News Briefs

NRC Fees Threaten Research Reactors

In a move that took nuclear researchers and educators by surprise, the Nuclear Regulatory Commission (NRC) has imposed new fees on 33 universities that operate 38 research and training reactors.

The $62,000 levied on each reactor, to cover NRC licensing and inspection costs, is payable September 20. The NRC plans then to bill each university reactor again for the same amount to cover the estimated costs of regulation during FY 1994. Of the 38 reactors now operating on U.S. campuses, all but two have annual operating budgets under $1 million, and most of these are under $300,000.

The new fee structure results from the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) which orders the NRC to recover 100% of its budget by assessing fees on the parties it regulates. Initially, the NRC exempted university research and training reactors on the grounds that such educational institutions could not reasonably pass the new costs on to their customers, who are usually students. However, on March 16, the U.S. Court of Appeals for the District of Columbia ruled that the inability to pass on costs is not sufficient basis for fee exemption.

Immediately after the ruling, the NRC solicited public comments on whether university reactors should continue to be exempt. Academic institutions argued for continuing the exemptions, but many other groups maintained that universities should pay their share. The NRC noted that such exemptions might be justified on the grounds that educational institutions offer "exceptionally large externalized benefits that cannot be captured in tuition or other market prices." According to NRC officials, nothing in the comments so far has undercut the original opinion that universities offer such benefits.

In the July 20 *Federal Register,* the NRC stated that it "is reluctant...to impose fees that could result in diminishing the already dwindling number of university programs. But the Commission is not in a position to analyze with any confidence the potential burden on educational benefits in comparison with the burdens that fees will impose on the beneficial activities of other licensees." The NRC then "reluctantly" withdrew its exemption from licensing fees for universities.

According to an NRC spokesperson, most of the affected institutions have submitted exemption requests or requests to extend payment. University reactors that shut down can avoid paying the current bill if they file for a "possession-only" license by August 19, noted James M. Taylor, the executive director for operations. The license allows reactor material to remain in the university's possession, but the reactor is essentially shut down.

Institutions wishing to file for an exemption will get an extension on paying their fees. If the request arrives by November 17, late penalties or interest will not accrue until the NRC resolves the case. ■

New Antibody for B-Cell Lymphoma

Researchers at the University of Michigan Comprehensive Cancer Center and the Coulter Corporation have developed a new monoclonal antibody to fight B-cell lymphoma.

According to a study published in the August 12 issue of the *New England Journal of Medicine*, the new drug, Anti-B1, successfully shrank tumors in 70% of patients with B-cell lymphoma. In one-third of the patients, the tumors have completely disappeared, with no recurrence, and none of the patients reported significant side effects.

Once the antibody has attached to the malignant cells, the radioisotope delivers a low dose of radiation lethal to those cells but sparing nearby healthy cells. By targeting the malignant cells, the antibody averts common severe side effects like suppression of the bone marrow's production of white and red blood cells, hair loss, and nausea. Researchers also believe that the new antibody is able to stimulate the immune system to fight off cancerous B-cells.

They expect that the new drug's trial, which is funded by the National Institutes of Health and the National Cancer Institute, will be completed by year's end. ■

FDA Overhauls Adverse Event Reporting System

Responding to spotty reporting of adverse drug effects and product defects, FDA planners are marketing a simplified, one-page reporting form—MEDWatch—which they hope will spark wider, more thorough records of adverse events.

"The time has come to recognize that reporting serious adverse drug or device events and product problems is a professional responsibility," says David A. Kessler, MD, commissioner of food and drugs. "Unfortunately, many health professionals do not think to report to the FDA or the manufacturer. We need to change that."

MEDWatch will make it easier, the FDA says, for clinicians to report serious events not only to the agency itself but to manufacturers and physicians as well.

"By launching MEDWatch, we are calling on all health professionals in this country to do their part to help ensure that every drug, biologic, device, OTC product, and nutritional product is as safe as possible," says Kessler. "Working with the FDA, health professionals have a very important part to play."

In the past, a variety of forms reported adverse drug reactions, drug and device quality problems, and adverse reactions to medical devices. These have been replaced by a single form. Simplified reporting may mean quicker response

(continued on page 34N)

NEWS BRIEFS

(continued from page 30N)

time between the detection of adverse events and FDA investigation, the agency says.

The MEDWatch form will be available in several publications, including the *Physician's Desk Reference,* the *FDA Medical Bulletin,* and *AMA Drug Evaluations.* To encourage participation in the program, the FDA will hold a special conference on drug-induced and device-induced problems for academics and practitioners. Richard Reba, MD, president of The Society for Nuclear Medicine, said that SNM supports it: "Most of us believe it's a good program and encourage our members to participate." The mailer for the September issue of the *Journal of Nuclear Medicine* carried a form for the program for readers to fill out. "We believe it's important to get a real database on this sort of information," Reba said.

Adverse events that need to be reported include those that have caused death, life-threatening illness or injury, hospitalization, disability, congenital anomaly, and events that required intervention to prevent permanent impair-

SNM Restructuring

(continued from page 26N)

would thus play a greater part in policy and socioeconomic issues.

— To preserve the uniqueness of the Technologist Section (TS) within SNM by recognizing it as the sole section. At the same time, the greater incorporation of councils described above would offset the intent of at least two councils to become sections (permitted under existing bylaws).

— To provide for a comprehensive and cohesive reorganization and restructuring of current SNM committees into commissions and subcommissions, standing committees, and subcommittees.

— To provide more appropriate and descriptive nomenclature for SNM's governing body—particularly because a board of trustees is not typically a governing body.

— To provide better training for leadership roles in SNM—as well as in medicine in general—and to build a more responsive, better-informed leadership.

— To streamline the bylaws by moving procedural items to standing rules/procedures.

New Responsibilities, New Offices

A crucial feature of restructuring, Murphy pointed out, is the distribution of presidential responsibilities among three officers in a new succession of offices. Under the restructured system, each president will have served first as vice-president-elect and then as vice-president; the vice-president would thus have a "dual" role as president-elect.

The approved restructuring plan stresses the greater leadership experience and shared presidential workload resulting from this new organizational design. Specifically, the vice-president would coordinate three major areas of responsibilities for the president: economic and government affairs, councils, and commissions. In practice, this would mean that the vice-president would assist the president on policy issues and would therefore work primarily with commissions of the HOD, with an additional focus on councils (for which there would be a commission on councils).

The vice-president-elect would assist the president with administrative aspects of SNM, like the TS, chapters, and committees. His or her focus would be on management issues.

The restructuring plan would also combine the roles of secretary and treasurer into secretary/treasurer. The six members of the Executive Committee would then be the president, vice-president, vice-president-elect, immediate past president, and the president of the TS.

Greater Representation Seen

Another major change from restructuring will be greater representation of all SNM members. The membership will elect all voting members of the HOD, Board of Directors, and Executive Committee. These three governing units will comprise progressively smaller numbers, with the House of Delegates the largest body and the Executive Committee the smallest. As each unit will be a subgroup of the next largest, there will be better division of responsibility between policy and management and greater accountability.

TS members will also see gains in representation, now sending eight delegates to the HOD—the section president plus seven elected delegates. In addition, a director-at-large, drawn from TS members of the House, will serve on the Board of Trustees, resulting in two TS members on the Board—the director-at-large and the Section president. Nontechnologist members of the HOD would elect the remaining six directors-at-large.

The plan has now been forwarded to the Bylaws Committee which will draft revised bylaws in collaboration with SNM's attorney and its parliamentarian.

"Once the membership approves the revised bylaws," said Murphy, "a transition schedule should be quite straightforward though lengthy. Even under the most optimistic scenario, it would take several years to be fully implemented... But that's appropriate for such a major change in the way we are organized and conduct our business."

Murphy hopes that revised bylaws will be complete in time for distribution to the membership in the spring with the annual ballot.

A copy of the complete Restructuring Plan approved by the Board of Trustees can be obtained from Mitch Poulos, The Society of Nuclear Medicine, 136 Madison Avenue, New York NY 10016. ■

News Briefs

ment of health. MEDWatch can also be used to report suspected contamination, questionable stability, defects, and poor packaging and labeling of regulated products.

Health care providers interested in requesting forms or the new FDA *Desk Guide to Adverse Event and Product Problem Reporting* can call 1-800-FDA-1088. ■

Thallium-201 Scintigraphy Improves Life Expectancy in Heart Attack Survivors

A study published in the *International Journal of Technology Assessment in Health Care* (1992; 9,1: 97-101) comparing thallium-201 scintigraphy, ambulatory cardiac monitoring (ACM), and exercise tolerance testing (ETT) with no testing whatsoever has shown that the noninvasive methods are better at detecting silent ischemia in heart attack survivors.

The study proved that any of the three tests were better than no testing (i.e., medical treatment only). Researchers estimated that each of these noninvasive techniques provided approximately a four-month gain in the life expectancy of a 55-year-old man with an average life expectancy of 16 years.

A second study compared the ability of ACM alone, electrophysiologic studies, and ACM followed by ETT to identify an effective and safe medication to control potentially life-threatening erratic heartbeats in heart attack survivors. The researchers found the three methods to be equally effective, but that ACM required fewer resources than EPS.

These studies were supported by grants from the Center for General Health Services Extramural Research of the Agency for Health Care Policy and Research and by a cooperative agreement between the Health Care Financing Administration, the RAND Corporation and Harvard University. ■

New Boss

(continued from page 24N)

place that says how the NRC is going to react to a report of a misadministration. Part of the problem with the Glenn hearings and the *Plain-Dealer* series is that issues came up, and if you couldn't find somebody with a corporate memory, nobody here knew anything about it, then there was that perception that the NRC doesn't know what's going on. A great deal of the issue is that we didn't know; you had different events happening, maybe at similar times, and the agency reacted to almost the same events very, very differently. The question is why, and the answer is: there is no policy."

Paperiello gave the NRC an outline of a management directive to remedy the problem of the NRC's disunity in responding to misadministration reports. The elements of the directive include on-site inspection of the problem facility, with a medical consultant to find out what the probable consequences are, and the assurance that the information gets into a central file and that the information is retrievable. "I live in the field, and some people in Washington think, 'Well, we know what we want to do.' If you haven't put that in a procedure and issued it to somebody in Chicago, they don't know what's going on. So different regions did different things. In fact, even in Region 3 where I was deputy regional administrator, in response to similar events over a period of three or four years, we did different things. So, if you want the staff to do something, and you want to know what they did and make it retrievable, you need a procedure out on the street."

Another set of Congressional hearings, this time in the House of Representatives under the chairmanship of Congressman Mike Synar (D-OK), has also got the NRC on its toes over the Agreement State Program and how the commission monitors it. "The chairman has told Congressman Synar that what we will probably be doing–what we are in fact working on—is to come up with common performance indicators for both the agreement states as well as the NRC regions to have some kind of measure of program adequacy: how do you know that the agreement states, and even you, are doing a good job? We don't have any good common quantitative measures of performance. Most of our effort in that response [to the hearings] is to develop some kind of indicators.

"The other issue that Synar brought up—and I don't know [the NRC's] final resting point—is over the years we have found that we were unable to find [states] compatible and unable to find them adequate. It's not that we've said they were inadequate, but we withheld findings. How bad would it have to be before the commission would take action to terminate the agreement? The commission doesn't have a written policy on that—and I assume the commission is going to react to that. But I don't think there has been a firm decision on how that's going to be addressed. The issue on the performance indicators is more certain; that has been discussed with the agreement states."

Straightforward as his proposals sound, he acknowledges that putting them into practice in the NRC is another matter. "What I'm finding in this agency," he said, "is that getting all the various offices to concur in" a policy is a trick in itself. "The attorneys have to agree to it, and the researchers have to agree to it...and everybody wants to do some of their own word engineering." Perhaps he has put a label on what he has found out about Washington so far: that it is a city of word engineers, and cleaning up town means both asserting the letter of the law and clamping down a good hard sentence. Just the job for a straight speaker like Paperiello.

Lantz Miller

To obtain a copy of the NRC regulations by credit card, call the Government Printing Office at (202) 783-3238 and ask for the "CFR, Title 10, Parts 0-51," stock order number 869-019-00029-1, list price $29; or send a check, payable to the Superintendent of Documents, PO Box 371954, Pittsburgh PA 15250-7954.