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Gadolinium-153 Shortage Averted

The lengthy disruption in supply of gadolinium-153 (^{153}Gd) that threatened to delay osteoporosis research efforts should end this month as the Department of Energy (DOE) begins providing the isotope to Medi-Physics, Inc., an Amersham company, for processing and distribution to users of dual-photon absorptiometry (DPA) devices for measuring bone density. Problems started brewing in March 1990 when Amersham Corporation lost its British supplier for the unprocessed target isotope.

The DOE also plans to process the isotope, used as a radiation source in DPA, at the Idaho National Engineering Laboratory (INEL) for possible sale to other companies, says Donald E. Erb, director of the department's Office of Isotope Production and Distribution.

After striking the agreement with DOE, Medi-Physics President Al Herbert said, "By July we should be back in shape. We fell victim to a change in reactor. . . it's been a precarious position." Medi- Physics assumed control of all customer accounts for ^{153}Gd from parent Amersham in April. Amersham, the major marketer of ^{153}Gd, had relied on DOE reactors to produce the isotope until 1987 when the company set up irradiation and processing facilities in Britain.

But in March 1990 the British government closed the two research reactors, named Dido and Pluto, that produced high specific activity ^{153}Gd at the Atomic Energy Research Establishment (AERE) Harwell facility. Shipments of ^{153}Gd sources slowed to a trickle. The resulting shortage of the isotope began to trouble growing numbers of clinical and experimental users of DPA.

"Our research was in great jeopardy," says Edward B. Silberstein, MD, associate professor of radiology at Cincinnati Medical Center in Ohio. His inability to replace a waning ^{153}Gd source threatened to bring to an early end a study of oral diphosphonate therapy for treating osteoporosis. Early results of the work showed that the experimental protocol stopped bone loss, and actually increased bone density in a majority of the patients. How long patients can safely remain on diphosphonate is uncertain because in large doses the substance starts to inhibit bone mineralization.

In its fourth year, the study depended on a DPA device to follow the rate of bone loss in patients. Dr. Silberstein considered buying a new dual-photon x-ray absorptiometer, but data collected would be exhaustively difficult to compare with data obtained using the original machine, he says. Obtaining enough money was another problem. "We were trying to find money in our budget to fund an x-ray machine so we could complete our research." Dr. Silberstein has awaited shipment of the source material since December 1990.

Faced with the loss of the Harwell reactors and a growing backlog of unsatisfied customers, Amersham contracted with a number of European commercial reactors last year to begin irradiations that would produce ^{153}Gd. "The yields of gadolinium-153 were very disappointing," says Barney Tyrwhitt-Drake, marketing director at Medi-Physics. The company then had to scramble for another source.

Through "just a coincidence," says physicist Robert E. Schenter, PhD, a batch of high-specific activity ^{153}Gd emerged from a DOE reactor in March after some seven months of irradiation, just as the shortage of the isotope was beginning to stir unease in the medical community. Dr. Schenter is chief scientist in isotope production at DOE's Fast Flux Test Facility (FFTF), operated by Westinghouse Hanford Co., Richland, Washington. The FFTF reactors have been used to produce ^{153}Gd periodically since March 1986.

Medi-Physics and the DOE arranged to ship the bulk material from the FFTF in Richland to England in June for processing at Harwell. After removal of high levels of europium-152 (^{152}Eu), the purified ^{153}Gd must be encapsulated for use in DPA devices. Medi-Physics expected to have supplies back to normal levels in July.

X-ray absorptiometers are supplanting ^{153}Gd DPAs, but the latter remain important, according to Richard B. Mazess, PhD, president of Lunar Corporation, a major seller of absorptiometry equipment. DPAs are slow, he notes, but provide results equal to x-ray absorptiometers. ■

Tilting at NRC User Fees

Objecting to a potential for "adverse impact" on health care, nuclear medicine representives have called upon the Nuclear Regulatory Commission (NRC) to reconsider major hikes in licensing and inspection fees scheduled to take effect next month.

"We are extremely concerned with the effect the proposed fees will have on the future and availability of nuclear medicine services," wrote Terence Beven, MD, president of the American College of Nuclear Physicians (ACNP), and Naomi Alazraki, MD, president of The Society of Nuclear Medicine (SNM) in a May 13 letter to NRC Secretary Samuel J. Chilk. "It is certain that the implementation of user/inspection fees will result in the closure of nuclear medicine facilities," the two presidents said, "especially those that are private and small."

Also on May 13, which was the last day the commission would accept comment on the pending fee revisions, the United States Council on Energy Awareness (USCEA) issued a commentary calling for the NRC to exempt nuclear medicine and research licensees as well as biomedical manufacturers from the fee schedule as proposed in the April 12 Federal Register.

The impact of the proposed fees "is incompatible with the congressional mandate to cap health care costs," wrote

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members of the USCEA committee on radionuclides and radiopharmaceuticals to the NRC. The fees "place an excessive financial burden" on medical licensees and manufacturers, the statement continues. "We therefore recommend that medical, life science research and biomedical manufacturers be exempt from increases in fees."

NRC officials "are looking very closely at the comments," says James Holloway, Jr., at the commission's office of the controller. The NRC flatly denied requests by the USCEA and others to extend the brief one month comment period. If the proposed fees are approved, the NRC would consider exemptions case by case and grant them only in cases of extreme hardship, according to Mr. Holloway.

The Omnibus Budget Reconciliation Act of 1990 halts federal funding of the NRC and requires the commission to fund itself entirely from fees assessed for licensing, inspection, and other services during fiscal years 1991 to 1995. The law means the commission must roughly triple user fees to collect some $445 million before September 1, 1991. For fiscal 1991, the NRC plan greatly expands existing fees and exacts about $27 million from previously exempt hospitals, doctors, irradiators, transportation certificate holders, and other nuclear material licensees. The fees are scheduled to take effect August 1, 1991.

Medical licensees might see their individual fees jump $8,600 to $25,000 this year, according to the ACNP/SNM calculations. Fees averaged $1,800 per user in 1990. The proposed schedule boosts fees for medical licensees 648% over 1990 levels and 1238% higher than in 1988.

ACNP and SNM leaders recommended the following to the NRC:

- Revise the user fee schedule to take into account medicine's inability to pass increased costs on to patients.
- Drop charges for NRC activities that duplicate regulation by other agencies.
- Limit user fees to "necessary" NRC services.
- Establish a congressional oversight system to ensure fair review of the setting of fees.
- Submit all fees to review by the Advisory Committee on the Medical Uses of Isotopes (ACMUI).

NRC officials declined to comment on requests. The commission is expected to publish a final fee schedule in July. ■

Lung Cancer Risk from Household Radon Overestimated

The risk of lung cancer from exposure to radon in homes is considerably smaller than previously estimated, according to a report released by The National Research Council (NRC) in May. The risks may be 30% lower for adults and 20% lower for children than earlier NRC estimates. The report, "Competitive Dosimetry of Radon in Mines and Homes," concludes that given a certain level of radon exposure, the dose to the lung tissues of a miner will be somewhat greater than the dose received in a home.

In an earlier study, the NRC's Biological Effects of Ionizing Radiation (BEIR) Committee used a risk model for the general population that was derived from miners' exposure to radon. The committee's results were published in the 1988 BEIR IV report, in which the committee cautioned that "further studies of dosimetric modeling in the indoor environment and in mines are necessary to determine the comparability of risks per WLM [working level month] in domestic environments and underground mines."

In response to public concern over household radon exposure as a public health risk, the Environmental Protection Agency (EPA) asked the NRC to study whether the dose models used to establish risk estimates for miners were applicable to the general population. The NRC found differences between the two groups and the committee revised its models of lung cancer deaths from household radon exposure.

Two main factors led to the revisions. Miners have a higher breathing rate due to their physical exertion in the workplace, which increases the amount of radon isotopes that they inhale. However, the average size of dust particles in homes is smaller than in mines, and since radon decay products attach to these particles, people in a household environment face a higher risk that the radon progeny will be deposited in their lungs. The combined effect of these two factors is that "the dose of alpha energy per unit exposure delivered to target cells in the respiratory tract tends to be lower for the home environment by about 30% for adults of both sexes and by about 20% for children." Children receive a higher dose because they breathe more rapidly and are typically more active, according to the committee.

The NRC notes that the EPA asked them to examine the dose per unit of radon exposure and not the levels of radon that exist in homes or mines. Thus, the report does not evaluate the risk of given levels of radon in the home and merely notes that "the findings that radon and its decay products are invariably present in indoor environments has prompted concern that lung cancer caused by radon is a public health problem."

The committee stressed that radon is not any less carcinogenic than previously believed and that much uncertainty remains when estimating the risk of lung cancer from domestic radon exposure. The report points out that new dosimetric models do not address "potentially important biological factors" and calls for further data gathering and analysis incorporating these factors. ■

Cancer Findings

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problems caused by energy policy, the nuclear industry, and the military."

Dr. Fry says the editorializing casually dismisses the benefits offered by the nuclear industry, particularly the benefits of nuclear medicine technology developed at Oak Ridge. She decries Dr. Wing's linkage of Oak Ridge to weapons production.

Co-author Dr. Cragle says that "to a certain extent" she disfavored the comments. "I told Steve that as first author he had the choice and he preferred to let the journal's editors decide if they were appropriate." (The editors of JAMA declined to discuss the peer review and approval of any individual article.) Judging the responses she's heard, Dr. Cragle says, "Most people's distaste lies with the expositional paragraphs in the discussion."

Dr. Wing likes to put politics out front, even in science.

Just a Piece in the Puzzle

Although critical of aspects of the paper, Dr. Fry defends the work as a whole. She's concerned that the findings of the paper are being widely misinterpreted. "It's not the basis for a conclusion that there's a causal relation between occupational exposure to radiation and an increased incidence in cancer," she says. More than 80% of the study population remains alive, meaning the current study draws its conclusions from less than 20% of the population, rendering it far from definitive. "By its nature," says Dr. Fry, "epidemiology makes progress very slowly and relies on many studies."

"I think people fear the paper is causing people to worry when there is no reason to," says fellow epidemiologist Dr. Cragle. Downplaying the significance of the paper, she says it has far too little impact to start revising standards for radiation exposure. "That's not the way epidemiology works," she says, "this paper is just another piece in the puzzle." Even if the low-level effects of radiation proved absolutely true, Dr. Cragle notes, Oak Ridge workers today —whose radiation exposures are much lower than in the 1930s and 40s—would not be affected. "They were getting two to three rems a year back then," she says. "It's unusual for [workers at DOE facilities] to get a rem anymore."

Dr. Hendee says, though the findings may prove insignificant, they pose a challenge. "We've been seduced into the belief that we can have the benefits without any risk," he says. "Now we face evidence that that's not true." The challenge is to understand the strange increased risk of cancer mortality that has appeared after a 20 year lag. Dr. Fry says, if projected over the entire population, this finding would imply that most cancers are caused by low levels of lifetime exposure to radiation. "That doesn't seem biologically possible," she says. "It's a finding that's unexplainable."

J. Rojas-Burke

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Letter from the Editors re: International PET

It is most gratifying to editors to know that the assembled published material has been read and found useful. It is therefore a bittersweet moment when we receive a letter identifying errors. We are pleased that *Newsline* is read so carefully but disappointed that the oversights were not found by us and corrected prior to publication.

In the recent PET issue (*Newsline*, April 1991), specifically the article "The International State of PET," two readers (to date) have pointed out errors of omission and commission. Professor Dr. W.D. Heiss from the Max-Planck Institute for Neurologische Forschung and the Klinik Fur Neurologie at the Universitat zu Koln (Cologne) informs us that the first PET installations in Germany were at the Kernforschungsanlange in Julich in 1979 and in Hannover in 1979–80. The PET facility in Cologne was established in 1981 and is possibly the most active center in Germany with a total of over 4000 cases studied to date. The Koln center has organized and hosted several international PET meetings as well as smaller workshops. Prof. Dr. Heiss also reports that the PET scanner at Heidelberg was installed in 1986 and that PET installations have been recently established in Dusseldorf, Aachen and Essen.

The status of PET in France was also neglected by our review.

Dr. B. Weissman informs us that the reported PET facility at the Royal Prince Alfred Hospital Camperdown, Sydney, is in its earliest stages of construction and certainly has not been completed.

We apologize to our readership for these errors and commit ourselves to better confirmation of sources as well as a more thorough report in the near future on the status of PET in the international community.

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