable radio telescope. Viking 1's jammed scoop (a short description of how engineers analyzed and corrected the problem).

As can be seen, several of the subjects involve not failed technologies but problems met and overcome. But one project that did totally bite the dust was three-dimensional radar for airports. The attempt to develop radar that could determine airliners' height was stimulated by the collision of two airliners over New York City in December 1960. Plans were announced, but the multimillion dollar project was dead within a year. Why? Great technical obstacles (massive 160-foot towers had to be held vertical within a fraction of an inch, and 528 vertically stacked antennas and 30 miles of waveguide were required for each tower) and great cost helped do it in. "It was too big and too expensive," recalls an FAA test official. "The radar system for one air terminal didn't cost as much as a single [air-height radar]." But the real death knell came from solid-state advances that gave the competitive edge to beacon transponders that could be installed in all planes and automatically report altitude on command from the ground.

The Illiac IV computer (SN: 10/13/73, p. 236) is examined for its impact on advanced computer hardware (it was one of the first to use all-semiconductor main memories and it helped usher in highly integrated bipolar logic circuits) and for

its dozens of other technological ups and downs. Its development brilliantly stretched the frontiers of computer science, but it is only a fourth its original designed size, its cost of \$31 million is four times the original estimate and, according to the report, there is controversy, even bitterness, over its abilities as a real, usable machine. One participant in the project is quoted as saying, "Any impartial observer has to regard Illiac IV as a failure in a technical sense. . . . It's not obvious to me how long it will be before they pull the plug."

Insisting on good laboratory practices

Each year the Food and Drug Administration receives hundreds of reports of animal studies on the safety of food additives, drugs and medical devices. The agency uses that data to decide whether to approve or reject each new product. Federal law assigns to the prospective manufacturer responsibility for testing new FDA-regulated products.

The agency formerly assumed the data it received was accurate and the experiments sound. It checked up on laboratories only when there were questions about procedures or inconsistencies in the report. Recent investigations, however, led the FDA to seriously question the general quality and integrity of the data it receives.

The FDA last week proposed a set of regulations that attempt to prevent sloppy and fraudulent research from being used as a basis for safety decisions. The regulations prescribe procedures for animal handling, equipment maintenance, division of responsibility, qualification of personnel and recording of data. The rules are titled "Good Laboratory Practice."

"Decisions about the safety of consumer products that are based, wholly or in part, on data derived from such testing are too important for the agency to accept anything less than the best scientific data that can be obtained," says the FDA proposal which was published in the Nov. 19 FEDERAL REGISTER.

The evidence is strong that at least some of the evidence previously submitted was far from the best. In one case, animals were reported as normal in appearance, awareness, appetite and thirst, when in fact they were dead. In another study, the FDA was told that animal tissues had been examined microscopically for pathology, when the samples had not even been collected. Another example, included in the proposal, involved animals that had been unintentionally sprayed and fogged with pesticides during the experiments.

The proposed regulations, which will go into effect only after a public hearing and further revision early next year, include sanctions against laboratories not meeting the standards. The consequences range from rejection of specific studies to

The IEEE SPECTRUM follows its case studies with a brief section called "What ever happened to . . . ?" It's a list of eight once-promising developments that got sidetracked, untracked or delayed somewhere along the way. They are ovonics (once ballyhooed as the successor to transistors), thermoelectricity, the Picture-phone, emitter-coupled logic, AM stereo, two-way cable TV, direct digital computer control, and ELF shore-to-submarine communications. Although none are dead, they all recall promises not (yet anyway) kept. □

disqualification of a laboratory from any future safety testing. Withholding of required information and misrepresentation of data submitted will remain subject to criminal prosecution.

The proposed regulations do not specify rigid or uniform experimental protocols. "The responsibility for good experimental design resides with members of the scientific community," the proposal states.

As proposed, the regulations will substantially increase laboratory paperwork. They call for records of equipment maintenance, written standard operating procedures, status reports of a "quality assurance unit," detailed protocol and approval of protocol changes in writing before their implementation. The FDA proposal states that complete and accurate reports are essential for reconstructing the study to assess the quality of the results and to reinterpret the data in light of later findings.

In deciding upon this proposal, the FDA turned down several alternatives. It concluded that requiring specific tests might hinder important experimental innovations. Licensing of testing facilities and full-time, on-site monitoring were rejected as time-consuming and not cost effective. Finally, the agency decided against shifting all or part of the burden for laboratory testing of products from the manufacturer to the FDA. "This approach would entail an enormous expenditure of agency resources because of the spectrum of regulated products, the diversity of the kinds of data needed, and the number of products submitted to the agency for approval; furthermore, it would necessitate congressional authorization," the proposal says.

Congress has added about \$17 million to the FDA annual budget to be used to ensure the quality and integrity of data submitted in support of regulated products. To evaluate the practicability of administering the proposed regulations, the FDA plans in the next few months to inspect a substantial number of previously uninvestigated testing facilities.

The regulations will not affect basic research, exploratory studies, chemical characterization or clinical trials. □