Security Problems Plague Scientific Meeting

Twenty percent of the papers were blocked by the Defense Department from open presentation; many were shifted to restricted sessions

In late March, officials of the Society of Photo-Optical Instrumentation Engineers (SPIE) received word from the Defense Department that 43 of the 219 papers scheduled to be presented at a meeting that they were holding 2 weeks later could not be given in open sessions. Thirteen of the papers were deemed to contain classified information, and the rest, although unclassified, were judged to be militarily sensitive.

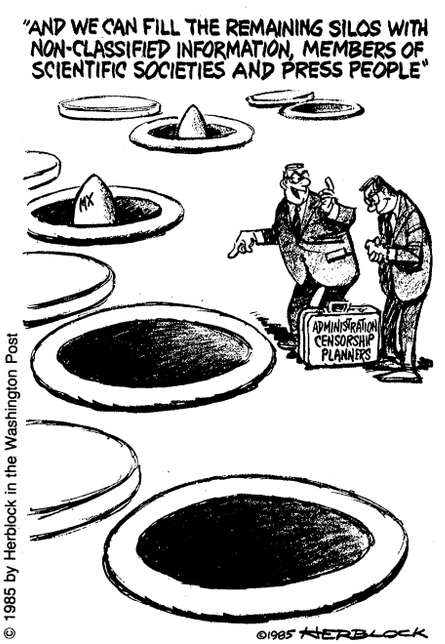
Faced with a potential disaster, the conference organizers appealed to Leo Young, director of research and laboratory management in the Pentagon's Office of Research and Advanced Technology. Young and his staff worked out an extraordinary arrangement under which 28 of the papers were presented in restricted sessions, in which attendees agreed not to divulge the contents to unauthorized people.

Young says he "salvaged the meeting." SPIE officials agree. "He stuck his neck out. We very much appreciate what he did," says R. Barry Johnson, the chairman of the conference organizing committee. There is, however, little agreement on many other facets of this episode or on what it may portend for future scientific meetings.

Some Defense Department officials have tried to blame SPIE for the problem that arose over the unapproved papers. According to their version of the events, many of the papers turned down for presentation in open sessions would normally have been shifted to a classified meeting that was to have been held in parallel with the SPIE conference. The classified meeting fell apart, however, because it was not properly organized and there was thus no forum for the unapproved papers to be presented. If the classified meeting had gone ahead, they argue, there would have been no problem.

SPIE officials point out, however, that the classified meeting was not an official part of their conference. Although organized by SPIE members, it was sponsored by the Defense Department and was to have been held at the Naval Research Laboratory, not at the hotel in a Washington suburb that housed the official proceedings. Although some of the papers may have ended up in the classified meeting, taking them out of the open SPIE conference would have left the conference badly depleted, SPIE officials note. Two of the planned sessions would have been decimated.

The nub of the problem, they argue, was that the Defense Department disapproved for presentation almost 20 percent of the papers scheduled for public sessions. This, they believe, represents yet another instance of the Administration's attempts to clamp down on the free flow of unclassified scientific information. It is not the first time that a SPIE meeting has been disrupted in this way.



Defense officials are not amused.

In August 1982, some 100 papers scheduled to be presented at a conference the society held in San Diego were withdrawn at the last moment, following Defense Department objections.

There is also concern both within SPIE and elsewhere that the measures used so effectively by Young to ensure that the contested papers were delivered, by moving them to restricted sessions, may be used in the future by the Defense Department as a way to restrict the presentation of unclassified but sensitive research papers.

Virtually all of the 43 contested papers were produced by Defense Department scientists or researchers working for defense contractors. All were required to submit their papers for clearance before presentation. SPIE officials say they would normally expect a few to encounter problems in the clearance process, but a disapproval rate of this magnitude is virtually unprecedented. Many of the disapproved papers dealt with various aspects of lasers, which could apply to "Star Wars" research.

When the problem was brought to his attention, Young and his staff worked out a novel use of regulations that are designed to limit release under the Freedom of Information Act of potentially sensitive information. In essence, the regulations, which came into effect only a few days before the meeting, permit Defense Department officials to withhold from the public unclassified information that they deem to be subject to export controls because it has potential military applications.

Twenty-eight of the papers that failed the security review were presented in sessions whose attendance was restricted to three categories of people: U.S. government employees; U.S. citizens, Canadian citizens, or permanent residents in the United States, all of whom had to show proof of their citizenship or immigration status; and citizens of allied countries who could produce a letter from their embassies certifying their citizenship and approving their attendance at the meeting. All attendees signed a statement acknowledging that the information contained in the papers comes under the export control laws and that it cannot be freely disseminated.

This use of an exemption to the Freedom of Information Act to shift papers into restricted sessions is viewed with apprehension in some quarters because it may be used as a precedent for imposing restrictions on unclassified scientific papers. "The SPIE incident sends several distressing signals," says Rosemary Chalk, executive director of the Committee on Scientific Freedom and Responsibility of the AAAS. "The imposition of export controls on papers scheduled for presentation in open sessions represents a significant broadening of government

controls beyond the normal sphere of classified research," she argues.

Allan Adler of the American Civil Liberties Union questions the legality of applying Freedom of Information exemptions in a situation for which they were never intended. Moreover, he argues that the new regulations themselves represent a worrisome extension of Defense Department authority over information that it does not own.

It is by no means clear that the Defense Department sees this episode as a model. Young notes that the procedures "worked well in the panic situation we were in," but says he would like to see a lot more discussion before they are applied routinely. "We can't use this as a model and put it in place without realizing what problems it creates for the societies," he says. "I don't know how it's going to end up."

SPIE officials believe, however, that technical societies may be forced to accept such controls. According to Lewis Larmore, the society's president, SPIE's governing committee held a meeting during the conference at which "all of us agreed that if we are going to stay in business we are going to have to kowtow to these rules." Although the bulk of the contested papers were salvaged by shifting them into restricted sessions, "we've lost our virginity," Larmore noted.

The incident also sent a shiver of apprehension through parts of the academic community because it threatened to undercut a policy worked out last year under which no restrictions would be placed on the publication of results of basic research funded by the Defense Department on university campuses (*Science*, 26 October 1984, p. 418). The policy was spelled out in a memorandum written by former Under Secretary for Research and Engineering Richard DeLauer and reiterated in a letter from Defense Secretary Caspar Weinberger to the head of the Institute of Electrical and Electronics Engineers. It applies to all Defense-funded research in the 6.1 budget category (essentially basic research), and on-campus research in the 6.2 category (essentially applied research) unless "there is a high likelihood of disclosing performance characteristics of military systems, or of manufacturing technologies unique and critical to defense."

Administration officials have been quick to deny that the SPIE episode has any bearing on the basic research policy. They point out that only one of the papers had academic authors and none was derived from basic research. (Although the budget categories under which the research was funded could not be ascertained, several observers suggested that the bulk of the projects would probably fall in the 6.2 or 6.3 categories.)

The Association of American Universities sought assurances from the Defense Department and the Office of Science and Technology Policy (OSTP) that the policy on the publication of basic research results has not changed. The association subsequently sent out a letter, which was cleared with Defense and OSTP officials, stating that "the Administration has no intention of using the new [regulations] to restrict the publication of fundamental research results or their presentation at scientific meetings."

The university community would, however, feel happier if the policy rested on a foundation more secure than a memo from a former Pentagon official and a letter from the Secretary. A draft statement establishing the policy government-wide has, in fact, been sitting in the National Security Council for more than 6 months with virtually no sign of movement. According to deputy OSTP director John McTague, "there is no disagreement on it in principle."

The SPIE episode may therefore have little direct impact on academic research. But the implications for researchers in Defense Department laboratories and defense contractors—and for the scientific and technical societies to which they belong—could be more worrisome.—**COLIN NORMAN**

Generics, Roche Joust for Valium Market

Roche claims differences in diazepams as generics race for FDA approval

On 27 February, after 22 years of patent protection and at least $3 billion of sales, Valium went off patent, starting a race among generic drug manufacturers to get a copy of the top-selling tranquilizer to market. Two weeks prior to Valium's patent expiration, however, Hoffmann–La Roche, the maker of Valium, petitioned the Food and Drug Administration (FDA) to block the agency's approval of any generic versions of the drug. Asserting that FDA's methods for judging the equivalency of copies of Valium are flawed, Roche argued that generic versions of the drug may not deliver correct therapeutic doses.

FDA officials and generic drug companies contend that the chief purpose of Roche's petition is to delay for as long as possible the marketing of competitors to Valium. They say Roche's line of argument is particularly significant because it foreshadows an escalation in rivalry between brand name and generic drug companies as the patents of other big money-making drugs expire.

The stakes are enormous. The National Council of Senior Citizens estimates that the introduction of more generic drugs could cut the nation's health care bill by $1 billion over the next dozen years. Last year's generic drug market rose to $4 billion, accounting for 20 percent of total prescription sales, according to the Generic Pharmaceutical Industry Association. But the amount is small change compared to potential future sales. Last year, patents expired on three major drugs with sales totaling $700 million. (The drugs were Inderal and Aldomet, used to treat hypertension, and Diabinese, used for diabetes therapy.) In the next 5 years, patents on 11 drugs, which individually had sales of $50 million to $173 million in 1982, will expire.

That generic drug manufacturers can now copy these off-patent drugs with relative regulatory ease is a result of a major bill passed by Congress last year (*Science*, 27 April, p. 369). After a long and bitter contest between generic and brand name companies and infighting among the brand name companies themselves, Representative Henry Waxman (D–Calif.) and Senator Orrin Hatch (R–Utah) pushed through compromise legislation designed to speed up the FDA approval process for generic drugs and at the same time give brand name companies additional patent protection for their drugs. Valium is the first major drug to go off patent under the legislation and is