DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date MAR 5 1992

From Richard P. Kusserow
Inspector General

Subject Review of National Heart, Lung, and Blood Institute Contract for Development of an Artificial Lung (A-15-92-00003)

To James 0. Mason, M.D., Dr. P.H.
Assistant Secretary for Health

The attached final report provides you with the results of our review of the National Heart, Lung, and Blood Institute process for awarding a contract for development of an artificial lung. Our review was performed in response to concerns by Congressman Fortney H. Stark that the contract was awarded based on factors other than scientific merit, that there was a questionable, last minute change in the selection process, and that the integrity of the procurement process was in question since the awardee appeared to have been pre-selected.

We found no evidence to indicate that the award was made based upon factors other than an independent evaluation of technical merit, or that the contractor was pre-selected. Also, there was nothing to indicate a last minute change in selection of the contractor. It appears that one unsuccessful offeror misunderstood a routine request for information from the Department of Labor as an indication they had been selected for the contract. In addition, we reviewed the significant internal controls related to this contract award and found those controls to be adequate and operating as designed.

We have provided Congressman Fortney H. Stark with a copy of this report. Should you wish to discuss this review, please contact me or your staff may call Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at (301) 443-3583.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE AWARD OF A NATIONAL HEART, LUNG, AND BLOOD INSTITUTE CONTRACT FOR DEVELOPMENT OF AN ARTIFICIAL LUNG

Richard P. Kusserow
INSPECTOR GENERAL

A-15-92-00003

Memorandum

Date MAR 5 1992

From Richard P. Kusserow
Inspector General

Subject Review of National Heart, Lung, and Blood Institute Contract for Development of an Artificial Lung (A-15-92-00003)

To James 0. Mason, M.D., Dr. P.H.
Assistant Secretary for Health

This final audit report provides you with the results of our review of the National Institute's of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI) process for awarding a contract for development of an artificial lung. Our review was requested by Congressman Fortney H. Stark on October 7, 1991, after one unsuccessful offeror expressed concerns that the contract was awarded on factors other than scientific merit.

Congressman Stark asked us to evaluate this contract award to determine if: (1) the selection was based upon scientific merit: (2) the recipient of the contract had been pre-selected: (3) there was a questionable, last minute change in the selection process: and (4) significant controls within the NIH are adequate to ensure the integrity of the research and development contract selection process.

We found no evidence that the NHLBI contract was awarded based on factors other than technical merit, or that the contractor was pre-selected. Furthermore, we could find nothing to substantiate one offeror's claim that there was a last minute change in the selection of the contractor. It appears that the unsuccessful applicant had misunderstood a routine request for information from the Department of Labor (DOL) as an indication that they had been selected for the contract. Also, we found that internal controls at the NHLBI contracts office related to this research and development contract appear to be adequate, and operating as designed.

BACKGROUND

Public Law 101-517, dated July 12, 1990, directed the NIH to expand research for the development of an artificial lung as an aid for patients with temporary respiratory problems or those awaiting lung transplants. The House Committee on Appropriations provided $2.5 million for this contract. On September 30, 1991, NIH's NHLBI awarded a $1.9 million 4-year contract to the Milton S. Hershey Medical Center,

Pennsylvania State University, located in Hershey, Pennsylvania, to perform research leading to the development of an artificial lung for eventual implantation in pediatric or adult patients with acute or chronic respiratory failure.

The University of Pennsylvania currently has a research facility for the study of artificial lung development. According to the NHLBI, the current research team is comprised of *'outstanding investigators who are experienced in all the areas required for development and testing of an artificial lung."

OBJECTIVES, SCOPE AND METHODOLOGY

We were asked to determine if the contract was awarded on scientific merit and not on the basis of other factors. Further, our objective included evaluating whether there were any indications that the offeror was pre-selected, and if the DOL affirmative action team had notified one of the unsuccessful offerors' that they had been awarded the contract. Our review included an examination of the NHLBI's Request for Proposal (RFP), contract, proposal evaluations, regulations, and significant internal controls within the NHLBI contracts office related to this award.

Our review was conducted in accordance with generally accepted Government auditing standards. The review was conducted during November 1991, at NHLBI offices in Bethesda, Maryland. We did not perform an evaluation of the sufficiency of technical criteria contained in the RFP or technical responses of each proposal.

DESCRIPTION OF SELECTION PROCESS FOR THIS CONTRACT

In accordance with Federal Acquisition Regulation (FAR) 15.605, dated October 1990, and the NHLBI Research Contracting Policies and Procedures, the NHLBI's RFP, issued on January 24, 1991, stated that the technical proposals received in response to the RFP would receive paramount consideration in the selection of the contractor(s) for this procurement. The RFP contained a statement of work identifying the requirements, and a technical evaluation criteria section with valuations or "weighting factors" for each criteria being evaluated. The primary objective, according to the statement of work, required the successful applicant to:

> "perform research to develop an artificial lung or improve upon an existing artificial lung for eventual implantation in pediatric or adult patients with acute or chronic respiratory failure."

Eight letters of intent were received by the NHLBI when the RFP was advertised in the Commerce Business Daily [1]. Of these, seven proposals were forwarded to the Special Review Committee convened by the NHLBI for analysis. The committee members found that six of these met the RFP requirements. This committee, included eight respiratory and lung specialists independent of both the NHLBI and the offerors. They evaluated the technical strengths and weaknesses of each of the proposals considering the objectives and technical requirements stated in the RFP. These evaluations and scores, used to develop the competitive range, were required by regulations and NHLBI policies and procedures to be supported by sufficient facts to substantiate the committee's ratings. Committee ratings and justifications were then reviewed by the NHLBI Contracts Branch and Division of Lung Diseases for accuracy, and evaluated to eliminate those proposals with significant deficiencies. Three offerors were determined to be in the competitive range who had a reasonable chance of being selected for award based upon the relative scores of proposals.

In accordance with FAR 15.610, and Health and Human Services Acquisition Regulation (HHSAR) 315.610, the NHLBI then conducted written and oral negotiations with the three offerors in the competitive range. During these discussions, each offeror was advised of any deficiencies in their proposal, and provided the opportunity to support, clarify, and adjust the price, to improve their proposal.

The NHLBI contracting officer, concurrent with negotiations, and pursuant to FAR 22.8, contacted the DOL and obtained pre-award Equal Employment Opportunity (EEO) clearance for all offerors whose proposals were included in the competitive range. This clearance is required as a condition of contract award, but does not constitute notification of contract award.
At the conclusion of the negotiations, all offerors in the competitive range were given the opportunity to submit a written best and final offer. Upon receipt, the NHLBI made its final evaluation of the best and final offer and proceeded to make an award. This final evaluation, contained in the selection documentation and approved by NIH officials, identified which proposal offered the greatest advantage to the Federal Government, when considering technical content as well as price and other factors.

'The Commerce Business Daily is a daily publication distributed by the Department of Congress to subscribers, synopsizing acquisition opportunities.

Prior to making an actual award, and in accordance with HHSAR section 304.71, proposed contracts prepared by NIH institutes such as the NHLBI that exceed $1 million, must be reviewed by the NIH Board of Contract Awards. These reviews are conducted to ensure that the award conforms to applicable regulations, and NIH policies and procedures.

CONTRACT AWARD BY NHLBI

We did not find any evidence to indicate the contract was awarded on a basis other than technical merit. According to NHLBI officials, the successful offeror, "proposed the device with the greatest advance over current technology and the highest likelihood of success."

According to the NHLBI's Special Review Committee, technical strengths and weaknesses were identified for each of the proposals, and each proposal was ranked in terms of ability to complete the objective. As noted earlier, there were three offerors determined to be in the competitive range. The committee reported having significant concerns with the two proposals in the competitive range that were not selected. Moreover, during both the negotiation and best and final offer stages of the award process, adequate responses to these concerns were not provided by the two offerors.

Further, the NHLBI contracts office indicated that neither formal protests or legal actions have been filed regarding this contract process, or award.

PRE-AWARD NOTIFICATION

With respect to pre-award notification, it appears that one offeror not awarded the contract, misunderstood the DOL request for pre-award EEO clearance documents (required as a condition of contract award) as an indication of contract award. Representatives of that offeror indicated they had been led to believe they were to receive an award based on information provided to them at a Department of Health and Human Services sponsored workshop on contracting. In the post-award debriefing, the NHLBI explained to the offeror that EEO clearance is required as a condition of contract award, but does not indicate that an award has been made. Such clearance was requested for all offerors whose proposals were included in the competitive range.

PRE-SELECTION OF CONTRACT AWARD

We could find no documentation supporting the allegation that the successful offeror was pre-selected. All proposals were submitted in accordance with RFP deadlines, and received an independent technical review during the May 1991 meeting of the

Special Review Committee. The final selection was not made until the entire selection process was completed and the NHLBI's selection was approved by NIH's Board of Contract Award.

INTERNAL CONTROLS OVER CONTRACTING

We found significant internal controls within NIH were operating properly to provide assurance that the selection was made objectively. Independent technical evaluations were performed and documented, and all offerors in the competitive range were furnished the opportunity to provide additional technical and pricing data in support of their position.
Further, the NIH Board of Contract Awards reviewed the entire process to assure compliance with all regulatory requirements.

CONCLUSIONS

This award appears to have been made properly and in accordance with applicable regulations and the requirements set forth in the RFP. Ratings were supported by the NHLBI's Special Review Committee's evaluations of the strengths and weaknesses of each proposal, and their conclusions regarding which device offered the greatest advances over current technology.

We have provided Congressman Fortney H. Stark with a copy of this report. Should you wish to discuss our review, please contact me or your staff may call Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at (301) 443-3583.