

in the Swedish Royal Academy of Sciences, financed by the Swedish government. The ICSU executive committee has appointed Thomas Rosswell of the University of Linköping, currently the secretary-general of ICSU's Scientific Committee on Problems of the Environment (SCOPE), to be the full-time executive secretary of IGBP.

Following discussion of the results of a meeting held in Ringberg Castle, West Germany, last year on the future of ICSU, the general assembly gave its approval to the creation by its executive committee of a working party on relationships with the scientific community and the mass media as a way of raising the organization's visibility, both with the public and the scientific community.

The general assembly also approved the idea that ICSU should seek support for a series of special lectures, to be given particularly in Third World countries. A separate proposal for awarding either prizes or honorary membership to selected individuals met with little enthusiasm and was subsequently dropped. So, too, was a proposal that emerged from the Ringberg discussions to launch a new policy journal, *Science International*; ICSU's current newsletter will be expanded to improve the dissemination of information about its activities.

The general assembly, which is made up of representatives from each of ICSU's 21 member scientific unions, as well as 71 national academies and research councils, gave its provisional approval to the creation of a new inter-union Committee on Biotechnology. This decision will be reviewed at the next general assembly, which will take place in Japan in 1988.

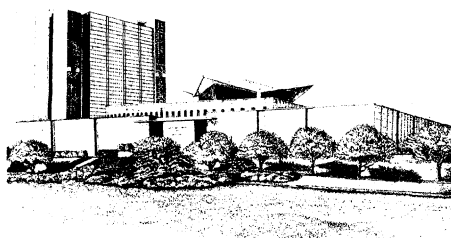
In the election of new officers, physicist M. G. K. Menon, scientific adviser to Indian Prime Minister Rajiv Gandhi, was chosen as president-elect over chemical engineer Heinrich Zollinger, a former chairman of the Swiss National Science Foundation. Menon received 77 votes out of the 106 cast, and will take over as President at the Japan assembly.

A resolution proposed by the International Union of Crystallographers, which would have required all ICSU-affiliated bodies to refuse to sponsor conferences in countries that require visa applicants to formally register their opposition to apartheid, was not put to a vote after discussions with the executive committee and ICSU president John Kendrew. However, the general assembly passed a resolution emphasizing its commitment to "nondiscrimination" as a principle for ensuring the free circulation of scientists, and said that such a commitment was a condition of membership for all scientific and national bodies. ■ **DAVID DICKSON**

Regulating Software for Medical Devices

Computer software used in the operation of medical devices poses new regulatory challenges to the Food and Drug Administration. At present, though, according to FDA commissioner Frank E. Young, the agency hopes to pursue a path of "least possible regulatory action."

Young outlined a tentative policy at a banquet celebrating the 150th anniversary of the National Library of Medicine. Calling medical devices "probably the most complicated area that the FDA has to deal with," Young listed a variety of new computer-assisted devices, such as heart pacemakers which are reprogrammable from the outside. In many of these cases, use of the device is inseparable from the software, in which case the software has to be regarded as part of the device.



National Library of Medicine.

Young made it clear that an expert system used as an aid to diagnosis would be no more subject to regulation than a textbook. But it is another story "when computer products move to direct patient care," he said. "When AI [artificial intelligence] is intended to be a total substitute for the judgment of the professional and directs the action in diagnosis and therapy, then software quality control is important."

Young cited a case where two patients were overexposed to an electron beam linear accelerator because of faulty programming. The infusion rate of a substance such as insulin could also be wrong because of errors in the software package. Quality control is an issue in any device in which decisions are based on computer monitoring or are made by the computer. When the floppy disc is sold separately from the apparatus, such as Magnetic Resonance Imaging, the FDA would "look at it as attached to the device" for regulatory purposes.

Young said some software occupies "gray zones"—such as devices monitoring cardiac output or calibrating chemotherapy. But "in principle, any time the physician's judgment can override the judgment of the computer or override the procedures, then FDA has little or no responsibility." He also said the agency had no responsibility over the use of

computer-assisted devices in teaching or nonclinical research, or over devices manufactured in particular institutions for their own purposes. ■ **CONSTANCE HOLDEN**

Congress Critical of Foot-Dragging on Critical Materials

Secretary of the Interior Donald Hodel has been named by President Reagan to be the chairman of the National Critical Materials Council. The appointment, made last week, came more than 2 years after the congressional act that provided for the formation of the council was signed into law. It also came one day before a House subcommittee called hearings to check on progress toward implementing the act. The understaffed council has long since missed an April 1985 deadline for the preparation of an advanced materials R&D plan.

Once limited to those strategic metals, such as chromium, whose main sources were overseas and unreliable, the term critical materials now spans the range from the basic metals, such as aluminum, to the advanced, high-technology alloys, ceramics, and composites on which the economic health and national security of the United States reside. The Critical Materials Act of 1984 addressed every aspect of these materials from technical to public policy questions. In particular, it established the critical materials council to help the government form coherent plans for dealing with materials-related issues ranging from the environmental consequences of mining operations to the optimum deployment of federal R&D funds.

In the hearings on 17 September, chairman of the House subcommittee on transportation, aviation, and materials George Brown (D-CA) argued that hundreds of thousands of jobs and tens of billions of dollars were at stake in the competition between the United States, Europe, and Japan to capture the markets for products using these materials. Brown was plainly distressed over what he characterized as "business as usual" in the United States when other countries were moving ahead.

The three-person critical materials council was filled only last November, just after an earlier round of hearings, and two of the members left within a short time. This left only Thomas Moore, who is also a member of the President's Council of Economic Advisors, as acting chairman and one staff person.

In his testimony before the subcommittee last week, Moore reported that Hodel was