MEMORANDUM

DEPARTMENT OF [illegible], [illegible], AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Director, NHLI
THROUGH: Deputy Director, NHLI

DATE: March 22, 1973

FROM : Director, DTA

SUBJECT: Present Status of DTA

Since the Director of DTA took over the Division a year ago, it has become increasingly evident that he was facing a series of problems and difficulties antedating his accession and involving both the T & E Facilities and the organization of the Division. It has now become evident that a number of urgent and rational steps need to be taken now in order to correct this inherited situation and to turn this Division in a constructive direction away from its previous shortcomings.

TEST AND EVALUATION FACILITIES

The situation in the Test and Evaluation Facilities has taken several months to study and to evaluate. It was the subject of a previous memorandum on January 23, a copy of which is attached. The situation has also been the subject of a continuing review carried from the original concept to present activities, supplemented with a recent site visit to each of the facilities.

The IITRI facility was opened for operation on June 30, 1969 and up to January 31, 1973 has cost NHLI $5,340,806. The UBTL facility was started on December 18, 1969 and reached full operational status in the new building in December 1971. The total cost of it up to December 31, 1972 has been $4,001,800.

Whereas IITRI was started in a remodeled but pre-existing physical plant, UBTL was installed in an extravagantly large and luxurious new facility capable of accommodating 40 calves simultaneously in the intensive care unit. The creation of these facilities on such a scale was predicated on two assumptions.

1. That work on the artificial heart would make a totally implantable heart ready for human implantation in 1970 (Hittman report), and

2. That funding for the program would continue to increase and would by the present time surpass $20 million dollars a year.

Both of these assumptions were wrong. The fallacy of them is underlined by the fact that DTA's budget for fiscal year '73 and presumably for fiscal year '74 will be limited to 9.6 million dollars, despite a program the scope of which has been vastly enlarged and by the fact that a sufficient number of functionally acceptable devices has not been developed.

As a result, neither of the two facilities has been able to utilize the potential capability fully. Because of the very different nature of the physical plants, the composition of the staffs, and the mode of operation of the two establishments, the cost of performing the same type of work is very different in the two institutions. These costs are pictured below:

UBTL*		IITRI**	
Projects costs	$.26	Projects Costs	$.61
Facilities costs	.74	Facilities costs	.39
	$1.00		$1.00

	UBTL	IITRI
For each $1.00 spent for the program,	$.26	$.61
goes for testing and evaluation of devices, and	$.74	$.39
goes for facility overhead. Effectively the overhead rates are	285%	64%
for the period 7/1/72-12/31/72.		

The differences are also indicated by the fact that at UBTL the cost of implanting 144 Gott vena caval rings in dogs is projected to be $122,000 in fiscal year '74 or about $850.00 per experiment. In this connection Mr. Harker himself volunteered the statement that costs at UBTL cannot be reduced and that, if anything, UBTL with 55 people is understaffed and insufficiently funded and cannot begin to function effectively until it has a budget in excess of $2,000,000.

Effectiveness of the T & E Facilities

As far as effectiveness of the T & E Facilities is concerned, the performance of both facilities to date has been, in general, unsatisfactory despite these levels of expenditures. The two facilities have studied and, in some instances, are studying a series of devices, the intraaortic balloon counterpulsation unit and console, the Dow Capillary membrane oxygenator, the creatine phosphokinase detector, the Westinghouse blood gas analyzer, etc. The performance of UBTL relative to the intraaortic balloon has been weak, and that relative to the Dow capillary oxygenator has been poor from the points of view both of scientific caliber of investigation and quality of reporting. On the same devices the performance of IITRI has been good to fair. In addition, UBTL has spent $295,000 on the VAB, a device developed

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*Project costs for UBTL include labor, services, consultants, equipment supplies, and travel which can be identified with a project.

**Project costs at IITRI include labor of "captive staff" that labor of the expendable materials, equipment, services/rentals and other direct costs which can be identified with a project.

by MDAP for an estimated $100,000 for the admitted purpose pf producing something to keep UBTL busy. (See attached photocopy of Reed Harker's notes of May 14, 1971 and DTA review of the VAB system dated January 19, 1973.) The VAB system was finally rejected, principally because it causes excessive hemolysis, a decision that could have been reached at a very early stage with very economical bench testing in an adjacent laboratory for developmental review.

With regard to another development within the Division, the Dow capillary membrane oxygenator, the device was prematurely hurried to clinical application for unscientific reasons (see attached detailed review, dated January 30--see also attached photocopy of notes by Mr. Reed Harker, May 14, 1971).

SHORTCOMINGS WITHIN THE STRUCTURE OF DTA

From the initial concept of the test and evaluation thesis and until a year ago, there have been serious shortcomings which can be laid, at least in large part, at the door of the structure of the Medical Devices Applications Branch. These shortcomings have contributed to the deficient performance of the T & E's. Members of the scientific staff without experience in investigative methods, in the running of a laboratory, or in biomedical research have been given the responsibility for making critical decisions for monitoring both development and test and evaluation, and for making judgments upon the caliber of reports from contractors. These include, specifically, virtually all of the commissioned officers including Dr. Allen Ream, Dr. Roger Ferguson, Dr. Sheldon Rabin, Dr. Thomas Militano, Dr. Glenn Sandberg, Dr. Richard Scott, Dr. Lowell Harmison, Mr. Frank Altieri. As a result, well stipulated portions of contracts with developers and with the test and evaluation facilities have been either distorted or not carried out at all.

Some of the causes of poor performance are crucial items. For instance, the contracts have specified the Contract Officer as the source of protocols. The Program Office has rarely furnished such protocols, chiefly because no one on the staff has been competent to do so or because the qualified staff has been inadequate in number to permit anyone to have time to do so. Protocols therefore have grown at times in clear violation even of the specified protocols of scientific task force groups, as in the case of DCMO in which the admonition of the task force not to use hemodilution carrying the hematocrit below 30% was ignored, so that the results in the T & E facilities have been inconclusive and much time and money have been wasted. Just as in regard to dealing with developers of devices, the component of the office of the Division of Technological Applications which deals with the test and evaluation activity must have sound expertise in sufficient depth on a day-to-day basis to avoid fiascoes like the Veno-Arterial Bypass. This, specifically, means men on the full-time staff, not periodic consultants.

VIEW OF THE DIRECTOR, DTA, ON NEEDS FOR THE IMMEDIATE FUTURE

The Director of DTA has now developed very strong views on the following points. Such opinions were also expressed very clearly in the individual reports of some of the Review Committee on T & E, April 10, 1971.

Preservation of T & E Function

It is positively essential to maintain the function of test and evaluation to maintain the effective operation of DTA. Loss of such facility would essentially emasculate the program of that division. If one is to have the essential objective evaluation of high quality, the purpose of test and evaluation cannot be done in the private sector, where objectivity is most unlikely. It can and must be done by an independently supported test and evaluation facility in close cooperation with a supervising staff such as a properly reorganized scientific staff of the Division of Technological Applications. This supervision is extremely important, for there is always a large measure of expertise which can and should be gained by the scientific staff of DTA during development of a device or pattern of instrumentation, and the participation of that scientific staff is required during development in order to gain the refinement of scientific protocol needed for test and evaluation later.

If there were to be no test and evaluation facility in the Division of Technological Applications, two results might be expected:

1. DTA might not participate in test and evaluation in any way. The result would be occurrence of more tragedies like the split aortic valve balls of silastic rubber; that is, systematic test and evaluation simply would not be done, and the public health would suffer.

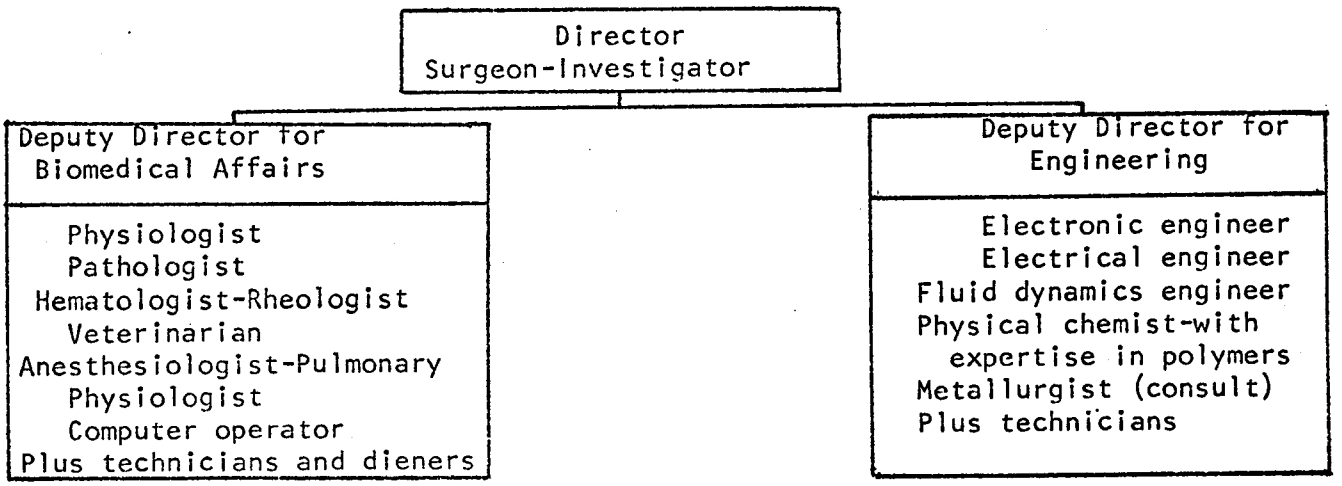
2. If DTA were to give test and evaluation to the private sector on a contract basis, the program would suffer as much by loss of objectivity as by a certain slowness and added cost as compared with a properly functioning test and evaluation facility within DTA. This is true because of the necessity for the contractor to gear up to the test and evaluation and because of the time needed for getting necessary equipment which would almost surely be on hand in a properly organized test and evaluation laboratory.

The work of one effective T & E facility is absolutely essential to effective operation of DTA. The following are devices and studies which are being investigated or will be within the next twelve months and for which the T & E function must be, and with the proposed plan can be, properly organized:

Pacemaker implants powered by plutonium, comparative study of all available oxygenators, Gott caval ring tests on materials for hemocompatibility, probably Kusserow aortic ring tests for the same purpose, completion of evaluation of the Westinghouse blood gas probe, comparative study of blood filters, completion of studies on the Dow capillary membrane oxygenator, nitrogen analyzer study for the Lung Division, the Tecna volume modulated respirator, comparative evaluation of artificial ventricles, and initial testing of devices for FDA if device legislation is enacted.

Proper Organization of a Test and Evaluation Facility

It has become clear than an effective test and evaluation facility, to solve or study biological problems, must have direction from a seasoned and accomplished surgical investigator. He should be flanked with a second man with the same qualifications and by an engineer of similar accomplishment, both of whom should be full time workers in the laboratory. The staff ideally should be as outlined:



Proper functioning in the test and evaluation facility can be expected only with the very closest cooperation with and guidance of the properly selected scientific staff of the Division of Technological Applications. It is this staff who must set up the protocols (as originally envisioned, but not carried through for lack of appropriate scientific expertise in the Division).

Criticisms of UBTL

Quite apart from the enormous size and cost of the facility, the staffing is not at all appropriate for a test and evaluation facility for the Division of Technological Applications. It is very heavily dominated by nonmedical people. Of the three top men in the administrative organization, Mr. Harker has a B.S. in Physics and a B.S. in Electrical Engineering, Mr. DeGroot has a B.S. in Electrical Engineering, and Mr. Couvillon has a Masters Degree. With this background it was Mr. Couvillon who organized and staffed the engineering department and who provides day-to-day technical leadership to this group.

The biomedical input is ineffective, even though Dr. Kralios, a physiologist, and Dr. Toronto, a cardiologist, are listed. Dr. Russell Nelson is listed as 50% time, but on no visit to the T & E has he been observed at work in the laboratory. Apparently his participation is in the clinical testing and in paper work. Mr. Harker has stated to one of us that the reason he hired Dr. Nelson was that Dr. Nelson's fine reputation would be invaluable to ready wide adoption of the Dow capillary membrane oxygenator if Dr. Nelson approved of it. Although there is no constantly present surgical investigator on the premises, Dr. Mortensen is listed as a consultant and comes in for the purpose of performing the dissections and cannulations but does not stay through the experimental procedures. Conversation with him suggests that his scientific input is minuscule.

Although the initial site visit discussions at Utah involved superb people like President Fletcher, Dr. Max Wintrobe, Dr. Homer Warner and Dr. Keith Reemtsma, and although it was formally agreed that organization and selection of staff would be performed only with the coordination and agreement of NHLI, the staff was oriented without biomedical direction in the top levels, without full-time surgical input and without engineering direction by a man with the expected high academic cridentials.

The original plan was that the T & E Facilities would provide objective testing and evaluation of devices as they became available. Had the artificial heart progressed as the Hittman report prophesied, had funding increased as originally anticipated, had MDAB (and later DTA) been staffed with experienced investigators in adequate depth, and had the Test and Evaluation Facilities developed as hoped, this would have proven a sound and essential plan, and the program of DTA would have been far ahead of what it is.

Criticism of IITRI T & E

With regard to the IITRI Test and Evaluation facility, the present memorandum is in supplementation of the memorandum of January 23, reflecting some changes in circumstances and detailed information which do not change the recommendations of that time with regard to organization and management, but do with regard to favored location. (Copy of memorandum attached) Since that memorandum the following changes have occurred.

1. Dr. Kaye has found opportunities to participate clinically in test and evaluation work.
2. A letter has been sent to each T & E facility indicating the necessity to economize or consolidate and requesting detailed information on costs and accomplishments (sample copy attache, responses attached).
3. The management at IITRI has been responsive and adaptable.
4. The management at UBTL has been obdurate concerning economy, biomedical leadership (or even full-time surgical input), and possible closure.
5. Dr. Kaye has understood the criticisms which have been made and indicated a sincere willingness to join forces with this office in setting matters on the proper course. This includes the relinquishment of certain personnel and acquisition of others of greater strength, concerning which Dr. Kaye and this office are in agreement.

Reorganization of Division of Technological Applications

In order to perform effectively, it is essential that the Division of Technological Applications be reorganized at the same time that the Test and Evaluation capability is being reorganized and consolidated in one facility. In a memorandum of February 20, 1973, recommendations were made for reorganization of the Division of Technological Applications (copy attached). This includes replacement of the commissioned officers by scientists of appropriate background and accomplishment in investigational work to monitor the running of the entire program in a scientifically proper fashion.

Adjacent Laboratory for Developmental Review

The proposed Adjacent Laboratory for Developmental Review is an entirely distinct and separate laboratory in location and in function from the Test and Evaluation Facility. The purposes of such a laboratory are these:
1. It will serve to permit exploraton of ideas originating in the Division and not covered in responses to RFP's in order to sharpen the focus of future RFP's to facilitate development.
2. The Laboratory will provide early testing of devices developed in the program in order to refine the protocols to be drawn for test and evaluation, and thus it will serve in a complementary fashion to the Test and Evaluation Facility.
3. Dr. Comroe pointed out in the recent Council meeting that the time to review RFP's is before and while they are being written and that the utilization of an Adjacent Laboratory for evaluation of new medical technical concepts should provide a capability within the office which is badly needed for that purpose.
4. The laboratory will serve to perform special testing that is not within the capability of the contractors, such as comparison of various membranes for membrane oxygenators to provide information which is essential to the office to make constructive judgments as to further procedure.
5. The Laboratory will serve as an area in which to do sufficient basic work to permit scientifically sound establishment of protocols for development of instrumentation or devices in the hands of contractors.
(Further details are included in the attached memo).

As indicated in the attached RFP letter, the Adjacent Laboratory will have four full time employees, including two co-Principal Investigators on the same basis as the expiring Meloy contract or the expiring Travenol contract (contracts which are being permitted to expire because of failure to engage the proper caliber of personnel). The time contribution of members of the staff of DTA will be in general only sufficient for frequent observation and direction, rarely for actual participation.

Had such a laboratory been in operation at the time the Veno Arterial Bypass system was introduced into the UBTL, the saving to the program would have been in excess of a quarter of a million dollars.

CONCLUSIONS

1. The facility to perform test and evaluation is absolutely essential to the success of DTA
2. DTA does not have the resources or the need to run two T & E Facilities
3. DTA does not have the resources or the need to operate a facility as large and costly as UBTL.
4. DTA can run a facility of the dimensions of IITRI T & E facility effectively and efficiently
5. The staff of IITRI understand the criticisms of past performance and express readiness to join in restructuring the organization and makeup of the staff
6. The staff of UBTL does not understand the criticisms of past performance, refuses to accept any limitations on previous modes of operation and demands still larger funding.
7. Effective operation of a T & E Facility and indeed of any of the contract program demands the reorganization of the staff DTA to provide men with expertise in investigation in each area involved in sufficient depth to do a meaningful job of supervision
8. An Adjacent Laboratory for Developmental Review will enhance immensely the effectiveness of the entire program.

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Sylvain Pitzele, M.D., Ph.D.

RECOMMENDATIONS:

The Director, DTA/NHLI vigorously recommends that the following measures be taken to redirect the Division

1. UBTL be phased out at the earliest moment.
2. IITRI be reorganized and maintained.
3. Proposed reorganization of DTA be approved.
4. Permission be granted to distribute RFP's for Adjacent Laboratory for Developmental Review.