PD-ABA-389

A.I.D. EVALUATION SUMMARY – PART I

1. BEFORE FILLING OUT THIS FORM, READ THE ATTACHED INSTRUCTIONS.
2. USE LETTER QUALITY TYPE, NOT "DOT MATRIX" TYPE.

IDENTIFICATION DATA

A. Reporting A.I.D. Unit:
Mission or AID/W Office: AID/W S&T/Health
(ES# _____)

B. Was Evaluation Scheduled in Current FY Annual Evaluation Plan?
Yes [X] Slipped [ ] Ad Hoc [ ]
Evaluation Plan Submission Date: FY 89 Q 2

C. Evaluation Timing
Interim [X] Final [ ]
Ex Post [ ] Other [ ]

D. Activity or Activities Evaluated (List the following information for project(s) or program(s) evaluated; if not applicable, list title and date of the evaluation report.)

Project No.	Project /Program Title	First PROAG or Equivalent (FY)	Most Recent PACD (Mo/Yr)	Planned LOP Cost (000)	Amount Obligated to Date (000)
931-0453	Malaria Immunity and Vaccine Research	4-86	4-90	11,808	

ACTIONS

E. Action Decisions Approved By Mission or AID/W Office Director

Action(s) Required	Name of Officer Responsible for Action	Date Action to be Completed
1. Clarify division of responsibilities between A.I.D. and contractor.	C. Diggs	3 Sept 89
2. Revise contract with AIBS to reflect present scope of work.	J. Austin	30 Sept 89
3. Preparation of position descriptions for AIBS personnel.	C. Diggs	30 Sept 89
4. Establish scientific consultant groups to assist A.I.D. with program decisions.	C. Diggs	30 Sept 89
5. Clarify roles of advisory committees to project.	C. Diggs	30 Sept 89
6. Investigate alternative methods to contract management.	C. Diggs	30 Mar 90

(Attach extra sheet if necessary)

APPROVALS

F. Date Of Mission Or AID/W Office Review Of Evaluation: (Month) 02 (Day) 15-28 (Year) 1989

G. Approvals of Evaluation Summary And Action Decisions:

	Project/Program Officer	Representative of Borrower/Grantee	Evaluation Officer	Mission or AID/W Office Director
Name (Typed)	Carter Diggs	Charles M. Chambers	Genease Pettigrew	Dr. Kenneth Bart
Signature	Carter Diggs	Charles M Chambers	Genease L. Pettigrew	Ken Bart
Date	21 July 89	27 July 1989	7/31/89	August 1 1989

ABSTRACT

H. Evaluation Abstract (Do not exceed the space provided)

For nearly 40 years A.I.D. has funded programs to reduce the impact of the world's foremost tropical disease-malaria. During the first decades these were mainly field programs to reduce the prevalence of disease through the use of insecticides against the vector mosquitoes. The objective during much of that period was to eradicate malaria. The failure of eradication efforts resulted in a shift of funds from vector control measures to a search for new methods of malaria control, and from field programs to laboratory research for a vaccine.

During two decades of research the A.I.D. effort to produce a malaria vaccine has grown from a few projects into a network of related grants, agreements and contracts. In excess of $75 million has now been expended on malaria immunity and vaccine research, more than half of it in the past four years. As the effort has multiplied and the complexity of the scientific issues has become more apparent so has the difficulty of effective direction and coordination of the multiple projects in the network.

The AIBS contributions to the malaria research network are many, but the activities defined in the Scope of Work of the present contract are no longer valid. These activities were changed by circumstances during a period of extreme difficulty, when the efforts of the contractor helped keep the network functioning. Site visits and evaluations of individual projects within the network have been carried out. AIBS organization of meetings and conferences has been effective. The consultant roster has become an effective tool for developing panels to review proposals; for arranging site visit teams, and for evaluating proposals for the use of non-human primates.

Generally AIBS has, whenever possible, adhered to its obligations to A.I.D. as defined in the contract. Both A.I.D. and AIBS made managerial adjustments in 1987; AIBS appointed an experienced Project Director (PD) soon after the A.I.D. CTO left. Thus, during much of the period when A.I.D. had a temporary, acting CTO (April 1987 - September 1988), AIBS was able to assume greater responsibility for technical support of the network. All necessary tasks were performed and primary goals have been reached by A.I.D., AIBS and the members of the network-an indication of the strength of the effort and the commitment of all parties. But there are difficulties within the network, many of which are due to the fact that scientific progress toward a vaccine has been slower than anticipated.

COSTS

I. Evaluation Costs

1. Evaluation Team

Name	Affiliation	Contract Number OR TDY Person Days	Contract Cost OR TDY Cost (U.S. $)	Source of Funds
Robert Scholtens	Management Sciences for Health CMSH	22	$9350.00	A.I.D.
Donald Knogstad	MSH	11.31	$4908.54	A.I.D.
Donald Luchsinger	A.I.D.	6		
Stephen Sacca	MSH	5.4	$2343.60	A.I.D.
McWilson Warren	CDC	App. 6	-0-	PHS
David Sensor	MSH	App. 3	-0-	MSH

2. Mission/Office Professional Staff Person-Days (Estimate) 10

3. Borrower/Grantee Professional Staff Person-Days (Estimate) 10

10

A.I.D. EVALUATION SUMMARY - PART II

SUMMARY

J. Summary of Evaluation Findings, Conclusions and Recommendations (Try not to exceed the three (3) pages provided)
Address the following items:

- Purpose of evaluation and methodology used
- Purpose of activity(ies) evaluated
- Findings and conclusions (relate to questio 4)
- Principal recommendations
- Lessons learned

Mission or Office:	Date This Summary Prepared:	Title And Date Of Full Evaluation Report:
S&T/Health	5-25-89	An evaluation:Coordination of Malaria Immunity and Vaccine Research

PURPOSE OF EVALUATION AND METHODOLOGY USED

This is not a total evaluation of AIBS activities and performance since the start of the contract in October 1985. Attention was focused on performance by AIBS since April 1987, and management, communications, collaboration, coordination and working relationships between A.I.D./S&T/H and AIBS were evaluated. Since these issues constitute management of the network of malaria vaccine research projects, a special effort to assess the effect of management methods on network productivity was made. Therefore the team was drawn into some complex management, performance and policy issues which were difficult to treat completely in the time available. The team interviewed AIBS and A.I.D. staff in the Washington, D.C. area and conducted telephone interviews of the Principal Investigators responsible for the other contracts in the project.

PURPOSE OF ACTIVITY EVALUATED

The malaria vaccine research network now consists of a loosely knit group of research and support agreements and contracts. There are six laboratories working on the identification and characterization of parasite antigens that may be used as immunizing agents. Another laboratory has begun studies on the host's cellular immune response to malaria infections. The likely immunologic potential of these antigens in humans can be tested in certain types of new world primates which are obtained and maintained by several support institutions, and tested for potential efficacy in another cooperating laboratory. There are, in addition, pathologic support, human volunteer clinical trial and field study projects to assist in understanding the effects of trial immunogens and to allow testing of candidate vaccines in malarious areas. Finally, the A.I.D. CTO responsible for all these contracts is assisted in the coordination and support of the network by a contract for services with the American Institute of Biological Sciences (AIBS).

FINDINGS:

1. The principal finding of this evaluation is that there is considerable confusion over the division of responsibilities in the malaria vaccine research network. It exists in AIBS, among many of the PIs in the network, and in A.I.D.. This may not be surprising, given the management difficulties in recent years and diminishing expectations for early development of a vaccine against malaria. But it is a condition that must be corrected if past gains are to be consolidated and research progress maintained. Our recommendations are all intended to help correct this problem.

2. But the larger concern should be the implementation of improved management methods. The continuous decline of A.I.D.'s operating budget has severely hampered its ability to supervise complex projects such as malaria vaccine research. It is now necessary for the Agency to meet many of its supervisory responsibilities by creative use of its program budget; sometimes by innovative employment of temporary staff, more often by contracting responsibilities. In the malaria project, A.I.D. has tended to rely substantially on temporary staff, retain many management functions, and contract mainly for support services. We find that temporary staff, those who do not have recognizable tenure with A.I.D., are not equivalent in experience or authority to A.I.D. direct-hire staff, which impairs project direction. It is therefore essential that more management responsibility for the malaria project be delegated by agreement.

CONCLUSIONS:

1. The AIBS contributions to the malaria research network are many, but the activities defined in the Scope of Work of the present contract are no longer valid. These activities were changed by circumstances during a period of extreme difficulty, when the efforts of the contractor helped keep the network functioning. Site visits and evaluations of individual projects within the network have been carried out. AIBS organization of meetings and conferences has been effective. The consultant roster has become an effective tool for developing panels to review proposals, for arranging site visit teams, and for evaluating proposals for the use of non-human primates.

2. Generally AIBS has, whenever possible, adhered to its obligations to A.I.D. as defined in the contract. Both A.I.D. and AIBS made managerial adjustments in 1987; AIBS appointed an experienced Project Director (PD) soon after the A.I.D. CTO left. Thus, during much of the period when A.I.D. had a temporary, acting CTO (April 1987 - September 1988), AIBS was able to assume greater responsibility for technical support of the network. All necessary tasks were performed and primary goals have been reached by A.I.D., AIBS and the members of the network - an indication of the strength of the effort and the commitment of all parties. But there are difficulties within the network, many of which due to the fact that scientific progress toward a vaccine has been slower than anticipated.

3. The malaria vaccine project has evolved into a complex network of interrelated and highly technical agreements and contracts. To monitor, understand and direct events has become progressively more difficult. This is now attempted with a mix of A.I.D. and contract technical staff, most of whom are in short-term, non-career positions. This dependence on junior staff was, for most of the time period considered, made more difficult by the prolonged absence of an experienced CTO. Relationship issues between A.I.D. and AIBS must be resolved if the more difficult and important scientific problems confronting the network are to receive appropriate attention.

4. Interviews with Principal Investigators in the network disclosed several concerns: confusion over responsibilities, reservations about the usefulness of site visits by large teams, questionable primate management, and a lack of feedback from progress reports.

PRINCIPAL RECOMMENDATIONS:

1. That the following changes be made: a) re-budgeting in conjuction with revisions in the scope of work and real costs of primates and equipment purchases, b) the level of effort be modified in light of revisions to the scope of work and the budget, c) AIBS prepare detailed position descriptions for all staff, and d) an equipment list be devised using the AIBS inventory list and and estimate of future needs.

2. That immediate scope of work revisions be made based on an assessment of accomplishments to date and what can reasonable expected to continue. Particular attention should be focussed on the assignment of specific responsibilities to AIBS which can be implemented independently of direct A.I.D. technical staff input. The scope of work should also clarify the responsibility and authority which AIBS exercises over the PI contracts implemented by A.I.D.

3. That all A.I.D. and AIBS managerial and technical responsibilities for support of the network be redefined. They must also be assigned in proportion to institutional ability to do the job. This means an ability to employ, support and supervise the necessary staff. A.I.D. should give full authority and responsibility for the malaria project to a permanently assigned CTO.

4. Because of the complex nature of the research, and the difficulty of assessing the rate of progress toward a practical immunological defense against malaria, permanent, independent sources of scientific advice are much needed. The initial steps taken to establish Scientific Consultant Groups are a start; A.I.D. should make these permanent bodies whose members serve fixed terms, that A.I.D. malaria network contract holders be excluded, and that the SCG's meet periodically. Their responsibilities should include defining practical research objectives for the network, determining that the spectrum of network research is comprehensive and the projects complementary, and continuous evaluation of the quality and pertinence of A.I.D. funded research results. Several changes in network management methods should be made: primary evaluation of projects should be by periodic advisory committee review of progress reports rather than site visits, and that necessary site visits employ teams of only 2-3 members addressing narrow, well-defined issues. Funding intervals should be scheduled so that most major projects should run concurrently in order to facilitate changes in the direction of network efforts.

5. The degree of scientific complexity, uncertainty of outcome, and the influence of accumulated vested interests all argue for substantial change in network management. Because of personnel limitations A.I.D. can no longer provide the needed level of day-to-day supervision. A competitively bid contract or cooperative agreement delegating broad management responsibility and authority for directing vaccine development research should replace the AIBS contract on expiry. This should be a short-term, tactical direction toward A.I.D. defined objectives; strategic direction should remain with A.I.D.. Only vaccine development and clinical trial research management should be contracted, and serious consideration should also be given to what separate mechanisms will be needed to supervise overseas field trials.

LESSONS LEARNED:

The principal finding of this evaluation is that there is considerable confusion over the division of responsibilities in the malaria vaccine research network. It exists in AIBS, among many of the PIs in the network, and in A.I.D.. This may not be surprising, given the management difficulties in recent years and diminishing expectations for early development of a vaccine against malaria. But it is a condition that must be corrected if past gains are to be consolidated and research progress maintained. The recommendations are all intended to help correct this problem.

ATTACHMENTS

K. Attachments (List attachments submitted with this Evaluation Summary; always attach copy of full evaluation report, even if one was submitted earlier. attach studies, surveys, etc., from "on-going" evaluation, if relevant to the evaluation report.)

"An Evaluation - USAID Project No. 931-0453.26, Coordination of Malaria Immunity and Vaccine Research", January - February 1989.

Comments by Borrower/Grantee, AIBS, on the full evaluation report.

Transmittal of comments of Borrower/Grantee, AIBS, to Program Officer Carter Diggs with comments of Borrower/Grantee, AIBS, on this Evaluation Summary.

COMMENTS

L. Comments By Mission, AID/W Office and Borrower/Grantee On Full Report

A theme which runs throughout the evaluation is the recommendation that AIBS be given more autonomy. Reference is made to giving AIBS responsibility for "tactical" issues with "strategic" responsibilities remaining within A.I.D.; at the same time it is stated that A.I.D. should have overall "authority and responsibility". The precise meaning of "tactical" vs "strategic" is not defined nor is it explained how AIBS can be autonomous if A.I.D. is to exercise it's responsibility.

Another theme is the desirability of having direct hire "permanent" (i.e., direct hire) A.I.D. staff (including the CTO). The evaluators recognize the reality of the severe constraints on direct hire personnel hiring, so that this latter notion translates into a situation in which only a very small number of people (probably only one, the CTO) would be attempting to manage the program from the A.I.D. Office of Health; i.e., de facto management would be by the management assistance contractor, in this case AIBS.

Although the mindset embracing these themes is in line with current trends in the federal sector imposed by a gross imbalance in dollar vs human resource authorization (as well as by doctrine), this does not automatically make it applicable to all cases. In a program of this size and complexity, the CTO, acting without assistance, could not long remain technically cognizant of a program in which management was contracted out. Abdication of cognizance by the Government of the activities of contractors has the potential for not being in the best interests of the taxpayer, as amply exemplified in the news almost daily.

These themes ignore several important facts:

(1) Since the malaria program is very complex, it is essential that we utilize all of the expertise and talant available to us in formulating courses of action; collectively, A.I.D. and AIBS staff is by no means numerically in excess of the need. AIBS has talented staff members, but not so talented that the A.I.D. CTO never needs to provide guidance to AIBS.

(2) People's effectiveness depend on their talent, training, level of development, and motivation, not on whether they are direct hire, detailed from another agency, or contractor. These categories are independent of "permanence", since an individual from another agency may well stay on station longer than a direct hire, and a contractor may have the greatest longevity of all! What is required is that people with the right mix of capabilities are arrayed in an effective organizational structure, not that they have certain labels associated with the mechanism of their employment.

In spite of these rather major differences in perspective, we feel that many of the teams recommendations are well considered. The AIBS contract, in it's present form, is not descriptive of current needs and must be modified. We also agree that is is necessary to clearly define the roles of A.I.D. and AIBS and of each member of the A.I.D./AIBS team; ie, an organizational development effort is in order. A.I.D. is eager to delegate authority and responsibility to AIBS in an orderly and appropriate manner, and this will be done. However, we believe that continued adequate oversite by A.I.D. is both necessary and appropriate.

Specific actions to be pursued are listed in Part I, section E .

Comments by Borrower/Grantee, AIBS, are attached to this summary

An Evaluation
USAID Project No. 931-0453.26

COORDINATION OF MALARIA IMMUNITY AND VACCINE RESEARCH

January-February 1989

Done By:

Management Sciences for Health
165 Allandale Road
Boston, MA 02130
Contract No. PDC-1406-I-00-7133-00
Delivery Order No. 102
April 27, 1989

TEAM:

Robert Scholtens (Team Leader)
Donald Krogstad
Donald Luchsinger
Stephen Sacca
McWilson Warren

Acknowledgments

We received exceptional cooperation from officials at both AID and AIBS. The helpful attitude at AID was especially important to understanding the intricacies of the malaria research network; without it we would not have attempted such a bold evaluation. During the review we met for group or individual discussions with many people who were invariably kind and helpful. To them we all express our gratitude.

TABLE OF CONTENTS

I. EXECUTIVE SUMMARY

A. AIBS Evaluation: Purpose and Methods

This evaluation of the American Institute of Biological Sciences (AIBS) management-assistance contract, one of fourteen subprojects under the AID Malaria Immunity and Vaccine Research Project, was requested by the Project Cognizant Technical Office (CTO) and the Office of Health, Bureau of Science and Technology, AID. It was performed as agreed in the Scope of Work between AID and Management Sciences for Health (Appendix D) and the Plan of Action submitted to AID on 19 January 1989. The team interviewed AIBS and AID staff in the Washington, D.C. area and conducted telephone interviews of the Principal Investigators responsible for the other sub-contracts in the project (Appendix A).

This is not a total evaluation of AIBS activities and performance since the start of the contract in October 1985. AID officials requested we focus our attention on performance by AIBS since April 1987, and asked that we evaluate management, communications, collaboration, coordination and working relationships between AID/S&T/H and AIBS. Since these issues constitute management of the network of malaria vaccine research projects we made a special effort to assess the effect of management methods on network productivity. We were therefore drawn into some complex management, performance and policy issues which were difficult to treat completely in the time available, but which we have attempted to deal with fairly nonetheless.

B. Findings and Conclusions

1. Scope of AIBS Activities

The AIBS contributions to the malaria research network are many, but the activities defined in the Scope of Work of the present contract are no longer valid. These activities were changed by circumstances during a period of extreme difficulty, when the efforts of the contractor helped keep the network functioning. Site visits and evaluations of individual projects within the network have been carried out. AIBS organization of meetings and conferences has been effective. The consultant roster has become an effective tool for developing panels to review proposals, for arranging site visit teams, and for evaluating proposals for the use of non-human primates.

2. AIBS Management

Generally AIBS has, whenever possible, adhered to its obligations to AID as defined in the contract. Both AID and AIBS made managerial adjustments in 1987; AIBS appointed an experienced Project Director (PD) soon after the AID CTO left. Thus, during much of the period when AID had a temporary, acting CTO (April 1987 - September 1988), AIBS was able to assume greater responsibility for technical support of the network. All necessary tasks were performed and primary goals have been reached by AID, AIBS and the members of the network-an indication of the strength of the effort and the commitment of all parties. But there are difficulties within the network, many of which are due to the fact that scientific progress toward a vaccine has been slower than anticipated.

3. AID-AIBS Relationships

The malaria vaccine project has evolved into a complex network of interrelated and highly technical agreements and contracts. To monitor, understand and direct events has become progressively more difficult. This is now attempted with a mix of AID and contract technical staff, most of whom are in short-term, non-career positions. This dependence on junior staff was, for most of the taime period considered, made more difficult by the prolonged absence of an experienced CTO. Relationship issues between AID and AIBS must be resolved if the more difficult and important scientific problems confronting the network are to receive appropriate attention.

4. Technical Assistance and Direction

As noted, technical assistance to the network has been excellent. But seven scientists at AID and AIBS are now involved in technical matters: the review of project progress reports, the formation of peer reviews, preparation of agendas for technical meetings, and project evaluations. This abundance of staff and the lack of well-defined responsibilities results in confusion and frequent disagreement between junior staff. This requires constant attention and intervention by the CTO and PD.

Interviews with Principal Investigators in the network disclosed several concerns: confusion over responsibilities, reservations about the usefulness of site visits by large teams, questionable primate management, and a lack of feedback from progress reports.

Some also questioned the size of the combined AID-AIBS administrative operations, and all asked for clarification of respective responsibilities.

The malaria vaccine project was initiated with great expectations. AID senior management has often expressed interest and sometimes, because of supervisory changes, been closely involved in its management. Interest escalated as success seemed imminent in the middle of this decade; so did management interventions, necessarily, when project direction was found to be flawed and the CTO replaced.

The recent steps by the AID CTO to establish independent, permanent, technical advisory committees is an important positive step away from the form of project management that has prevailed. When fully implemented these Scientific Consultant Groups (SCG), along with the Primate Use Committee, will greatly strengthened technical support and direction of the malaria research network.

1. Contract Changes

We recommend the following changes: a) re-budgeting in conjunction with revisions in the scope of work and real costs of primates and equipment purchases, b) the level of effort be modified in light of revisions to the scope of work and the budget, c) AIBS prepare detailed position descriptions for all staff, and d) an equipment list be devised using the AIBS inventory list and an estimate of future needs.

2. Scope of Work Changes

We recommend immediate revisions based on an assessment of accomplishments to date and what can reasonably expected to continue. Particular attention should be focussed on the assignment of specific responsibilities to AIBS which can be implemented independently of direct AID technical staff input. The scope of work should also clarify the responsibility and authority which AIBS exercises over the PI contracts implemented by AID.

3. Changes in Working Relationships

We recommend that all AID and AIBS managerial and technical responsibilities for support of the network be redefined. They must also be assigned in proportion to institutional ability to do the job. This means an ability to employ, support and supervise the necessary staff. On a related issue-we recommend that within AID full authority and responsibility for the malaria project again be delegated to a permanently assigned CTO.

Because of the complex nature of the research, and the difficulty of assessing the rate of progress toward a practical immunological defense against malaria, permanent, independent sources of scientific advice are much needed. The initial steps taken to establish Scientific Consultant Groups are a start which we commend; we strongly recommend that these be made permanent bodies whose members serve fixed terms, that AID malaria network contract holders be excluded, and that the SCG's meet periodically. Their responsibilities should include defining practical research objectives for the network, determining that the spectrum of network research is comprehensive and the projects complementary, and continuous evaluation of the quality and pertinence of AID funded research results. We also recommend several changes in network management methods: that primary evaluation of projects be by periodic advisory committee review of progress reports rather than site visits, and that necessary site visits employ teams of only 2-3 members addressing narrow, well-defined issues. It would also be advantageous to arrange funding intervals so that most major projects run concurrently in order to facilitate changes in the direction of network efforts.

4. Continuation of Contract Funding

The degree of scientific complexity, uncertainty of outcome, and the influence of accumulated vested interests all argue for substantial change in network management. Because of personnel limitations AID can no longer provide the needed level of day-to-day supervision. We therefore

recommend that a competitively bid contract or cooperative agreement delegating delegating broad management responsibility and authority for directing vaccine development research replace the AIBS contract on expiry. We emphasize that this be short-term, tactical direction toward AID defined objectives; strategic direction should remain with AID. We also recommend that only vaccine development and clinical trial research management be contracted, and serious consideration should also be given to what separate mechanisms will be needed to supervise overseas field trials.

D. Lessons Learned

The principal finding of this evaluation is that there is considerable confusion over the division of responsibilities in the malaria vaccine research network. It exists in AIBS, among many of the PIs in the network, and in AID. This may not be surprising, given the management difficulties in recent years and diminishing expectations for early development of a vaccine against malaria. But it is a condition that must be corrected if past gains are to be consolidated and research progress maintained. Our recommendations are all intended to help correct this problem.

But the larger concern should be the implementation of improved management methods. The continuous decline of AID's operating budget has severely hampered its ability to supervise complex projects such as malaria vaccine research. It is now necessary for the Agency to meet many of its supervisory responsibilities by creative use of its program budget: sometimes by innovative employment of temporary staff, more often by contracting responsibilities. In the malaria project it has tended tc rely substantially on temporary staff, retain many management functions, and contract mainly for support services. We find that temporary staff, those who do not have recognizable tenure with AID, are not equivalent in experience or authority to AID direct-hire staff, which impairs project direction. It is therefore essential that more management responsibility for the malaria project be delegated by agreement.

Finally, while this is not within our scope of work, we think lthat a full deliverate, evaluation of the current sate of malaria immunology knowledge, the implications of what is known on the development of any vaccine, and recommendations on the size and extent of the AID funded projects in achieving this objective would be in tha Agency's interest. This would be a logical extension of the examination started at the symposia sponsored by AID at the December 1988 meeting of the American Society of Tropical Medicine and Hygiene. AID may wish to enlist WHO as a partner in such a scientific review.

A. Background and Methods

1. AID Malaria Support Programs

For nearly 40 years AID has funded programs to reduce the impact of the world's foremost tropical disease-malaria. During the first decades these were mainly field programs to reduce the prevalence of disease through the use of insecticides against the vector mosquitoes. The objective during much of that period was to eradicate malaria. The failure of eradication efforts resulted in a shift of funds from vector control measures to a search for new methods of malaria control, and from field programs to laboratory research for a vaccine.

During two decades of research the AID effort to produce a malaria vaccine has grown from a few projects into a network of related grants, agreements and contracts. In excess of $75 million has now been expended on malaria immunity and vaccine research, more than half of it in the past four years. As the effort has multiplied and the complexity of the scientific issues has become more apparent so has the difficulty of effective direction and coordination of the multiple projects in the network.

The malaria vaccine research network now consists of a loosely knit group of research and support agreements and contracts. There are six laboratories working on the identification and characterization of parasite antigens that may be used as immunizing agents. Another laboratory has begun studies on the host's cellular immune response to malaria infections. The likely immunologic potential of these antigens in humans can be tested in certain types of new world primates which are obtained and maintained by several support institutions, and tested for potential efficacy in another cooperating laboratory. There are, in addition, pathologic support, human volunteer clinical trial and field study projects to assist in understanding the effects of trial immunogens and to allow testing of candidate vaccines in malarious areas. Finally, the AID CTO responsible for all these contracts is assisted in the coordination and support of the network by a contract for services with the American Institute of Biological Sciences (AIBS). This report is the result of an evaluation of the services provided through that contract. Because of the close, joint efforts of AID and AIBS staff in management of the malaria network this review also covers the nature and effectiveness of the overall relationship between these two groups.

At the outset we would like to emphasize three points:

a. The Role of AID in the Struggle Against Malaria. We feel compelled to commend the agency for its commitment to reduce the impact of malaria - which is an overwhelming problem in the lesser developed countries of the world. The present program exists because AID recognized long ago the lack of technology necessary to control malaria in the developing world. Although the means of interrupting the transmission of malaria on a large scale are still lacking we believe that the role of AID in developing the necessary knowledge represents an important commitment of the U. S. Government over several decades and Administrations which is of inestimable value to the Developing World.

b. Program Difficulties We recognize also that this Program has just been through a very difficult period, accompanied by major changes in personnel at both AID and AIBS. To the credit of both AID and AIBS we believe the program has improved significantly despite these stresses.

c. Goals of this Evaluation. We were told that the broadest goal of this evaluation was to learn how the present process of finding new ways to control malaria could be improved. Because progress is dependent on integration of new information developed both inside and outside the network, we have attempted to understand the overall state of affairs within the network and in the malaria scientific community.

2. History of AIBS Involvement

In 1982 AID let the first contract for management assistance: a three year agreement with AIBS to provide technical support and assist in coordination. Among the assistance provided were network coordination workshops, the establishment of new projects to improve the availability and quality of non-human primates for use in the research, improvements in external evaluations of network projects, property management improvements, and peer review panels for project proposals. In 1984 responsibility for the planning and coordination of all clinical and field trials of new vaccines was added to the technical support provisions of the original contract. An evaluation of the project in late 1984 lauded the contributions of AIBS to the overall effort.

During 1984-1985 the funds supporting the malaria research network were increased and there was considerable optimism that useful vaccines would be available soon for testing. An expansion of the network into clinical and field research was anticipated and it was necessary to expand medical and epidemiological capabilities. This was the prevailing situation when AID negotiated a second contract with AIBS for greatly expanded services in late 1985.

3. Evaluation: Constraints and Methods

The new contract called for AIBS to "make available facilities and personnel to complete a program of design, implementation, evaluation, monitoring, quality-control and cost-effectiveness of malaria immunology programs in AID." Great emphasis was placed on the provision of support for clinical research trials, field trials, vaccine efficacy testing in non-human primates, and the coordination of a program to supply the anticipated large numbers of non-human primates.

The contract was for direct assistance to AID; responsibility was delegated mainly for "liaison and coordination between all interested parties which include AID, network principal investigators and their respective universities or institutions, investigators outside the AID network, FDA, NIH, pharmaceutical companies, CDC, WHO, PAHO, national or international foundations or organizations and Ministries of Health." The contract said that AID would work directly with the contractor monitoring program activities to establish specific direction or redirection of the project, that AIBS would provide reasonable assistance in the review of the overall effectiveness of the project, and that AID was to approve most actions (travel, consultants, staff appointments, equipment purchases, and

details of any meetings arranged). The contract was apparently intended to achieve a working alliance, with strong emphasis on the provision of technical support and coordination.

This second contract was implemented in October of 1985. Although it calls for three evaluations this is the first to be performed. The circumstances surrounding activities and performance between October 1985 and April 1987 were unusual, and because they are under official review are not included in this evaluation. As requested, we focused our attention on what was attempted and accomplished from April 1987 through January 1988, while the AIBS PD was Dr. Phil Winter and the AID CTOs were Dr. James Heiby (April 1987 to September 1988) and Dr. Carter Diggs (since September 1988).

This evaluation was requested by the Office of Health, Bureau of Science and Technology, AID. It was performed as agreed in the Scope of Work between AID and Management Sciences for Health (Appendix D) and the Plan of Action submitted to AID as required by that Scope of Work. The team interviewed AIBS and AID staff in the Washington, D.C. area and conducted telephone interviews of the Principal Investigators responsible for the other sub-contracts in the project (Appendix A). Three of the team members attended planning meetings at AID and AIBS offices on January 11-13. The interviews scheduled by the team leader in mid-January were confirmed and final arrangements made on January 30-31. The entire team met with various AID and AIBS officials and staff in Arlington, VA between February 1-3, 1989. Drafting of sections of the report started on 2 February but most writing was done independently and copy exchanged by mail.

A narrow evaluation of this project was not requested; we were also asked to consider context and make broad recommendations. We therefore examined the long history of AID support for malaria vaccine research, the nature of the AID-AIBS relationship, the untoward events associated with this project between 1985 and 1987 on overall performance, and, most difficult of all, the effect of the joint AID-AIBS management methods on the technical output of the research network. The influence of management methods on research direction and productivity is of critical importance.

We have done our best to consider, understand and carefully express what has been learned and accomplished. But although we are confident in our conclusions they are the result of but a limited effort. This is therefore an overview - we hope it is but the predecessor of a more comprehensive review of the current state of scientific knowledge and likely rate of progress in this complex effort to discover a practical means of preventing malaria transmission.

B. AIBS Project Performance

1. AIBS Project Activities

In this section of the report is information collected in a review of AIBS activities, the work done to support AID in its management of the malaria research network. We found 20 identifiable areas of work under the AIBS contract. The information was collected in the format detailed in Appendix B; it is summarized here under 20 discernible types of activity.

a. Provide Technical and Management Assistance to AID Staff

AIBS provides support services and augmentation to AID staff on an as-needed basis. These have included: a limited market surveyto identify commercial firms and non-profit organizations engaged in malaria vaccine development, the services of a patent law firm to provide assistance to network investigators in pursuing patent registration for products of their research, and arrangements for the storage of botanical specimens formerly stored at the Biomedical Research Institute.

Such support services are carried out by AIBS staff from their Washington offices, generally, and have been primarily administrative tasks. There are no indications of specific AID counterpart staff involvement.

There is no established schedule for these activities but are carried out as needed. The methods for carrying out these requests are depend on what is to be done and generally require considerable diligence and innovation by the AIBS staff. Final approval in any arrangements in this activity rests with the CTO for the AID Malaria Vaccine Program.

Evaluation of the quality of each specific activity is not possible. However there is no indication that requests for special assistance such as noted here were not dealt with on a timely basis.

b. Conduct Scientific Peer Review of Proposals and Applications (Initial and Renewal) to AID for Funding Under the Program

The process involved in the review of both initial and renewal, solicited and unsolicited, proposals includes the formation of a panel of experts representing the skills and disciplines to be addressed in the research proposals, arranging (when necessary) for the travel and support of these experts, managing the actual review, and preparing a report on each proposal for the CTO in the AID Malaria Vaccine Development Program.

All of the AIBS technical and support staff participate in this activity, especially, as is currently the case, when the number of proposals for review is large. AID staff are directly involved through (1) reviewing and approving the panel of experts; (2) directly participating in the review process (3) taking whatever action is indicated by the review.

Eventually, all renewals should take place on a predictable schedule. The current spate of both solicited and unsolicited proposals is apparently the result of specific actions on the part of AID.

The panel of experts is drawn from the roster of consultants maintained by AIBS. Suggested names are submitted to AID for review and approval. Approved experts are contacted by AIBS to ascertain their willingness to participate in the review. The actual review is scheduled and managed by AIBS including the handling of necessary travel arrangements, payment of per diems, etc. Reports of the panel's individual reviews are submitted to AID for necessary action.

It seems that the AIBS responsibilities in this activity have been completed on a timely basis. There is no direct evidence of serious questions with regards to the basic process of the activity and the way it

is managed. A true evaluation would involve assessment of the scientific effectiveness of the process and that is not possible at the present time and with the resources, time and information available.

This is an area about which there has been considerable controversy, and there is clearly a significant level of conflict concerning relative levels of expertise and responsibility. There have been comments from both sides concerning the inappropriateness of the panel members, either those proposed by AIBS or suggested by AID. This is one of the areas where there is great need for improved understanding.

c. Conduct Periodic Scientific and/or Management Evaluation of the Progress of Ongoing Program Projects.

The basic responsibilities in the organization of this activity are: (1) establishment of the review team including the team leader; (2) contacting the members of the proposed team to arrange their participation in the review; (3) manage the review in terms of schedules, travel arrangements, payment of per diems, etc; (4) participate in the review by having at least one AIBS staff member participate in the site visit. (5) review the report prepared by the review team.

This activity requires a great deal of support work by both the technical and administrative staff of the contractor both in the Washington, D.C. area and at the individual project site.

All members of the AIBS technical and support staff are required to participate in this activity. One member of the AIBS technical staff will be the primary contact for each site visit and will therefore assume the basic responsibility for the review of a specific project.

It seems that site visits are scheduled on an as needed basis, and the primary criteria for deciding when a project will be evaluated are not clear. All members of the network were evaluated in 1988 and there are no site visits scheduled this year. However, this situation could change if events warrant.

The site visit is initiated by AID, that is the decision to conduct such a review is communicated to AIBS. AIBS then begins to develop the membership of the site visit team from its master list of consultants. The proposed team membership is submitted to the CTO, AID for suggestions and eventual approval. The project to be visited is informed of the proposed review and a date is established for this activity. One member of the AIBS technical staff accompanies the team as a management and support person. One or more members of the AID technical staff also participate directly in these activities as advisors and to directly represent AID in terms of policy and procedures. The team leader prepares a report which is reviewed in AIBS and is then submitted to AID. Communication to individual PI's is the responsibility of the CTO.

There is no direct way to evaluate AIBS' role in this activity.

Contacts with individual PI's and a report of their impressions of the process and the results of the site visit will appear in another part of

this report. There is no indication that AIBS has not completed its management functions associated with this activity in a timely fashion.

Here again is an area of serious contention between AID and AIBS; the selection of the site visit team is fraught with difficulties. Much of the controversy seems to rest the perception of technical competence. AIBS selects individuals they consider to be technically competent for the review of a specific project. AID makes suggestions or may dictate changes in the roster (both sides contend that the other is selecting people who are not qualified to review a particular project). Reports are reviewed by AIBS who may introduce changes (inappropriate according to AID staff people). Communication of evaluation results to the PI are either long delayed or may not occur (according to AIBS conversations). Suggested changes in objectives, indications that objectives are not being reached, appropriate alterations of contracts to accommodate changes in needs or objectives, are all perceived by AIBS to be needed by the PI's or site visits will be of little value. These issues are perceived by AIBS to be poorly addressed by AID.

d. Review and Evaluate Individual Protocols and Requests for Allocation and Use of AID-Owned Non-human Primates

The Primate Use Committee (PUC) receives and reviews all requests for the use of monkeys that are under the control of the AID. Responses are generated as needed by requests from network members. The decision of the PUC goes to AID and final approval of the specific request is made by the CTO of AID.

Support is required from the AIBS administrative staff and Dr. Jackson serves as executive secretary of the PUC. The Committee meets as needed to respond to requests for monkeys from PI's within the network. The protocol associated with a specific request for monkeys is received by AIBS. A meeting of the PUC is scheduled, and the protocol is reviewed in terms of appropriate use of animals, fit of the protocol with the objectives of the project in question, adherence to PHS guidelines for primate useprotocol review and decisions concerning the use of non-human primates have been dealt with on a timely basis. Scientific evaluation of the use of monkeys is not possible within current mandates and the resources available.

This activity seems to be confronted with less internal controversy than some of the other activities reported here. The PUC has been in place for a relatively short period of time, but seems to have its responsibilities reasonably well defined. Functions appear to be timely and appropriate. Conflicts may well arise if the PUC begins to arrive at different conclusions than mandated Institutional Animal Care and Use Committees at the PI's location.

e. Coordinate Program Activities and Facilities Information Exchange Among Program Projects

There was little information available on this activity. The general impression was that the computerized exchange of information to be monitored by AIBS has not been particularly productive, and that this effort occupies little or no time of the AIBS staff.

f. Analyze and Maintain all Periodic Progress Reports Submitted by Program Projects

Reports from each member of the network are received twice each year from every member of the network. AIBS sends reminders when a report is not received from an investigator as scheduled . These reports are analyzed and distributed to other members of the network as well as to AID.

All technical and support staff of AIBS participate in this activity, which takes place on an established schedule of twice each year. The reports are received by AIBS from each member of the network. Any PI failing to submit a report on time is contacted by AIBS. These reports are then redistributed to AID and to other members of the Malaria Vaccine Development network. The quality of the reports and their scientific validity are not being reviewed. Apparently this process proceeds smoothly and on a timely basis.

g. Establish and Manage Research and/or Support Subcontracts which Further Program Goals.

Advertisements were placed announcing the availability of funds to support scientifically meritorious small research studies. A total of 75 inquiries were received and these individuals were provided instructions for submitting proposals. A total of 24 proposals were received. AIBS established a review team from its roster of consultants. The team was approved by AID and will meet in February to determine which proposals will actually be funded. Final selection will be a joint AID/AIBS effort.

This is a new activity and no specific schedule has been established. The advertisements are prepared and submitted to professional publications by AIBS. The contractor receives and responds to inquiries resulting from the announcement. The scientific review team is proposed by AIBS to AID for approval. The review process is managed by AIBS including travel arrangements, payment of per diems, etc.

The initial effort for this activity appears to be proceeding smoothly and on a timely basis. There has been no evaluation of this segment of the program. Predictably, there have been controversies in the establishment of this segment of the program. AIBS and AID staff are at odds concerning the selection of a qualified team to carry out the reviews. Both sides contend that the other is manipulative and essentially uninformed as to what constitutes a qualified reviewer. AIBS has expressed concerns over the fact that established members of the network have been invited by AID to submit proposals for this program. They (AIBS) feel that this approach tends to perpetuate the science that is already in the program and does not serve to introduce new approaches and ideas which they contend was one of the reasons for the small research proposal program in the first place.

h. Assist in Development of Individual Study and Clinical Trial Protocols and Preparation of Regulatory Submissions

There has been no activity in this area and this segment of the AIBS activity was not reviewed.

i. Analyze Program Projects on a Continuing Basis to Provide Information upon which AID can Make Timely Decisions

AIBS, usually at the direct request of AID will provide information on a more or less ad hoc basis on the status of projects in the network. This activity is usually initiated by such issues as a request for a new piece of equipment, the usefulness of which must be analyzed. There may be a request to change one or more approved objectives in a particular project. Sometimes a PI will ask for specific technical assistance in the resolution of a problem. In these situations, AIBS technical staff will analyze the situation and report to AID on the status of the project as it relates to that particular request.

All of the AIBS technical staff participate in this activity, and there is no regular schedule for these activities. The initiating request is received from the PI and the AIBS technical staff member assigned to that request carries out and analysis and provides the pertinent information to the CTO, AID. There is no direct information to indicate that this phase of the activity does not proceed on a smooth and timely basis. However, the potential for conflict exists here as in all areas where technical input is required from AIBS.

j. Develop for AID Consideration, Draft Policy and Procedures for Program Management on an As-needed Basis

This particular activity received little specific attention during the process of the review. Policy issues and the AIBS contribution to them are discussed in the specific concerned segments of this report.

k. Provide Technical Assistance to Program Projects

This is, relatively speaking, much less complex than other features of the contractor's responsibilities. Such issues as the support of one technician in the CDC Project and editorial assistance in the preparation of a monograph on renal pathology in monkeys are included here. There are no indications that these activities are not carried effectively and on a timely basis.

l. Establish and Manage a Body of Technical and Management Consultants to Provide Assistance in Carrying Out this Statement of Work

One of the first tasks of AIBS was to develop and maintain a roster of consultants who are capable of dealing technically with the large variety of subject areas in the network projects. AIBS has the responsibility of reviewing backgrounds, C.V.'s, interests and experience of a large variety of scientists and preparing lists of potential consultants for consideration by AID to review various program segments and individual projects. This responsibility includes a constant effort to see that the roster is current and reflects not only the interests of the individual consultants but of the network as well. Consultant services have also been developed for management and computer needs, but the latter are of much less importance than the former.

This is a continuous process for AIBS. Lists of potential consultants are generated through personal contacts, technical knowledge of the field, review of literature in the areas of malariology, primatology, entomology, immunology, molecular biology, etc. Potential members of the consultant roster are contacted for more recent information and an indication of their interest in participating in the program. This list is constantly being expanded and upgraded.

There is no primary factual evidence to be used in an evaluation of the phase of AIBS' activities under the contract. Consultants have always been available on a timely basis to serve the needs of the network and its various reviews requiring Scientific Consultant Groups. Methods for evaluating their individual effectiveness have not been developed. As in all areas where elements of scientific judgment have been involved, this phase of the contractor's activities has been subject to controversy. Since the technical qualifications of individuals and their ability to contribute to specific projects is sometimes quite subjective, there is always a potential argument over the relative value of one consultant over another for a particular task.

m. Establish and Manage Technical Advisory Committees as Required for Effective, Scientifically Credible Management of the Program

Two Scientific Consultant Groups (SCG) have recently been established: the Malaria Vaccine Research and Development Project (MVRD) and the Malaria Vaccine Epidemiological Studies and Evaluation Project (MVRESE). The consultant group on Primate Use (PUC) has also been established in a similar fashion. AIBS has also submitted a proposal for a Malaria Vaccine Technical Advisory Committee (MVTAC) to AID, and potential members identified. Members of working groups are selected from the Roster of consultants maintained by AIBS (see Item 13). Specific nominees for a specific SCG or the PUC are sent to AID for review and approval. Individuals considered eligible for a particular group are then contacted to ascertain if they are prepared to serve.

This is clearly a pivotal activity on the part of AIBS and its support of the AID Malaria Vaccine Development Program. This activity has become the center of a considerable amount of controversy. Proposed consultant lists for SCG's have been submitted to AID for consideration but the action taken is mostly unclear to AIBS. The AIBS role in support of the SCG's, if any, needs clarification.

n. Organize, Sponsor, Conduct, and/or Administer Technical or Management Meetings to Support Program-related Activities

AIBS has made the necessary arrangements for a number of meetings: the attendance of representatives from network laboratories at a meeting on Adjuvants in Greece, a meeting of the Malaria Vaccine Epidemiological Studies Evaluation SCG in Hawaii, meetings of the Primate Use Committee in Washington, D.C., and assisted in the development of a Malaria Workshop at the 7th Ann Arbor Red Cell Conference in Ann Arbor, Michigan.

These activities have taken place in the Washington, D.C. offices of AIBS and in the various locations indicated above. All AIBS technical and support staff have been involved in one or more of these activities, which

are part of a continuous process. Involvement is initiated in several ways. AID sometimes makes direct requests for assistance in some instances, or they may come from the PI's. And in some cases a meeting may result from the course of general support services provided by AIBS technical staff. There have been no problems or controversy associated with this activity.

o. Conduct or Arrange for Technical Training for Personnel Associated with AID- Supported Vaccine Related Field Studies Overseas

No training requests have been received.

p. Publish Technical Reports, Monographs and Conference Proceedings in Support of the Program

Two publications have been produced and distributed: An Atlas of Renal Disease in Aotus Monkeys with Experimental Plasmodial Infection by Masamichi Aikawa and Proceedings of the Conference on Malaria in Africa, edited by Alfred Buck.

q. Maintain Technical Information Files, Which May Include Subscriptions to Journals, Database Services and Purchase of Books of Special Interest to Program Staff

This is a relatively minor component of the AIBS activity in support of the AID Malaria Vaccine Development Program.

r. Maintain Informal Technical Liaison with Organizations and Agencies Involved with Malaria Vaccine Research, Development, and Evaluation on a Worldwide Basis

This activity includes such efforts as sponsorship of the Federal Malaria Vaccine Coordinating Committee; participation of the AIBS Program Director in the WHO IMMAL/FIELDMAL joint Scientific Working Group in Geneva and the Program Director attending the American Public Health Association Meetings in Boston. These would appear to be appropriate activities for the contractor.

s. Maintain Automated Data Management and Transmission Capabilities as Needed for Program Operations

This is clearly an important part of the contractor's efforts to develop a program that will provide as much support as possible to the Malaria Vaccine Development Program. Although computer hardware and databases of technical information related to the network are in place, it is not possible to determine if this effort is being more broadly applied.

t. Make Arrangements for Payment of Transfer Costs and Temporary Care of Non-human Primates which have Newly Arrived in the United States and are Awaiting Shipment to Program Projects or Other AID Designated Location

The transfer costs have been associated with the program of obtaining monkeys from South America and distributing them to specific program areas within the network. The temporary care responsibility came when the number

of monkeys available for use in the Malaria Vaccine Development Program exceeded the prepared space dedicated to their housing. AIBS is apparently filling this responsibility on a timely and effective basis.

2. AIBS Project Accomplishments

We found the level of professional competence and quality of institutional effort and memory of the contractor impressive. Here, under the headings of change and particular strengths, is a summary of our findings:

a. Changes in Infrastructure and Project Support Capabilities:

There have been a number of difficulties in getting the AIBS contract team to its current level. Initially the AIBS contract was geared primarily to support activities; technical input into the program was once clearly the responsibility of AID staff. Changes in emphasis (especially with regards to the developing potential for the early need for well documented field trial sites) and AID administrative problems brought about a need for more technical contributions from AIBS. The first move in this direction came with the recruitment of Dr. Peter Contacos to "develop and coordinate all aspects of the pre-clinical, clinical and overseas field trials of prototype malaria vaccines." In 1986 and 1987 the lack of sufficient technical expertise in AID became acute; consequently Dr. Winter was appointed director of the AIBS program and AIBS technical support of the malaria network increased. Since that time the headquarters staff of AIBS in Washington has been augmented with Drs. Woollett and Jackson-providing scientific background, technical expertise and an expanded capacity to deal with the activities which AIBS was delegated or assumed during the difficult years of 1987 and 1988. This organization continues to provide strong support services through Ms. Souza, who has performed impressively to develop management procedures that deal effectively with a large variety of complex issues, and Ms. Beamon. There seems no question that the present AIBS staff is adequate, except in the area of subcontracts, to handle the current level of demand for support from AID and its needs in the management of the Malaria Vaccine Development Network.

b. Principal AIBS Strengths and Contributions:

The reputation of AIBS as a non-profit organization and its long association with the scientific establishment in the U.S. adds significantly to its stature as a contractor and consequently to its potential for dealing with the technical and management needs of AID and the complexities associated with the Malaria Vaccine Development program. AIBS has managed to recruit staff members with excellent technical expertise and experience in the field of malaria biology thus enhancing the scientific base for AID's relationships with the established Malaria Vaccine Development Network.

AIBS' contributions to this program are many. During a period of extreme difficulty the efforts of the contractor helped to keep the network functioning. The organization can take much of the credit for keeping a very unpleasant situation from becoming completely chaotic. In spite of the problems that have occurred, the management system for site visits and associated in depth evaluation of individual projects within the network have been carried out and primary goals for this activity have been

achieved. The organization of meetings and conferences has been effective and these activities have proceeded smoothly. The consultant roster has become an effective tool in developing panels for review of proposals, setting up site visit teams, and evaluating proposals for the use of non-human primates. The management system established for non-human primates appears to be effective, serve the needs of the network investigators, and to assure compliance with the Public Health Service Guidelines for the care and maintenance of experimental animals in medical research institutions.It is difficult to see how the AIBS role in the Malaria Vaccine Development Program could be enhanced in terms of actual functional elements. The activities currently in place are comprehensive and varied. If there is an expansion of the subcontract program the staff of AIBS must be increased in order to respond to this demand, but additional activities on the part of the contractor would not seem likely. At the same time, there would seem to be no real prospect for a reduced role for AIBS in this program unless AID is prepared to make a major commitment to additional staff for the Malaria Vaccine Development Program.

3. AIBS Performance

Generally AIBS has performed well in fulfilling its obligations to AID as defined in the original contract document. Both AID and IBS have survived a very difficult period, and in spite of some notable problems management of the Malaria Vaccine Development Program continues to function with reasonable effectiveness. The fact that all of the necessary tasks have been performed and primary goals reached by AID, AIBS and the members of the network is an indication of the strength of the effort and the commitment of all parties to the ultimate production of an effective malaria vaccine. There are clearly criticisms of various aspects of the program, but many of these rest with the fact that scientific progress toward a vaccine has been much slower than anticipated.

This fact tends to focus attention on discernible problems and may give management issues a greater sense of importance and impact than is warranted. In other words, success in the production of an immunizing antigen would markedly diminish the apparent problems.

But there are relationship issues between AID and AIBS, and they must be resolved in order that the scientific problems confronting the network receive more attention. AIBS has considerable difficulty understanding its technical role in the program. During a period when AID had little or no technical capacity, AIBS assumed a much greater responsibility in dealing with scientific issues and functioned more or less in a peer group relationship with the investigators in the network. Some of these activities probably went beyond the original intent of the contract, were necessary, and were unquestioned or encouraged by AID officials. This need has diminished with the detail of Dr. Carter Diggs to the AID Malaria Vaccine Development Program and the presence, now, of three additional AID funded technical staff. With these new developments the AIBS role has not changed but perceptions have altered. It is clear that the AIBS professional personnel cling to their technical responsibilities and are committed to the program and its goals. It is equally apparent that some AID personnel now again tend to look upon the AIBS contract as a service mechanism, and may resent the effort of AIBS professional staff to remain

deeply involved in the scientific issues of the network.

The kinds of conflicts being discussed here are frequently associated with personality conflicts, and one of the AID staff is involved in most of the controversy. The problem is recognized and understood by both the CTO and PD; and they are circumventing the problem as much as possible by acting as intermediaries between AID and AIBS technical staff. This is highly inefficient and cannot be tolerated for long. The resolution lies in the urgently needed redescription of institutional and individual responsibilities.

C. Contract Design and Implementation

1. Background

The current contract between AIBS and AID is the product of an unsolicited proposal developed by AIBS and designed as a follow-on to an AIBS/AID contract implemented during the period September 1982 to October 1985. This proposal was written as an application to AID for a Cooperative Agreement to continue the relationship in laboratory and field based research for five more years. Specifically, AIBS intended to concentrate on the organization and implementation of research network reviews, plan and coordinate clinical and field immunization research trials; conduct meetings and seminars, assist in the evaluation and processing of proposals; maintain immunization data for FDA requirements and provide overseas coordination of research efforts. When the proposal was presented to the AID Contracting Officer, her preference was to implement this project as a contract rather than a cooperative agreement. The major distinction between these mechanisms is one of authority and control. A contract specifies certain "deliverables" which the contractor agrees to provide under the direction of AID. A cooperative agreement indicates a shared interest in the activity between AID and a organization, many times being undertaken by an organization with or without AID support. Cooperative agreements usually have less AID direct management oversight and hence offer greater flexibility for the recipient during implementation. When considering the nature of the tasks to be undertaken by AIBS as specified in the scope of work, a contract seems to be the most appropriate mechanism.

2. Contract Design

Although this agreement is in contract form, administratively it possesses certain features of a cooperative agreement and should be considered a favorable contract from AIBS' perspective. It allows for flexibility between budget line items "as reasonably necessary" without approval from AID and delegates many aspects of contract management to the CTO rather than the Contract Officer. Although specific suggestions for modifications to the contract will be detailed later in this section, it should be noted here that some parts of the contract as originally written were weak or inaccurate. They are:

a. Scope of Work (SOW). Discussions between several people and members of the evaluation team indicated that the SOW as written fails to provide clear direction to AIBS regarding their responsibilities.

b. Position Descriptions. No position descriptions appear in the contract for any personnel, nor do they appear in sufficient detail in the AIBS proposal. In addition, discrepancies exist in the staffing pattern proposed by AIBS and that delineated in the contract.

c. Equipment specifications. Although the SOW specifies the need for expanding the AIBS computer facility and section H.2 directs AIBS to modify computer equipment to be compatible with AID hardware and software, no provision exists for the purchase of computer equipment in the contract budget, nor does a comprehensive list of equipment exist as stated in Section H.3, "Government Property". An extensive amount of equipment has in fact been purchased, all with AID/CTO approval and allocated against the "Other Direct Cost" line item.

3. AIBS Contract Management

During the period this evaluation is primarily intended to address, April 1987 to present, AIBS has approached contract management in a generally responsible manner with a trend towards constant refinement of procedures. Findings as they relate to specific areas are detailed below.

a. Subcontracts AIBS has executed eleven subcontracts and letter agreements with seven different organizations since the contract began. These agreements range from a short letter which accepts a proposal and instructs the Investigator to proceed with work to substantial and complete second-tier contracts which comply fully with AID regulations. The range of quality varies significantly between subcontracts and is primarily attributed to the variety of people who have been involved with development of these documents during the course of the contract. Several comments can be made regarding the development and management of these contracting arrangements. For simplicity, all arrangements will be referred to as subcontracts in the points which foilow.

Quality of subcontracts. The most common problems with the documents relate to the omission of AID Acquisition Regulations (AIDAR) and Federal Acquisition Regulations (FAR), some of which are required to be included in all second-tier contracts; the lack of a termination clause; scopes of work which are vague and do not permit accurate measurement of objectives and financial provisions which do not clearly state payment terms, including a statement which permits AIBS to withhold payment if the scope of work has not been completed satisfactorily. It should be noted that the problems noted above pertain to subcontracts which tend to be small in dollar size and may be considered less critical to the overall implementation of the AIBS contract.

Timeliness of preparation and signature. In most cases, both parties signed the subcontracts after the start of activities. This is a potentially dangerous practice because if mutually satisfactory terms can not be reached after implementation has begun, settlement of the work expended is in dispute

AID approvals. In one form or another, approval for all but two subcontracts was found, either from AIBS or AID contract files, or from information obtained from interviews conducted with AIBS and AID staff.

AIBS staff expertise. During the period from October 1987 to February 1988, an AIBS staff member held the position of Program Manager and assumed some responsibility for subcontract development and negotiation with AID. Before and since that period the responsibility for subcontract management has rested with a variety of people, none of whom have specific expertise in that area. AID staff interviewed cited this situation as problematic for AIBS and AID. Attempts have been made by AIBS to recruit for this position but to date, none have been successful.

b. Consultant Management AIBS currently maintains a well-developed system for the selection, deployment and provision of logistic support of its external consultants. This system consists of a computerized consultant roster file and various pre-printed forms which assist at various stages of consultant management. The roles and responsibilities of the AIBS staff in this area are well defined and seem to operate smoothly. Although some problems existed with AID regulations regarding consultant rates, the situation has been corrected and all consultants are now remunerated according to AID guidelines.

c. Financial Management/Cost effectiveness Financial reporting is managed by AIBS headquarters staff and appears to be done in a timely and efficient manner and according to AID requirements. However, a review of the most current fiscal data revealed some points which should be noted:

The AIBS expenditure report (number 39, dated 13 December 1988) for the period November 1988 indicates a budget amount which is not consistent with the cumulative obligation stated on amendment 4 dated August 1988 nor with the current contract total.

An internal fiscal status report displayed a budget which was not updated to reflect contract budget category changes made in AID amendment 3 to the contract, dated August 1987. That same report labeled the "Other Direct Cost" category incorrectly as "Miscellaneous"

Although section B.6 of the contract grants AIBS authority to adjust line items as "reasonably necessary", no request has been made to AID to request a modification to the budget

to adjust the "Primate Acquisition" line item, which has been exceeded by almost $300,000 through November 1988. It should be noted that the circumstances which have led to this budget over-run are clear to AID and are accepted.

Assessing the cost-effectiveness of AIBS is difficult because the level of detailed financial information available from AIBS or AID does not permit measurement in a meaningful way against those components of the scope of work which have been implemented to date nor could an estimate of the total staff or consultant months expended to date be obtained.

However, toward this end, the following table represents expenditures through November 1988 expressed in percentage terms against the total contract amount by contract budget line:

Salaries	1,392,974.00	616,974.00	44.00%
Travel	1,965,257.00	461,984.00	23.00%
Consultants	650,573.00	278,352.00	43.00%
Primate Acq.	375,000.00	667,888.00	178.00%
Subcontracts	1,100,000.00	117,148.00	11.00%
Other Direct	661,169.00	557,175.00	84.00%
Training	193,000.00	1,715.00	.90%
Overhead	2,038,925.00	1,017,791.00	50.00%
Total	8,376,898.00	3,719,027.00	44.40%

NOTE: As of November 1988, 37 months (61.7%) of contract life

d. Equipment purchase/Inventory Management As mentioned, no specific provision could be found in the AIBS proposal budget for the purchase of equipment, and most notably, computer equipment. A substantial amount of computer equipment has been purchased to support some of the technical objectives of the scope of work, in addition to other standard types of office equipment, such as photocopiers, typewriters and a facsimile machine. All purchases appear appropriate in light of the technical and administrative support AIBS is called upon to give to AID. Based on a partial audit of equipment approvals, it appears that AIBS has complied with the terms of the contract and has received CTO approval for all purchases and maintains a complete inventory list which is periodically updated.

e. Administrative Staffing The staffing structure for administrative functions under this contract seems appropriate for all aspects of implementation with the exception of subcontract development and management. It appears that at the project level and at AIBS headquarters, the only person who was identified as having responsibility for contractual issues was the AIBS Executive Officer. Conversations with AID officials commented that "things were on track" when the Program Manager was on staff and suggested it was problematic not having a consistent contact for day to day issues which may arise. If AIBS proceeds with the plan to develop subcontracts with up to 15 institutions for Peer Reviews, it will be imperative to have strong administrative support to develop and monitor all aspects of these agreements with adequate headquarters support.

f. Personnel Approvals The Key Personnel section of the contract (H.6) has never been formally modified to reflect any changes in the AIBS staff. In July 1987, AIBS did request AID approval of a staffing reorganization/augmentation, which AID responded to affirmatively but never actually amended the contract. To remain in compliance, AIBS should have pursued this more frequently during the past three years and with more vigor with AID. Ultimately, it is the responsibility of a contractor to ensure that the terms of the contract remain accurate.

g. Primate Management As a result of factors beyond the control of AIBS, this aspect of the AIBS contract has required a greater degree of contract management and contract resources than anticipated originally. The primary focus of this technical area centers around the Perrine Primate Center (University of Miami). While AIBS has been operating on an informal basis with the Perrine Center for the past 18 months, they have made several good faith attempts to replace this arrangement with a well-developed subcontract which already has CTO and Contracting office approval. Until the subcontract is implemented, for their owr protection, AIBS should be certain any interim arrangements pass on all of the contract terms required of AIBS to the Perrine Primate Center.

h. Timeliness of reports We were given all the reports we asked for: annual work plans, biannual progress reports, fiscal reports and trip reports. We found, in addition, special reports summarizing issues or situations that had evidently been prepared at AID's request. All reports and documents relating to program activities were found readily; the files maintained, both paper and computer, were in good order and familiar to all AIBS staff.

4. AID Contract Management

a. Quality of amendments Five amendments have been processed by AID over the life of the contract. Three have incrementally funded the contract, the remaining two have, in addition to providing incremental funding, modified the funding method and clarified certain aspects of contract administration. No modifications have been made to the scope of work, the illustrative level of effort (section B.2) or Key Personnel (section H.6) despite a request by AIBS made to AID in July 1987 for staff reorganization.

b. Timeliness of approvals AIBS Contract files indicate that approvals from the contract office and the technical office are generally handled in an expedient manner. However it was noted that AIBS has never received approval of their workplans.

c. CTO management and oversight While all AIBS staff interviewed expressed optimism that the AID management had improved significantly over the past several months, it was still problematic. The major focus was on lack of clear guidance from one person within AID. In an attempt to keep communication between AID and AIBS as clear as possible, AIBS seeks direction from the designated CTO only, as specified in the contract. While this may be perceived as a bureaucratic and time consuming procedure from the AID technical staff, it is contractually and managerially appropriate and should be maintained. In addition, AID does not consistently provide information required by AIBS for completion of their work. For example, the scope of work calls upon AIBS to coordinate the network, including site evaluations which among other things, reviews the contractual and budgetary aspects of the PI's work. AIBS has found it difficult to measure these aspects of the PI evaluations because AID has not provided up-to-date contractual information (such as PI contract amendments) which specifies incremental increases and other administrative changes to the contracts.

5. Nature of the Contract

a. Changes that should be made in the AIBS contract It should be noted here that AIBS has developed a document which proposes to change various aspects of the current contract. Many of the suggested modifications below cover the same points addressed in the AIBS document.

Scope of Work An assessment of the work which has been accomplished to date and can reasonably be expected to continue or initiated in the remaining period of the contract should be made. The outcome of this exercise should be the basis for a revised scope of work. Particular attention should be focussed on the assignment of specific responsibilities to AIBS which can be implemented independently of direct AID technical staff input. The responsibility and authority which AIBS exercises over the PI contracts implemented by AID should also be altered.

Budget A re-budgeting exercise should be performed in conjunction with revisions to the scope of work, taking into consideration the computer equipment which has been purchased to date and what is envisaged for the remainder of the contract period.

Level of Effort The level of effort specified under section B.2 should be modified in light of revisions to the scope of work and budget.

Position Descriptions AIBS should develop detailed descriptions for all professional and administrative staff working under the contract, which will be incorporated into the contract. Each description should, at a minimum, outline the general and specific responsibilities, who that person takes direction from and the necessary qualifications. From this roster of personnel, AID may determine who should be key personnel and modify section H.6 accordingly.

Equipment Using the AIBS inventory list and combined with some estimate for future equipment needs, a comprehensive equipment list should be developed, incorporated in the budget and labeled "Attachment 2" to be consistent with the current wording of section H.3 of the contract.

b. Changes that AIBS should consider

Project/Headquarters staffing AIBS should consider augmenting their Project staff with a Program Manager who would have responsibility over the development and management of subcontracts. It is also recommended that AIBS strengthen their permanent headquarters staff with people that possess expertise in contract administration and are able to devote substantial effort to this aspect of management.

D. Impact of Management Methods on the Network

1. Survey of Principal Investigators

Evaluation of the role of AIBS included a telephone survey of Principal Investigators to determine their perspective on the relative roles of AIBS and AID, and to obtain their suggestions for improvement. This survey was based on a list of 15 persons most of whom are Principal Investigators in the AID Malaria Vaccine Program. At the time of this summary (February 27, 1989), 14 of these 15 persons had been interviewed. The basis of these interviews was the Phone Questionnaire for Principal Investigators, which is attached as Appendix B. This interview format was proposed to (and approved by) the Evaluation Team on Thursday February 3, after the Team had completed interviews with critical persons from both AIBS (Drs. Phil Winter, Peter Jackson, and Gillian Woollett) and AID (Drs. Carter Diggs, Caryn Miller, Kirk Miller and Sandy Fairfield) to determine the issues most relevant to the performance of AIBS.

2. Site Visit Performance

AIBS played a major role in arranging 14 Site Visits within 12-14 months to the laboratories of each of the Principal Investigators (PIs). Because the information obtained on these visits was used to make funding decisions, it was the most important interaction of most of the Principal Investigators with AIBS since the major changes in AIBS that took place 1.5 - 2 years previously.

a. Composition of the Site Visit Teams Four of the 13 PIs interviewed who had had a Site Visit (1 of the 14 PIs interviewed received his first funding in the fall of 1988 and has not yet had a Site Visit), expressed significant reservations about the persons chosen for their Site Visit Team. These concerns included potential conflicts of interest in three cases, as well as concern that the persons chosen were not sufficiently knowledgeable in three cases. Two investigators were concerned that other investigators in the AID network were on their Site Visit Team. (One PI was concerned that other network PIs on Site Visit teams would have an incentive to reduce the budget of the Project being visited so that there would be more money left for their own projects - because the network PIs had been told that AID had insufficient funds to support all the studies which had been approved.)

b. Performance of the Site Visits Four of the 13 PIs had significant reservations about the performance of their Site Visits. These concerns revolved primarily around the perception of these PIs that the Site Visit Team had come to find fault with their work and to reduce their budget, rather than to evaluate their scientific progress on the objectives outlined (and approved) in their Proposals.

c. Accuracy of the Final Written Report and its Relationship to the Oral Summary (Debriefing) at the End of the Site Visit. Seven PIs felt that there were significant discrepancies between the Oral Summary (or Debriefing) at the end of their Site Visit and the subsequent Formal Written Report. In 6 of these 7 instances, the Oral Summary was presented in part by personnel from AID and/or AIBS.

d. Handling of Responses (Rebuttals) to the Written Report (Summary) of the Site Visit. Six of the PI's replied formally to the Written Reoport on their Site Visits. In at least 1 instance, there has reportedly been no reply to a PI's request for additional instructions (from either AID or AIBS). In 5 other instances, the issues involved were related to changes in funding, were discussed further between AID and the PIs, and were acted upon.

e. Changes in Objectives or Research Plans as a Result of the Site Visits Eight of the PIs reported significant changes in their Objectives as a result of the Site Visits. Two of the eight felt that the changes suggested by the Site Visit Teams were constructive and appropriate. The other six had changes in Objectives associated with budget cuts and did not agree with the assessments of their Site Visit Teams on those objectives. The PI who has not had a reply to his response to the Written Report said that he was willing to modify his objectives if he could find out how he was supposed to modify them.

f. Formal Notification from AID Three of the 13 PIs interviewed who had had Site Visits received formal notification from the CTO at AID about changes in their Objectives, and one had a formal amendment of his Cooperative Agreement with AID.

g. Conclusions We sympathize with the magnitude of the task faced by persons at AIBS and AID, as they confronted both the reorganization of their own groups and a mandate to visit each of the network PIs to rigorously evaluate the entire AID Malaria Vaccine Program within a 12-14 month period. The logistics of these visits were formidable, as was the demand to assemble credible teams of experts without conflicts of interest for each Visit.

Likewise, we sympathize with the PIs, who also were facing the unknown. As a group, the PIs assumed (incorrectly) that their programs had been judged acceptable in terms of relevance to the AID Malaria Vaccine Development Program, and that the purpose of the Site Visit was solely to examine the quality of their science. This misunderstanding emphasizes the need to clarify the purpose of Site Visits when they are performed in the future. (Although AIBS can provide consultants with expertise to render opinions on this issue, we believe that ultimately only AID can take responsibility for stating what material is sufficiently close to their goal to deserve funding. We expect that with Dr. Carter Diggs at AID, these issues will be addressed clearly in the future.)

In our opinion, several areas deserve additional consideration. These include:

> Conflict of Interest Although the individual reviewers for whom this might have been a question reportedly acquitted themselves well, this is an important issue. Because there are a limited number of persons with expertise relevant to the development of a malaria vaccine, the need to perform a substantial number of Site Visits within a relatively short period of time exacerbated this problem. [In a practical sense, this limitation favors more extensive use of written evaluations, based on Progress Reports and publications, and less extensive Site Visits.]

Site Visits vs.. Evaluations based primarily on Progress Reports and other Written Evidence We suggest that AID consider performing fewer Site Visits and evaluating the progress of the network PIs more by the review of written reports. Although this would represent a marked departure from the previous pattern, we suggest that AID consider abolishing Site Visits except to answer specific questions. When Site Visits are necessary, it may be possible to obtain the necessary factual information with 1 or 2 people, rather than a large team. Relying primarily on written reviews would permit AIBS to assemble a group of consultants once or twice a year (rather than 14 times) and should thus make it easier to enlist the assistance of the most highly-qualified consultants. Limiting the number of Site Visits should also free up money for research that would otherwise be spent on Site Visits. [We estimate that the recent round of Site Visits cost between $300,000 and $350,000.]

Oral Summary vs the Final Written Report Because the Final Report should be the product of the Site Visit Team (not that of AIBS or AID), significant participation by AID and/or AIBS representatives in the Oral Summary session at the end of the Site Visit may unintentionally mislead the PIs about what to expect in the Written Report. We suggest that respective responsibilities be emphasized at the time of the Site Visit, especially when representatives of AID or AIBS play a major role in the Oral Summary (Debriefing).

3. Handling of Progress Reports

Each of the 14 PIs contacted was aware of the need to send Progress Reports to AIBS every 6 months, and reportedly does so.

a. Feedback from AID and/or AIBS None of the 13 PIs interviewed who ha submitted Progress Reports previously recalled having received feedback on his/her Progress Reports from either AID or AIBS, and several questioned whether those reports were evaluated after they arrived in Washington. One PI has reportedly included specific questions in his Progress Reports but has not received any responses. [Our impression from the On Site Evaluation of AIBS is at variance with these comments and suggests that the Progress Reports are reviewed in detail at AIBS, and again at AID.]

b. Sharing of Information among Members of the Network The PIs are clearly aware that Progress Reports are shared among members of the network. In fact, this is an important concern for 7 of the PIs we interviewed. The PIs who are developing antigens for use in a malaria vaccine view themselves as competing with one another. For this reason, they often provide in their Progress Reports only information which has already been published or accepted for publication (because they know that copies of their Progress Reports will be sent to other PIs in the network whom they view as competitors). Obviously, this approach undercuts the presumed purpose of sharing Progress Reports, i.e., the idea of a network. Although this concern does not apply to PIs with unique roles within the network (such as performing electron microscopy, maintaining animal facilities, or testing specific antigens in primates), it is an important consideration that will need to be reviewed by both AID and any Scientific Consultant Group. We recognize that the scientific community has changed considerably since the AID network was created. As a result, it is

possible that the idea of a network may no longer be as realistic or appropriate as it was originally. We urge the Scientific Consultant Group of the AID Malaria Vaccine Program to examine this issue critically and realistically.

We recognize that there are ways in which these concerns could be minimized (e.g., by assigning the individual PIs to work only on certain antigens and by assigning no more than one PI to each potentially promising antigen). However, such changes would alter the present situation markedly and could be counterproductive scientifically (i.e., they might discourage the participation of the most productive investigators of the network).

c. Submission of Publications Each of the PIs who publishes regularly in scientific journals said that he/she included copies of publications supported by AID in his/her Progress Reports.

d. Conclusions We believe that careful review of Progress Reports may be an efficient and economical way to assess the progress of most PIs in the network and to spot potential problems. Our impression from this Evaluation is that the Progress Reports are read carefully at AIBS, but that there is not yet any organized feedback to the PIs from either AIBS or AID about their reviews of these reports. We suggest that this be implemented and that questions which arise during the review of these Reports be addressed by limited Site Visits if they cannot be resolved within 1-2 months by correspondence or telephone calls.

We believe the question of sharing information among members of the network goes substantially beyond the Progress Report, to the question of whether one can create a truly cooperative network of investigators if they see themselves as potential competitors of one another. Because the answer to this question will impact directly upon decisions about which investigators should continue to receive AID funding, we suggest that this question be considered by the AID Scientific Consultant Group and that Committee request the opinions of the participating PIs, as well as outside investigators, in its deliberations.

4. Review of Proposals

a. Review of Major Proposals None of the 14 PIs interviewed has yet had a Major Proposal reviewed by AIBS after the changes of the last 2 years. Six of the 14 PIs interviewed have Major Proposals currently under consideration (which were reviewed in late February, 1989).

Conclusions The way in which Review Committees (i.e., Study Sections) have been chosen and assembled by AIBS bodes well for the quality and the integrity of the review process. Major questions to be considered include whether the availability of this funding should be announced so that the AID Program will have the opportunity to examine proposals from the widest possible group of investigators. An interesting counterpoint to this approach is that it may be important to offer established investigators in the network some degree of protection if one wants them to be open and frank in their frequent Progress Reports, and in their discussions with one another.

We suggest that AID consider arranging the funding intervals so that most Major Proposals run concurrently in order to facilitate the implementation of changes in the direction of the network when Major Proposals are reviewed.

b. Review of Small Subcontract Research Proposals None of the 14 PIs interviewed has yet had a Small Subcontract Research Proposal reviewed by AIBS after the changes of the last 2 years. Only one of the PIs interviewed submitted a Small Subcontract Research Proposal for review in February 1989.

Conclusions The Evaluation Team believes that this offering is an important positive step on the part of AIBS in order to permit AID to learn about investigators presently outside the network who have potentially useful ideas and approaches to contribute to the goal of developing an effective malaria vaccine. However, if this was the goal of the Small Subcontract Research Proposals, we do not understand why established investigators in the network were permitted to apply for these funds.

5. Principal Investigator Meetings

The last PI Meeting focused primarily on organizational and administrative changes - as they affected the individual PIs. Thus although organizing these meetings is a function of AIBS, the individual PIs did not believe this role of AIBS could be evaluated in the last 1-2 years because the only recent PI meeting was devoted primarily to administrative rather than scientific issues.

Conclusions One observation from the effort to plan the next PI meeting may be relevant, however. While this evaluation was proceeding, the date for the 1989 PI Meeting was changed on short notice. While this may have been unavoidable, it should be possible in the future to be sure that such dates are cleared with those at AID who desire to attend before the dates are given to AIBS. In practical terms, such confusion at AID leads the PIs to believe that the contractor (AIBS) has been sloppy, which did not appear to be the case. We suggest that the authority to make and implement these decisions at AID, including the approval of the meeting agenda, be delegated to the Division Head or CTO in charge of the AID Malaria Vaccine Program. Without one such person clearly designated, we believe it will be impossible for AIBS (or any other contractor) to assist AID effectively in running the AID Malaria Vaccine Program.

6. Equipment Purchasing

Six of the 14 PIs interviewed had requested the approval of the CTO at AID to purchase equipment which was not originally budgeted in their Major Proposals. Five of these PIs said their requests had been granted without difficulty. The request of the sixth was denied at a time when his funding was being reduced and ultimately eliminated.

Conclusions This system appears to be working remarkably well, especially considering that it may not be written down anywhere. The current CTO is

actually uncertain what the guidelines are - i.e., whether he must ask for outside review of a requested expenditure if it exceeds a certain amount and if so, what that amount is. The role of AIBS is primarily to provide outside expertise with which to assist the CTO in the evaluation of requests which are either unclear or expensive. Our impression from this Evaluation is that AIBS performed well when it was called upon to contact consultants who could provide such advice.

7. Letting of Subcontracts

Three of the 14 PIs interviewed had subcontracts included in their Major Proposals. These varied greatly - from mechanisms to compensate outside consultants such as veterinarians in two instances to a substantial proportion of the primary research in the third.

Conclusions This issue seems to be largely beyond the purview of AIBS. Because the uses made of this mechanism are so varied, it is not possible to make any general recommendations. However, when the amount of money is substantial (e.g., > $100,000), it may be appropriate to require the subcontracting institution to provide accounting information directly to AID. (Although the primary tie of the subcontracting institution is obviously to the PI, we believe most PIs are poorly prepared to examine such financial records in detail.)

8. Primate Use Committee

Four of the 14 PIs interviewed work directly in the care, testing or record-keeping of primates for AID. Of the other 10 PIs, 4 of the 5 who have proposed to test antigens in primates said they felt that the Primate Use Committee was a major problem.

Our assessment of the situation was hindered by uncertainty about the proposed role of the Primate Use Committee - i.e., Is its mission to review proposals de novo or to implement projects approved as part of Major Proposals and to review new proposals in greater detail? Some of the PIs felt that individuals on the Primate Use Committee were in direct competition with them for use of the same animals. If one role of the Primate Use Committee is to provide guidance to the persons maintaining primates for AID, it would be reasonable to involve those persons as advisors to the Primate Use Committee.

Conclusions The mission of the Primate Use Committee should be clarified. The information currently being sent from AIBS to the individual PIs (on the membership and mission of the Primate Use Committee) should clarify the role of the committee and alleviate some concerns. We suggest that the Primate Use Committee be discussed at the upcoming PI meeting in early March. It is also important that PIs whose primary responsibilities are the care, testing and/or record-keeping of primates be given at least Advisory appointments to the committee, and that the Primate Use Committee formally address the questions that have been raised about AID's long-term objectives in maintaining these animals.

9. Field Trials

None of the PIs interviewed has had any direct contact or experience with the proposed Field Trial Site in Papua New Guinea.

10. Overall Assessment

Of the 14 PIs interviewed, 2 were very positive about the performance of AIBS, 3 others (whose funds had been cut or eliminated as a result of the recent series of Site Visits) were highly critical, and 9 were relatively neutral.

Ten of the 14 PIs interviewed expressed substantial confusion about the relative roles of AIBS and AID. The PIs who are most comfortable with the present arrangement deal with the system by sending copies of all transactions to both AID and AIBS, by dealing primarily with long-time colleagues whom they know well at AID and AIBS (Drs. Diggs and Winter), or by calling AID first to ask for guidance. (The PIs most comfortable with the present arrangement are persons who are now working within the Federal government, who have done so previously, or who have substantial grants from other Federal agencies such as the NIH.)

Four of the PIs (each of whom had had significant reductions in support) said that AIBS received a substantial amount of money that should be channeled into research support, rather than administration. [We have not been able to find a standard for an "appropriate" percent of administrative expenses in running a research program. If this information does not exist it should be obtained in collaboration with NIH and other Federal agencies that support research.]

Conclusions As suggested above, it appears likely that the opinions of individual PIs about the performance of AIBS are related to the results (in terms of financial support) of the AIBS-arranged Site Visits to each of the network laboratories. Nevertheless, there is one obvious and important theme among the many comments of the PIs:

> Delineation of Responsibilities Even the most savvy of the PIs reported some confusion about the relative roles of AID and AIBS. Each agreed that a specific written summary of their roles would be helpful. Because there is disagreement about their roles between AID and AIBS, it will be essential to settle these issues in Washington before attempting to clarify the roles of AIBS and AID to the individual PIs.

Despite the concern at both AID and AIBS about personality conflicts, none of the PIs interviewed volunteered that he/she noticed or had been adversely affected by personality conflicts between workers at AID and AIBS. (This question was not raised as part of the interview.)

E. Malaria Network Management

1. Decision Making at AID

We recognize that the main focus of this evaluation is the role and performance of AIBS under its contract-not that of AID. However, because AID and AIBS share a number of responsibilities for the management of the malaria vaccine research network the actions of AID may impinge directly on the AIBS ability to function, and have considerable impact on performance in the research network.

During the course of our evaluation we concluded that many of the present and previous difficulties would be mediated if the CTO and his immediate superior held more independent authority.

We recognize that there are historical reasons for AID senior managements close involvement in this project. But we feel compelled to say that it is now time to reestablish the authority of the CTO and his immediate superior. In our opinion, these people cannot function and the program cannot run effectively if they do not have the authority to make essential program-related decisions. Although these comments may seem obvious and unnecessary, we include them because it is our perception that their authority has been greatly restricted during the last several years, and that exceptionally well-qualified staff like the recent CTO's cannot be expected to function well or to remain under these conditions.

2. Research Management Methods

AID utilizes a variety of management systems to implement and direct its projects. These systems vary from the standard AID project management method (AID staff project manager-implementing agency) to agreements delegating full responsibility to an outside manager who subcontracts to other entities. In the latter case AID monitors the overall results but retains no authority over day-to-day operations. A variety of management methods between these two extremes are also in effect. No one system used in the Bureau of Science and Technology has proved ideal, and the availability and experience of AID direct-hire staff influences the system adopted. Other important factors include the dollar value of the project, its duration, the number and location of activity sites, and whether the project is service, development or research in nature.

The Malaria Immunity and Vaccine Research Network is a large, complex, enduring research and development project which requires extensive technical and managerial skills. Since 1982 AID has contracted for technical and administrative support skills to help administer and coordinate this project, but has officially retained nearly complete management responsibility. It has attempted to avail itself of sufficient staff by using young professionals temporarily attached to AID by one means or another. There has been considerable misunderstanding, disagreement and conflict between these earnest but mostly inexperienced temporary AID staff and staff of the contractor. We conclude that this is largely because of supervisory difficulties and the lack of practical wisdom and insecurity of these non-career employees. Ideally projects such as the malaria network should be managed by regular, career staff of the

agency; when this is not possible AID should adopt a suitable alternative system from its own, or outside, research contract management experience. Here, briefly, are the alternatives.

a. Management by AID: Contract for Non-technical Support
There is no doubt that AID staff are severely hampered by a shortage of direct-hire support staff and inadequate clerical and administrative support services. An outside contractor to provide secretarial services, travel arrangements, organize meetings, coordinate reports, etc. would be very helpful. But we think such an arrangement would be inadequate; it would not meet the acute need for greater technical and managerial strengths in directing the network.

b. Management by AID: Contract for Technical and Non-technical Support
This is essentially the current method of operation with AIBS. Through the efforts of the current CTO and contract PD many improvements have been made, but the limitations of this arrangement are evident: continuing confusion over respective responsibilities, conflict between insecure, temporary staff in both offices, an obsession with particulars, and a lack of attention to strategic issues. We feel that the complexities of this project and difficulty of perceiving future courses of action require a greater delegation of responsibilities than is currently practiced.

c. Management by Cooperative Agreement In this model the full responsibility for day-to-day management of the malaria vaccine research network would be delegated by agreement. AID would maintain close oversight, but be principally involved in assessing the implications of network findings and developing longer term strategies and policies. All project coordination, evaluation and much of the necessary effort for the division of resources to cover the spectrum of technical effort required to develop a vaccine would be delegated.

Numerous institutions in the U.S. are capable of managing such research, but few are experienced in dealing effectively with foreign countries where any vaccine will be tested and developed. We think that AID, with the help of its regional bureaus, should be concerned mainly with monitoring strategic issues associated with malaria vaccine development, determining when field trials will be needed, and preparing for them. This represents a marked change from the current situation. It would eliminate most of the existing confusion over respective responsibilities since virtually all day-to-day program responsibilities would be with an agreement holder. The CTO would retain control over certain financial and procurement procedures and could be the sole AID staff overseeing the vaccine research project. Additional AID staff would be required for technical support of vaccine field trials and strategic planning responsibilities.

d. Management by a Consortium Malaria is a major problem and of great concern in other institutions. In the U.S. the Army, National Institutes of Health, Centers for Disease Control and AID are all members of the Federal Malaria Vaccine Coordinating Committee. International organizations and foreign countries are also concerned, and it is possible that the numerous bilateral malaria projects may someday be replaced by multilateral support for research and development coordinated by a consultative group. This model has been used to great advantage by the

International Agricultural Research Centers. The U.S. agricultural universities also work through various consortiums to manage and implement AID projects. The main advantages of these are the broad base of scientific knowledge available to the consortium. Such management systems usually result from an evolutionary process-but the widespread concern over the disease and need for broader scientific inputs into the malaria research network suggest a multilateral management system deserves some consideration.

APPENDIXES

APPENDIX A: Interviews

11 January

John Austin, AID, Head, Communicable Disease Division
Carter Diggs, AID, CTO
Kirk Miller, AID, Malaria Project
Caryn Miller, AID, Malaria Project
Sandy Fairfield, AID Malaria Project

12 January

Charles Chambers, Executive Director, AIBS
Don Beem, Asst. Executive Director, AIBS
Phil Winter, Project Director, AIBS
Peter Jackson, AIBS Project Staff
Gillian Wollett, AIBS Project Staff

13 January

John Austin, AID
Jim Heiby, AID, Former CTO

30 January

Ann Van Dusen, Deputy Director, Office of Health, AID
Carter Diggs, AID
Caryn Miller, AID

31 January

Phil Winter, AIBS
Angela Beamon, AIBS

1 February

Phil Winter, AIBS
Carter Diggs, AID
Caryn Miller, AID
Sandy Fairfield, AID
Ruth Nussenzweig, PI

2 February

Noel Souza, Administrative Associate, AIBS
James Nindel, Acting Contracting Officer, AID
Gillian Wollett, Research Analyst, AIBS
Peter Jackson, Research Manager, AIBS
Ann Van Dusen, AID
Genese Pettigrew, Program Officer, Office of Health, AID
Doug Sheldon, Director, Program Office, S&T, AID
Garland Stanrod, Program Officer, Program Office, S&T, AID
Joyce Frame, former Contracting Officer, AID
C. C. Campbell, PI
Charles Watson, PI
Mike Hollingdale, PI
Werner Zolg, PI

3 February

Judith Johnson, former Contracting Officer, AID/W (telephone)
Charles Chambers, Executive Officer, AIBS (telephone)
Jim Heiby, AID
Ken Bart, Director, Office of Health, AID

6 February

John Martin, PI
Richard Weller, PI
Masamichi Aikawa, PI

7 February

Russell Howard, PI
Wasim Siddiqui, PI

10 February

Miodrag Ristic, PI

21 February

Bob Reese, PI
Harley Sheffield, PI
Myron Levine, PI

APPENDIX B: Telephone Survey Questionnaire

PHONE QUESTIONNAIRE FOR PRINCIPAL INVESTIGATORS

Date _____

Principal Investigator: _____
Site: _____

1. Site Visits and Evaluations:
   Composition of the Site Visit Team: _____
   Performance of the Visit per se: _____
   _____
   _____
   Accuracy of the Report, including format and apparent editing:
   _____
   _____
   Handling of Responses (Rebuttal) to the Evaluation: _____
   _____
   Revision of Project Objectives in Response to the Site Visit:
   _____
   Formal Recommendations from AID on the Basis of the Site Visit:
   _____
   Amendment of the Agreement or Contract with AID? _____

2. Progress Reports:
Perceived role of AIBS: _____
Changes Based on the Site Visit: _____
Are publications sent with Progress Reports? _____

3. Review of Major Proposals:
Can any conclusions be drawn about the relative roles of AIBS and AID in this process ? _____

4. Review of Small Subcontracts Research Proposals:
Can any conclusions be drawn about the relative roles of AIBS and AID in this process at this time? _____

5. PI Meetings:
What are the major virtues and problems of these meetings? Can any conclusions be drawn about the relative roles of AIBS and AID? _____

6. Purchasing of Equipment:
Is the current mechanism functioning as it should in relation to the Cooperative Agreement, Contract or Grant? Are the relative responsibilities of AIBS and AID clear in this process? _____
_____

7. Letting of Subcontracts:
Is this occurring as it should? Does it facilitate the performance of the research? _____

8.Use of Primates and the Primate Use Committee:
Are primates available for studies relevant to vaccine development? What is the role of the Primate Use Committee in these studies?

9.Field Trials:
What are the relative responsibilities of AIBS and AID in these trials (for investigators currently involved and those who expect to be involved in the future)?

10.Overall:
What is the practical impact of the dual involvement of both AIBS and AID in this project?

How should the system be changed to make it function better?

How do you decide whom to contact for what?

PHONE QUESTIONNAIRE FOR PRINCIPAL INVESTIGATORS

General Guidelines:

1.We have been asked to review the relative roles of AIBS and AID in running the AID Malaria Vaccine Program, and how they have affected the performance of the research by individual Principal Investigators,

2.We are primarily interested in the way the system has functioned during the time when Jim Heibey and Carter Diggs have been at AID

3.We would like to have specific suggestions for improvement, including models of how the system should be run, including suggestions for model mechanisms to facilitate the performance of the research.

APPENDIX C: A.I.D. Evaluation Summary, Part II

A. Findings

The principal finding of this evaluation is that there is considerable confusion over the division of responsibilities in the malaria vaccine research network. It exists in AIBS, among many of the PIs in the network, and in AID. This may not be surprising, given the management difficulties in recent years and diminishing expectations for early development of a vaccine against malaria. But it is a condition that must be corrected if past gains are to be consolidated and research progress maintained. Our recommendations are all intended to help correct this problem.

But the larger concern should be the implementation of improved managemen methods. The continuous decline of AID's operating budget has severely hampered its ability to supervise complex projects such as malaria vaccine research. It is now necessary for the Agency to meet many of its supervisory responsibilities by creative use of its program budget: sometimes by innovative employment of temporary staff, more often by contracting responsibilities. In the malaria project it has tended to rely substantially on temporary staff, retain many management functions, and contract mainly for support services. We find that temporary staff, those who do not have recognizable tenure with AID, are not equivalent in experience or authority to AID direct-hire staff, which impairs project direction. It is therefore essential that more management responsibility for the malaria project be delegated by agreement.

B. Conclusions

The AIBS contributions to the malaria research network are many, but the activities defined in the Scope of Work of the present contract are no longer valid. These activities were changed by circumstances during a period of extreme difficulty, when the efforts of the contractor helped keep the network functioning. Site visits and evaluations of individual projects within the network have been carried out. AIBS organization of meetings and conferences has been effective. The consultant roster has become an effective tool for developing panels to review proposals, for arranging site visit teams, and for evaluating proposals for the use of non-human primates.

Generally AIBS has, whenever possible, adhered to its obligations to AID as defined in the contract. Both AID and AIBS made managerial adjustments in 1987; AIBS appointed an experienced Project Director (PD) soon after the AID CTO left. Thus, during much of the period when AID had a temporary, acting CTO (April 1987 - September 1988), AIBS was able to assume greater responsibility for technical support of the network. All necessary tasks were performed and primary goals have been reached by AID, AIBS and the members of the network-an indication of the strength of the effort and the commitment of all parties. But there are difficulties within the network, many of which are due to the fact that scientific progress toward a vaccine has been slower than anticipated.

The malaria vaccine project has evolved into a complex network of interrelated and highly technical agreements and contracts. To monitor, understand and direct events has become progressively more difficult. This

is now attempted with a mix of AID and contract technical staff, most of whom are in short-term, non-career positions. This dependence on junior staff was, for most of the taime period considered, made more difficult by the prolonged absence of an experienced CTO. Relationship issues between AID and AIBS must be resolved if the more difficult and important scientific problems confronting the network are to receive appropriate attention.

Interviews with Principal Investigators in the network disclosed several concerns: confusion over responsibilities, reservations about the usefulness of site visits by large teams, questionable primate management, and a lack of feedback from progress reports.

C. Recommendations

We recommend the following changes: a) re-budgeting in conjunction with revisions in the scope of work and real costs of primates and equipment purchases, b) the level of effort be modified in light of revisions to the scope of work and the budget, c) AIBS prepare detailed position descriptions for all staff, and d) an equipment list be devised using the AIBS inventory list and an estimate of future needs.

We recommend immediate revisions based on an assessment of accomplishmen to date and what can reasonably expected to continue. Particular attention should be focussed on the assignment of specific responsibilities to AIBS which can be implemented independently of direct AID technical staff input. The scope of work should also clarify the responsibility and authority which AIBS exercises over the PI contracts implemented by AID.

We recommend that all AID and AIBS managerial and technical responsibilities for support of the network be redefined. They must also be assigned in proportion to institutional ability to do the job. This means an ability to employ, support and supervise the necessary staff. On a related issue-we recommend that within AID full authority and responsibility for the malaria project again be delegated to a permanently assigned CTO.

Because of the complex nature of the research, and the difficulty of assessing the rate of progress toward a practical immunological defense against malaria, permanent, independent sources of scientific advice are much needed. The initial steps taken to establish Scientific Consultant Groups are a start which we commend; we strongly recommend that these be made permanent bodies whose members serve fixed terms, that AID malaria network contract holders be excluded, and that the SCG's meet periodically. Their responsibilities should include defining practical research objectives for the network, determining that the spectrum of network research is comprehensive and the projects complementary, and continuous evaluation of the quality and pertinence of AID funded research results. We also recommend several changes in network management methods: that primary evaluation of projects be by periodic advisory committee review of progress reports rather than site visits, and that necessary site visits employ teams of only 2-3 members addressing narrow, well-defined issues. Funding intervals so that most major projects should run concurrently in order to facilitate changes in the direction of network efforts.

The degree of scientific complexity, uncertainty of outcome, and the influence of accumulated vested interests all argue for substantial change in network management. Because of personnel limitations AID can no longer provide the needed level of day-to-day supervision. We therefore recommend that a competitively bid contract or cooperative agreement delegating delegating broad management responsibility and authority for directing vaccine development research replace the AIBS contract on expiry. We emphasize that this be short-term, tactical direction toward AID defined objectives; strategic direction should remain with AID. We also recommend that only vaccine development and clinical trial research management be contracted, and serious consideration should also be given to what separate mechanisms will be needed to supervise overseas field trials.

APPENDIX D.

SCOPE OF WORK

MALARIA IMMUNITY VACCINE RESEARCH CONTRACT
MID-TERM FORMATIVE EVALUATION
American Institute of Biological Sciences (AIBS)

OBJECTIVES:

MSH is requested to provide the services of several persons to participate in the evaluation of the AIBS contract. One direct hire A.I.D. person will be a part of the team.

This team will be charged with reviewing and evaluating the administrative, managerial, and technical aspects of the AIBS contract.

GOALS:

1. To evaluate the accomplishments of the AIBS contract, up to the time of the evaluation, in relation to the contract objectives (Section C) and specific items in Section B.1 of the contract agreement, namely:

   a. Annual work Plan, (page 2);
   b. Six month summary, (page 2);
   c. Fiscal reports, (page 2);
   d. Trip reports, (page 3).

2. To evaluate their performance in carrying out the scope of work (SOW) (Section C, item B) and their contributions to the overall contract conduct.

3. To prepare a set of recommendations for S&T/H relating to:

   a. Changes that should be made in the contract managed by S&T/H which will improve its effectiveness;

   b. Changes that should be made in AIBS's Scope of Work for the remainder of the contract, that will improve its ability to serve A.I.D. needs;

   c. Changes that should be made in AIBS's working relationships with other entities (inside and outside A.I.D.) to enhance its impact in malaria vaccine development research;

   d. Continuation of funding of the contract, and if so, what similarities and differences it should have from the resent contract. For example, should vaccine development aspects be separated from field trials efforts.

MSH SCOPE OF WORK

1. MSH is requested to provide the services of several persons to participate in the evaluation of the AIBS contract. One direct hire A.I.D. person will be a part of the team.

2. The team will be responsible for preparing an evaluation report, addressing items in the following Evaluator's Scope of Work and any other items added in consultation with the Cognizant Technical Officer (CTO) during the evaluation period.

3. The team will meet in the Washington area initially for a two-day team planning meeting to organize the evaluation process, to make assignments and clarify the SOW, review background, set up an action plan for conduct of the evaluation process (e.g., whom to meet with, when to meet, questions to ask, team meeting times, etc.) and draft an outline of the report's content. MSH will select a person qualified to conduct the team planning in collaboration with the CTO, who will also approve the action plan. Assignments will be made for each section of the report and amount of time required for each person for collecting and analyzing information, writing and finalizing the report.

4. The team should include persons with experience in:

   a. Broad areas of competence

      1.) Management and evaluation of research programs
      2.) Background in malaria (immunology preferred)
      3.) Familiarity with vaccine development issues

   b. Background experience required

      1.) A.I.D. project and contract management:
      Experience is required with all aspects of managing centrally-funded projects and/or managing projects in the field.

      Requires familiarity with use of sub-contractors and consultants, office management, management information systems, and report preparation.

      2.) Project coordination and collaboration:
      Experience with coordination and collaboration of A.I.D. (or other US Government) projects with other federal agencies, international agencies, professional organizations, research institutions, and with the A.I.D. malaria vaccine program.

      3.) Technical aspects of malaria vaccine research and development in relation to activities of program.

      4.) Policies and processes for animal care and use.

5.) Policies and processes for conducting ethical and scientific peer review of proposals, reports, and research protocols.

6.) Scientific and managerial evaluations of on-going MIVR contracts and agreements.

7.) Assistance in development of technical and managerial aspects for field activities necessary for vaccine evaluation.

c. Major issues to be addressed

1.) General: To evaluate the assistance to the A.I.D. vaccine development project; if original objectives are being satisfied; if the efforts of contractors are in concert with A.I.D. research and management objectives; where general changes in its mandate might improve its effectiveness; and, adequacy of staffing and budget vis-a-vis A.I.D. needs and demands.

2.) Scope of AIBS activities: To evaluate the appropriateness and balance of the key areas of AIBS activities. To address the issue of long-term institutional memory and cumulative lessons learned in the management of the malaria vaccine program.

3.) AIBS management: To evaluate responsiveness and cost effectiveness of AIBS activities; quality and timeliness of reports; response to requests; adequacy of AIBS staff; quality of liaison with A.I.D. and other organizations; procedures used to select personnel, consultants, subcontractors to assist implementation, and quality of logistic support.

4.) S&T/H and AIBS relationships: To evaluate management, communications, collaboration, coordination, and working relationships between the two groups. Is A.I.D. management of AIBS adequate: Is AIBS responsive to A.I.D. staff?

5.) Technical assistance: To evaluate the effectiveness and appropriateness of direct and indirect technical assistance provided to program projects and the A.I.D. management. Elements of this assistance include advisory groups, research subcontracts, technical meeting, publications, and staff and consultant utilization.

6.) External relationships: To evaluate AIBS relationships with other professional groups, universities, international organizations, US government agencies and foreign governments. Are these activities in appropriate balance with goals and resources of the project? What improvements could be made from the standpoint of these groups?

d. These persons will be selected in collaboration with the CTO, and with his concurrence. None of the persons selected should have any association with the contract.

5. MSH will be responsible for all contracting, typing and reproduction of the evaluation report and making travel arrangements.

FINAL REPORT

1. MSH will review draft outline prepared in team planning meeting with CTO before team members begin and obtain approval from CTO.

2. MSH should review draft material, as prepared, with CTO to determine if any changes in action plan are needed.

3. MSH should be sure that action plan is realistic in time and that team member allocation of talent in preparation of final report is adequate. MSH will be responsible for meeting time deadlines and meeting quality requirements laid out in Team Planning Meeting and comments received from CTO.

4. MSH should be sure that the standard A.I.D. Evaluation Summary Form is completed and included in the report. MSH will make arrangements with AIBS Program Director to review contract records, arrange interviews with project staff, and scheduling (if needed), etc.

5. As time of completion of report approaches, MSH will schedule a briefing for the CTO, and other staff. A second briefing will be scheduled for the contractor.

6. 25 copies of the final reports will be submitted to S&T/H.