



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

April 7, 1975

Refer to RFP No: NO1-CN-55212-03

Title: Implementation and Assessment of a Demonstration
Cancer Control Detection and Prevention Program in
a Cohort of Industrial Workers

Attn: Carlo Tamburro, M.D.
Associate Professor

Gentlemen:

You are invited to submit a proposal in accordance with the requirements of this Request for Proposal (RFP):

Your proposal shall be submitted in two (2) separate documents: The first, the Technical Proposal, shall contain no cost information: Proposed manpower levels, equipment needs, travel requirements, however, may be identified in the technical proposal provided associated dollar amounts are not included: The second, the Business Proposal, shall include all information relative to costs and pricing: Fifteen (15) copies of your Technical Proposal and Four (4) copies of your Business Proposal, including an original of each, shall be submitted:

No legal liability on the part of the Government for payment of any money shall arise unless and until funds are made available to the Contracting Officer for this procurement and notice of such availability, to be confirmed in writing by the Contracting Officer is given to the Contractor:

Copies of your proposal must be received by the close of business, 5:00 P.M. local time at the place designated for receipt of offers, on
Your outside envelope should be marked with the RFP number shown above:
Proposals should be mailed to the Contracting Officer, National Cancer Institute, Research Contracts Branch, Blair Building, Room 201, Bethesda, Maryland 20014:

NOTE — Any proposals which are being hand carried by either the proposer or his agent should be delivered directly to the Contracting Officer, Blair Building, Room 201, 8300 Colesville Road, Silver Spring, Maryland:

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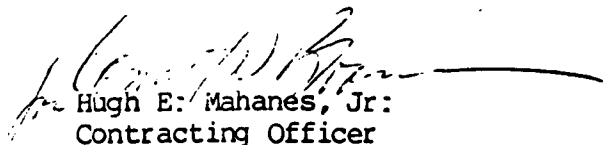
Special attention is directed to the "Certification of Nonsegregated Facilities" of this solicitation: You are cautioned that failure to agree to the certification shall render your proposal nonresponsive to solicitations involving awards of contracts exceeding \$10,000 which are not exempt from the provisions of the equal opportunity clause:

Your proposal must be prepared in accordance with the attached instructions:

The RFP does not commit the Government to pay any cost for the preparation and submission of a proposal: It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with this proposed procurement:

Requests for any information concerning this RFP should be referred only to Mr: Donald W: Broome, Contract Specialist, who may be called on Area Code: 301/427-7984: (Collect calls will not be accepted:)

Sincerely yours.


Hugh E: Mahanes, Jr:
Contracting Officer
Research Contracts Branch
National Cancer Institute

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EXHIBIT A
STATEMENT OF WORK
IMPLEMENTATION AND ASSESSMENT OF A DEMONSTRATION
CANCER CONTROL DETECTION AND PREVENTION PROGRAM IN A COHORT OF
INDUSTRIAL WORKERS

BACKGROUND AND OBJECTIVES

The National Cancer Institute's Division of Cancer Control and Rehabilitation (DCCR) was established to develop and implement a coordinated national effort to reduce cancer incidence, morbidity and mortality. The program helps ensure that existing knowledge about cancer is disseminated and applied as rapidly and effectively as possible. DCCR provides for demonstrations to the medical community of preventive, diagnostic, and therapeutic measures now ready for general application, and improved methods of cancer rehabilitation. DCCR supports studies to develop more effective ways to expedite the diffusion of new knowledge, skills, and technology in an effort to prevent cancer, relieve its effects, and improve the quality of life for its victims.

The purpose of this contract is the implementation and assessment of a medical surveillance cancer control program including a data bank for early detection and prevention education of vinyl chloride induced cancer in a cohort of Louisville, Kentucky, VC/PVC workers. The project would be of a demonstration nature and provide a model for utilization at other VC/PVC facilities in this country and throughout the world.

TASK I - MEDICAL SURVEILLANCE PROGRAM

The contractor shall develop and implement a medical surveillance program which will cover a cohort of vinyl chloride/polyvinyl chloride workers from the B.F. Goodrich plant in Louisville, Kentucky. Provisions will be made so that the workers will be brought into the clinic for a medical examination at appropriate intervals which will provide a continuous medical surveillance of the groups who are at high and varying risk to cancer.

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The contractor shall identify and conduct a series of commonly used laboratory tests on all of the workers for the detection of neoplastic disease of the liver. In addition to tests for liver cancer, other tests, as deemed appropriate by the contractor and the Government may be used for the detection of malignancies or pre-cancerous lesions in other organs of the body. The tests for screening and detection will be funded in this contract. Work for the research and development of tests will not be funded on this contract.

In those cases where a pre-cancerous lesion or a malignancy is found; a built-in recall system must be in operation which will enable the worker to be recalled for further tests. At this time, a definitive diagnosis and pre-treatment evaluation should, if possible, be made. If a diagnosis cannot be made, the worker will be followed at appropriate intervals designated by the physician.

The contractor shall develop an appropriate statistical/data bank for the data generated by the medical surveillance program. Appropriate data forms for background information on the worker, including his physical examinations and results from his laboratory tests are to be provided. The data bank should be managed by a epidemiologist and/or bio-statistician, who will perform the analyses, evaluations and assessment of the program. From these analyses, changes in the detection program might well be warranted. For example, those at high risk might be examined on a quarterly or semi-annual basis, while those at low risk might be examined less frequently. Identification of high risk groups would also allow a manageable detection program to be undertaken for former employees. This should be a segment of the medical surveillance program.

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TASK II - TREATMENT

A treatment program which covers such areas as surgery, chemotherapy radiation and combined modalities shall be reviewed and treatment protocols developed, however, costs of the treatment and continuing care of the patients will not be funded by this contract. The conduct of a clinical trail for the treatment of proven cases of angiosarcoma will not be considered in this particular proposal. Any data collected from Task I may be used in the treatment section as deemed useful for the conduct of this portion of the program.

TASK III - PREVENTIONA. Worker Education Program

The contractor shall devise an education program to include 1200 vinyl chloride workers and the families of the workers, which will also include a professional education component. It may also include the ex-workers and families. In an effort to keep the workers and their families fully informed as to the benefits of participation in the surveillance protocol, a program must be developed that will include a combination of informational meetings, printed material, periodic updates, etc. An individual who will be responsible for the full development and conduct of this associated education program must be hired. This individual will design a program built around the objective: To decrease the mortality, morbidity, and disability associated with chemical exposure, via an education program designed to help the workers and their families achieve, as complete as possible, an understanding of the vinyl chloride angiosarcoma liver disease problem. The evaluation of this education program must be developed and submitted with the proposal.

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The contractor shall also develop a program for current vinyl chloride workers which will provide, as adjunctive to the NCI funded medical surveillance program, the physical and psychological restoration necessary to return those workers with cancer to early optimal functioning. A rehabilitation program shall be provided for those found to have cancer.

B. Professional Education Program

A seminar must be conducted at the University's Health Sciences Center on the topic of Chemical Exposure Associated Liver Disease at which the latest information on detection, diagnosis, treatment, and prevention of vinyl chloride associated cancer will be illuminated. The meeting will be open to the public, and the proceedings will be published in a format acceptable to the contractor and made available for public distribution.

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7. The contractor will obtain informed consent.

Full information will be given to the subjects. Some elements of such information might be: source of hazard; estimates of hazard; estimates of success or improvement due to intervention; degree of confidence of contractor in his information and estimates; possible damage due to intervention; anticipated side effects of intervention process (disruption, time required, special behaviors required, etc.); possibilities of amended interventive procedures.

8. Contractor will give pretests to determine how well the subjects understand the program and reasons for it; and must carry out measures to make sure that subjects do understand, if it is determined that they were not fully aware at first communication.

9. Contractor will give continuing information to the subjects as program proceeds and as contractor learns about new facets of the problem.

10. Contractor will give feedback to subjects when he has been able to establish how effective the procedures were.

11. Contractor will give full information to subject's physician unless subject forbids it.

12. Subject's understanding and wishes will be carefully recorded.

13. The costs for the definitive diagnosis and pre-treatment evaluation if done in a hospital will not be funded in this contract.

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14. Contractor shall enter into a contract with the contractor for the collection, processing, submission, and analysis of data required for the program as described. Costs for collection, processing, and analysis of other personal, demographic, or medical data not specified in the program must be borne by the contractor and are not chargeable to the contract.
15. The contractor must make full use of private groups and other resources in effectively reaching the target group. Groups with legitimate interests would include scientific and professional societies and organizations, voluntary organizations, organizations representing populations at risk, especially labor unions, business organizations whose employees or customers may be included in at-risk populations, the press, other media, and those concerned with health care programs.
16. Open publication of scientifically-relevant results is encouraged, with due regard for the protection of the privacy of subjects.
17. The contractor will insure that there is adequate treatment (at no cost to contract) and follow up of each patient found to have a malignant lesion.

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