THE CANCER LETTER

Vol. 6 No. 22

May 30, 1980



Subscription $125.00 per year

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

## NCAB GIVES LIFE TO THREE CBCCP CONTRACTORS MARKED FOR TERMINATION; COMPROMISE "REASONABLE"—DEVITA

The National Cancer Advisory Board last week recommended against complete immediate termination of three of the six Community Based

(Continued to page 2)

*In Brief*

### LOUISVILLE CANCER CENTER DEVELOPED WITH NO FEDERAL, STATE MONEY OR FUND RAISING COSTS

**NEW REGIONAL** Cancer Center now under construction in Louisville will be operated under contract with the Univ. of Louisville when it opens May 1, 1981. The center is being developed by the nonprofit Regional Cancer Center Corp. which has raised over $12 million and will require no federal or state contribution. There were no expenses for fundraising or administration, "a unique and unprecedented fact," according to Laman Gray, president of the corporation. The center is planning for 90,000 patient visits a year, serving Louisville, Western Kentucky and Southern Indiana, and will provide space for all phases of cancer research. . . . **INSTITUTE FOR FAMILIAL** Cancer Management and Control at Creighton Univ. School of Medicine has been founded by Henry Lynch, chairman of the department of preventive medicine and public health, and other faculty members. The institute will study the genetics of cancer susceptibility in humans and provide physicians with information to help them estimate possible cancer risks in blood relatives of cancer patients, Lynch said. . . . **NCI STAFF** changes: Stephen Ficca, budget officer in the Financial Management Branch, to administrative officer of the Div. of Cancer Cause & Prevention replacing John Miller, who is moving to the Dept. of Energy; Jean Stein, from the Heart & Lung Institute to administrative officer of the Div. of Extramural Activities, replacing Edith Phillips, who retired; Robert Denniston, to chief of the Information Projects Branch in the Office of Cancer Communications; Joseph Bangiolo, to chief of the Information Resources Branch in OCC, and Margaret Layton, to chief of the Graphics & Audiovisuals Section in that branch. . . . **MARJORIE EARLY**, NCI committee management officer and recording secretary of the National Cancer Advisory Board since the Board was established in 1972, will retire in mid-September. The Board approved a resolution commending Early ("Her great efficiency lies behind whatever order has prevailed at our meetings," Harold Amos commented) and Samuel Price, who will retire soon from the Div. of Cancer Research Resources & Centers. . . . **MEARL STANTON**, NCI pathologist whose studies helped evaluate the carcinogenicity of fibers such as asbestos, died last week at age 57. He was a former editor of the *Journal of NCI* and edited the monograph series published by the IARC.

## ALL CBCCP CONTRACTORS MAY CONTINUE TO COMPLETION; PARTIAL PHASEOUTS DUE

(Continued from page 1)

Cancer Control Program contracts, as suggested by NCI staff and the merit review committees. Instead, the three probably will be allowed to complete the five years in their contract periods with some major reductions in their scope of work.

Merit reviewers and staff had recommended that the contracts with New Mexico, Rhode Island and Long Island be terminated July 31. New Mexico has one year remaining on its contract, Rhode Island and Long Island two years.

Reviewers and staff also had recommended that certain portions of the programs in the remaining three contracts, with Hawaii, Los Angeles and Detroit, be phased out.

Acting Director Vincent DeVita decided that the NCAB should be consulted before the terminations were implemented. It was the Board's approval of the concept of the program in 1975 which put it into motion.

"The Board did just what a Board is supposed to do," DeVita said. "I think it is a reasonable compromise."

A Board subcommittee of Sheldon Samuels, Maureen Henderson and Harold Amos reviewed the staff and merit review recommendations and rebuttals provided by the contractors. The subcommittee presented its findings and recommendations to the entire Board in closed session.

Each of the six contractors was receiving in excess of $1 million a year on five year contracts to demonstrate whether a coordinated effort by a variety of institutions and programs in a community could effect reductions in incidence and mortality of specific cancer sites.

Henderson was not present when the subcommittee's report was given. Samuels and Amos reviewed the background of the program, NCAB's discussion and decision to proceed over the objection of then President's Cancer Panel Chairman Benno Schmidt, and implementation of the program.

The subcommittee concluded that the original RFP was confusing; that NCI staff involvement after the awards were made probably was not as adequate as it could have been; and that the merit review probably was adequate in assessing the worthiness of the program.

The subcommittee recommended that only those elements in all six programs which reviewers found meritorious should be continued.

William Terry, acting director of the Div. of Cancer Control & Rehabilitation, said that the subcontracts in the Hawaii, Los Angeles and Detroit programs which reviewers said should be dropped will be discontinued. But in addition, the Board's motion can be interpreted to mean that other subcontracts should be looked at again. "We will have to look at the discussion by the merit review committees. It could be that other subcontracts did not generate much enthusiasm, and we will have to determine if the reviewers considered them meritorious."

Another consideration is that each element of each program must be determined as complying with the workscope of the RFP. And, federal regulations must be considered.

Another factor which could be important to the three originally marked for complete termination is that NCI will have to determine if the structure of each organization remains viable enough to continue the program. Some have lost staff due to the threatened phaseout.

"The sense of the Board's motion was that none of the six were considered fully satisfactory," Terry said, "and all should be considered in the process of phasing out." No consideration should be given to renewing any of the contracts beyond the original contract period, the Board emphasized.

That was the intent of the program from the start. It was emphasized then that any continuation would have to be supported by non-NCI money.

Other matters brought up at the Board meeting included:

* Announcement by Panel Chairman Joshua Lederberg that Harold Amos will be the new member of the Panel, replacing Elizabeth Miller. The appointment has not been officially made nor, according to Amos, communicated to him. He will continue as a member of the Board, with his term continuing to 1982. The Panel appointment is for three years.

* Announcement by DeVita that Henry Pitot has been reappointed by President Carter to another two year term as chairman of the Board.

* Two of the new Board members were unable to attend the meeting—LaSalle Leffall, chairman of surgery at Howard Univ.; and Mrs. Jules Lederer, better known as Ann Landers.

* The 1981 budget "is lean," DeVita said. Research contracts have been decreased by 10 percent. "The principal is that no investigator initiated research will be funded by contracts." But he defended the contract process, citing examples where its use is essential, and said, "We're all disturbed by the general attack on contracts." The provision in the Waxman bill (renewing the National Cancer Act and other NIH research) which would require NCAB review and approval of contracts over $500,000 "would be the death knell of contracts."

DeVita argued that NCI contracts receive concept review by the appropriate oversight groups in the program divisions, as well as the technical review by contract review committees. "Concept review is one by one; they do not receive block approval. We have 1,500 contracts, and one by one review is not pos-

sible by this Board. Concept review is best done by the division boards."

"Not all of us agree with your view of contracts, or your interpretation of the Waxman bill," Board member Sheldon Samuels said.

"I know," DeVita answered. "I was thinking of you when I said that, and I understand your position."

"Contracts account for 25 percent of the total budget," Board member Irving Selikoff said. "Yet the Board has very little input on them. You correctly state that the boards of scientific counselors of the divisions can make changes. Yet our Board has little awareness or knowledge of their discussions. I suggest that the question of contracts goes beyond yes or no to the question, how do we advise you."

"You're probably right," DeVita said. "There is a problem in consistency. We should take the time to look at contract programs, and devise some link with the boards of scientific counselors, perhaps have their chairmen sit here. We're not trying to hide anything. There is safety in having you look at controversies and helping us decide. . . . Resource contracts is the key issue."

Pitot noted that Board members are being supplied with copies of all RFPs; with information on their fate; and minutes of all boards of scientific counselors meetings.

Board member Rose Kushner asked what percentage of NCI contracts represented work that could not be done inhouse because of the position ceiling.

"That is a minor part. There is some work that we would never want to internalize, such as drug development. Pharmaceutical firms and universities can do that work well, and it changes so much that it would not be efficient to do inhouse."

Kushner noted that public education efforts involving distribution of huge quantities of materials are handled by the Office of Cancer Communications and other offices "which are terribly understaffed."

"I agree, but parts of that are changing," DeVita said. "If it can be shown that it is cheaper to do inhouse than with contracts, we still would have to convince OMB to give us the positions. I don't believe that will happen."

Samuels said, "The area of disagreement is not large. I know we have to live in the real world. OMB, for short term, political reasons, has forced you to operate illegally. But this Board is not bound by short term political considerations."

Amos pointed out that the Board has had some influence on contracts. "The Board's review of the Virus Cancer Program, resulting in the Zinder report, touched off far reaching changes."

DeVita noted that the Waxman bill requires Board (and in the case of other NIH institutes, Council) review of all contracts over $500,000, and that amount includes everything over the life of the contract. "Essentially, all contracts would be brought to the Board. The staff would rather not deal with contracts, but some of the finest work has been done by that mechanism. Frequently it is the only way to get something done." He cited Bernard Fisher's breast cancer adjuvant chemotherapy studies as an example.

Fisher, sitting on the Board as a member of the Panel, said, "Good research can be done as well by contract as by grant. There is nothing in my mind that says you can't do as well with contracts as with grants, and sometimes better."

## NCAB UNENTHUSIASTIC ABOUT TRANSFER OF CARCINOGENESIS PROGRAM TO NIEHS

The vote by the National Cancer Advisory Board approving transfer of the Carcinogenesis Testing Program to the National Institute of Environmental Health Sciences was not given enthusiastically (and was not unanimous, with Philippe Shubick voting against it), a mood shared with NCI staff members.

The decision to recommend the transfer was made, Acting Director Vincent DeVita said, for managerial reasons. "It's always better to work for one manager . . . and not split the program between Bethesda and North Carolina."

The transfer seemed inevitable, although former Director Arthur Upton was hopeful when the National Toxicology Program was started and the Carcinogenesis Testing Program was assigned to it that the experiment in joint agency management could work. Even before then, some NCI executives had felt that routine testing of compounds was not an entirely appropriate activity for a research institute. They looked forward to the assumption of that responsibility by another agency.

Others felt strongly that a national carcinogenesis testing effort properly belonged with the agency administering the nation's major carcinogenesis research effort. That view began to lose out when the philosophical decision was made that carcinogenesis and other toxicity testing should be under the same roof, leading to the creation of NTP.

Contributing to that decision was the impression that NCI was not doing a very good job with the testing program, an impression fostered by the development of the backlog of more than 200 finished but unreported tests. The backlog had been cleared up before HEW Secretary Joseph Califano ordered NTP into existence, but the critics were not convinced.

Shubick did not agree that the testing program was being mismanaged by NCI. "There were a great number of problems when the program was started," he said, "But it developed effectively. I thought the program was not doing too badly here. . . . I don't understand why this is happening. I hesitate to lend my support (to the transfer), when we have no idea where it is going. It may be that in the end it will be all right, but it is in error to make this decision today.

. . . I don't understand why we are having this discussion. If the decision has been made, why not tell us?"

Board Chairman Henry Pitot replied that NIH Director Donald Fredrickson had asked DeVita to seek the Board's opinion.

Pitot and Board member Irving Selikoff urged that NCI's role in the testing program, through representation on NTP's advisory groups, be maintained. "The science of carcinogenesis research remains at NCI, and recognition of that should be assured," Selikoff said. "We should make it clear that this is not an abdication of NCI's interest in carcinogenesis but a matter of coordination with other toxicology testing."

"Perhaps the Board should have been more involved with the development of NTP," member Bruce Ames commented. "We weren't, and it is a managerial nightmare."

"We're going to rid ourselves of the whole thing?" Board member Harold Amos asked, referring to routine carcinogenesis testing. "That's the best thing that could happen."

Gregory O'Conor, director of the Div. of Cancer Cause & Prevention which is losing the 80 positions and $40 million plus carcinogenesis testing now commands, said he was "surprised by the discussion questioning whether the science of carcinogenesis will leave NCI. DCCP's budget is about a quarter of a billion dollars, and almost all of it is related to the science of carcinogenesis. There is no question of this passing to NIEHS or anyone else."

O'Conor pointed out that the transfer will involve only the routine testing plus related areas of test development and test validation.

David Rall, NIEHS director and also director of NTP, and some members of his staff discussed the program with the Board:

* Rall noted that as NTP director, he reports directly to the Surgeon General; and that the major advisory group is the Executive Committee which consists of the heads of the four contributing agencies –NCI, FDA, NIEHS (giving Rall one vote on the committee), and the National Institute of Occupational Safety & Health. Those four are all within the Dept. of Health & Human Services. Thre agencies outside HHS are also represented on the committee, the three major health regulatory agencies–Environmental Protection Agency, Occupational Safety & Health Administration, and Consumer Product Safety Commission.

* NTP also has an eight member Board of Scientific Counselors chaired by Norton Nelson. The Board is studying three problems, Rall said–the best way to select chemicals for testing; the mechanism of reviewing the technical reports; and the "major problem of how to get our arms around all the data involved," through data processing.

* NIEHS has a mutagenicity test development program, and this being integrated with NCI's short term test development, Rall said.

* In answer to a question by NCAB member Morris Schrier concerning technology transfer, Rall said the primary method now is publication of bioassay reports in the *Federal Register*. "That is not sufficient, and we need better ways."

*** Rall praised Carcinogenesis Testing Program Director Richard Griesemer, who will return to Oak Ridge July 1, for his efforts in starting NTP "and for his monumental, superb job in eliminating the backlog."**

Griesemer listed what he said were significant changes in the program since it became part of NTP–broadening of the tests, improving the chemical selection process to involve more government agencies and thus gain greater assurance of the importance of the compounds selected, and improvement in interagency communication. He described "some pressing needs:"

–As TOSCA (Toxic Substances Control Act) and other laws are implemented (placing the burden of testing on industry), the program will be able to diminish its testing efforts. It still will need to monitor industry testing and there still will be a need for long term tests of selected compounds.

–Tests for combinations of chemicals will have to be developed and carried out.

–Tests for systemic promoters will have to be developed and carried out.

–New test methods will be needed for integrating tests of chemicals with other substances, such as hormones, and for chemicals which present physical effects rather than chemical ones.

Rall told the Board that the NTP Board of Scientific Counselors had agreed to establish an ad hoc group to review bioassay reports before they are published, a function previously performed by the now disbanded Clearinghouse on Environmental Carcinogens. The group will include four members of the NTP Board–Margaret Hitchcock, who will be the chairman; Curtis Harper, Thomas Shepard and Alice Whittemore. It also will include Norman Breslow, Univ. of Washington; Joseph Highland, Environmental Defense Fund; Charles Irving, VA Hospital, Memphis; Frank Mirer, International Union, Auto Workers; Sheldon Murphy, Univ. of Texas; Svend Nielsen, Univ. of Connecticut; Bernard Schwetz, Dow Chemical; Ray Shore, New York Univ.; James Swenburg, Chemical Industry Institute of Toxicology; and Gary Williams, American Health Foundation.

The group will meet June 27 in Washington, at the HHS Switzer Building (formerly HEW South), 330 C St. SW, Rm 1331, starting at 9 a.m. The entire meeting will be open to the public.

## GAO REPORT REFUTES ALLEGATIONS AGAINST CONTROL PROGRAM, TERRY SAYS

The General Accounting Office investigation of the Cancer Control Program has determined that, contrary to the charges which stimulated the probe by the congressional watchdog agency:

* Congress had not been misled on the reasonableness of cancer control/technology transfer when it was written into the National Cancer Act of 1971.

* NCI's Div. of Cancer Control & Rehabilitation has closely followed the advice of the various advisory bodies convened to develop positions on the division's programs and project proposals.

* Contract practices involving DCCR programs have not been deficient.

DCCR Acting Director William Terry summarized for the Cancer Control & Rehabilitation Advisory Committee the thrust of GAO's findings which he said were in the preliminary draft of the investigation report.

GAO decided to rewrite the report as a result of strenuous objections by NCI executives who challenged the factual content, analysis and recommendations in it (***The Cancer Letter***, March 7). The revised report has not yet been released.

Other matters discussed at the CCRAC meeting included:

–Cancer control core grants for centers. CCRAC last year approved the concept and the RFA was published, resulting in a good response, Terry said.

–The new Div. of Centers, Community Activities & Resources, which will assume all DCCR activities when the reorganization is approved, plus the centers, construction, organ sites and manpower training programs. Committee member Anthony Miller noted the "enormous scope of this division, with a wider range than any other, will require people with broad expertise. . . . This division should have an intramural program (DCCR does not, and the other programs the new division will assume are all extramural activities). You will have recruiting difficulties with no strong intramural program."

Terry agreed. "If we are going to recruit quality personnel, they will have to have the opportunity to continue some of their own research, where it will not conflict with extramural management. The alternative is not palatable."

Terry said that by fall of this year, assuming the reorganization has been approved, CCRAC will be reconstituted into a Board of Scientific Counselors for the new division, with representation for each of the major program areas it will include. "This could lead to a highly fractured advisory body which can't provide advice. I hope that can be avoided by getting people with a broad background, for instance people familiar with centers and control, and prevention and education."

Committee member Harold Rusch asked if there was going to be any money for construction. "I don't know the answer," Terry said. The 1981 budget has only $1 million for construction. "Sooner or later reason will have to prevail. We have to consider the needs in carcinogen handling. We can't expect laboratory workers to work in an environment which will endanger their health."

–CCRAC members' suggestions on the future of the Cancer Control Program and the new division.

"Research has to be part of the division's activities," Miller said. "The program started with a large amount of money poured into screening without understanding what we were doing. Medical oncologists in communities are not necessarily the same as medical oncologists working with research protocols. They do not have time to go to ASCO. What he knows about treating advanced Hodgkin's disease is six courses of MOPP, then look at it. That may not be the optimal treatment now."

"I would like to see the division more involved with prevention than with detection," said Anthony Mazzocchi. "We haven't addressed the industrial sector. People don't understand the magnitude of the problem."

"Programs should be designed with more community input," said Gale Katterhagen. "The Community Based Cancer Control Program would have been considerably modified with more community input. We think oncology units offer superior care to chemotherapy in an oncologist's office, but that has not been proven. We pour money into training nurse oncologists on the assumption they do better than staff nurses, but we don't know if that is true."

"The concept that research should not be part of the Cancer Control Program has been inhibitive," said Gussie Higgins. "We were supposed to have had all this magic technology that only needed to be transferred. We need to look at the failures of CBCCP and failures of DCCR. We should avoid initiating projects without some front end planning to continue the program if it is successful, and they should have concrete evaluations built in."

"What are the roles of community cancer centers?" asked Paul Engstrom. "They are closer to the community and to the materials to do control research. The challenge of the 80s will be how to pay for services once they are defined as useful."

"The challenge of the 80s will be how to make different comments and still sound erudite," needled committee member Willie Dell, a member of the Richmond, Va. city council. She suggested that there has not been enough involvement of lay persons in developing cancer control efforts. Control programs are needed "to help people cope with effects of treatment," she said.

"We need public involvement in lifestyle change programs," said Kenneth Casebeer. Also, "coordina-

tion with other agencies such as OSHA and EPA."

"Cancer research is an intergral part of cancer control," said Jane Wright. "I hope that whatever process is delineated, it will be a flexible, reasonable thing."

"We are never sure when the signals will change," said Beverly Ware. "We are still arguing about research versus demonstration. Programs are truncated, picked up one year, dropped the next. CBCCP was labeled a failure a long time ago. The worst part of the problem was the labeling. I would no way consider them to be failures."

"You don't use your committee enough," said Glenn Sheline. "We don't do much, and don't feel effective."

"Why not more emphasis on anticarcinogens?" Rusch asked. "Little has been said about anticarcinogens in the diet. We should take the information we have from animals and apply it to people."

"Those of you who end up on the new board may live to regret Dr. Sheline's comment," Terry said.

## NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR JUNE AND JULY

**Prostatic Cancer Review Committee**–June 2, Roswell Park Research Study Center, open 8:30-9 a.m.
**Second World Congress for Bronchology**–June 2-4, Dusseldorf.
**Clinical Trials Committee**–June 3-4, Bethesda Holiday Inn, open June 3, 9–9:30 a.m.
**Fifth National Oncological Meeting**–June 4-7, San Jose, Costa Rica.
**Developmental Therapeutics Committee**–June 5-6, Landow Bldg Rm A, open June 5, 9–9:30 a.m.
**Large Bowel Cancer Review Committee**–June 5-6, Prudential Bldg., Houston, open June 5, 7:30–8 p.m.
**Bladder Cancer Review Committee**–June 5-6, Ramada Inn, Pittsburgh, open June 5, 8–9 a.m.
**Cancer Research Manpower Review Committee**–June 5-7, Bethesda Marriott, open June 5, 9–10 a.m.
**Pancreatic Cancer Review Committee**–June 9-10, Tidewater Place, New Orleans, open June 9, 7–8 p.m.
**Cancer Control Grant Review Committee**–June 9-10, NIH Bldg 31 Rm 7, open June 9, 8:30–9 a.m.
**Second World Conference on Lung Cancer**–June 9-13, Copenhagen.
**Clinical Cancer Education Committee**–June 11-12, Landow Rm A, open June 11, 8:30–9:30 a.m.
**Conference on Biological Carcinogens**–June 11-14, Michigan Cancer Foundation, Detroit.
**Symposium on Recent Topics in Cancer Research**–June 12-13, Osaka, Japan.
**Symposium on Cancer Causation & Environmental Factors**–June 13, Concourse Hotel, Madison, Wisc.
**Modern Trends in Human Leukemia**–June 17-19, Wilsede, Germany.
**UICC Pan American Conference on Public Education about Cancer**–June 17-19, Bogota, Colombia.
**Cause & Prevention Scientific Review Committee**–June 19-20, NIH Bldg 31 Rm 9, open June 19, 9–9:30 a.m.
**Cancer of the Colon-Rectum**–June 21, Roswell Park continuing education in oncology.
**Third International Symposium on Cancer Therapy by Hyperthermia, Drugs, and Radiation**–June 22-26, Colorado State Univ., Fort Collins.
**Assn. of American Cancer Institutes**–June 22-24, New Haven Sheraton Park Plaza and Yale Univ., semiannual meeting.
**Diagnostic Research Advisory Group**–June 23-24, NIH Bldg 31 Rm 8, 9 a.m., open.
**Clinical Cancer Investigation Review Committee**–June 23-25, NIH Bldg 31 Rm 4, open June 23, 8:30–9:30 a.m.
**Seventh International Conference of the International Assn. of Oral & Maxillofacial Surgery**–June 24-26, Dublin.
**Current Concepts in Cancer Chemotherapy**–June 25, M.D. Anderson auditorium, Adria symposium, 8:30 a.m.
**National Toxicology Program Board of Scientific Counselors Report Review Subcommittee**–June 27, HHS Switzer Bldg R Rm 1331, 330 C St., SW, Washington D.C., 9 a.m., open.
**Fifth International Congress of Dentomaxillofacial Radiology**–June 28-July 2, Portland, Ore.
**International Symposium on Mouse Teratocarcinoma, Oncofetal Proteins, & Human Testis Cancer**–June 26-28, Minneapolis.
**UICC Special Project on Breast Cancer Epidemiology & Prevention**–June 26-29, Leeds Castle, Kent, UK.
**FDA Oncologic Drugs Advisory Committee**–June 26, Parklawn Bldg, Conference Room G, 9 a.m., open.
**Czeckoslovak Congress of Phthisiology & Pneumology**–July 1-4, Prague.
**Criteria of Response in the Treatment of Prostate Cancer**–July 3, Paris.
**Second International Congress of Toxicology**–July 7-11, Brussels.
**Symposium on Cancer & Genetics**–July 12-13, Sapporo, Japanese Cancer Assn.
**NIH Consensus Conference on Adjuvant Chemotherapy of Breast Cancer**–July 14-16, Masur Auditorium, 9 a.m., open.
**Fourth International Congress of Immunology**–July 21-26, Paris.
**Fourth International Cyclic Nucleotide Conference**–July 22-26, Brussels.
**NIH Consensus Development Conference on Cervical Cancer Screening**–July 23-25, Masur Auditorium, 9 a.m.
**Fourth International Symposium on Prevention & Detection of Cancer**–July 26-Aug. 1, London.

## HHS CARCINOGEN GUIDELINES FOR LABS EVENTUALLY COULD APPLY TO OTHERS

The Dept. of Health & Human Services is in the process of developing guidelines for the laboratory use of chemical carcinogens by HHS intramural labs, including those at NIH. Although they initially would not be required practice for nongovernment labs, it is likely that the HHS guidelines or something like them eventually will be applied to most laboratories handling chemical carcinogens.

Emmett Barkley, director of the NIH Office of Research Safety, is chairman of the Laboratory Chemical Carcinogen Safety Standards Subcommittee of the HHS Committee to Coordinate Enviromental & Related Programs. David Rall is chairman of the parent committee.

Barkley and Rall presented the latest draft of the proposed guidelines to the National Cancer Advisory Board Subcommittee on Environmental Carcinogenesis last week. A final draft is still being written.

Barkley later told *The Cancer Letter* that NIH has no intention of making compliance with the guidelines a condition of grants or contracts. "We hope they will be a reasonable model and prove useful to others," he said. "They are for the government's internal use, but we recognize they may have major influence on extramural laboratories."

Even if NIH does not make the guidelines mandatory for its grantees and contractors, the Occupational Safety & Health Administration could do so. OSHA is looking carefully at them, with the prospect they will serve as a model for regulations that agency may develop. University laboratories in general must comply with OSHA regulations. An exception would be in those states without an OSHA-approved plan, in which case the state universities would be exempted since OSHA regulations would not apply to state employees. Twenty-six states have OSHA-approved plans.

The guidelines were developed after Barkley's committee held open hearings on the problem. More than 100 letters were received by the committee, and many of the suggestions they made were incorporated into subsequent drafts.

"Did you check with a half dozen research institutions, to find out how this would affect them?" NCAB member Irving Selikoff asked.

"No, but the comments we received covered the entire spectrum," Barkley said.

"We had two public open meetings," Rall said. "We felt that was adequate opportunity for participation. There is always another group you could refer to."

"But those were self selected," Selikoff said. "If you would go to a half dozen research institutions with good safety committees, and with legal departments, you might get some good ideas."

Selikoff was particularly interested in the legal aspects of the guidelines. Barkley said they had not been reviewed for legal liability, but that government agencies are legally liable anyway for their laboratories.

Board member Philippe Shubik agreed with Selikoff. "You need a legal committee to determine the reasonableness of the guidelines and to give assurance to the institutions they will not be held liable at a future date."

Board member Bruce Ames questioned the guidelines' requirement for physical examinations of lab workers. "If they get an annual x-ray, they would be getting something far more dangerous than the carcinogens they might be exposed to. When OSHA inspectors came to our lab, I calculated there was more benzopyrene coming out of their car exhausts than was going up our exhausts. If a worker eats a charcoal broiled hamburger for lunch and gets 100 times more carcinogens than from his lab exposure, it's ridiculous to worry about that."

Rall pointed out that the guidelines do not call for annual x-rays or even annual examinations but only for a periodic health assessment.

The various drafts of the guidelines have not been published, and HHS does not plan to publish the final version. If OSHA decides to incorporate them into its guidelines, the rulemaking procedures will be followed, including publication. To provide those responsible for laboratory operations an earlier look at procedures which may affect them significantly, *The Cancer Letter* will publish here and in following issues as space permits the latest available draft.

**Introduction**

The purpose of these guidelines is to recommend safeguards for use of chemical carcinogens in laboratories of all operating agencies of the Dept. of Health, Education & Welfare [now HHS]. They apply to all chemical substances posing a carcinogenic risk to laboratory workers. These include chemical carcinogens regulated by standards promulgated by the Occupational Safety & Health Administration and to chemical substances that, in the judgment of the operating agency, pose a carcinogenic risk to their employees.

The guidelines define the responsibilities of the operating agencies, the principal investigators and all employees for ensuring the safe conduct of work involving chemical carcinogens. The guidelines also provide recommendations for health surveillance and employee education. The control measures recommended in the guidelines consist of good laboratory practices and relevant engineering controls that are necessary to protect laboratory workers and the environment from exposure to carcinogenic agents that are used in the laboratory.

The guidelines are based on the assumption that any exposure to a chemical carcinogen, regardless of how small, may carry some risk. While the complete elimination of exposure is the ideal objective, this may not be obtainable in every case. However, the potential for exposures must be reduced to the lowest practicable level.

The application of these guidelines to a specific laboratory activity must be based on the judgment of the principal investigator who is responsible for the safety of operations involving chemical carcinogens. No set of guidelines can be uniformly applied to every situation. It is imperative, therefore, that the principal investigator assess those variables peculiar to each planned activity in establishing appropriate safeguards. Variables that require specific attention include (1) quantity of the chemical carcinogen to be used in the particular activity, (2) physical and chemical properties of the agent, (3) comparative carcinogenic potency and (4) the type of experimental procedures that will be involved in the proposed use of chemical carcinogens.

Safety monographs and safety data sheets will be published to supplement these guidelines. The safety monographs will provide general information on subject areas pertaining to laboratory safety. The safety data sheets will provide specific technical and safety information pertaining to the use of individual chemical carcinogens. This information will be provided to assist the user of chemical carcinogens in making informed judgments as to the selection of appropriate control measures for the safe conduct of work involving chemical carcinogens.

The laboratory practices and engineering controls described in these guidelines may serve as helpful guides for establishing control measures for the safe handling of other toxic chemicals.

**I. Responsibilities**

A. Operating Agencies

The operating agency is responsible for reducing employee and environmental exposures to chemical carcinogens used in its laboratories to the lowest practicable level. In order to ful-

fill this responsibility the operating agency should:

1. Establish and implement policies that provide for the safe conduct of work involving chemical carcinogens.

2. Establish a safety committee and assign to it the responsibilities detailed in Section I-B (these responsibilities may be assigned to an existing committee, provided that this committee is involved with issues pertaining to laboratory safety).

3. Appoint a safety officer and assign to this person the responsibilities detailed in Section I-C and ensure that the safety officer has the capabilities and resources to carry out these responsibilities.

4. Ensure that any principal investigator using chemical carcinogens is qualified by training and experience, has the equipment and facilities to handle the material safely, and uses procedures that reduce the potential for exposure to the lowest practicable level.

B. Safety Committee

The safety committee is responsible for:

1. Recommending to the operating agency policies that provide for the safe conduct of work involving chemical carcinogens.

2. Identifying chemical substances used in laboratories of the operating agency which may pose a carcinogenic risk.

3. Determining conditions of use (e.g., quantity, experimental situation) for which safety plans shall be required. A safety plan shall be required for use of any chemical carcinogen regulated by standards promulgated by OSHA.

4. Reviewing and approving safety plans prepared by each principal investigator.

5. Advising the operating agency on specific programs for health surveillance.

The membership of the safety committee should include individuals who possess expertise in chemistry, toxicology, medicine, engineering, and laboratory safety. The members should be recognized by their colleagues as persons of good judgment and each should have a personal commitment to laboratory safety.

C. Safety Officer

1. Assisting the principal investigator in the selection of laboratory practices and engineering controls.

2. Providing technical guidance to personnel at all levels of responsibility on matters pertaining to laboratory safety.

3. Inspecting laboratories at least annually to assess compliance with policies and approved safety plans.

4. Investigating all reported accidents which result in the exposure of personnel or the environment to a chemical carcinogen and recommending corrective action to reduce the potential for recurrence.

5. Supervising decontamination operations in those cases where accidents have resulted in the overt contamination of laboratory areas.

D. Principal Investigator

The principal investigator has the primary responsibility for:

1. Selecting laboratory practices and engineering controls for handling chemical carcinogens.

2. Preparing a safety plan for use of chemical carcinogens regulated by standards promulgated by OSHA and other chemical carcinogens for which safety plans are required by the safety committee. The safety plan should specify the chemical carcinogens expected to be used, the general type of experiments to be carried out, the amounts of these chemicals anticipated to be used, the persons authorized to handle chemical carcinogens, the laboratory practices and engineering controls be to employed, procedures for dealing with accidents which would result in the exposure of personnel or the environment to a chemical carcinogen, and the name of the person who will be responsible for maintaining storage of the chemical carcinogens.

3. Submitting the safety plan to the safety committee for its review and approval.

4. Making available to program and support staff copies of the approved safety plan.

5. Instructing and training the staff under their supervision in the laboratory practices and engineering controls required to ensure safety and in planned procedures for dealing with accidents involving chemical carcinogens, and assuring that staff are informed of the potential hazards associated with the use of chemical carcinogens.

6. Supervising the safety performance of the staff to ensure that the required laboratory practices and engineering controls are employed.

7. Arranging for immediate medical attention and reporting to the safety officer any accident that results in (a) inoculation of chemical carcinogens through cutaneous penetration, (b) ingestion of chemical carcinogens, (c) probable inhalation of chemical carcinogens, or (d) any incident causing overt exposure to personnel or danger of environmental contamination by chemical carcinogens.

8. Providing assistance to the occupational medical program concerning health surveillance activities.

9. Assisting the safety officer in investigating accidents.

10. Investigating and reporting in writing to the safety officer any problems pertaining to operation and implementation of laboratory practices and engineering controls.

11. Correcting work errors and conditions that may result in the release of chemical carcinogens.

E. All Employees

Each employee is responsible for:

1. Complying with oral and written safety rules, regulations and procedures required for the task assigned.

2. Reporting unsafe conditions to the principal investigator or immediate supervisor.

3. Reporting to the principal investigator or immediate supervisor all facts pertaining to every accident resulting in exposure to chemical carcinogens.

## NCI CONTRACT AWARDS

**Title:** Immunological and biochemical studies of mammalian viral oncology, continuation
**Contractor:** Meloy Laboratories, $59,999.

**Title:** Support services for molecular studies of human and animal cancer, continuation
**Contractor:** Meloy Laboratories, $47,333.

**Title:** Spontaneous and virus induced neoplastic transformation, continuation
**Contractor:** Meloy Laboratories, $61,333.

**Title:** Replication of oncogenic RNA viruses and its relation to human cancer, continuation
**Contractor:** Columbia Univ., $50,450.

**The Cancer Letter** _Editor Jerry D. Boyd

Published fifty times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter. 