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Report to Rep. David R. Obey; by Elmer B. Staats, Comptroller General.

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In May 1973 the National Cancer Institute (NCI) renewed, for 18 months, a sole-source contract with the Eppley Institute for cancer research. Since the \$3.4 million renewal, the contract has been modified several times so that, as of November 1977, 36 months and \$9.4 million have been added to the contract period and cost. NCI awarded a 1-year, \$3.6 million extension to the contract in November 1977.

Findings/Conclusions: In renewing the contract, NCI used an ad hoc group to make technical reviews of the proposal rather than the standing committees chartered for this purpose.

Recommendations were apparently disregarded in negotiating the scope and amount of the contract, and justification for noncompetitive procurement was not based totally on facts.

Problems identified in contract administration and performance were: contract monitoring was ineffective; the contractor did not fulfill reporting obligations; Eppley officials carried out and financed 11 projects with contract funds without obtaining initial formal approval; Eppley made charges to contract funds for personnel, laboratory animals, supplies and equipment which were not used for contract work or were not adequately

controlled; and Eppley received approval to refurbish its breeding facility which was breeding more animals than were needed for research. Eppley has taken some action to reimburse the contract for noncontract costs. A review of the contract by the Department of Health, Education, and Welfare (HEW) Audit Agency is under way.

Recommendations: The Secretary of HEW should: require that the audit of the Eppley contract cover matters relating to improper use of Federal funds and equipment and obtain appropriate corrective actions; require that NCI officials obtain and analyze data on the need for research animals at Eppley before approval is given to refurbish the animal farm; provide for necessary inventory controls and use of equipment and personnel under contract funds; require that

recommendations of scientific reviewers, a management group, and auditors be used in negotiating a budget for future work; require that noncompetitive procurement be based totally on facts; require that the contractor's budget proposal contain data on each proposed project; and consider adding provisions to any future contract to clearly state conditions for project approval, personnel use, contract modifications, and inventory control. For future contract work with Eppley, the Secretary of HEW should improve contract monitoring and administration. (HTW)

5430

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**REPORT OF THE
COMPTROLLER GENERAL
OF THE UNITED STATES**

RELEASED
2/21/78

**Need To Improve Administration
Of A Carcinogen Testing And
Carcinogenesis Research Contract**

Contractor and National Cancer Institute officials have been lax in administering a contract costing more than \$12.8 million. This has resulted in the contractor making unauthorized use of Federal funds and equipment and not complying with all the terms of the contract. Institute officials were unaware of these situations.

Problems under the contract are being reviewed. Procedures are being strengthened for monitoring future work under this contract which will be carried out under a 1-year, \$3.6 million contract extension awarded in November 1977.



COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

The Honorable David R. Obey
House of Representatives

Dear Mr. Obey:

In response to your June 6, 1977, letter, we reviewed a National Cancer Institute contract with the University of Nebraska's Eppley Institute. Our report describes (1) the National Cancer Institute's actions in awarding and monitoring the contract, (2) the adequacy of contractor control over funds and property, (3) personnel matters pertaining to the professional staff at the Eppley Institute, and (4) results of work done under the contract.

Also, as you requested, the report contains our conclusions and recommendations, and written comments on the report by the Department of Health, Education, and Welfare and the University of Nebraska.

As agreed with your office, only officials of the Department of Health, Education, and Welfare and the University of Nebraska will be sent copies of the report at the same time it is delivered to you. We will not make any additional distribution of the report for a period of five working days after you have received it or until you publicly announce its contents.

Sincerely yours,

A handwritten signature in cursive script, reading "Thomas B. Steeds".

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT
TO THE HONORABLE DAVID R. OBEY
HOUSE OF REPRESENTATIVES

NEED TO IMPROVE ADMINISTRATION
OF A CARCINOGEN TESTING AND
CARCINOGENESIS RESEARCH
CONTRACT

D I G E S T

In May 1973 the National Cancer Institute renewed, for 18 months, a sole source contract with the University of Nebraska's Eppley Institute for Research in Cancer. Since the \$3.4 million renewal, the contract has been modified several times so that as of November 1977, 36 months and \$9.4 million have been added to the contract period and cost. The award of the contract renewal and its administration had several weaknesses. As a result there was unauthorized use of Federal funds and equipment by Eppley, and Institute officials were not fully aware of how Eppley was administering the contract or what was being achieved. In October 1976 Eppley proposed to continue work for 3 additional years at an estimated cost of \$16.4 million. The National Cancer Institute awarded a 1-year, \$3.6 million extension to the contract in November 1977.

INSTITUTE'S CONTRACT ADMINISTRATION

In renewing the contract in 1973, the Institute used an ad hoc group to make technical reviews of the contract proposal. Standing committees which were chartered for such a purpose should have been used. Recommendations were apparently disregarded in negotiating the scope and amount of the contract. Also, the justification for noncompetitive procurement was not based totally on facts.

Institute monitoring of the contract was ineffective. The contracting officer was not aware of some situations which required his attention and claimed that he lacked the leverage needed to require the contractor to comply with reporting

requirements. The project officer stated that he could not fulfill all of his duties because the contract was too big and complex for one individual to administer.

CONTRACT OBLIGATIONS AND RESULTS

The contractor did not fulfill reporting obligations under the contract. In another instance, information was not available to show whether a contract obligation for level of effort had been met.

Institute officials were not familiar with the contents of progress reports or papers published on the results of projects carried out under the contract. While they could recite some achievements, they said that the value of what had been done under the contract was intangible and therefore not capable of being equated with the money spent.

EPPLEY MANAGEMENT PRACTICES

Eppley officials carried out and financed 11 projects with contract funds for which they did not obtain initial formal approval from the Institute. Charges to contract funds were made for personnel, and laboratory animals and supplies which were not used for contract work. Equipment either furnished by the Government or purchased with contract funds was not being adequately controlled and, in some cases, was improperly used for noncontract work. Federal regulations for certifying personnel services charged to the contract were not being followed.

Controls for recording employees' leave were inadequate. Also Eppley received approval to refurbish its breeding facility which was breeding many more animals than it needed for research purposes.

CORRECTIVE ACTIONS TAKEN

Eppley officials have made some adjustments to reimburse the contract for noncontract costs originally paid for with contract funds. The Institute has requested the Department of Health, Education, and Welfare Audit Agency to review the Eppley contract. That review is currently under way. Three Institute officials have been designated as new project officers. Also, Eppley has been instructed to defer awarding a contract for refurbishing the animal-breeding facility until the Institute determines what size facility is needed.

RECOMMENDATIONS

GAO is making several recommendations which should help correct problems under the contract and assure improved administration on any future contract work with Eppley. (See p. 43.)

HEW AND CONTRACTOR COMMENTS

HEW concurred with all but part of one of GAO's recommendations. Corrective actions have already begun on several matters and additional actions are planned. (See p. 46.)

Although the contractor acknowledged the validity of some findings and reported that new procedures have been implemented to control contract activities, it disagreed with other findings. GAO reviewed the contractor's comments but concluded that its findings are valid. The contractor also expressed concern that burdensome administrative procedures could be imposed if GAO's recommendations are adopted. (See p. 47.)

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ABBREVIATIONS

CCPMG	Carcinogenesis Contract Program Management Group
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
NCI	National Cancer Institute
NIH	National Institutes of Health
RFP	Request for Proposal

CHAPTER 1

INTRODUCTION

We reviewed a sole source contract awarded in 1973 by the National Cancer Institute (NCI) to the University of Nebraska's Eppley Institute for Research in Cancer. We were asked to report on (1) the actions taken by NCI in the award and monitoring of the contract, (2) the contractor's controls over the use of Federal funds and property, (3) various personnel matters pertaining to the professional staff at Eppley, and (4) the work performed under the contract with a determination, if possible, of its usefulness. (See app. I)

BACKGROUND

The goal of the National Cancer Program is to develop the means to significantly reduce the incidence, morbidity, and mortality of cancer in man, and ultimately to develop the means to eliminate all human cancer. As an integral part of this program, NCI's Carcinogenesis Program has become a collective effort of some 200 laboratories using multidisciplinary approaches to study cancer prevention. The program is characterized by the integration of basic research and applied research oriented toward specific disease problems.

For fiscal year 1976 about \$42.5 million was obligated for the contract segment of the Carcinogenesis Program. About two-thirds of the contract funds have been spent in testing various substances to determine if they cause cancer while much of the remainder has been spent for cancer research. Carcinogen 1/ testing involves studies aimed at defining the role of environmental, chemical, and physical factors in producing cancer. Carcinogenesis 2/ research includes the development of better biological models and mechanism studies which provide a basis for the future understanding of the effects of cancer producing substances and for the development of preventive measures.

1/ A carcinogen is a cancer-causing agent or substance.

2/ Carcinogenesis is the causation of cancer.

THE EPPLEY INSTITUTE FOR RESEARCH IN CANCER

The Eppley Institute was established through an agreement between the Eppley Foundation of Omaha, Nebraska, and the University of Nebraska. Its facilities are located in Omaha and include about 55,000 square feet of space for research. Administratively Eppley is a component of the Nebraska University Medical Center. Its Director reports to the Chancellor of the Medical Center.

Eppley's program is oriented towards the collaboration among chemists, biochemists, biologists, pathologists, and epidemiologists in studying carcinogenicity and related research in carcinogenesis. Included in its program are:

- Testing of suspected carcinogens of major environmental importance.
- Development of specific new techniques for chronic toxicity testing.
- Chemical and analytical methodology for the detection of carcinogens.
- Study of the mechanisms of chemical carcinogenesis.
- Initiation of epidemiological studies into the action of chemical carcinogens in man.
- Provision of personalized research training for younger investigators.

HISTORY OF CARCINOGENESIS RESEARCH AND CARCINOGEN TESTING AT EPPLEY

The research program in environmental carcinogenesis being performed at Eppley began in 1950 at the Chicago Medical School. It was initially devoted to the study of the mechanisms of chemical carcinogenesis, using both experimental pathological and biochemical methods. Subsequently, the program became a combination of research into mechanisms of carcinogenesis and research to identify those carcinogens in the environment of importance to human disease. Until 1961 these efforts were supported by a series of NCI research grants. On NCI's initiative, the research grants were discontinued and a contract was negotiated to underwrite the operation.

Because of a decision by the Chicago Medical School to reduce its emphasis on research, including the elimination of the Institute for Medical Research, Division of Oncology, the principal investigator for the contract relocated his program, laboratory, and staff to Eppley in 1968.

From March 1968 to May 1973, Eppley was to perform a balanced amount of carcinogenesis research and carcinogen testing under an NCI contract amounting to approximately \$6.4 million.

A renewal of the noncompetitive contract was negotiated for the period May 1973 to November 1974, under which Eppley was to perform a balanced amount of carcinogenesis research and carcinogen testing. Through subsequent modifications, the contract will run to November 15, 1978, with total estimated costs amounting to more than \$16.4 million. (For details on contract funding, see app. II.)

DESCRIPTION OF WORK UNDER THE CONTRACT RENEWAL

The May 1973 contract renewal for the carcinogenesis program at Eppley is a negotiated cost-reimbursement type award between NCI and the Board of Regents of the University of Nebraska.

Under the contract renewal Eppley is to conduct an integrated program of carcinogen testing, primarily with respect to potential environmental carcinogens and related research in carcinogenesis. The carcinogen testing program is to be concerned principally with substances judged to constitute the greatest hazards to public health, such as, but not restricted to, environmental carcinogens, foods, additives, and selected pharmaceuticals, and coal tar and petroleum combustion products. The selection of specific substances to be tested is to be made jointly by the NCI Project Officer and Eppley.

The contract renewal required that Eppley continue performance on 95 projects previously started under the contract and initiate 59 new projects proposed by Eppley in February 1973. In February 1975 a major revision to the contract authorized Eppley to initiate research on an additional 30 projects.

In October 1976 Eppley made a proposal to NCI to continue the contract for three additional years at an estimated cost

of about \$16.4 million. In November 1977 NCI awarded a 1-year, \$3.6 million extension to the contract which authorized work on 28 new projects and the continuation of 36 other projects.

OTHER EPPLEY RESEARCH

In addition to performing cancer research for the Government, Eppley has also performed research for the American Cancer Society, the World Health Organization, and some industrial concerns. However, as shown below, most research at Eppley for fiscal year 1976 was paid for by the Government.

<u>Source of funds</u>	<u>Total expenditures</u>	<u>Percent of total expenditures</u>
NCI contract	\$2,725,100	69
Other Federal projects	438,200	12
Non-Federal projects	<u>765,300</u>	<u>19</u>
	<u>\$3,928,600</u>	<u>100</u>

SCOPE OF REVIEW

We made our review at the NCI headquarters in Bethesda, Maryland, and at the Eppley Institute for Research in Cancer in Omaha, Nebraska. At NCI headquarters our review concentrated on the award and monitoring of the May 1973 contract renewal and its modifications, as of June 1977. We also reviewed the procedures being followed in the current contract renewal process. 1/ At Eppley we concentrated our review on contract activities occurring since the beginning of fiscal year 1976.

Our objectives were to determine the effectiveness of NCI's administration and monitoring of its carcinogen testing and research contract with Eppley and to evaluate Eppley's management of the contract. To meet these objectives we:

- Interviewed present and former officials of NCI and present Eppley representatives.

1/ Since our field work was completed in August 1977, all the actions taken on the 1-year \$3.6 million modification awarded in November 1977 were not reviewed.

- Reviewed NCI policies, procedures, and regulations involving awarding and monitoring of cancer research contracts and determined the procedures followed for the Eppley contract.
- Examined selected records, reports, and other documentation relative to Eppley's activities performed under the contract with NCI.

CHAPTER 2

NCI ADMINISTRATION OF THE

EPPLEY CONTRACT

The National Cancer Institute has not properly or diligently administered a contract for carcinogen testing and carcinogenesis research at the University of Nebraska's Eppley Institute.

Technical reviews made of the contractor's work proposals did not comply with the normal procedures used by NCI at the time because the reviews were made by an ad hoc group rather than by standing committees chartered by NCI. No consensus opinions or recommendations were rendered by the reviewers who comprised the ad hoc group, and recommendations of individual reviewers appear to have been disregarded in awarding the contract renewal in 1973.

Furthermore, the justification for noncompetitive award to Eppley was weak and not totally supported with facts. Changes to the work scope were made without being properly approved by NCI and overall monitoring of the contract has been inadequate.

The following is a summary of selected issues which we believe demonstrates the weaknesses in administering the contract and the need for NCI to improve its administration of any future contract work with Eppley.

NCI CONTRACT REVIEW PROCEDURES

In January 1973 NCI implemented new contract review procedures, referred to as the Orange Book. It detailed procedures for documenting contract awards and actions, and requirements for committee review to be followed by all NCI groups. While the Orange Book represented official NCI procedures, it was, according to one National Institutes of Health (NIH) contracting official, general enough to allow flexibility in reviewing contracts. The Orange Book established minimum requirements for project review at NCI, including (1) dual review, (2) technical review by a standing committee for noncompetitive awards, and (3) justification for noncompetitive procurements.

Dual review is defined as a review by each of two separate committees: a review for priority, relevance, and need by an NCI senior staff committee, and a review for scientific merit by a technical committee or a source evaluation

committee. Review by a technical committee means a review by recognized experts in the field from within and/or outside the National Institutes of Health. According to the procedures, all new projects, projects without an approved project plan, or projects extended for 1 year or more beyond the approved project plan were to receive a dual review.

For noncompetitive awards the procedures stipulated that a standing technical committee ^{1/} will review the proposal and make a recommendation for consideration by the senior staff committee. Also a justification for noncompetitive procurements must be prepared as required by NCI procedures and Federal Procurement Regulations (FPR 1-3.210) citing the circumstances that preclude competition.

The Orange Book has specific requirements for NCI's Division of Cancer Cause and Prevention to follow in reviewing solicited and unsolicited new proposals. For solicited proposals the Request for Proposal (RFP) and project plan prepared by NCI program staff are to be reviewed by the Carcinogenesis Contract Program Management Group (CCPMG), the equivalent of the previously mentioned senior staff committee, for need, relevance, and priority. Contractor proposals submitted in response to RFP are then reviewed for scientific merit by a technical committee, and one or more organizations are recommended for an award.

Procedures for unsolicited proposals differ somewhat because the project idea begins with the contractor rather than with the NCI program staff. As a result there is no RFP to be reviewed, but a Justification for Non-Competitive Procurement is needed. Unsolicited proposals are reviewed initially for scientific merit by a technical review committee and then by CCPMG for need, relevance, and priority.

Technical review committees are established by the Director, NCI, under authority granted to him by the National Cancer Act (42 U.S.C. 286d). Seven ad hoc technical review committees, referred to as segment advisory groups, were established within the Division of Cancer Cause and Prevention during 1971 and 1972.

^{1/} A standing technical committee is one having a fixed membership and chartered in accordance with the 1972 Federal Advisory Committee Act, 86 Stat. 770. See following page.

The 1972 Federal Advisory Committee Act (86 Stat. 770) required that all standing committees be chartered and that no committee could meet or take action until the charter was filed. In line with this requirement, the seven segment advisory groups and an advisory panel were chartered in February 1973. In August 1973 one segment advisory group was split into two segments and new charters were filed. In April 1974 all nine advisory groups were abolished and their functions incorporated into three chartered scientific review committees, one of which was later incorporated into the two remaining committees. According to an NCI contracting official, any of the chartered committees could be the standing technical review committees referred to in the Orange Book.

The National Cancer Institute's Committee Management Procedures and Guidelines state that a group which includes at least one non-Federal employee called together by NCI to provide advice and/or recommendations as a group or consensus action is an advisory committee within the meaning of the 1972 Federal Advisory Committee Act and should be chartered. The guidelines further state that ad hoc groups called together to give group advice, including contract review, are advisory committees subject to the act, even if there is only one meeting. A footnote in the guidelines states that the criteria of giving individual opinions, rather than group advice, should not be applied to grant or contract review committees to avoid requirements of the Federal Advisory Committee Act. The committees are part of the "dual review" system and typically provide consensus opinions and advice by vote.

The Orange Book also contained a requirement for a site visit to be made for all contracts of \$100,000 or more annual funding before an initial award is made. One of the purposes cited for making site visits is to obtain information for use in considering contract awards or renewals. Visits are to be made by NCI staff and persons from the outside research community who have expert knowledge and experience.

RENEWAL ACTIONS

In 1973 a proposal from the Eppley Institute was reviewed by NCI for a noncompetitive contract renewal. Subsequently a renewal was awarded for an 18-month period from May 15, 1973, to November 15, 1974. The contract was later extended until February 15, 1975, to provide NCI time to complete the necessary review and approval actions for the next renewal.

Renewal actions were undertaken on a noncompetitive basis in 1974 and a modification renewed the contract for 21 months from February 15, 1975, to November 15, 1976. Additional modifications to allow time for review of a renewal proposal extended the contract through November 15, 1977. As noted earlier the contract was recently renewed to November 15, 1978.

In considering renewal of the contract in 1973, 1974, and 1977, NCI subjected the contractor's proposals to (1) reviews for scientific merit by a technical review group, (2) reviews for program relevance by the senior staff committee, (3) budget reviews to determine the reasonableness of the estimated budget, and (4) sole source justifications to show why it was not necessary to seek competitive bids for the work to be done. The actions taken in carrying out these four activities are described below.

Technical review

1973 review

When the 1973 renewal proposal was submitted there were seven segment advisory groups in operation which could have made technical reviews of the proposal. Approximately half of the work proposed was in the area of expertise of the bioassay segment advisory group. However, neither this group nor any of the others was asked to review the proposal for scientific merit. Instead, an ad hoc group composed of 16 reviewers, 9 NCI staff, and 7 outside consultants, was chosen to review the proposal.

The review was accomplished by having the ad hoc reviewers mail their comments to NCI after reviewing the contractor's February 1, 1973, proposal. No site visits were made by the group members for the purpose of helping to evaluate the contractor's proposal. The reviewers submitted their comments to NCI on any sections of the proposal which they felt qualified to review. Several reviewers commented on only one section while others commented on several. At no time did the reviewers meet or express a consensus opinion on any of the sections or on the overall proposal either by means of a single recommendation, priority scores, or by a mailed ballot.

When we inquired whether the ad hoc group met the requirements for a review by a standing technical committee, the NCI official responsible for coordinating the review said that the ad hoc review did not constitute a formal review

by a standing technical committee, as required by NCI guidelines.

The ad hoc group also did not meet the Federal Advisory Committee Act requirement that before any advisory committee can meet or take action, it must be chartered. Although members of the group did not meet or give a consensus opinion as required by the act, NCI guidelines specifically state that technical committees which review grants or contracts are advisory in nature, and further state that the criteria of not meeting or not providing a consensus opinion should not be applied to such committees. Therefore, this group should have been chartered.

In addition the Orange Book requires treating renewal awards as a new award if a project plan does not exist. A project plan did not exist for this contract. Therefore a formal dual review process by a chartered technical review committee and a senior staff committee should have been initiated.

According to an NCI official, an ad hoc group was used because the multidisciplinary aspect of the contract proposal made it impossible for any one segment advisory group to have the technical expertise to review the total proposal. This should not have precluded NCI from requesting the segment advisory groups to comment on those sections they were technically competent to review since this was the approach taken by the ad hoc reviewers.

Our review of the comments provided to NCI by the ad hoc reviewers showed that several reviewers were critical of the (1) presentation of the proposal, (2) rationale for testing, (3) details of experimental design, and (4) general quality. In a summary of reviewers' comments, an NCI official wrote that several sections of the proposal dealing with lung, intestinal, in vitro 1/, and transplacental 2/ carcinogenesis

1/ Literally, "within a glass," in this context referring to tests in which animal or human cells are grown in a culture where they are exposed to test substances. If carcinogenic, the substances will kill the cells or cause them to grow abnormally.

2/ Meaning through the placenta. Indicating studies in which pregnant animals are exposed to test substances. The substances, if cancer-causing, will produce cancer in the offspring after having passed through the placental barrier.

were criticized and a recommendation was made that the intestinal carcinogen section not be funded. Twenty-one projects in other sections of the proposal were identified as being of low priority. NCI, however, approved funding for all the proposed work except for the in vitro carcinogenesis section consisting of four projects.

We believe that, except for the in vitro carcinogenesis section, NCI disregarded reviewers' comments in awarding this contract. For example, one section of the proposal that dealt with intestinal carcinogens was funded although the technical reviewers recommended that it not be funded. For the section on transplacental carcinogens, one reviewer stated that he had no detailed comments because previous experience had shown that reviewers' criticisms and suggestions are uniformly ignored. He cited one project proposed for continuation under the contract which he specifically suggested be omitted during the previous year. The only other reviewer of this section cited the same project and said that he could not see the justification for it. Despite the reviewers' comments, funding for the project was continued. An NCI official defended this action by offering an example that once NCI has spent \$100,000 or more funding a study by the contractor, it might as well spend another \$20,00-30,000 to complete it, even if its value is doubtful.

In the one instance where NCI appeared to follow the reviewers comments, four projects on in vitro carcinogens were not listed in the contract under work to be performed. During our review, however, we found that the contractor did perform work on these projects. (See p. 22.)

1974 review

The 1974 review was also conducted by an ad hoc group which this time was composed of eight outside consultants and one NCI staff member. At the time of the review, however, there were no standing technical committees available to review the contract proposal. During 1974 the original segment advisory groups were abolished and three new program scientific review committees were chartered. Although the committees received their charters in April 1974, none became active until 1975, making it impossible for any of the committees to review the 1974 proposal.

Again, the ad hoc group was not chartered, as required by the Federal Advisory Committee Act and NCI guidelines. As in 1973 group members did not meet or provide a consensus opinion. This ordinarily would have precluded the need for

chartering the group, except that NCI guideline point out that such a group is advisory in nature and subject to the act, even though group members did not meet.

The ad hoc group members who made the review mailed in their individual comments to NCI. Prior to submitting their comments, four reviewers did make a site visit to the Eppley Institute. All reviewers submitted comments on the sections of the proposals they considered themselves qualified to review. One change from the 1973 review was that the reviewers were asked to designate a priority for the projects they reviewed--1(highest priority) to 5 (lowest priority). Most of the reviewers complied with this request.

Several of the reviewers were critical of the (1) presentation of proposals, (2) lack of rationale for testing, (3) lack of details of experimental design, and (4) relationship of new to ongoing projects. These criticisms are similar to those expressed by reviewers during 1973. One of the reviewers did not comment on the proposal because it did not contain adequate information. NCI did use the priority scores to recommend that 27 new projects not be started, 3 ongoing projects be terminated, and 15 ongoing projects be phased out. It appears that in 1974, NCI followed the comments of the reviewers much more than in 1973.

1977 review

In 1977, as required by NCI guidelines, the contract was reviewed by the carcinogenesis program scientific review committee A, a standing technical committee, chartered in accordance with the Federal Advisory Committee Act. Prior to the review by the committee, a site visit was conducted on March 14 and 15, 1977. The site visitors included members of review committee A and also review committee B, an equivalent group, as well as NCI staff. The site visitors reviewed projects, assigned priority scores, and made various recommendations. A series of reports from the site visitors were compiled into a volume and submitted to review committee A for its consideration.

On April 14, 1977, review committee A met to review the contract proposal. A series of motions was made including disapproval of some projects, funding of other projects for a limited time with a further review later, and reductions in staff needed to perform the projects. A vote was taken on each motion. It appears that the committee considered the site visitors' recommendations.

Program review

As part of the dual review system, the contract proposals were reviewed for need, relevance, and priority by CCPMG. CCPMG is made up of senior staff within NCI's Division of Cancer Cause and Prevention. CCPMG reviewed and approved the renewals of the Eppley contract.

1973 review

Prior to the CCPMG meeting in April 1973, a member of CCPMG prepared a summary of the technical reviewers' comments which was provided to two other CCPMG members. Also a summary sheet was prepared that contained information on the proposal but did not include reviewers' comments. There is no evidence available, however, to show whether all CCPMG members had been provided copies of these documents before the April 1973 meeting.

The minutes of the CCPMG meeting, at which time approval was given to fund the proposal, contain only a brief discussion of the proposal. According to the then CCPMG Executive Secretary, discussions were often brief because of the many proposals to be considered at each meeting (25 proposals were reviewed at the April 1973 meeting). The discussion of the proposal recorded in the minutes does not show that reviewers' comments were discussed.

Except for a comment about the need to avoid duplication of funding and effort between this proposal and grants proposed by investigators at the Eppley Institute, there is no indication that a reduction in the proposed scope of work or in the funds requested was considered. The CCPMG's recommendations do not reflect the concerns and recommendations offered by the technical reviewers.

Subsequent to the CCPMG meeting, a summary review and evaluation checklist, and a summary of negotiation were prepared containing a statement which says that an administrative decision was made to renew the contract for 18 months instead of the 12 months requested in the proposal. This was justified on the basis of (1) the size and complexity of the program, (2) the need to provide time for the contractor to develop a program more closely aligned with segments of NCI's carcinogenesis program, and (3) the need to allow sufficient time for the contractor to submit the next proposal and for NCI to review it. NCI officials did not know nor did written records show what official or group made this administrative decision which increased the contract

by more than \$1.1 million (50 percent) without adding any new projects to the scope of the work.

1974 review

In December 1974 CCPMG convened and a renewal proposal from the Eppley Institute was considered. Prior to the meeting, CCPMG members were furnished copies of the proposal, the 1973 CCPMG recommendation on the contract, and a memo by the project officer showing that most of the technical reviewers made a site visit in September 1974. Also a summary review sheet was prepared which grouped projects into priority categories based on reviewers' opinions. From the minutes of the CCPMG meeting, it appears that the program plan was also furnished to the CCPMG members. The only reference to the reviewers' comments contained in the minutes indicates that the project officer said that the reviewers recognized that weak spots existed but that their overall impression was one of strength and good research. In 1974 the CCPMG's recommendation for funding the proposal showed that the reviewers priority rankings of projects were considered, and for the most part, followed.

1977 review

CCPMG met on November 2, 1977, to consider the latest proposal for renewal of the Eppley Institute contract. At that meeting it was decided to approve a 3-year project plan and phaseout contract work over the 3-year period.

Budget review

Actual negotiation of the contract budget occurs after CCPMG recommendations are made. A summary of negotiation is prepared which records actions taken to arrive at the final contract budget.

1973 review

The negotiations in 1973 were conducted through a series of telephone calls between NCI and contract or officials. The contractor's proposed budget of about \$3.7 million for an 18-month period was negotiated down by about \$268,000. The reduction reflected elimination of some equipment and avoidance of overlap between some of the proposed projects and three grants already approved for funding by NCI.

Prior to the budget negotiations, an NCI official prepared a memorandum for CCPMG members which suggested that based on the technical reviewers' recommendations for eliminating or reducing some projects and questions about a change for central management, a \$398,000 reduction be made to the budget. This suggested reduction only applied to the 12-month period originally proposed by the contractor and not the 18-month period for which the contract was subsequently negotiated. Furthermore, it did not include the \$189,000 eliminated by NCI officials because of possible duplication of grant work.

The negotiated budget did not reflect the recommendations of the technical reviewers. If it had the budget would have approximated the following.

Contractor's proposed 18-month budget	\$3,714,000
Less: duplicated grant work	\$189,000
questioned central management for 18 months	169,000
projects eliminated or reduced	<u>285,000</u>
Total reductions	<u>643,000</u>
Budget negotiated	<u>\$3,071,000</u>

This table indicates that had the technical reviewers' comments been more closely followed, the contractor's proposed budget would have been reduced by about \$643,000, instead of by \$268,000.

1974 review

The budget negotiations for the 1974 renewal were again conducted through a series of telephone conversations. The contractor's proposed budget for 24 months of operation was about \$7.6 million. The final negotiated amount was \$5.4 million for a 21-month period. The \$2.2 million difference resulted primarily from eliminating estimated costs associated with projects that the technical reviewers rated as low priority and eliminating costs for a 3-month period which were funded under a contract extension while the 1974 proposal was under review. In this instance budget negotiations more nearly followed recommendations of the technical reviewers, CCPMG, and carcinogenesis program staff.

1977 review

Preliminary negotiations were held for the 1977 contract renewal prior to the CCPMG meeting. The negotiations resulted in funding being cut for projects recommended for disapproval or given low priority by the technical reviewers. Funding for central contract management and support services were undergoing negotiation to recognize reduced effort resulting from the technical review. Based on information furnished by NCI contracting officials, the contractor's proposed budget of \$5.2 million for 1 year was negotiated down to \$3.8 million. Since there were unexpended funds of \$.2 million available, the final award was negotiated at \$3.6 million.

So'e source justification

It is the Government's policy that wherever practical all procurements of goods and services from outside organizations be made on a competitive basis. When it is not practical to seek competition, a Justification for Non-Competitive Procurement must be prepared citing the circumstances that preclude competition. According to NIH instructions the justification must contain the factual basis for absence of competition and must avoid unwarranted assumptions and unsupported conclusions.

NIH instructions state that the contracting officer should challenge and reject justifications if they contain unwarranted assumptions and unsupported conclusions alleging a source's unique capabilities. However, according to an NCI contracting official, NCI contracting personnel do not normally question the justification unless one of the review committees raises questions.

The justification prepared for the Eppley contract in 1972 reads, in part, as follows:

"The research group under the Principal Investigator and the facility in which they are housed represent a unique national resource in conduct of carcinogenesis research and advanced training in the field. The Eppley Institute for Research in Cancer, of the University of Nebraska, is a seven story building on the campus of the University of Nebraska Medical Center, which was constructed with NIH matching funds of \$1,500,000 as well as funds from the Eppley Foundation of Omaha. In addition NIH has provided approximately \$54,000 in matching funds for an extension of the institute facility of almost 40,000 square feet to

be devoted to animal facilities and biochemical research laboratories. In addition to this investment in laboratory facilities, the National Cancer Institute has an investment of approximately \$660,000 in equipment which is accountable to this contract. A major portion of this equipment was transferred from the Chicago Medical School, Chicago, Illinois, with NCI funds of \$16,470. In addition to the moving of equipment an additional \$6,655 of NCI funds was spent for the assembly at the contractor's animal farm, of sixteen government-owned prefabricated buildings. An additional \$18,080 was spent for installation of equipment and renovations of laboratory space to accommodate the equipment. In short, the National Cancer Institute has a substantial investment in this facility."

* * * * *

"The contract will support the research efforts of approximately 100 individuals, 24 of whom are professional in the area of pathology, cell biology, biochemistry, chemistry, toxicology and food chemistry. The staff of the contractor's Eppley Institute would be impossible to match in any other single organization in the United States."

* * * * *

"To consider another contractor to perform any aspect of the proposed work would not be in the best interests of the Government. The substantial Government investment, the valuable resource of professional and support personnel, and the outstanding background which the group has developed in chemical carcinogenesis, prevent the consideration of any other contractor to perform the proposed continuation of work. In addition the contractor is currently performing approximately 81 long-term projects which by varying degrees could not be completed for several years."

* * * * *

"Although the contractor is proposing to perform several new projects with additional cost to the Government, all of these programs are within the context and intent of the existing work scope."
(Underscoring supplied)

Subsequent justifications in 1975 and 1976 are similar in content insofar as they cite (1) the uniqueness of the facility, (2) the quality of the staff, (3) NCI's investment in the contractor's facility, and (4) that new projects are closely related to the original scope of work. Although this justification may have been more valid when the contract work was transferred to the Eppley Institute in 1968, and for a few years thereafter, we believe that validity of this justification has substantially diminished.

Several individuals knowledgeable in the field of carcinogenesis research have told us that while the statement that the research group and facilities are unique was true a few years ago, it is no longer true because other organizations are doing comparable carcinogen testing and carcinogenesis research. In addition at least one or two other NCI contractors have large multidisciplinary efforts. The associate director for Carcinogenesis stated at a meeting of CCPMG in 1974 that the statement in the project plan that this program (at the Eppley Institute) is among the best 5% of all activities in the carcinogenesis program is an overstatement and does not accurately reflect the carcinogenesis staff members' assessment or the reviewers' comments.

Although the sole source justification states that the staff at the Eppley Institute cannot be matched elsewhere in the United States, it offers no evidence of this. As stated in other parts of this report, technical reviewers have criticized the research value of some of the work at the Eppley Institute. Also, NCI elected not to fund any of the projects proposed to be carried out by a few principal investigators at the Eppley Institute under the 1974 contract renewal. (See p. 12.) Finally many of the original staff at the Eppley Institute which transferred there from the Chicago Medical School when the NCI contract was transferred have left the staff.

The sole source justification cites the large Government investment in the plant and equipment at the Eppley Institute. While the statement is true, it may be a faulty justification. Although it can enhance the opportunity to obtain reliable results, the investment of the Government has not and cannot guarantee the success or the quality of research done under the contract.

This, however, is not the same as the Government furnishing equipment to produce a predetermined product. We believe that the Government's investment is a questionable

justification to continue noncompetitive awards since much of the investment is in the form of equipment which can be moved, just as much of it was moved to Eppley, and since the investment cannot guarantee achievement of predetermined end results.

The statement that several new projects to be started are within the context and intent of the existing work scope needs to be supported with facts. Our review showed that members of the technical review committee sometimes raised questions as to the relationship between ongoing and proposed projects. If a valid relationship does not exist, consideration could be given to funding these projects under a separate contract.

It appears that NCI considers itself to be "locked in" to continue making noncompetitive awards to the Eppley Institute. For example the contractor was awarded \$237,650 for facility renovations at a time when the contract was to expire and was soon to be considered for renewal. Even the 1976 sole source justification concludes with this statement:

"It is recommended that this justification for contract renewal on a non-competitive basis be approved through March 1, 1980. This contract project is to be funded incrementally in amounts of approximately \$1 million the first three and one half months, \$3.5 million March, 1977 through March, 1978, \$3.8 million March, 1978 through March, 1979 and \$4.1 million March, 1979 through March, 1980." (Dollar signs furnished)

We believe that before any more funds are awarded to Eppley, NCI officials should justify on the basis of facts that a valid justification exists for sole source, noncompetitive contract awards to the Eppley Institute. If not any new proposed projects should be opened to competition.

On November 1, 1977, a new justification for noncompetitive procurement was prepared to cover a 3-year period during which time all projects will be completed, phased out, or subjected to competition. This action will allow for an orderly and timely conclusion of ongoing research and prevent a loss to the Government of an estimated \$3 million worth of incomplete and unreported research, which is not at a stage where it can be transferred to another researcher.

MONITORING ACTIONS

Monitoring of the contract with the Eppley Institute has been mostly informal, inadequate, and ineffective. Much

of the problem is due to the number and complexity of projects being carried out under the contract and the few NCI officials given direct responsibility for monitoring. As a result (1) Eppley conducted certain projects using contract funds without NCI authorization, (2) Eppley did not submit required progress reports and inventories of Government-owned property, and (3) NCI has provided only limited technical and administrative support.

Monitoring by the contracting officer

NCI does not have many written procedures, guidelines, or directives for contracting officers to use in monitoring contracts. However, Federal procurement regulations cite the contracting officer as being the one responsible for administering the contract. In addition the contract with the Eppley Institute states that the contracting officer is responsible for directing or negotiating any changes in the terms, conditions, or amounts cited in the contract.

According to an NCI contracting official, contract monitoring is weak because of a shortage of personnel and a lack of criteria. NCI, according to this official, is more concerned with negotiation of the contract and obligation of funds than with monitoring contract activities. As a result, monitoring is on an exception basis. If a problem arises the contracting officer tries to solve it. Otherwise monitoring is restricted to reviewing various financial reports.

Although the contracting officer is the NCI official responsible for authorizing changes to the contract, he was not involved in nor even aware of oral approvals given by the project officer to the contractor for changes in the work. (See p. 22.) The contracting officer told us that he has no way of knowing about technical changes which affect the administrative aspects of the contract unless the project officer informs him.

The contracting officer did not take action when the contractor failed to submit required progress reports, although he is responsible for assuring that the terms and conditions of the contract are fulfilled by the contractor. On two consecutive occasions the contractor failed to submit a required semiannual progress report. Also no reports of inventories of Government-owned property were submitted by Eppley officials for either fiscal year 1975 or 1976. The contracting officer has not required the contractor to submit reports showing whether professional and nonprofessional staff time spent on the contract approximates what is required

under the terms of the contract. (See p. 26.) The contracting officer stated that he has little leverage to use to require the contractor to submit such reports since the contractor has already received payment under a letter of credit arrangement. However, in January 1977, the Department of Health, Education, and Welfare (HEW) instituted procedures whereby the contracting officer can arrange to have payments halted under the letter of credit arrangement when the contractor materially violates the terms and conditions of his contract. NCI, however, was not made aware of this technique until August 1977.

Monitoring by the project officer

In several instances, the project officer has not fully met the responsibilities assigned to him for monitoring the NCI contract with the Eppley Institute. Part of this problem was due to the size and complexity of the contract and the inability of one individual to cope with it. The failure of the project officer to formalize and to initiate some actions also caused monitoring problems.

Project officer responsibilities are contained in the contract and in an HEW publication, The Negotiated Contracting Process--A Guide for Project Officers. The responsibilities listed in these documents include monitoring the contractor's technical performance, recommending changes in contract requirements, resolving technical problems, and reviewing progress and technical reports.

Although the HEW project officer guide shows that a project officer is responsible for reviewing and approving progress reports, technical reports, and other items required for approval, the project officer did not review or approve semi-annual progress reports submitted by the contractor. He was not even aware that the contractor failed to submit two consecutive semiannual progress reports in 1975, as required by the contract, until we discussed the matter with him. These reports are to be used in monitoring and evaluating progress under the contract. The project officer stated that he believed that the contractor already submitted too much material. He also believed that the reports were not needed since bioassay research takes 2 to 3 years to complete and there might not be much progress to show in 6 months.

We believe that since projects are individually started and completed at different times, it would not be repetitive to report on their progress. Also since progress reports are

now required only annually, the importance of receiving and reviewing them has increased.

In the event the contractor desires to propose a change to the contract, the project officer is required to review the proposed change and advise the contracting officer as to whether the proposed change should be incorporated into the contract. He is also responsible for assuring that changes in work under a contract are not implemented before written authorization or a contract modification is issued by the contracting officer. According to HEW's guidelines for project officers, costs for work performed may not be allowed if not authorized under the contract. Except in one instance, we could find no evidence that the project officer had reviewed proposed technical changes and advised the contracting officer as to whether they should be made.

During our review we found Eppley worked on 11 projects for which no evidence of NCI approval could be located. According to the contractor, seven of the projects were orally approved by NCI officials. Contractor officials were unable to explain how or from whom they obtained approval to perform the remaining four projects. The project officer informed us that while he was unable to remember orally approving as many as 11 projects, he concedes that it is possible that he or other officials might have approved changes in existing projects. In addition he stated that some projects could represent name changes, extensions, or spinoffs of completed projects. The contractor, however, informed us that these are 11 new projects and were not changes, extensions, or spinoffs to existing projects.

We found that four of these projects were actually the projects in the in vitro carcinogenesis section of the 1973 proposal which the reviewers highly criticized and which were not listed as projects to be performed under the 1973 contract renewal. The contractor told us that he was unaware that these projects were not contained in the 1973 contract renewal. It appears that the contractor has performed projects not officially approved by NCI and that the project officer may have exceeded his authority by orally authorizing changes in the work scope. The contracting officer has advised us that expenses claimed on unauthorized projects should be disallowed and NCI should take steps to identify and recover the funds involved.

The project officer is responsible for monitoring technical aspects of the contract. This responsibility can be carried out through various means such as site visits, monitoring technical progress, and helping to resolve technical problems. The project officer made several site visits and reportedly conferred often with the contractor by telephone. He made some recommendations in his site visit reports, but we could not find where he followed up to assure that they were implemented. According to HEW, if subsequent site visits did not raise the same question, this is evidence that action had been taken.

According to the project officer, monitoring has been limited because the size and complexity of the contract make it impossible for one person to possess the technical expertise needed to oversee all its aspects. He stated that his major responsibility was to aid the contractor with problems which might affect the studies done under the contract. As a result he often helped the contractor to obtain compounds, animals, and special feeds needed for the studies.

Between 1969 and 1977 several suggestions were made by NCI staff, site visitors, and technical reviewers to use assistant project officers and to have more NCI staff involvement in the contract. Until May 1977 no action had been taken on these suggestions. Now, three individuals have been assigned project officer responsibilities for the Eppley contract.

Monitoring by segment staff

Guidelines for the NCI inhouse segment staffs ^{1/} indicate that either the segment officials or staff were required to assist with project monitoring by reviewing progress, making site visits, evaluating ongoing research in relation to modifications and future plans, and evaluating completed research.

Although the guidelines indicate that the inhouse segments are to monitor projects in addition to the project officer, they did not perform such duties in relation to this contract. Officials within the segments told us that the contract was administered by the Carcinogenesis Program associate director's office, and they were neither asked nor allowed to be involved.

^{1/} The carcinogenesis program was divided into several sub-programs or segments. The NCI staff assigned to each of these segments was referred to as segment staff.

They did not (1) review proposals, except occasionally as ad hoc reviewers, (2) have access to or review progress reports or publications resulting from contract work, (3) make site visits, or (4) have any type of normal input into the contract. In fact two NCI officials stated that the only site visit arranged by a segment was canceled by the contractor on very short notice as an inconvenience due to other matters. Although the contractor agreed to contact NCI at a later date when it would be more convenient, this was never done and the site visit never took place. Increased NCI staff involvement was repeatedly suggested by technical reviewers and various NCI officials; however, the staff was never involved in reviewing or monitoring this contract. With the designation of three individuals from the segment staffs as project officers for the contract, segment involvement should increase.

CHAPTER 3

CONTRACT OBLIGATIONS

AND RESULTS

National Cancer Institute officials have not made a diligent effort to assure that the contractor has met his obligations under the contract. They are not very familiar with what has been done under the contract nor have they made full use of bioassay results. Furthermore, it is difficult, at best, for these officials to place a value on the results achieved under the contract so that an objective assessment can be made of benefits derived in comparison to costs incurred.

CONTRACTOR OBLIGATIONS

The contract calls for the contractor to try its best to accomplish projects itemized in the contract, to submit required reports, and to use certain categories of staff for the approximate amount of time cited in the contract. The obligation of the contractor is considered complete if (1) work is done with high scientific and professional skills, (2) the approximate level of effort has been diligently applied, and (3) all other requirements are met, including delivery of reports and materials, as required under the contract.

Required reports

For the contract period May 1973 through September 1976, the contractor should have submitted six required progress reports, but only four were submitted. These reports were to provide NCI officials with information on progress, problems, and results of projects carried out under the contract. From interviews with NCI officials, we learned that, except for when the reports were used to consider renewal of the contract, very little use was made of them. Some technical reviewers complained that information provided was not sufficient to permit a judgment on the priority of the work being done. The fact that two consecutive progress reports were not submitted and no action was taken to request them indicates that NCI's use of them was limited.

NCI officials believed that it would be better to ask for one comprehensive annual report describing important results on all projects performed because the projects

conducted under the contract often take two to three years to complete and require a substantial effort by the contractor to prepare reports of several hundred pages. In September 1976 the reporting requirements were changed. Instead of submitting a report every 6 months, NCI intended for the contractor to submit an annual report. However, our review showed that an error was made when amending the contract to require the annual report. Instead of reducing the requirement from two semiannual reports to an annual report, NCI inadvertently increased the reporting requirements to three required reports by failing to delete the requirement for the semiannual progress reports. Therefore, the contract requires that the contractor furnish two semiannual reports and one annual report. NCI has clarified the reporting requirement in the November 1977 contract renewal.

Level of effort

One of the requirements to be met by the contractor is to exercise a level of effort which approximates the staff hours cited in the contract for both professional and non-professional staff. While the contractor reports monthly on the percent of staff members' time spent on the contract and the costs of this time, NCI neither received nor required information on hours spent by professional and nonprofessional staff. This did not permit NCI to readily determine how much time is being spent by the two categories of staff. NCI officials agree that this situation existed and that they had not tried to determine whether the effort exercised approximates what is called for in the contract. As of November 1977 NCI requires vouchers to contain accrued hours rather than the percentage of an individual's time spent on the contract.

Status of projects

The Eppley Institute has been authorized to work on two basic types of projects under the May 1973 contract renewal--testing and research. Project status as of September 30, 1976, is as follows:

<u>Status</u>	<u>Projects</u>		
	<u>Testing</u>	<u>Research</u>	<u>Total</u>
Completed	49	32	81
Ongoing	<u>47</u>	<u>40</u>	<u>87</u>
	<u>96</u>	<u>72</u>	<u>168</u>

The Eppley staff have also worked on 34 projects not shown above. These projects were either terminated/phased-out before completion or are supported by NCI grants. The staff also worked on 11 projects using NCI contract funds that have not been formally approved by NCI. (See p. 30.)

As shown above Eppley maintains a balance between testing and research projects, as required by the contract. Eppley's associate director stated that the two types of projects support each other and all the work is eventually integrated.

Eppley officials do not maintain records on when projects are begun and completed, and are not required to do so under the contract. Individual investigators maintain scientific records for their own projects, and the principal investigator for Eppley informally contacts investigators to learn the status of their work.

Although the contract specified which projects are to be performed, neither the contractor's principal investigator nor NCI's project officer controls when new projects should begin. We believe that it is important for NCI to know when individual projects are planned to begin so that the NCI staff may have an opportunity to first discuss them with the contractor's staff and also because it could help prevent unauthorized projects from being performed.

PROJECT RESULTS

Since NCI will have paid about \$12.8 million for the work at the Eppley Institute over a 4-year period, we were interested in determining what had been received for the money spent and whether its value could be assessed. As previously shown we learned that 49 testing and 32 research projects have been completed. We were also advised that 58 articles on the work done under the contract have been published, as of October 1976, and 11 more were either planned or in preparation.

Although projects completed under the contract have been easy to determine, the same is not true for trying to assess the value of the end products which are generally reports or papers prepared on the results of the projects. HEW noted when commenting on this report that productivity can sometimes be measured by the number of publications, which are a primary means of disseminating information to the scientific community. In this vein it should be noted that Eppley contributed 16 percent of the publications resulting from the carcinogenesis program contract funds in fiscal year 1976

while receiving 6.5 percent of the funding. When we asked NCI officials if the value of the end products could be measured in any objective way, they replied that it could not. They emphasized that the value of research is generally intangible. Some examples of benefits, such as scientific advances achieved from contract work, were cited to demonstrate why the value of end results is considered to be intangible.

The contractor has prepared a document of contract highlights which lists reports, papers, and articles published since 1969; agents tested (bioassays) since 1970; and examples of project results and appointments to prestigious positions outside Eppley for members of the Eppley staff. For the most part the document fails to identify the significance of research results or actions taken as a result of bioassays completed. Such information is needed before any attempt can be made to assess the benefits derived from the contract.

Publication of project results

NCI does not exercise much control over the publication of project results, except to require acknowledgement of NCI's support under the contract. For the project results to be beneficial, they must be conveyed to those persons who can use them and in a clear and concise format. In this regard the Manager of the Bioassay Segment of the Carcinogen Testing Program, NCI, stated in a March 1977, site visit report,

"An issue of considerable importance to NCI, but perhaps of smaller impact scientifically is the issue of reports from the Eppley Institute. All of the chemicals Eppley has tested are listed in the backlog of chemicals on which NCI has taken no official position with respect to carcinogenicity in animals; consequently, it appears that no reports have been prepared. This is a result of resistance on the part of the Eppley Institute to file forms for entry of data into the NCI computerized Carcinogenesis Bioassay Data System (CBDS), a recalcitrance partially justified by the 'special' nature of Eppley's studies and the incompatibility of results from special studies with the CBDS reporting format. NCI, for its part, is embarrassingly unfamiliar with the 115 publications Eppley has submitted for review. The Carcinogen Testing Program proposes to rectify this situation as soon as possible by reading

the material submitted, classifying it according to the CBDS chemical identification numbers involved, and drawing conclusions with respect to the carcinogenicity of the compounds tested and the adequacy of the tests. The Program will enlist the help of Eppley personnel in this effort and will present the results in summary form to the NCI Data Evaluation Working Group and the Clearinghouse Subgroups on Data Evaluation and Human Risk Assessment. In effect, NCI will be advertising the results of the Eppley tests which otherwise remain buried in the scientific literature without the public acclaim afforded by proper review."
(Underscoring supplied)

This site visit report corroborates what other NCI officials have told us--in many cases NCI officials are not aware of the articles published nor what has been found as a result of the projects completed.

CHAPTER 4

EPPLEY INSTITUTE'S MANAGEMENT PRACTICES

Contrary to the contract's terms Eppley officials carried out and financed, with Federal funds, projects which they did not have contractual authority to initiate. Eppley has either not established or implemented the necessary administrative controls and procedures to

--assure that only authorized costs are charged to the National Cancer Institute contract,

--assure that Government-furnished equipment is used only for authorized purposes, and

--adequately account for equipment that is Government-furnished or purchased with NCI contract funds.

Eppley is also not complying with Federal regulations for recording and charging personnel service costs to the contract. In addition, (1) Eppley is not required to notify NCI when researchers whose projects were disapproved are realigned with approved contract activities, (2) controls over employee leave were inadequate, and (3) NCI contract funds have been advanced for travel not directly related to the contract. These management practices have led to actual and potential misuse of Federal funds and property.

PROJECTS UNDERTAKEN WITHOUT WRITTEN AUTHORITY

The contract and its supplemental agreements specify research projects that the Eppley Institute is to initiate or continue. Under the terms of the contract, only the contracting officer has the authority to direct and negotiate changes which affect the terms, conditions, or amounts cited in the contract. We found that the Eppley Institute initiated 11 projects not specified in the contract without obtaining proper authorization from NCI.

For 7 of the 11 projects, the Eppley associate director said they had received oral approval from NCI to initiate the work. Although the NCI project officer said oral permission may have been given for changes in existing projects, he had no evidence to support which projects he may have orally approved. For the four remaining projects, the Eppley associate director was unable to explain how or from whom approval had been obtained to initiate these projects.

Through the contract renewal process, NCI gave Eppley permission to work on three of the 11 projects and required two others to be phased out. However, this occurred as long as 16 months after the work had already started.

Expenses incurred by Eppley in working on the 11 projects were paid with funds provided for projects covered in the contract. The Eppley Institute's associate director said that the availability of funds for this work resulted from (1) projects ending sooner than expected, (2) ongoing projects which did not require an investigator's full attention as anticipated, and (3) delays in starting new projects.

Because project cost records were not available, we were unable to determine Eppley's costs for work being performed on the 11 projects. However, Eppley reports showed that they had anticipated spending about 15,300 hours of staff time on nine of these projects. At current salaries this level of effort would cost about \$99,400. Time estimates on the remaining two projects were not available.

PERSONNEL PROVIDING SERVICES FOR NONCONTRACT RESEARCH

To support all ongoing research, Eppley has 11 service support units which employ 74 full-time and 2 part-time employees, as well as 5 researchers who spend part of their time on support activities. The salaries of 58 full-time and 2 part-time employees were paid entirely from the NCI contract. In addition 2 full-time employees and 5 researchers received part of their salaries from the contract. As of March 1977 the annual salaries for support operations charged to the NCI contract total about \$701,400. Details are shown in the following table.

Number of Employees

<u>Support unit</u>	<u>Total no. of employees</u>	<u>Entire salary paid by NCI contract</u>	<u>Part of salary paid by NCI contract</u>	<u>Annual salary paid by NCI contract</u>
Physical plant and engineering	10	5	-	\$ 64,744
Photography	4	4	-	44,861
Program management and business services	5	1	-	8,114
Animal care and breeding	24	22	-	204,308
Publications	1	1	-	12,000
Histology	<u>a/ b/ 17</u>	<u>a/ 14</u>	<u>b/ 1</u>	112,076
Electron microscopy	<u>b/ 5</u>	4	<u>b/ 1</u>	54,302
Chemical services	<u>c/ 7</u>	4	<u>c/ 3</u>	98,291
Mass spectrometry	<u>b/ 4</u>	3	<u>b/ 1</u>	45,396
Epidemiology	2	-	1	23,135
Microbial assay	<u>2</u>	<u>2</u>	-	<u>34,205</u>
	<u>81</u>	<u>60</u>	<u>7</u>	<u>\$701,432</u>

a/ Includes two part-time employees whose entire salaries are paid by the contract.

b/ Includes a researcher who has part of his salary paid by the contract.

c/ Includes two researchers who have part of their salaries paid by the contract.

Several of the support personnel whose salaries are paid with contract funds provide support to noncontract research. Procedures to allocate these costs to the noncontract projects generally have not been established, and our tests showed that substantial amounts of noncontract support are being furnished with contract funds. Some examples follow.

Histology unit

Employees of the histology unit are responsible for the preparation of animal tissue slides for microscopic examination. About \$112,100 in salaries is paid annually to employees in this unit with NCI contract funds. For 1976 we

identified about 5,000 slides that personnel paid with contract funds prepared for non-Federal industrial projects. Therefore, about \$4,600 of the unit's salary costs should have been charged to industrial projects, not to the contract. After we pointed out the above example to Eppley officials, they credited the contract for \$18,700 for costs associated with services provided by the histology unit to various industrial projects from July 1974 to February 1977. Officials said that all future histology work for industrial projects would be performed by personnel not paid from contract funds.

Photography unit

The Eppley Institute has a photography unit which provides illustrative and photographic services to support Eppley's research. The unit's four employees are paid entirely by the NCI contract. Their salaries are about \$45,000 annually. The photography unit does not have procedures to allocate costs incurred in providing noncontract services. Our analysis of records from July 1, 1976, to March 22, 1977, showed that of the 105 requests for illustrative services, 26 were made by employees who are not solely engaged in NCI contract research and, therefore, may not be properly chargeable to the contract. Two requests came from employees who are not performing any contract research. Yet none of the costs associated with these 28 requests have been allocated to noncontract accounts.

Animal care and breeding unit

The animal care and breeding unit is responsible for the care and feeding of animals being bred and those being used in cancer research projects. The unit has 24 employees working at three different locations. Twenty-two of these employees are paid about \$204,300 annually under the contract. Other costs associated with the breeding, caring, and feeding of animals are also initially charged to the contract. Although procedures existed for allocating costs to noncontract activities, our analysis of selected unit records and Eppley cost data for the period December 1975 through February 1977 showed that an additional \$5,060 of animal care and breeding costs should have been allocated to noncontract research, as follows:

--From January 1976 to February 1977, 2,460 animals bred at Mead farm and valued at about \$2,600 were used on industrial research projects.

- From January 1976 to February 1977, two (NIH) grants were not charged for 274 animals bred at Mead farm and valued at about \$450. During this same period, the NIH grants were charged for 117 animals.
- From December 1975 to June 1976, a third NIH grant was not charged for 190 animals bred at Mead farm and valued at about \$250. This grant was also not charged for about \$300 in care and feeding costs incurred while its animals were undergoing experimentation.
- From November 1976 to February 1977, Eppley had not allocated, to noncontract project accounts, about \$1,300 in animal care costs incurred while the animals were undergoing experimentation. About \$350 of the \$1,300 should have been allocated to industrial projects.
- During 1976 the university was undercharged about \$160 for animals supplied by Eppley.

Also all the salaries associated with breeding more than 53,000 animals which were not used for any research (see p. 39) were charged to the contract.

EQUIPMENT CONTROL AND USAGE

Government-furnished and contractor-purchased equipment has not been adequately controlled and accounted for by Eppley and the University of Nebraska Medical Center. The Eppley Institute controls about \$900,000 of equipment that was purchased with NCI contract funds and about \$500,000 of Government-furnished equipment.

Control over equipment

During its most recent physical inventory of Eppley equipment (March-April 1977), the Medical Center's inventory control department could not locate 44 pieces of equipment costing about \$59,700 that were either furnished by the Government or purchased with NCI contract funds. Two of these items were not reflected on current inventory records because they had not been located during the previous physical inventory and had been removed from the records. On May 17, 1977, Eppley's contract administrator said that he had not received a listing of the missing items from the

inventory control department and, therefore, he had not had an opportunity to locate these items.

This could have occurred because:

--Eppley had moved equipment without properly notifying the inventory control department, and

--Inventory records do not always identify those pieces of equipment that were purchased with NCI contract funds or were furnished by the Government.

Our review of inventory records identified 60 equipment items having a total purchase price of \$113,900 that were not properly identified on the current inventory listing either because the purchaser account number was incorrect or not shown, or the NIH identification number was not shown. Some additional property in the possession of Eppley for more than three years had not been recorded on inventory records.

Seven of the 60 pieces of equipment costing about \$45,300 were shown on latest inventory records as being purchased with non-Federal funds, when they had been purchased with NCI contract funds. Depreciation charges for five of these seven items were erroneously included in the indirect cost pool used in determining Eppley's overhead rates. We were unable to determine what effect this action had on the overhead rate because the overhead rate is negotiated.

Equipment usage

Federal regulations require that, unless approved by the NCI contracting officer, Government-furnished property can only be used for the performance of the contract. Although the NCI contracting officer has not provided this approval, Eppley has used some Government-furnished equipment for non-contract research.

Procedures to prohibit the noncontract uses of Government-furnished equipment have not been established by Eppley. Although usage of most Government-furnished equipment is not recorded, we determined that both a mass spectrometer and a Varian spectrometer have been used for noncontract research. The mass spectrometer which cost about \$123,200 had been used for noncontract work at least 20 times for about 88 hours since January 1, 1976. Most of this work had been done for departments located on the University of Nebraska's Lincoln campus.

The Varian spectrometer which had cost about \$78,180 had been used at least three or four times a year for work unrelated to the contract. In addition records indicate that the item had also been used to support research performed under an American Cancer Society grant from September 1972 to July 1976.

Eppley's associate director stated that they now have an informal agreement with other university departments that \$35 per sample will be charged for samples analyzed by the mass spectrometer. This revenue is to be credited to the NCI contract. Eppley officials have not yet, however, requested the NCI contracting officer's approval to use any Government furnished equipment for noncontract work.

OTHER ADMINISTRATIVE PROBLEMS

Eppley has not complied with Federal requirements for charging and recording personnel service costs to the contract. In addition some Eppley researchers who do not have approved contract projects continue to work on contract activities and have all or a substantial portion of their salaries paid for by the contract. Excessive breeding of research animals has resulted in unnecessary contract expenditures. Other problems noted are:

- Controls over leave taken by professional staff assigned to the contract are not adequate to assure that leave taken is charged against their leave balance.
- Supplies purchased with NCI contract funds have been used on noncontract activities.
- Contract funds have been improperly advanced for noncontract travel.

Time certification procedures

Federal Management Circular 73-8 states that professional and professional staff will be charged to Federal programs and activities based on the institutional payroll systems. This circular requires that such institutional payroll systems be supported by either of the following:

- " * * * (1) an adequate appointment and workload distribution system accompanied by monthly reviews performed by responsible officials and a reporting of any significant changes

in workload distribution of each professor or professional staff member, or

- (2) a monthly after-the-fact certification system which will require the individual investigators, deans, departmental chairmen, or supervisors having first-hand knowledge of the services performed on each research agreement to report the distribution of effort."

The Medical Center has elected the after-the-fact certification system for its departments.

Monthly the Medical Center's grants administration office prepares a listing of managerial, professional, and Eppley faculty personnel who have at least part of their salary paid for by the contract. The list shows the percent of time each employee should be charging to the contract according to Eppley's budget document. The listing is sent to Eppley's contract administrator who certifies the time spent on the contract by annotating the list with the percent of time he believes that Eppley employees are actually spending on contract projects. The contract administrator said that he does not compare the budgeted percents of time shown on the list to appropriate personnel action forms nor does he check with Eppley employees or principal investigators to verify that the percent of time recorded is correct. He stated that he relies on the employees, a principal investigator, or Eppley management to notify him of any changes in the percent of time an employee is spending on the contract. From July 1, 1976, to June 30, 1977, Eppley will receive about \$1.3 million based on this certification.

Although interviews with six researchers indicated that there were only minor variations between the amounts certified and the amounts they said they spent on contract work, we believe that Eppley's procedures do not meet the Federal certification requirements for the following reasons:

- The certification performed by the contract administrator is based on the budget document which indicates the time a researcher is obligated to spend on contract research rather than the time that is actually spent.
- There is no documentation to support the percents on the monthly listing by the contract administrator.

--The contract administrator does not verify the percents of time he shows on the monthly listing.

The Eppley contract administrator believed that he was in compliance with the Federal requirements. In a January 1975 report, the HEW Audit Agency stated that the Medical Center, of which Eppley is a part, did not have a time certification procedure that complied with Federal Management Circular 73-8. Medical Center officials concurred with this point. No change has been made to the certification process at Eppley although the Director said that a revision to the certification process would be considered.

Salaries paid with contract funds

The contract proposal submitted to NCI includes budget data showing, by functional area, the number of positions in each area, the percent of time to be charged to the contract, and the salaries to be paid. For the professional positions, the names of staff members are provided if the positions are occupied and positions to be filled are requested. In negotiating the contract budget, NCI uses this data to determine which positions will be funded and what percent and amount of salaries will be paid. Individuals occupying professional positions are designated to work a certain percentage of their time on the contract and have the corresponding percentage of their salaries paid. In the contract key personnel are identified for each functional area involving research.

We found several instances where paying salaries with contract funds is questionable. For example two key personnel who did not have any of their projects approved under the contract were moved to another functional area to work on approved projects. Although none of their salaries was included in the negotiated contract budget, \$46,679, or 87 percent, of their combined salaries of \$53,577 was paid by contract funds from July 1, 1976, through June 30, 1977. Three other professional staff members, not listed as key personnel, also did not have projects approved but had \$69,370, or 90 percent, of their \$77,081 combined salaries paid for by the contract. Furthermore, the portion of eight researchers' salaries being paid with contract funds exceeded by at least 20 percent the portion of their salaries negotiated to be paid under the contract. Therefore, an additional \$66,376 in salaries is being paid with contract funds for these eight researchers.

We found two examples of questionable actions in filling vacant positions. In the first case a professional staff member was assigned to fill a vacant authorized position budgeted to pay a \$10,800 salary. But \$23,125, or 75 percent of the staff member's salary, is being paid with contract funds. Two other professional staff members have been assigned to contract projects, and \$33,400, or 90 percent, of their combined salaries is being paid with contract funds. We could not, however, identify which vacant positions they filled to determine how much of their salaries should be paid with contract funds.

The Eppley contract administrator said that contract funds are made available to pay these salaries by not filling all the positions of staff members who leave the Eppley Institute, by not filling new authorized positions, and by cutting back on supplies used on approved projects. The Eppley associate director said that contract funding needs to be flexible enough for Eppley to find productive work for investigators whose proposals are not approved by NCI. He said this is not difficult for those researchers who work on many projects because usually enough projects are approved to fully occupy their time. He said, however, that it is more difficult for those researchers who do not have any approved projects. The associate director also stated that prior to assigning these investigators to contract projects, Eppley considered which projects could use extra staff, the researcher's area of expertise, and which approved projects had not been started. The associate director said that Eppley has to retain those tenured researchers who do not have approved projects. Two of the five researchers shown previously as having no projects approved under the contract have tenure.

Eppley personnel are sometimes moved from one project to another and may fill a vacant authorized position. NCI, however, does not require Eppley to provide notification of such personnel shifts nor does it reserve the authority to approve such shifts. The budgetary effects of the shifts are therefore unknown to NCI officials.

Overbreeding of research animals

During calendar year 1976 more than 84,300 animals (mice, rats, and hamsters) were bred by the animal care and breeding unit. The veterinarian at Eppley who oversees most of the breeding operation provided records showing that only 30,727 animals were sent to researchers for use while 53,015 were killed before any research use was made of them. Using

costs estimated by Eppley officials, we estimate that animals costing about \$65,600 were not used for research purposes. However, the total cost of breeding and caring for them was charged to the contract.

Several individuals familiar with research animal breeding operations have indicated that 10 to 20 percent overbreeding is common to assure that the minimum number of animals needed for research is available. They said that in this case there was excessive overbreeding.

In August 1975 Eppley requested funds to upgrade its animal breeding facilities at the Mead farm which consist of 16 Government-furnished prefabricated steel buildings and a former ordinance plant building. Concern over temperature control and sanitary conditions are cited as reasons for needing to upgrade the animal breeding facilities.

In a September 1976 contract modification, NCI allotted \$237,650 for alterations and renovations for about 8,800 square feet of floor space of the animal breeding facility that was subject to the contracting officer's review and approval of blueprints and specifications. Since Eppley is currently breeding animals in the Government-furnished buildings which have a floor space of 4,480 square feet and use a limited portion of another building for cage-washing and support materials, it appears that NCI may be financing an expansion of the animal breeding facility. Because of the overbreeding that has been found, it appears that NCI may finance expansion of an operation which may already be larger than needed.

Leave accounting discrepancies

Eppley is not properly recording vacation leave taken by contract employees. Contract funds are used to pay for unused accrued leave when contract employees terminate. According to the contract administrator, Eppley's records are used for determining the amounts of unused leave to be reimbursed.

Our limited test showed that Eppley had not recorded leave taken as shown on available absence reports for three employees. The leave used ranged from 8 to 24 hours. The Eppley contract administrator said that there is no review function to insure that used leave as shown on absence reports is properly recorded on employee leave records.

We also found that two employees paid with contract funds had taken 5 weeks of vacation leave during 1976 for which

there were no absence reports and the leave used had not been recorded on the employees' leave records. The Eppley contract administrator said that it is the individual employee's responsibility to insure that an absence report is submitted. One employee told us that he had turned in an absence report but had not given it to the individual responsible for leave records. The second employee was not sure he had submitted an absence report.

Eppley officials said that they would strengthen controls over leave accountability.

Expendable supplies and materials

During 1976 Eppley purchased about \$44,500 of expendable supplies and materials, which were initially charged to the NCI contract, from the Medical Center's general supply facility. To allocate the cost of supplies used on other contracts or grants, the storeroom manager periodically sends all issued requisition forms to the contract administrator who prepares a charge ticket which transfers the costs to the appropriate research account. However, since the requisition forms are not sequentially numbered, there is no assurance that the contract administrator receives all of them. In addition, we found one storage area for which procedures had not been established to credit the contract account for the cost of supplies used in noncontract research. As a result of our review, the contract administrator allocated \$530 to industrial and other noncontract accounts after reviewing daily use records from January 1976 to February 1977.

Travel expenses

The Eppley Institute has advanced NCI contract funds to pay for travel costs which were not properly chargeable to the contract. The contract administrator said that this was done so that employees would not have to use their personal funds for travel. During 1976 about \$2,150 in contract funds had been used for this purpose. Prior to our review of travel expenses, the contract was reimbursed for these costs. Because of our audit Eppley officials said that they have discontinued advancing NCI contract funds for travel not directly related to the contract.

CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS, AGENCY AND CONTRACTOR COMMENTS, AND OUR EVALUATION

CONCLUSIONS

Since 1968 the National Cancer Institute has continuously contracted with the University of Nebraska's Eppley Institute on a noncompetitive basis for carcinogen research and testing. Federal regulations and HEW guidelines, together with the terms of the contract, set forth the responsibilities of both NCI and contractor officials in awarding and administering the contract. However, we found numerous weaknesses in NCI's awarding of the renewal and in both NCI's and contractor officials' administration of the contract under the contract renewal which was awarded in 1973. This has resulted in unauthorized use of Federal funds and equipment, and in NCI officials not being readily aware of how the contract was being carried out by the contractor and what was being achieved.

In awarding the contract renewal, the routine procedure for using a chartered standing technical committee to make a technical review of the contract proposal was not followed. Furthermore, members of the ad hoc group selected to make the review did not meet as a committee or provide any consensus opinion of the proposal. Budget negotiations did not always reflect the recommendations of the technical reviewers and, in one case, an administrative decision was made to add more than \$1.1 million to the contract without adding any projects to the scope of the work. Also the sole source justification for noncompetitive procurement was not based totally on facts, as required by NIH instructions.

Monitoring of the contract was lax and ineffective. The contracting officer did not fulfill all of his responsibilities either because he was not aware of the situations which required his attention or because he did not believe that he had the leverage necessary to require the contractor to submit certain reports. The project officer, by his own admission, was unable to carry out his duties because the contract was too large and complex in nature for one person to monitor. The inhouse staff was not used to help monitor the contract despite several suggestions by various NCI officials that more inhouse staff involvement in the contract was needed.

NCI officials either did not require the contractor to fulfill all the terms of the contract or did not obtain the data necessary to determine whether the contractor had met

contractual requirements. Instead an NCI attempt to reduce reporting requirements has resulted in increasing the requirements. Furthermore, NCI officials were not very familiar with the contents of progress reports and papers published on results of projects carried out under the contract. They have stated that they cannot estimate the value of the end products received for the \$12.4 million awarded for the contract since May 1973.

Management practices at the Eppley Institute have not been adequate to assure that necessary administrative controls over contract activities have been established or carried out. This has led to (1) projects being undertaken without proper NCI approval, (2) charges for personnel, supplies and animals not being used for contract purposes, (3) lack of control over equipment and its use, and (4) improper time certification procedures. In addition Eppley officials have been awarded Federal funds to refurbish animal breeding facilities which are producing animals far in excess of research needs.

We have concluded that the causes of the problems identified are directly related to the actions or lack of action on the part of both Eppley Institute and NCI officials. Improvement in the administration of the Eppley Institute contract is needed. NCI officials have already taken some steps to correct the problems reported. Three NCI carcinogenesis program officials have been named as project officers. NCI has requested an audit of the contract so that the extent of problems can be identified and corrective actions taken. Also, the contractor has been instructed not to award a contract for refurbishing the animal breeding facility until NCI determines what size facility is needed.

RECOMMENDATIONS TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

In order to correct problems under the contract with the Eppley Institute and to assure improved administration of any future contract work with Eppley, we recommend that the Secretary of HEW take the following actions:

- Require that the audit requested of the Eppley contract cover the matters discussed in this report relating to improper use of Federal funds and equipment, and that appropriate corrective actions and financial restitution be obtained on the resulting findings.

- Require that NCI officials obtain and analyze data on the annual need for research animals at Eppley and how it can best be provided before approval is given to proceed with the refurbishing of the animal farm using contract funds.
- Direct Eppley officials to provide NCI with an inventory of all equipment furnished by the Government or purchased with contract funds which contains evidence that property numbers have been assigned to the equipment identifying it as property in which the Government retains ownership rights.
- Instruct Eppley officials to furnish evidence that the amount of professional and support personnel efforts claimed for reimbursement under the contract approximates the amount of hours allotted for each category of staff in the contract.
- Have NCI officials reach an agreement with Eppley officials on whether Government-furnished property can be used for noncontract purposes, and if so, whether a fee for such use should be established and reimbursed to the contract.
- Require that recommendations of the scientific reviewers, the Carcinogenesis Contract Program Management Group, and the auditors be used in negotiating a budget for future work.
- Require that a new sole source justification for noncompetitive procurement be prepared based totally on facts.
- Require that the contractor submit a budget proposal which contains data on each proposed project so that future contract budget negotiations can be facilitated.
- Consider adding provisions to any future contract with the Eppley Institute which would clearly state that
 - no research or testing project approved under the contract be started without the approval of the project officer,

- the contractor shall furnish evidence of the amount of time spent on contract activities by all professional and support personnel,
- professional staff members not be moved from one project to another, added to, or removed from a project by the contractor unless prior approval is given by the project officer,
- all changes to the scope of work, terms, or conditions of the contract be approved in writing by the contracting officer, and
- the contractor will supply an annual inventory of all equipment furnished by the Government or purchased with contract funds.

In administering future contract work with Eppley, we also recommend that the Secretary of HEW

- improve monitoring by increasing communication between the Eppley staff and NCI's carcinogenesis program staff,
- instruct the project officers and contracting officer to work together toward providing better contract administration, and
- require that the contracting officer assure that the contractor has established:
 - Adequate controls and procedures to identify and allocate costs that are chargeable to the contract.
 - A better system for recording new equipment in the inventory and for assigning property numbers to it.
 - A time certification procedure that meets Federal requirements.
 - An improved leave accounting system.
- encourage the project officer and contracting officer to use the HEW procedures to withhold payments when the contractor materially deviates from the terms of the contract.

HEW COMMENTS AND OUR EVALUATION

HEW generally concurred with all of our recommendations except for part of the one calling for certain clarified provisions to be added to any future contract. HEW responded that two of the five suggested provisions are already incorporated by reference or included under general contract provisions, and a third suggestion to control the start of projects is unnecessary. We continue to believe that these points need to be clearly stated in future contracts because of repeated violations by the contractor. We were advised that remedial action had been instituted in many areas to improve the management and administration of this contract, and that additional corrective actions will be taken following the current HEW audit at Eppley Institute. In addition NCI intends to followup to assure that the contractor's procedures are proper. We believe that HEW has demonstrated a great interest in clearing up the problems noted in our review and that actions taken and planned will be effective.

In its comments HEW stated that it failed to see how weaknesses in the award and administration of the contract could have resulted in unauthorized use of Federal funds and equipment by the contractor since normal contract administration would not necessarily uncover such unauthorized use. HEW cited (1) accounting errors by the contractor, (2) proceeding without authorization, and (3) unauthorized use of equipment and supplies as the causes of unauthorized use of Federal funds and equipment.

Although we agree that the unauthorized use of Federal funds and equipment resulted, in part, from Eppley's management of the contract, we do not agree with HEW's contention that normal contract administration would not have uncovered such misuses. As an example Eppley routinely reported its work on several unauthorized projects in progress reports to NCI. A comparison of projects reported in the progress report with the list of projects authorized in the contract would have been sufficient to uncover these projects. As a further example, NCI would have been able to account for the equipment at the Eppley Institute by comparing the required annual inventory with the listing of equipment authorized in the contract. However, NCI failed to have Eppley submit annual inventories, as required by the contract. We believe that these examples show that NCI exercised weak contract administration.

HEW stated that NCI was generally aware of contract performance and was and is aware of contract results. Much

of the contract return has become known to the scientific field through interim reports and publications. We agree that NCI, with the current assignment of three project officers, has improved its awareness of contract performance and results. However, we do not agree that NCI officials were aware to the extent they should have been of what was being carried out and achieved under this contract in prior years. NCI officials did not know that progress reports had not been submitted and also did not know that unapproved projects were being carried out, even though the contractor reported fully on these projects. As cited on page 28, an NCI official reported in March 1977 that NCI was embarrassingly unaware of what was in the publications that Eppley submitted for review.

In commenting on our conclusion that NCI did not follow the routine procedure for using a standing committee to review the proposal for renewal of the contract, HEW stated that experts were used to provide independent advice and not as an ad hoc committee. It also stated that this was not a violation of NCI guidelines since dual committee review was required of new contracts but not renewals. We do not agree with HEW's comments because NCI guidelines do require dual committee review for renewal awards where an approved project plan did not exist, as was the case with the Eppley Institute for the 1973 contract renewal. In addition NCI Committee Management Procedures and Guidelines, as discussed on page 8, provide that the criteria of giving individual opinions, rather than group advice, should not be applied to contract review committees. In fact, the ad hoc group members did review the contract proposal and provided advice on whether or not projects were deserving of support, which is exactly what is done by a technical review committee.

HEW stated that the addition of \$1.1 million for an additional 6 months was for the work specified in the proposal and also stated that our conclusion indicated that the money was added with no increase in the work scope. HEW argued that our conclusion is not true because the number of staff-hours was increased. We agree that the number of staff-hours was increased, but we do not agree that this constitutes an increased work scope. All NCI did was allow the contractor to carry out work on the same projects for an additional 6 months.

COMMENTS BY THE UNIVERSITY OF NEBRASKA'S
MEDICAL CENTER AND OUR EVALUATION

Although not in agreement with several specific findings in our report, the Medical Center generally acknowledged our

findings as valid. Corrective action in the areas of accountability and control over Federal funds and equipment has been or will be taken according to the comments received. Several matters of particular interest were included in the comments received from the Medical Center.

UNAPPROVED PROJECTS

The Medical Center stated that Eppley officials had received oral approval from NCI to work on seven of the 11 unapproved projects that we uncovered. In addition one other project was considered an extension of an approved project. For the remaining three projects, no explanation was provided on how or from whom they received approval. The Medical Center reported that Eppley was tightening control over new projects by requiring written NCI approval before work is started. HEW states, however, that it did not approve these projects and, therefore, it must determine whether or not to obtain reimbursement for the cost of performing the projects.

Overbreeding of research animals

The Medical Center's comments indicate that the report reflects a misunderstanding regarding the breeding of research animals. Explanations were given for animals (1) destroyed because they were not suitable for research, (2) used to replace breeding stock, (3) used for research, and (4) which were an unavoidable excess. The Medical Center stated that oral Government approval had been given for others to use excess animals without charge, and that administrative procedures have been initiated to more accurately predict research needs and to minimize excess breeding.

We agree that some excess breeding must take place to guarantee an adequate number of animals for research. The information in the Medical Center's comments did not provide evidence to show that there is not a large amount of overbreeding at the Eppley Institute. Given the extent of planned renovations and the possibility of large-scale overbreeding, we believe that NCI should continue to withhold funds for renovation of the animal facility until HEW auditors or NCI scientific staff members can determine what constitutes an adequate breeding level of research animals. In addition NCI officials informed us that while providing excess animals to other federally sponsored research projects was acceptable, it was not acceptable for the Eppley Institute to provide them free-of-charge to industrial concerns and it did not justify large-scale overbreeding.

The Medical Center's comments also noted that the animal facility is inadequate, obsolete, and in need of renovation. Also the comments stated that the actual space available for animals will be 706 square feet less than is presently used. Since sufficient data is not available to compare the old and the proposed facilities, we cannot address this point.

Reporting requirements

In response to our findings that the Eppley Institute failed to submit two consecutive progress reports, the Medical Center contends that the requirement was excessive and that annual reports, not 6-month reports, are sufficient for monitoring purposes. The Medical Center stated that Eppley submitted manuscripts and publications directly to NCI and to Federal regulatory agencies during this time period that covered the same material the reports would have covered.

While the requirement for reporting every 6 months may have been excessive, it was a contractual requirement which, in lieu of a contract modification, should have been adhered to by both NCI and the Eppley Institute. In stating that annual reports are sufficient for monitoring purposes, the Medical Center fails to note that Eppley's failure to submit two consecutive 6-month reports resulted in an 18-month gap between reports which may have been too long for monitoring purposes.

Staff charged to the contract

The Medical Center stated that the use of contract personnel to perform noncontract work is minimal and that substantial contract work is being supported from noncontract sources. The Medical Center also stated that new procedures have been implemented in two of the support service units to allow allocation of noncontract work to the proper sources. Although we identified only a small amount of improperly allocated contract funds, our review only covered a limited number of support unit activities over a short time period. The potential total misallocation could be far greater, especially considering the more than 4-year duration of the contract. HEW auditors are currently following through on these findings to determine the total amount of misallocated costs. The recently instituted procedures are commendable but need to be utilized by all support units; not only those we cited. If the Medical Center's contention that contract work is being supported by noncontract sources is valid, these costs should be allocated to the contract as a legitimate cost of the research.

The Medical Center stated that it has initiated new time-certification procedures and an improved leave-accounting system which will minimize discrepancies, such as those mentioned in our report. While this is a positive step, the adequacy of these systems will have to be evaluated during the current HEW audit.

Equipment and supply accountability

The Medical Center indicated that Eppley has been able to locate most equipment items which were not found during its original inventory and states that continued emphasis will be placed on upgrading and improving its inventory reporting procedures. The use of Government-furnished property for noncontract purposes was caused by confusion resulting from a contractual technicality. Furthermore, the Medical Center stated that Eppley will request NCI approval for any such use in the future. In addition procedures are being taken to improve allocation of supply costs to proper sources.

The problems encountered in property accounting for Government-furnished or contractor-acquired property occurred because the Eppley Institute failed to follow university rules for equipment control. Equipment was either being moved without notifying the inventory control department or was not properly identified when purchased. Some pieces of equipment had been in Eppley's possession more than 3 years without being recorded on the inventory. Without doubt the Eppley Institute could locate all of its equipment if given enough time, but we do not believe that this represents adequate control over the property nor does it solve the basic problems which are causing poor control. Depreciation charges for some equipment paid for with Government funds were being used in determining the overhead rate for the contract because of these problems. The adequacy of new procedures to allocate supply costs should be determined during the HEW audit.

Research results

The Medical Center stated that while the results of research are often intangible, some positive effects in the area of carcinogenesis have been achieved and a few examples were cited. The number of publications produced for the funding received was reported as being well above the average of other NCI contractors. We did not question the number of publications the Eppley Institute produced, but questioned the lack of familiarity on the part of NCI officials with the contents of progress reports and published papers. We also

questioned NCI's inability to cite more than a few notable accomplishments for more than four years of work and more than \$12 million of funding on this contract.

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 Washington, D.C. 20515

June 6, 1977

APPROPRIATIONS
 SUBCOMMITTEE
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 CHAIRMAN
 CONGRESSMAN BY
 ADMINISTRATIVE REGION
 WASHINGTON OFFICE
 300 BAYBURN HOUSE OFFICE
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 PHONE: 505-62-6200
 ADMINISTRATIVE ASSISTANT
 LYLE BERRY

Honorable Elmer B. Staats
 Comptroller General of the
 United States
 General Accounting Office
 441 G Street, N.W.
 Washington, D.C. 20548

Dear Mr. Staats:

In January 1976, I requested the General Accounting Office to investigate a National Cancer Institute contract with the University of Nebraska's Eppley Institute. At that time, I asked for a briefing from GAO prior to the House appropriations hearings on the National Cancer Institute, and indicated my intention to request a full written report on the GAO investigation.

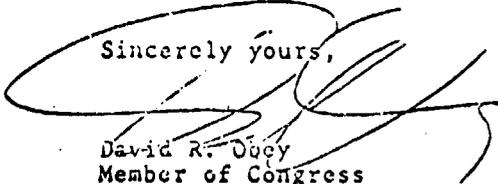
Your staff has been most helpful in keeping my office apprised of the results of their efforts. Because of the need for an objective reporting on the Eppley Institute contract, and considering the interest that has been shown in audit of this contract by other members of the Congress and by the news media, I believe it is most important to have the results of the GAO work recorded in an audit report.

Therefore, I am requesting that the General Accounting Office prepare and issue a report to me as soon as possible which covers at least the following aspects of the contract with the Eppley Institute.

1. What actions have been taken by the National Cancer Institute in awarding and monitoring the contract since 1973?
2. Are contractor controls over the use of funds and property adequate?
3. Have various personnel matters pertaining to the professional staff at the Eppley Institute been handled in an effective and proper manner?
4. What work has been done under the contract since 1973 and can its usefulness be determined?

Comments on the report by National Cancer Institute and Eppley Institute officials should be solicited and included in the report along with any conclusions or recommendations you may wish to offer.

Sincerely yours,



David R. Obey
 Member of Congress

GAO note: Congressman Obey's original letter was incorrectly dated January 1976. The correct date was January 1977.

CONTRACT FUNDS AWARDED BY NCI FOR
CANCER TESTING AND RESEARCH
AT THE EPPLEY INSTITUTE

<u>Contract</u>	<u>Term</u>	<u>Amount</u>
PH43-68-959	3/18/68-3/17/69	\$ 750,000
 Supplemental Agreements		
#1	3/18/69-3/31/69	0
#2	4/ 1/69-3/15/70	958,000
#3	No extension	50,000
<u>a/</u> #4	No extension	0
#5	3/16/70-5/15/70	171,000
#6	5/16/70-5/15/71	1,030,000
#7	5/16/71-5/15/72	1,335,058
<u>a/</u> #8	No extension	0
#9	5/16/72-6/15/72	158,300
#10	6/16/72-5/15/73	1,741,700
		<u>\$6,194,058</u>
 NO1-CP-33278	 5/16/73-11/15/74	 \$3,446,000
 Amendment/Modification		
#1	11/16/74- 2/15/75	680,131
#2	2/16/75-11/15/76	5,414,177
<u>a/</u> #3	No extension	0
#4	No extension	49,938
<u>a/</u> #5	No extension	0
#6	11/16/76- 4/ 1/77	1,504,621
#7	No extension	(206,981)
#8	4/ 2/77- 6/30/77	662,313
<u>a/</u> #9	No extension	0
<u>a/</u> #10	No extension	0
#11	7/1/77- 9/29/77	812,000
#12	9/30/77-11/15/77	406,000
#13	11/16/77-11/15/78	3,630,910
		<u>\$16,399,109</u>
 Total amount awarded		 <u>\$22,503,167</u>

a/ These supplemental agreements involve miscellaneous items such as method of payment, various reports, furnishing equipment, etc.



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20492

DECEMBER 8, 1977

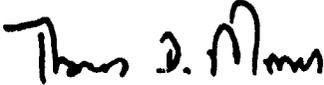
Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Additional Efforts Needed to Improve Administration of a Cancer Testing and Research Contract." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,


Thomas D. Morris
Inspector General

Enclosure

**COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE
COMPTROLLER GENERAL'S DRAFT REPORT TO CONGRESSMAN DAVID R. OBEY ENTITLED
"ADDITIONAL EFFORTS NEEDED TO IMPROVE ADMINISTRATION OF A CANCER TESTING
AND RESEARCH CONTRACT"**

General Comments

We acknowledge that many points covered in the GAO report are valid and require corrective action. We hope that the report in final form will reflect that remedial action in many areas to improve the management and administration of this contract had been instituted prior to the GAO audit. Additional corrective actions will be taken following an assessment of the HEW audit findings of Eppley accounting practices. In addition, the NCI intends to follow-up to assure that the contractor's procedures are proper.

Following are comments on each of the GAO's recommendations and comments on specific points and conclusions presented in the draft report, including recommended changes to improve the accuracy of reported material.

HEW Comments on GAO Recommendations

GAO Recommendation

The Secretary, HEW, should require that the audit requested of the Eppley contract cover the matters discussed in this report relating to improper use of Federal funds and equipment and that appropriate corrective actions and financial restitution be obtained on the resulting findings.

HEW Comments

We concur.

GAO Recommendation

The Secretary, HEW, should require NCI officials to obtain and analyze data on the annual need for research animals at Eppley and how they can best be provided before approval is given to proceed with the refurbishing of the animal farm using contract funds.

HEW Comments

We concur. The need for animals at Eppley is being examined, particularly in view of our belief that the research portion of the contract may be suitable for competition in one year and the need for animals for the testing program may be reduced and fulfilled elsewhere. Eppley would have a small scale production facility and the economy of that must be weighed against the availability and cost of animals elsewhere.

We are carefully reexamining the need for refurbishment at this time. Refurbishment on the part of Eppley has been stopped and will not be supported in the renewal modification unless fully justified.

GAO Recommendation

The Secretary, HEW, should direct Eppley officials to provide NCI with an inventory of all equipment furnished by the Government or purchased with contract funds which contains evidence that property numbers have been assigned to the equipment identifying it as property in which the Government retains ownership rights.

HEW Comments

We concur. Eppley has furnished copies of NIH Form 308 which lists Government-owned equipment. Regulations do not require property decals (numbers) for property where title vests in an educational institution and Eppley is part of the University of Nebraska.

GAO Recommendation

The Secretary, HEW, should instruct Eppley officials to furnish evidence that the amount of professional personnel and support personnel efforts claimed for reimbursement under the contract approximates the amount of hours allotted for each category of staff in the contract.

HEW Comments

We partly concur. In the past the Eppley invoices reported the percentage of time spent by the staff on the contract and these percentages approximated the contract specified manhours. The current vouchers will report manhours worked (accrued) by labor category with the names of the professionals involved. In the future these manhours will be further broken out by task.

It is not necessary that Eppley accrue the specific number of hours estimated in the contract. However, as we have specified to Eppley, it is necessary that we have suitable financial reporting in order to judge the appropriateness of the labor expended.

GAO Recommendation

The Secretary, HEW, should have NCI officials reach an agreement with Eppley officials on whether Government furnished property can be used for non-contract purposes, and if so, whether a fee for such use should be established and reimbursed to the contract.

HEW Comments

We concur. We have never authorized Eppley to use Government property for other than contract purposes and do not intend to include such a

provision in the renewal. Should a special situation arise Eppley is, and always has been, required to obtain written authorization from the contracting officer.

GAO Recommendation

The Secretary, HEW, should require that recommendations of the scientific reviewers, the CCPMG, and the auditors be used in negotiating a budget for future work for the proposal now under consideration.

HEW Comments

We concur. All available recommendations from advisors such as the CCPMG, scientific review committee, and auditors have been, and are being, utilized in the negotiation of the renewal. Where such advice appeared to be ignored in the past, the documentation failed to explain the situation. Proper contracting procedures require the full consideration of all advice and an explanation where such advice is deemed inappropriate. However, one need not follow the advice of each individual reviewer, particularly where it contrasts with that of another reviewer. However, the documentation should clearly explain these inconsistencies.

GAO Recommendation

The Secretary, HEW, should require that a new sole source justification for non-competitive procurement be prepared based totally on facts for the proposal now under consideration.

HEW Comments

We concur. Immediately following the GAO "exit" conference, we began the examination of the justification for non-competitive procurement (JNCP). It is being rewritten with advice from the peer review committee as well as various in-house staff to ensure that it is entirely consistent with the facts.

GAO Recommendation

The Secretary, HEW, should require the contractor to submit a budget proposal which contains budget data on each proposed project so that future contract budget negotiations can be facilitated.

HEW Comments

We concur. A prospective budget has been obtained from Eppley and significant negotiations for the renewal were conducted at Eppley on September 21.

GAO Recommendations

The Secretary, HEW, should consider adding provisions to any future contract with the Eppley Institute which would clearly state:

- (a) that no research or testing project approved under the contract can be started without the approval of the project officer,
- (b) the contractor shall furnish evidence of the amount of time spent on contract activities by each professional personnel and support personnel,
- (c) professional staff members cannot be moved from one project to another, added to, or removed from a project by the contractor unless prior approval is given by the project officer,
- (d) all changes to the scope of work, terms, or conditions of the contract must be approved in writing by the contracting officer, and
- (e) the contractor will annually furnish an inventory of all Government furnished equipment and equipment purchased with contract funds.

HEW Comments

- (a) We do not concur. Once a project is approved and included in the contract, it is not appropriate to require further approval by the project officer. The award document in itself is approval to start. On the other hand, projects outside the scope of the contract may not be started without a proper modification to the contract.
- (b) We concur. We intend to obtain proper time accounting reports on a regular basis.
- (c) We concur for key personnel. The key personnel article of a contract specifies those professional staff members for whom we wish to retain approval. We are considering the inclusion of more professional staff members in this article for the renewal.
- (d) We do not concur. Under the General Provisions of the contract itself no one but the contracting officer can change the workscope, etc. It would be redundant to include a special provision in the contract to cover this point. However, this requirement will be re-emphasized during negotiations of the renewal modification.
- (e) We do not concur. The requirement for periodic inventories is already specified in HEW Pamphlet 74-115, "Control of Property in Possession of Contractors," which is incorporated in the contract by reference. However, this requirement will be reiterated during negotiations.

GAO Recommendation

The Secretary, HEW, should improve monitoring by increasing communication between the Eppley staff and NCI's Carcinogenesis Program staff.

HEW Comments

We concur. By appointing three co-project officers, each responsible for a specific scientific area, we will improve communications. The co-project officers will be advised to carefully monitor all activity under the contract.

GAO Recommendation

The Secretary, HEW, should instruct the project officer and contracting officer to work together toward providing better contract administration.

HEW Comments

We concur. The co-project officers and the contracting officer have established an excellent interface and are working together to provide better contract administration.

GAO Recommendations

The Secretary, HEW, should require the contracting officer to assure that the contractor has established:

- (a) adequate controls and procedures to identify and allocate costs that are chargeable to the contract,
- (b) a better system for recording new equipment in the inventory and for assigning property numbers to it,
- (c) a time certification procedure that meets Federal requirements and,
- (d) an improved leave accounting system.

HEW Comments

We concur. The contracting officer will assure that Eppley establishes proper controls, procedures, and systems. This will be done by offering technical advice. To further insure that these procedures and controls are implemented, we plan to request a follow-up audit of the Eppley contract.

GAO Recommendation

The Secretary, HEW, should encourage the project officer and contracting

officer to use the HEW procedures to withhold payments when the contractor materially deviates from the terms of the contract.

HEW Comments

We concur. NIH is aware of the procedure for withholding payment from Letter of Credit contractors and will use that procedure, as appropriate, when the terms of the contract are not fulfilled.

HEW Comments on GAO Conclusions

The following comments respond, in the same order, to the statements presented on pages 64-67 of the GAO draft report.

In its draft report GAO concludes that weaknesses in awarding and administering the contract have resulted in unauthorized use of Federal funds and equipment. The unauthorized uses resulted from Eppley's accounting errors, proceeding without authorization, and unapproved use of equipment, supplies, etc. Normal contract administration would not necessarily uncover the unauthorized use of Federal funds and equipment. Therefore, we fail to see how weaknesses in the award and administration processes could have caused such unauthorized uses.

The GAO concludes also that NCI officials were not readily aware of how the contract was being carried out and what was being achieved. We feel that the NCI staff was generally aware of the contract performance and was, and is, aware of the contract results. Through interim reports and publications much of the contract "return" has become known to the scientific field. A monetary value cannot be attached to research results which could cover the spectrum from "no result" (which can be a positive finding) to a new discovery.

The NCI did not follow the routine procedure of using a standing committee. Experts were used as consultants and were not to act as an "ad hoc" committee but rather were to provide independent advice directly to Program. The use of consultants in this fashion was not precluded by the existent guidelines and in the judgment of the responsible NCI staff at that time the use of a standing committee was not appropriate because the expertise did not exist in a committee. We feel that such a procedure was not a violation of NCI guidelines. NCI's contracting procedures at that time made dual committee review mandatory for new awards rather than renewals.

The addition of \$1.1 million was for an additional six months of the work specified. It was decided to write an 18 month extension instead of a 12 month extension. The GAO conclusion indicates that money was added with no attendant increased scope of work. This is not true. The number of manhours was increased.

The present JNCP was written in good faith. However, it is being fully reexamined for strength and factual content.

The NCI contracting officers are instructed to require delivery of all items so designated in the contract schedule and are furnished with a description of the means to carry out this function.

There may have been some laxity due to inadequate staffing. Action has already been taken to improve monitoring of the contract.

We agree that the delivery of some items was apparently informally waived and that necessary attention was not given to modifying the contract to reflect our desires. Steps are being taken to improve this phase of our operation in the future.

Appropriate NCI staff is confident that it is familiar with the accomplishments of the contractor. During the course of the review, GAO was furnished with many interim reports which indicated progress by the contractor.

The nature of biomedical research often precludes valuation of the results. The true value of new information may not be determined until arrayed with other knowledge gained through other as yet incomplete research. Judgment must be made relative to whether a scientist is progressing and whether the possibility of an end result is worth the money being spent. Sometimes productivity can be measured by the number of publications which are a primary means of dissemination of knowledge to the scientific community. It is interesting to note that Eppley received 9.2% of the carcinogenesis collaborative research funds in fiscal year 1973 and contributed 28% of the publications resulting from the same funds.

The problems resulting from Eppley management actions are being investigated and funds will be recovered as appropriate. As stated in the GAO report, there have already been some chargeback corrections.

The refurbishment of the animal facilities has been suspended pending a full analysis.

We agree that contract administration must be improved and will continue to give that goal our attention.

GAO note: The remainder of the comments have been deleted because they addressed general or technical matters which have been incorporated into the report.

THE UNIVERSITY OF NEBRASKA MEDICAL CENTER
 42ND AND CUMBY AVENUE
 OMAHA, NEBRASKA 68105

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COLLEGE OF MEDICINE
 SCHOOL OF ALLIED HEALTH PROFESSIONS
 COLLEGE OF BUSINESS
 COLLEGE OF PHARMACY
 UNIVERSITY HOSPITAL AND CLINICS
 EPPLEY INSTITUTE FOR RESEARCH ON
 CANCER AND ALLIED DISEASES
 LOUIS BRYER CHILDREN'S
 REHABILITATION INSTITUTE
 NEBRASKA PSYCHIATRIC INSTITUTE

September 28, 1977

Mr. Gregory J. Ahart
 Director of Human Resource Division
 United States General
 Accounting Office
 441 G Street N.W.
 Washington, D.C. 20548

Re: Proposed GAO Report Concerning the Eppley Institute

Dear Mr. Ahart:

The University of Nebraska Medical Center and the Eppley Institute for Research in Cancer sincerely appreciate the opportunity to comment on the proposed General Accounting Office Report.

The attached comments are offered in a spirit of constructive cooperation, while not in agreement with several specific findings in the proposed report. We are confident that the comments will be received in that spirit.

Again, Mr. Ahart, we are pleased to have had the opportunity to comment on some aspects of the proposed report. For us, the audit was a useful experience. We trust you will call on us if we can provide you or your staff with further information. You are assured of our continuing cooperation.

Sincerely,

Neal A. Vanselow

Chancellor,
 University of Nebraska
 Medical Center

Comments of the University of Nebraska Medical Center and the Eppley Institute for Research in Cancer on the Draft of Proposed General Accounting Office Report, "Additional Efforts Needed to Improve Administration of a Cancer Testing and Research Contract, National Institutes of Health, Department of Health, Education, and Welfare"

Reporting Obligations Under the Contract

The proposed General Accounting Office (GAO) report indicates that the Eppley Institute (Eppley) did not submit two of six progress reports between May, 1973 and September, 1976. As was mentioned (p. 38), many research projects require two to three years to complete and preparation of comprehensive reports is an expensive process which takes investigator time from research projects.

Project results and progress are reported to the National Cancer Institute (NCI) in an annual report, when manuscripts are submitted to a journal, and when they finally appear in print. Annual reports provide an overall view of progress and problems and are sufficient for monitoring purposes. All manuscripts of papers prepared for publication in scientific journals are sent to the Project Officer at the same time as they are submitted to journals. These manuscripts provide continual updating of significant progress and the current procedure assures that the NCI has this information, usually six to nine months before publication.

In addition, in the past two years, results which appear to have special significance have, with the concurrence of the Project Officer, been forwarded directly to the appropriate regulatory agency. For example, results showing that clinically used drugs are carcinogenic, as for instance with hycanthone, niridazole, griseofulvin and dilantin, have been forwarded to the Food and Drug Administration; results with chlorinated pesticides such as hexachlorobenzene to the Environmental Protection Agency. The Institute welcomes the decision by NCI Carcinogenesis Bioassay Program to further publicize its work. Eppley has published its results through normally accepted scientific channels and has been more than compliant in supplying information to NCI.

NCI recognized that the contract requirement for semi-annual reports was excessive, and in September, 1976, it changed from semi-annual to annual reporting requirements.

With respect to "level of effort" reporting of staff hours, it should be noted that monthly reports on the percentage of time spent by the staff on the contract were provided.

Conduct of Operations

Unapproved Projects

The reports states (p. 44) that 11 projects were initiated by Eppley without proper NCI authorization. Of these, six were proposed in the report of November 15, 1975. The Project Director was advised during a telephone conversation with the former Deputy Associate Director for Carcinogenesis, NCI, to initiate

these projects pending the next comprehensive technical review of the contract (originally scheduled for November, 1976), provided no additional funds were required. This NCI official stated that he had discussed the matter with the Associate Director for Carcinogenesis.

One project was proposed in the report of December 15, 1973, following discussions between the Project Director, Project Officer, and Associate Director for Carcinogenesis. It was formally reviewed following the report of August 15, 1974, and approval was affirmed by Contract Modification No. 2, dated February 16, 1975.

Another project was described in the December 15, 1973 and August 15, 1974 reports. This experiment was a logical extension of a previously approved project and could have been considered the addition of one group of animals to an experiment in which six groups were already being treated. A new project number was assigned because starting dates of the groups were different.

The three in vitro carcinogenesis projects cited by the report were proposed in the report of February 1, 1973. There appears to be no written approval of these projects until approval was affirmed by the contract renewal dated February 16, 1975. Progress on these projects was described in our reports dated December 15, 1973 and August 15, 1974. Eppley kept NCI informed of the progress on these projects and there was ample opportunity for review. Some errors in interpretation of the contract workscope were regretablely made. Three projects of a total of 213 (GAO count, p. 39) should not be considered a major lapse. These projects were initiated during a period when NCI was increasing its emphasis on in vitro studies. It is significant that the Eppley in vitro program received highly favorable comments during the most recent contract review. The projects cited were essential to development of this successful program.

The report suggests (p. 40 and p. 69) that Eppley obtain separate approval by the Project Officer to start each new project, even though the projects have been already approved by the Review Committee and NCI and are so listed in the contract. It is essential that the Project Director and Investigator have the authority to schedule project initiation. Availability of personnel, animals, equipment and space must be considered in determining starting dates and effective research management requires that the Project Director have this authority. Procedures initiated by Eppley in 1974 insure that no new projects are started without authorization from NCI. It is now required that this authorization be in writing. These controls are sufficient to prevent a recurrence of the errors cited in the report.

Overbreeding of Research Animals

(Period considered: from January 1, 1976 to December 31, 1976).

The proposed report reflects a misunderstanding of the mechanics of breeding research animals. This part of our comment will concern (i) the required level of breeding, (ii) the reason a research institute such as Eppley requires its own supply of research animals, and (iii) reasons for the level of production of animals maintained by Eppley.

The Report's comments concerning overbreeding are based on a list detailing the approximate number of newborn offspring in the breeding colony. The exact number of newborn was not recorded by the animal breeders since the degree of disturbance of litters required for precise counting is likely to stress the

animals and leads to cannibalism. The purpose of this record is to indicate to the animal breeder the fertility and productivity of the breeding animals and to prevent continued breeding from the offspring of animals deficient in these characteristics. At an appropriate time (4-5 days of age), runts must be killed and the litter size reduced to the number of available nipples on the rodent breast (ten) to insure that high quality healthy animals are produced for research purposes. It is estimated that approximately 77,916 newborn animals led to 62,195 weanling animals. Of these, a further number estimated at 10% (6,200) was culled before shipping because they were considered not to be of the highest quality necessary for research.

The report did not recognize the need for replacement of breeding stock. In the period under consideration, this required approximately 6,200 animals (10% of production). Certain NCI-funded projects required animals of only one sex. For example, in skin painting experiments, female mice are generally used, since males, unless individually housed, fight and cause skin lacerations which prevent clear-cut interpretation of test results. Similarly, only male rats are required for specific contract-funded, biochemical investigations. If animals of the opposite sex are not concurrently required, they are usually destroyed. We estimate that 8,263 animals of a single sex were required. Thus, an approximately equal number had to be destroyed. Furthermore, some biochemical experiments require rats of a narrow weight range (for example, 55-65 g) to be supplied on a particular day. This research requirement necessitates a degree of over-breeding of at least 50-70%. Wastage due to this factor totaled approximately 5,250 rats (based on the 70% factor).

Thus, the production of 55,995 first class weanling animals resulted in an unavoidable excess of 9,001 or 16.1% (55,995--27,281 shipped for contract experiments, 6,200 replacement breeders, 8,263 non-required sex, 5,250 animals not in required weight range).

The conduct of high quality research in any aspect of chemical carcinogenesis requires that the investigating institute have complete control over its experimental animals from conception to death. Otherwise there can be no guarantee that the animals used have not at some time been exposed to infection (e.g., viral) or contamination by environmental chemicals which will render the interpretation of the results difficult and their significance, at best, questionable. In view of the potential economic consequences of tests of specific substances for carcinogenicity and the large intrinsic costs of these tests, it would seem to be a false economy to deny researchers responsibility for and control over their own animals. Most of the animal strains bred by Eppley have been under the control of Eppley, or the team previously working in the Chicago Medical School, for more than 20 years. This means that there is a long history of the naturally occurring tumors in these animals, and, especially important, the variations in the yield of these tumors with time. This is of the utmost importance in assessing the significance of incidences of tumors thought to be induced by test chemicals. It can go far to prevent substances being wrongly identified as carcinogens with the attendant economic impact on the community of incorrectly based regulatory decisions.

The required level of breeding is a matter of balanced judgment. While in many cases, it is possible to predict the demand for specific experimental animals in an orderly fashion, in other cases, there is a need to commit animals to experiment almost on an emergency basis. For example, there can be losses in animals in a bioassay due to unexpected chemical toxicity. If animals are not available, there may be a delay of 3 to 6 months in performing an experiment. In addition,

the underutilization of professional and technical personnel would represent greater inefficiency than the breeding of a few excess animals. Thus, an adequate supply of animals is necessary for good management of the total contract.

Recognizing that production of a small percentage of animals in excess of research requirements is inevitable, Eppler has initiated administrative procedures which will more accurately predict research needs and, hopefully, minimize this excess.

Renovation of Animal Breeding Facility at Mead, Nebraska

The present Eppler Institute Breeding Facility is housed in government-furnished, temporary buildings which were aged when they were transferred in 1968 from the Chicago Medical School. Today, the buildings present a considerable and continuing problem in maintenance. These buildings were not designed for, nor do they conform to, modern standards for animals breeding. Eppler requested funding for renovations on one government-furnished building to replace the present facility. Failure to make the proposed renovation will result in the continuing total decay of the present inadequate and obsolete facility. Without an adequate facility, the high quality breeding program cannot be maintained, irrespective of the level of breeding. The report's concern about the increase in floor space in the proposed new facility is groundless. The actual space available for animals will be less by 706 square feet (16%) than that presently used.

Funds Accounting

It is stated in the report (p. 47) that "several of the support personnel whose salaries are paid with contract funds provide support to non-contract research. Procedures to allocate these costs to the non-contract projects generally have not been established. Our tests showed that substantial amounts of contract support is being furnished with non-contract funds."

It is believed that the instances of the use of contract personnel in non-contract research is minimal. It should also be noted that there are personnel paid from non-contract funds who provide support to the contract. It is believed that more definitive tests and reviews than have been conducted to date need to be completed before statements or allegations speculating on the amount of each are made. Any corrective action noted by such review will be taken.

Eppler administration diligently attempts to insure that all support services are utilized in conformity with contractual commitments. This effort is complicated by the fact that many investigators use these services and, occasionally, errors are made. The error cited by GAO (p. 49) in allocation of histology costs arose because of an erroneous request for services by a single investigator. New procedures have been instituted in the Histology and Photography Units to require all investigators to include a project or account number on all requests for services. Non-contract projects will be charged for services and these charges will be credited to the contract. Monthly animal inventories, breeding and delivery records are now being maintained by the Associate Director's office to insure that animal costs are allocated properly. The report indicates that the Photography Unit performed work for non-contract projects (p. 50). There is no indication that the 26 requests cited were not for contract projects. It is not necessary that an employee be engaged solely in NCI contract research in order for the request to be proper. Therefore, the test applied by GAO is invalid.

Another charge to the contract said to be improper is that for animals. Oral government approval was obtained for others to use excess animals, which would otherwise have been destroyed, without charge.

There is a practical problem in strictly segregating the personnel, equipment and facilities which are used for NCI work from those used for other research. It is neither effective nor efficient to have duplicate sets of resources reserved exclusively for each. Eppley is discussing this problem with NCI and working towards its solution.

Every reasonable effort is being made to insure that the government receives maximum value for the funds spent at Eppley. The most important contractual commitment, high quality research, has been performed diligently and within budget estimates. In fact, Eppley has returned to the government unexpended funds totaling \$356,000 during the contract period.

Equipment Accounting

Concerning the control of government equipment, the University of Nebraska Medical Center (UNMC) established in 1972 an inventory control section, developed a computerized inventory control program, and initiated a system whereby equipment is inventoried annually with listings cross-verified to monthly financial reports.

During inventories, the Inventory Control Department cannot always identify and locate all of the equipment, due to the nature of some of the scientific equipment. Any differences that occur are transmitted to the department and a follow-up visit by the manager of Inventory Control, along with a department representative, is made to reconcile differences. The list mentioned in the report was obtained before any reconciliation had occurred. This list had not been forwarded to the department nor had the follow-up by Inventory Control taken place. Upon such subsequent investigation, of the 36 items costing \$52,477 included on a list provided by the GAO auditors to the Eppley Contract Administrator, thirty items costing \$50,377 have been reconciled.

It is Eppley's policy that government-furnished property be used only for performance of contract research, in conformity with federal regulations. A contractual technicality has resulted in some confusion in implementing this policy. The contract general provisions recognize two classes of property: government-furnished property, and property acquired by the contractor, the cost of which is reimbursed by the government. All equipment purchased between 1968 and 1976 is in the second category and occasional usage for non-contract purposes does not require prior approval of the Contract Officer. Equipment transferred to Eppley from the Chicago Medical School in 1968 was originally in this second category, but was reclassified as government-furnished property when it was transferred. UNMC was unaware of this reclassification until it was brought to our attention by GAO auditors. Eppley will request approval for any occasional non-contract usage in the future.

The example of usage of the mass spectrometer for work for departments on the University of Nebraska-Lincoln campus cited by GAO (p. 53) is a special case. The Chemistry Department on the Lincoln campus operates a mass spectrometry laboratory which provides services to all components of the University. The government-furnished spectrometer at Eppley was used on the few occasions cited in the report when the Chemistry Department instrument was not operational. Eppley

provided the service as a professional courtesy because the Lincoln facility is available for contract use in similar situations. Other instruments on the Lincoln campus, including a nuclear magnetic resonance spectrometer, have been used for NCI contract research with no charge to the government. Eppley is working with NCI to obtain approval for such professional courtesy usage and for occasional compensated service to other groups.

Continued efforts will be made to improve and upgrade the inventory reporting as refinements can be made.

To allocate the cost of supplies used on other grants or contracts, procedures have been modified so that the storage area used for solvents is now locked and solvents are issued by requisition only (p. 62). The past procedure of allowing staff members to take solvents as needed and record their own usage on forms provided for that purpose has been discontinued. The old procedure was employed for convenience since the solvent storage area, a recently added fire-proof room, is located on the sixth floor and the main stockroom is in the basement. Both areas are maintained by one clerk. Eppley now uses sequential numbering of requisition forms to insure that all forms are accounted for.

Personnel Accounting

UNMC instituted a new time certification procedure for professional staff in January, 1977, after several months of drafts and reviews with the Department of Health, Education and Welfare ("HEW") in order to comply with HEW requirements. Time spent on research is now certified by individual investigators or supervisors in accordance with these revised procedures.

The flexibility to utilize available personnel in performance of research is an important management requirement. Personnel have been assigned to projects and transferred between projects, based on the judgment of the Project Director, to insure efficient utilization of staff in accomplishing the research objectives. Personnel requirements often change during the course of research as new problems occur or change in emphasis is required to exploit new findings. The Project Director must have the authority to respond rapidly to these changes and utilize available personnel in positions for which they are qualified.

The automated leave accounting system provides leave balance information on approximately 4,000 full-time employees of the Medical Center. The employees are distributed over approximately 130 departments which are grouped into 9 units.

Due to some difficulties in the past, the leave accounting system was undergoing some revisions at the time of this audit. Improvements that have been incorporated include:

1. Biweekly employees will no longer be required to turn in absence reports. This information will come directly from respective time cards.
2. All monthly employees will be required to turn in absence reports to the Personnel Records Office no later than one day after they return to work. Supervisors and Administrators will be responsible for enforcing this for their employees.

3. The frequency of reports has increased from 1 a month to every 2 weeks.
4. The format of the reports has been altered to improve readability and usage.

The Medical Center is optimistic that the preceding improvements will enhance the reliability of the system and eliminate discrepancies such as those mentioned in the report.

Results of Research

The report questions whether the significance of project results is adequately measured (p. 41). Eppley agrees with NCI officials that much research has a generally intangible value. However, in the carcinogenesis area covered by the Eppley contract, the volume of work of intangible value is considerably less than in areas in which basic science is being considered. The variable in work concerned with chemically induced cancer is the time from the first discovery in an area to its use in the prevention of human cancer. It is regrettable that the contract highlights document did not make this apparent to the auditors; the document was written in concededly scientific terms for the NCI Project Officer. A few examples of the level of practical application are:

Highlight Document II 6a) ii) records the inhibitory effect of ascorbate on the interaction of nitrite and secondary or tertiary amines and amides to form N-nitroso compounds, many of which are potent carcinogens. Eppley's observations were now applied by members of the meat industry to reduce public exposure to these carcinogens as far as possible without forgoing the anti-bacterial protection afforded by nitrite against acutely and lethally toxic microbes such as C. botulinum.

Highlight Document II 1 a) -d): Eppley test results are reported through the NCI Project Officer to the Bureau of Drugs and, where appropriate, to the World Health Organization. Eppley has been informed that the demonstration that the anti-schistosomal drug niridazole is a potent animal carcinogen has already led to its abandonment in the treatment of schistosomal disease in Egypt, where large numbers of human patients were previously receiving appreciable levels of this drug. Eppley anticipates that the results will prevent the Puerto Rican population, some of whom carry schistosomal disease, from being treated with this carcinogenic drug.

Highlight Document II 5: In the case of model systems such as those developed at Eppley for cancer of the pancreas, peripheral nervous system tumors, respiratory cancer and esophageal cancer, the impact on human health is less direct and consequently more delayed. These systems provide: (1) models for testing potential carcinogens against a specific tissue, as has been amply demonstrated with the respiratory cancer model; and (2) systems for elucidation of factors modifying the development of the disease.

Another way to assess the value of a scientific discovery is to quantify the level of scientific effort which the discovery has generated. Eppley's work on the nitrosation of amines and amides combined with the inhibitory effect of ascorbic acid, and the discovery and development of a model for pancreatic cancer, both rate high by this method of assessment.

Results of research conducted by Eppley have been thoroughly reviewed by competent scientific authority. The assessment of the quality and value of a particular piece of scientific research requires a high level of scientific understanding if the conclusions are to be meaningful.

A traditional measure of the extent of one's contribution to scientific knowledge is the number of scholarly articles which one's research has generated. "The Carcinogenesis Program, Fiscal Year 1976 (Division of Cancer Cause and Prevention, NCI)," the most recent document in which scientific publications are listed for intramural and contract programs, states that Eppley was in fiscal year 1976 responsible for 86 of 536 publications (16%) in the contract area. The total carcinogenesis budget for fiscal year 1976 was stated to be \$42,469,000, of which Eppley was awarded \$2,741,284 (6.46%), which suggests that, on the basis of peer-reviewed publications, Eppley's contribution is well above the average of other contractors. The corresponding percentages for 1973, the first year of the current contract, were 28% of publications compared to 9.2% of the collaborative research funds.

General Comments

Most of the comments contained in the proposed GAO report concern Eppley's reporting, accounting, and control measures in administering the contract. Several of these have been acknowledged as valid and in most cases, steps have already been taken to correct the problems. We are appreciative of the GAO recommendations.

Eppley and NCI must weigh the value of new extensive allocation and accounting procedures against the benefits to be gained. It has never been the purpose of Eppley to construct a rigid bureaucracy. Our task is to conduct research into the causes and prevention of cancer.

Another consideration is that unduly strict monitoring of research is not conducive to effective scientific investigations. These inquiries should not be limited by cost-ineffective administrative requirements, well intentioned though they may be. Buying research is quite different than buying a desk, a building or even a new warplane.

Finally, the extent of the problems which the GAO has discovered should be considered. The fact is that the propriety of only a small percentage of the total expenditures of the Eppley contract is questioned. It is hoped that the final report will reflect that condition.

GAO note: The page numbers cited refer to a draft of this report and do not correspond to the page numbers in the final report.

PRINCIPAL HEW OFFICIALS RESPONSIBLE
FOR ADMINISTERING ACTIVITIES
DISCUSSED IN THIS REPORT

	<u>Tenure of Office</u>	
	<u>From</u>	<u>To</u>
SECRETARY OF HEW:		
Joseph A. Califano, Jr.	Jan. 1977	Present
David Mathews	Aug. 1975	Jan. 1977
Casper W. Weinburger	Feb. 1973	Aug. 1975
ASSISTANT SECRETARY FOR HEALTH:		
Julius Richmond	July 1977	Present
James F. Dickson III (acting)	Jan. 1977	July 1977
Theodore Cooper (note a)	Feb. 1975	Jan. 1977
Charles C. Edwards	Mar. 1973	Feb. 1975
DIRECTOR, NATIONAL INSTITUTES OF HEALTH:		
Donald S. Fredrickson	July 1975	Present
Ronald W. Lamont-Havers (acting)	Jan. 1975	July 1975
Robert S. Stone	May 1973	Jan. 1975
DIRECTOR, NATIONAL CANCER INSTITUTE:		
Arthur C. Upton	July 1977	Present
Guy R. Newell, Jr. (acting)	Nov. 1976	July 1977
Frank J. Rauscher, Jr.	May 1972	Nov. 1976

a/ Acting Assistant Secretary of Health from Feb. 1975 to May 1975.