

WMC FILE COPY

2

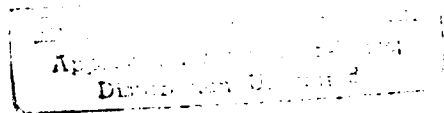
BIOMEDICAL EQUIPMENT MAINTENANCE AND REPAIR
NAVAL REGIONAL MEDICAL CENTER
CAMP PENDLETON, CALIFORNIA

AD-A202 685

DTIC
SELECTED
JAN 25 1983
S D

A Graduate Research Project
Submitted to the Faculty of
Baylor University
In Partial Fulfillment of the
Requirements for the Degree
of
Master of Health Administration

by



Jack D. Chapman

Lieutenant, MSC, USN

August 1983

89 1 18 066

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1a. REPORT SECURITY CLASSIFICATION		1b. RESTRICTIVE MARKINGS	
2a. SECURITY CLASSIFICATION AUTHORITY <u>Unclassified</u>		3. DISTRIBUTION / AVAILABILITY OF REPORT	
2b. DECLASSIFICATION / DOWNGRADING SCHEDULE			
4. PERFORMING ORGANIZATION REPORT NUMBER(S) <u>119-88</u>		5. MONITORING ORGANIZATION REPORT NUMBER(S) <u>Approved for public release; Distribution unlimited</u>	
6a. NAME OF PERFORMING ORGANIZATION <u>US Army-Baylor University Graduate Program in Health Care Admin/HSMA-IHC</u>	6b. OFFICE SYMBOL <i>(If applicable)</i>	7a. NAME OF MONITORING ORGANIZATION	
6c. ADDRESS (City, State, and ZIP Code) <u>Ft. Sam Houston, TX 78234-6100</u>		7b. ADDRESS (City, State, and ZIP Code)	
8a. NAME OF FUNDING / SPONSORING ORGANIZATION	8b. OFFICE SYMBOL <i>(If applicable)</i>	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER	
8c. ADDRESS (City, State, and ZIP Code)		10. SOURCE OF FUNDING NUMBERS	
		PROGRAM ELEMENT NO.	PROJECT NO.
		TASK NO.	WORK UNIT ACCESSION NO.
11. TITLE (Include Security Classification) <u>BIOMEDICAL EQUIPMENT MAINTENANCE AND REPAIR, NAVAL REGIONAL MEDICAL CENTER, CAMP PENDLETON, CALIFORNIA</u>			
12. PERSONAL AUTHOR(S) <u>LT Jack D. Chapman</u>			
13a. TYPE OF REPORT <u>Study</u>	13b. TIME COVERED FROM <u>Jul 83</u> TO <u>Jul 84</u>	14. DATE OF REPORT (Year, Month, Day) <u>AUG 83</u>	15. PAGE COUNT <u>72</u>
16. SUPPLEMENTARY NOTATION			
17. COSATI CODES		18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number)	
FIELD	GROUP	SUB-GROUP	
		<u>Health Care, Biomedical Equipment Maintenance Preventive management. (SDW/KT)</u>	
19. ABSTRACT (Continue on reverse if necessary and identify by block number)			
<p>Recent growth in the field of biomedical equipment technology has been rapid, producing a proliferation of increasingly complex medical devices. In order to assure continuous, efficient, and accurate utilization of equipment, a comprehensive, well designed maintenance and repair program is mandatory. Many facilities use service contracts to assist indigenous biomedical staffs in maintaining their equipment. This study attempts to determine the optimal method for a cost effective management system to be used in deciding whether individual medical equipment items are to be contracted out for maintenance and repair, or serviced by in house Biomedical Equipment Technicians. The cost effective model was developed specifically for the NRMC at Camp Pendelton, but nothing would preclude its use at other Navy hospitals. <i>Keywords:</i></p>			
20. DISTRIBUTION / AVAILABILITY OF ABSTRACT <input type="checkbox"/> UNCLASSIFIED/UNLIMITED <input type="checkbox"/> SAME AS RPT. <input type="checkbox"/> DTIC USERS		21. ABSTRACT SECURITY CLASSIFICATION	
22a. NAME OF RESPONSIBLE INDIVIDUAL		22b. TELEPHONE (Include Area Code)	22c. OFFICE SYMBOL

ACKNOWLEDGEMENTS

Several individuals have contributed to the writing of the Graduate Research Project. The author is especially indebted to his Preceptor - Commander, E. L. Wilson, Medical Service Corps, United States Navy, and his reader, Captain G. Bloom, Medical Service Corps, United States Army, for their encouragement, understanding, and cooperation.

I am indebted to the many Navy Biomedical Technicians who provided the major part of the input which made this study possible. Special thanks go to HMC J. E. Pinkerton, USN, for his invaluable assistance and suggestions.

I would be remiss if I failed to mention the outstanding support of the Word Processing Section of the Patient Affairs Department, who accepted my many hand written roughs and consistently produced flawless finished products throughout my residency.

While the author is a lieutenant in the U.S. Navy Medical Service Corps, the views and opinions expressed in this paper are solely his own and are not to be construed as statements of policy or endorsement by any agency of the Department of the Navy.

Finally, the author is eternally grateful to his wife and family for their many sacrifices, unwavering support, and inspiration during this entire post-graduate program.

Jack D. Chapman II

TABLE OF CONTENTS

ACKNOWLEDGEMENTS 11

LIST OF FIGURES v

LIST OF TABLES vi

Chapter

I. INTRODUCTION 1

 Development of the Problem 1

 Background 1

 Medical Equipment Maintenance and
 Repair Program in the Navy 3

 Conditions Prompting the Research 9

 Statement of the Research Question 10

 Limitations on the Research Study 10

 Review of Literature 11

 Research Methodology 20

 Overview 20

 Objectives 20

 Research Process 21

 Chapter I Footnotes 23

II. DISCUSSION 25

 Introduction 25

 Structural Review of the NRMC Biomedical Equipment
 Maintenance and Repair Program 25

 Current Program Evaluation 29

 Existing Decision Process 31

 Primary Factors 32

 Mission Essential 33

 Resident Staff Skills 33

 Resident Staff Time 34

 Training 36

 Personnel Turnover 36

 Equipment Sophistication/Complexity 37

 Cost Effectiveness 37

 Advantages/Disadvantages of Decision Alternatives 39

III. CONCLUSIONS 42

 Research Question 42

 Related Research Findings 42

 Problems 43

 Recommendations 43

 Research Findings 45

 Qualifying Statement 48

APPENDIX

 A. DEFINITIONS OF TERMS 50

 B. QUESTIONNAIRE 53

 C. EXISTING SYSTEM FOR PREVENTIVE MAINTENANCE 55

 D. NINE PART WEIGHTED CHECKLIST WITH PROGRAM EVALUATION 57

 E. EXAMPLES OF COST-EFFECTIVE ANALYSIS 67

BIBLIOGRAPHY 71



ALBANY	✓
NEW YORK	
STATE	
LIBRARY	
UNIVERSITY	
OF THE STATE	
OF NEW YORK	
ALBANY	
A-1	

LIST OF FIGURES

1. Organization Evolution from the 70's to the 80's	16
2. Model for Biomedical Equipment Maintenance Departments in V.A. Hospitals	18

LIST OF TABLES

1. Clinical Engineering Survey Response by Geographic Area	13
2. Clinical Engineering Survey Response by Hospital Size	14
3. Maintenance Cost Survey	17
4. Nine Part Program Evaluation	30
5. Primary Factors	34
6. Productivity Levels	36
7. Cost-Effective Analysis Model	38

CHAPTER I

INTRODUCTION

DEVELOPMENT OF THE PROBLEM

BACKGROUND

Today's delivery of health care depends in an ever increasing manner on the developments made in medical technology. There is not one health-care-providing department within the hospital that has not felt the impact of electrical, electronic, or mechanical instrumentation in its daily routine. The recent growth in the biomedical equipment technology field has been rapid, producing a proliferation of increasing complex medical devices. As a result of this growth, there exists an increasing degree of direct interface between patient and equipment. This situation has imposed a moral, as well as a legal, obligation on hospital medical engineering personnel to insure the safety of the patient, as well as that of the staff. Assuring continuous, efficient, and accurate utilization of equipment and staff is also an obligation. In order to achieve such safety and efficiency, a comprehensive, well-designed maintenance and repair program is mandatory. Until the past few years, the biomedical or clinical engineering program in most hospitals was so straightforward that the term program was inappropriate. In time past, the amount of medical instrumentation was such that the general hospital could employ a very small staff to look after its maintenance and minor repair problems. Most hospitals simply

had some provision for having the hospital's patient-care equipment repaired when necessary. Most repairs were accomplished by the individual department head's negotiating service contracts with either the equipment manufacturer or a small independent service company. Until approximately the past five years, the typical annual budget that covered these service costs would only amount to 0.5 percent of the hospital's annual operating expenses.¹ Innovations, in the past ten years, have subsequently led to a new generation of sophisticated medical equipment that requires more frequent maintenance and technical expertise to repair. Advancing technology, while supporting medical developments, created a demand for even further instrumentation.

The consequence of this trend was an increasing complexity of medical equipment and dependence on a technology in which fewer and fewer hospital-based personnel had the knowledge or training to maintain and repair. The hospitals that contracted out such services saw a 50 percent increase in the budget expense element covering medical equipment service and repair contracts.² Ironically, the design and proliferation of medical equipment that simplified operations by technical staff required a new complex technology that added to maintenance and repair demands. In addition, environmental safety requirements imposed by various regulatory bodies, insurance underwriters, health system agencies, and various other groups have all brought their brand of pressure upon hospitals to add further technological capabilities to their treatment modalities. These events can only add to the expenditures for maintenance and repair programs for biomedical equipment.

As programs for the maintenance and repair of biomedical equipment

expanded to meet these new requirements and as its budget grows, it becomes more important to make sure that it is managed properly. One of the many unanswered questions about current programs for the maintenance and repair of medical equipment is: "Are we using the best combination of service contracts and other biomedical service resources in our program?". To answer such a question would require that a hospital be able to measure current performance and to analyze how that performance would be affected by changes in the program. At present, the Medical Department of the Navy has not developed any system to appropriately evaluate the above question.

A few articles were found that addressed evaluation of existing programs, but none included, as part of the analysis, either performance criteria and standards or a decision model to support contracting out or performing in-house maintenance and repair of medical equipment. An extensive analysis done by a task force of multi-specialists on the Medical Engineering Department at North Carolina Memorial Hospital provides a good example of the trend of making recommendations with no measurement or decision criteria to support the position or further evaluate the program after adoption of recommendations.³

Medical Equipment Maintenance and Repair Program in the Navy

The overall responsibility for the medical equipment maintenance and repair program lies with the Naval Medical Command, Washington D.C. It provides the planning, direction, and coordination of the technical aspects of the program through directives and instructions prepared by the Equipment and Logistics Division. The objectives of the program are:

to establish and to maintain an effective program throughout the Navy,

to provide optimum maintenance and repair of medical equipment,
to reduce expenditures for local maintenance contracts,
to ensure adequate planning for equipment modernization programs, and
to develop, train, and maintain a work force to meet the objectives.⁴

The accomplishment of the objectives is intended to further develop and maintain an effective program that ensures optimum equipment readiness in support of Navy shore establishments and the Operating Forces, and to maintain effectiveness and economy in mission performance. The program is to be operated using a mix of internal and external support services consistent with available resources.⁵

Naval regional medical centers and naval hospitals are required to establish a medical equipment maintenance and repair facility to provide service to all elements of the medical center or hospital, adjacent shore activities, and local elements of the Operating Forces.

The cost of equipment, tools, repair parts, and any miscellaneous expenses in establishing the medical equipment maintenance and repair facility at a medical center or hospital is borne by the command at which the facility is located. The cost of maintenance and repair contracts are borne by the activity having custodial responsibility of the equipment items. Technical training of medical equipment repair personnel, exclusive of the basic technical training to obtain a Navy Enlisted Classification, is paid by the activity where the member is stationed.

Established medical repair facilities have five functions which they are responsible to discharge:

- (1) Develop standard operating procedures to cost effectively use all maintenance and repair resources.

(2) Implement a command preventive maintenance and repair program to ensure cyclic inspection and service to all equipment.

(3) Establish a work control and priority system to ensure equitable service to all elements and units.

(4) Evaluate all medical equipment at least semiannually for the specific purpose of recommending replacements based upon repair histories and life expectancies.

(5) Condition code all equipment.⁶

In order to carry out its functions, the medical equipment maintenance and repair program is required to complete the following task:

- a. Conduct a functional preventive maintenance program and correlate with the below tasks to determine the effectiveness of the preventive maintenance program.
- b. Perform equipment modifications.
- c. Condition code equipment.
- d. Perform receiving inspections on all transferred or newly acquired equipment.
- e. Conduct semiannual equipment inspections to plan replacement requirements.
- f. Establish adequate administrative procedures for the control and documentation of work.
- g. Establish adequate and economical repair parts management.
- h. Provide assistance to chiefs and service in planning for new equipment procurement.
- i. Install newly procured equipment items.
- j. Repair equipment in a timely manner (including assistance to units of the Operating Forces).
- k. Maintain a technical library of operating and service manuals, miscellaneous technical manuals, parts and price listings, and schematics and wiring diagrams for all equipment items.
- l. Train personnel in user maintenance Procedures.⁷

Facility size and accouterments, while left to the discretion of the hospital commanding officers, are only required to be adequate to

perform its maintenance and repair mission.

Staffing of medical repair departments at naval hospitals is primarily achieved with Navy trained Biomedical Equipment Technicians (BMET). There are two Navy Enlisted Classifications (NEC's) for medical repairmen. The NEC's are: 8477 - Biomedical Equipment Technician, Basic; and 8478 - Biomedical Equipment Technician, Advanced. The basic BMET maintains and repairs mechanical and electromechanical medical equipment under the supervision of an advanced BMET. The advanced BMET performs the following tasks: Maintains, repairs, and installs mechanical, electromechanical, electronic, X-ray, and general medical and surgical diagnostic and treatment apparatus; supervises and conducts preventive maintenance programs; manages repair parts inventories; advises local medical equipment survey and procurement boards; coordinates medical equipment safety programs with local safety officers; and renders technical advice and assistance as required.⁸

Medical Repair Departments are to repair all equipment within their capability. Maintenance contracts can be awarded on items for which the department has no repair capability and when conditions warrant their existence to ensure medical material readiness.

The medical equipment maintenance and repair program has four formal reports and uses 13 prescribed forms to control the collection and documentation of program requirements. While data collection is nothing short of extensive, there are no work performance standards or evaluation criteria to measure program effectiveness or efficiency.

In addition, the Navy's medical equipment maintenance and repair program is also subject to the established standards of the Joint Commission on

Accreditation of Hospitals (JCAH). In the Accreditation Manual for Hospitals, 1983 edition, there are 24 separate areas with established standards, and reference to a preventive maintenance program can be found in 11 of the 24 areas. They are anesthesia services, dietetic services, emergency services, functional safety and sanitation, hospital-sponsored ambulatory care services, nuclear medicine services, pathology and medical laboratory services, radiology services, rehabilitation program/services, respiratory care services, and special care units.

The basic requirements for a preventive maintenance program are found in the engineering and maintenance section of the functional safety and sanitation services. The section requires that policies and procedures are written for methods and frequency of preventive maintenance on all electrical and electronic patient care equipment and that there is verification of performance-specifications and use-specifications. That all electric/electronic patient care equipment be tested prior to use and preventive maintenance performed at least every six months thereafter.⁹ Records are required to support performed preventive maintenance and they must also reflect status of all equipment, including the need for replacement and the people notified of the need.¹⁰ Information regarding each item of medical equipment must be readily available to those responsible for its operation, maintenance and inspection, and that a second copy of each equipment instruction booklet be kept in a master file¹¹, although there are provisions in the Program on Hospital Accreditation Standards Manual that when the information is not readily available that its location can be noted on a label on the equipment.¹²

When preventive maintenance is contracted out, there is a JCAH

requirement that the written agreement include that the provider meet JCAH standards for such services.¹³

Other services with specific requirements include:

Anesthesia Services - regularly scheduled preventive maintenance on operating room electrical equipment, preferably on a monthly basis, with written documentation of work performed;¹⁴

Emergency Services - regularly scheduled preventive maintenance in accordance with facility preventive maintenance program;¹⁵

Nuclear Medicine Services - all safety survey equipment will be calibrated at least annually and instrument calibration will be performed and recorded each day the instrument is used;¹⁶

Laboratory Services - conduct preventive maintenance periodic inspections, and performance testing of equipment and instruments with maintenance of appropriate records;¹⁷

Radiology Services - documented annual calibration of both diagnostic and therapeutic equipment to meet federal, state, and local requirements;¹⁸

Rehabilitation Services - equipment calibrated as required by manufacturer's directions and preventive maintenance as required by facility program;¹⁹

Respiratory Care Service - all equipment operated and calibrated according to manufacturer's specification, and preventive maintenance as required by facility program;²⁰

Special Care Units - documentation of device-safety testing along with performed preventive maintenance.²¹

This concludes the major requirements, by higher and outside authority, of a medical equipment preventive maintenance program.

Conditions Prompting the Research

In recent years, technology has made great advances and become very complex in the health care industry. While the cost of maintenance and repair is an identifiable fraction of total operating expenses, the proliferation and subsequent increased use of sophisticated biomedical equipment together with increased demands on the operating budget have increased the significance of performing maintenance and repair in the most economical fashion.

The decision of whether to contract out or perform in-house maintenance and repair functions on individual units of medical equipment has become a complex issue. The best method to arrive at this decision is unknown at this time, and represents a vital void in the necessary information needed for the proper management and effective cost control of medical repair functions at navy medical treatment facilities.

Medical equipment maintenance and repair cost at the Naval Regional Medical Center, Camp Pendleton, California for fiscal year 1981 was 289 thousand, and for fiscal year 1982 it was 370 thousand.²² A better management system is needed to justify the expenditure of funds for maintenance and repair of medical equipment. At present, the major factors of consideration in such decisions or their appropriate weight on such decisions are not clearly defined.

One of the primary objectives of the medical equipment maintenance and repair program is to reduce expenditures for local maintenance and repair service contracts. The total elimination of contracts is not considered prudent in effecting a total equipment maintenance management program. The Biomedical Equipment Technician is a highly trained and skilled person;

however, complete training in all specialized equipment is not practical nor feasible. Hence, the requirement for limited commercial contracts must remain an available alternative for effective overall management. An effective, systematic process--involving identified factors of consideration to determine what medical equipment should be contracted out for maintenance and repair and which should be accomplished in-house--remains undeveloped.

Statement of the Research Question

The dilemmas and questions continually arising about the Medical Equipment Maintenance and Repair Program indicated the urgent need for a comprehensive study in terms of requirements, implementation, and results. The primary question to be addressed by the research project is summarized as follows:

What is the optimal method for a cost effective management system for deciding whether individual medical equipment items are to be contracted out for maintenance and repair or maintained and repaired in-house by Biomedical Equipment Technicians?

Limitations on the Research Study

The most obvious limitation on any study involving the Navy's Medical Equipment Maintenance and Repair Program is the lack of tested and proven measures of the program's effectiveness. Because of this limitation, development of the research project required utilization of textbook methods not known to have been applied to this particular problem in the past. The use of local data as a management tool for program evaluation was precluded

because there are no standards provided against which to measure the available information.

Two other major limitations affected the research effort. First, the lack of computer support at the medical center meant that data had to be manually collected and analyzed. Second, because no manpower could be provided, all data had to be collected and analyzed by the researcher alone.

There were two limitations which narrowed the problem solving options. In order to provide medical equipment maintenance and repair to Navy units deployed world wide, on the high seas, and additional requirements under certain mobilization contingencies, the option to contract out all maintenance and repair of medical equipment is not considered within the scope of possible solutions. Conversely, the advances and increasing complexity developed within the field of medical equipment technology over the past ten years preclude the Navy from training Biomedical Equipment Technicians to maintain and repair all the specialized medical equipment now employed by navy medicine.

Review of Literature

The diversification of approaches to the issue of how to accomplish maintenance and repair of medical equipment is well documented in the literature over the past eight years. The Journal of Clinical Engineering is published four times a year, and almost every issue for the past six years has had at least one article on a particular hospital's approach to medical equipment maintenance and repair. The articles basically go about

describing the facilities at the hospital in question, its need for a medical equipment maintenance and repair program, and the success of the program they instituted. What is lacking is that none of the articles explains the process that lead to the decision about the type of medical equipment maintenance and repair program that was adopted.

A good example of the different approaches being used was identified by a nationwide survey, published in 1979, that wanted to find out the extent of usage of clinical engineers in hospital based programs of medical equipment maintenance and repair. The survey included 1120 hospitals with 250 or more beds, and 51 percent of the hospitals sent replies for a total of 537. Sixty percent of the respondents had an in-house program, of which 31 percent employed clinical engineers and 29 percent employed only BMET's.²³ Equally important is the fact that 40 percent did not have in-house programs for medical equipment maintenance and repair. The results of the survey are shown in Table I by geographical area, and in Table II by hospital size in beds.

Table II clearly shows that the size of a hospital is a contributing factor to a facilities approach to maintenance and repair of medical equipment. As seen in Table II, hospitals with over 700 beds utilize a higher percentage of clinical engineers. At the same time, they use fewer BMET's and have the lowest percentage for use of shared services. In opposition, hospitals with 250 to 400 beds show relatively low usage of in-house clinical engineers, increased usage of BMET's and the highest use of the shared service organization. Most of the figures for the 400 to 700 bed hospitals fall somewhere between the two extremes.

Not only are there issues to have or note to have in-house programs and

TABLE I
SURVEY RESPONSE BY GEOGRAPHICAL AREA

GEOGRAPHICAL AREA	(1) CE Employed in Hospital		(2) Want to Employ CE		(3) Future Inter-est in CE		(4) Use BMET Only		(5) Use Shared Service		(6) Not Interested		Total No.
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
FAR WEST	21	34.4	3	4.9	1	1.6	29	47.5	5	8.2	2	3.3	61
WEST CENTRAL	8	42.1	0	0.0	2	10.5	5	26.3	3	15.8	1	5.3	19
MID-WEST	24	28.2	8	9.4	12	14.1	30	35.3	4	4.7	7	8.2	85
EAST CENTRAL	44	31.9	16	11.6	21	15.2	30	21.7	16	11.6	11	8.0	138
NORTHEAST	5	19.2	1	3.8	1	3.8	12	46.2	4	15.4	3	11.5	26
SOUTH	27	27.3	8	8.1	14	14.1	37	37.4	5	5.1	8	8.1	99
EAST	47	32.4	11	7.6	29	20.0	24	16.6	24	16.6	10	6.9	145
NATIONAL	176	30.7	47	8.2	80	14.0	167	29.1	61	10.6	42	7.3	573

SOURCE: Warren D. Berryman and W. Sanford Topham, "Present Use of Clinical Engineering in Hospitals: A Nationwide Survey," Journal of Clinical Engineering, Vol. 4, No. 2 (April-June 1979):109.

TABLE II
SURVEY RESPONSE BY HOSPITAL SIZE

HOSPITAL SIZE	(1) CE Employed in Hospital		(2) Want to Employ CE		(3) Future Inter- est in CE		(4) Use BMET Only		(5) Use Shared Service		(6) Interested Not		Total No.
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	
250 to 400 Beds	56	19.0	25	8.5	55	18.6	96	32.5	41	13.9	22	7.5	295
400 TO 700 Beds	85	39.7	18	8.4	21	9.8	59	27.6	18	8.4	13	6.1	214
Greater than 700 beds	35	54.7	4	6.3	4	6.3	12	18.8	2	3.1	7	10.9	64

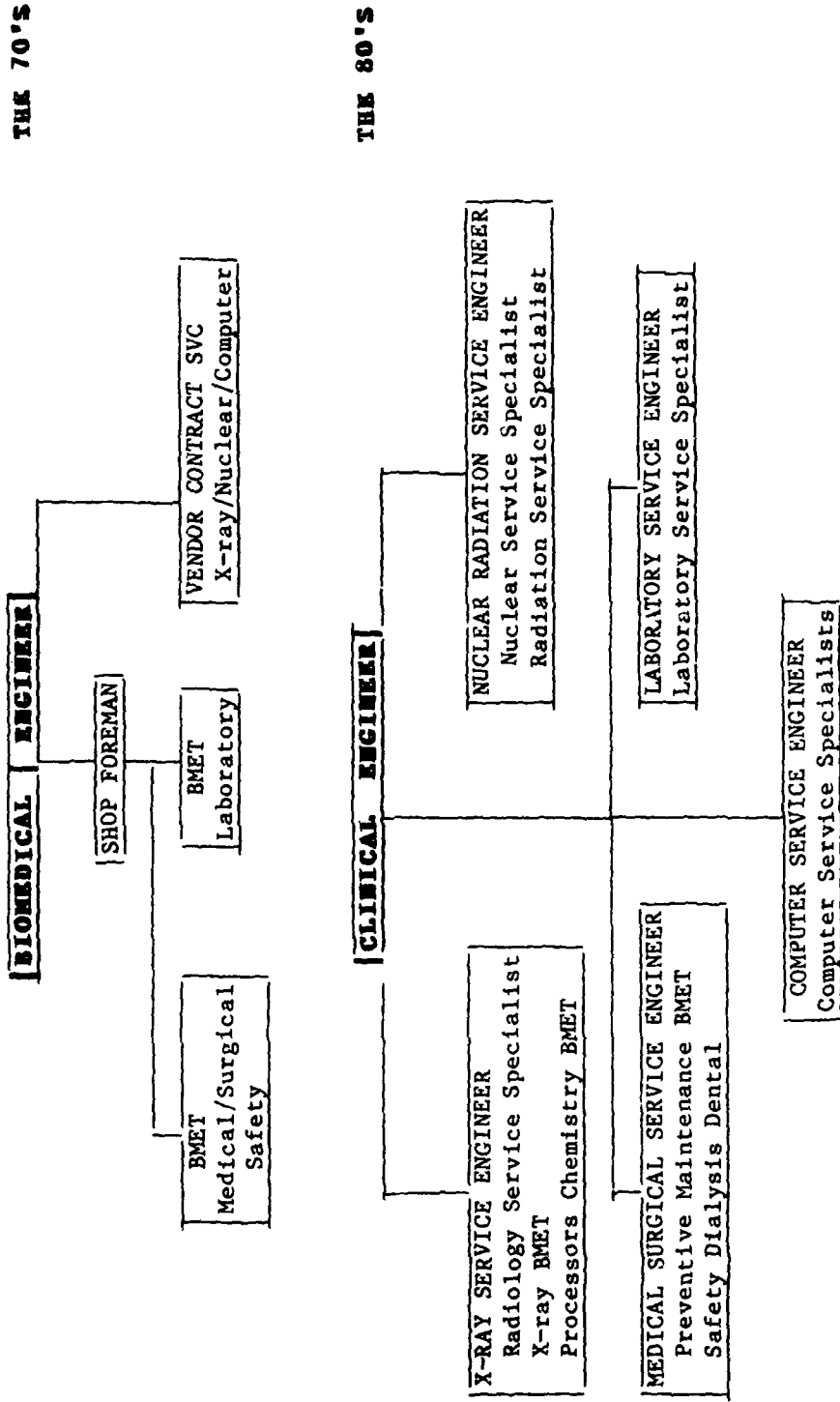
SOURCE: Warren D. Berryman and W. Sanford Topham, "Present Use of Clinical Engineering in Hospitals: A Nationwide Survey," Journal of Clinical Engineering, Vol. 4, No. 2 (April-June 1979):110.

programs with different ideologies on staffing patterns, but there have also been issues in the organizational structure of in-house programs for maintenance and repair of medical equipment. The first in-house programs had few personnel. This limited staff had multiple responsibilities because the majority of medical equipment was simple, high volume-usage type machines, which were uncomplicated electro-mechanical devices with limited electronics.²⁴ The 70's gave birth to new organizational patterns because medical equipment was, by design, turning to computer-micro-processor-based electro-mechanical systems. This latest electronic technology continued into the 80's and predicted even further necessary changes to up-date most existing in-house programs. These basic changes in organizational patterns were best demonstrated by Thomas Robertson and are presented in Figure 1.

The literature search did reveal that increasing problems of cost, personnel qualifications, task assignment, and productivity involved with establishing and running an in-house program for maintenance and repair of medical equipment led to the establishment of an industry standard for a basic program. A basic department consisting of a Clinical Engineer, a Biomedical Equipment Technician, a Testing Technician and a Clerical Assistant, can be expected to provide a full range of clinical maintenance and repair services to a hospital with 225 instruments. This medical equipment would include x-ray, nuclear medicine, and clinical laboratory instrumentation. The annual cost, including materials, of operating the in-house department is expected to be in the area of \$90,000. This is approximately the anticipated break-even point because the capital investment for the 225 instruments is expected to be in the area of \$861,000, and full range contract services are averaging about ten percent

FIGURE I

Organizational Evolution from the 70's to the 80's



SOURCE: Thomas L. Robertson, "Clinical Engineering Services at the VA Medical Center, Los Angeles," Journal of Clinical Engineering, Vol. 5, No. 2 (April-June 1980):132.

of acquisition cost.²⁵ This methodology establishes the staffing levels of an in-house program based on the acquisition cost of a complete medical equipment inventory. In addition, this method presented the only cost-based analysis found in the literature to base a decision on whether to have a maintenance and repair program dedicated basically to either contracting out or in-house performance.

However, the lack of standards is presumably responsible for a large part of the wide range in variability among hospital costs for maintenance to medical equipment. Table III reflects the results of a maintenance cost survey and reflects the striking variance in annual cost.

TABLE III
Maintenance Cost Survey

Bed Size	Annual Maint. Cost/ Equip. Cost%	Annual Maint. Cost/ Bed \$
0-99	3.6/38.5	13/424
100-299	2.6/19.3	48/595
300-499	3.8/11.7	106/642
500+	.8/16.7	30/400

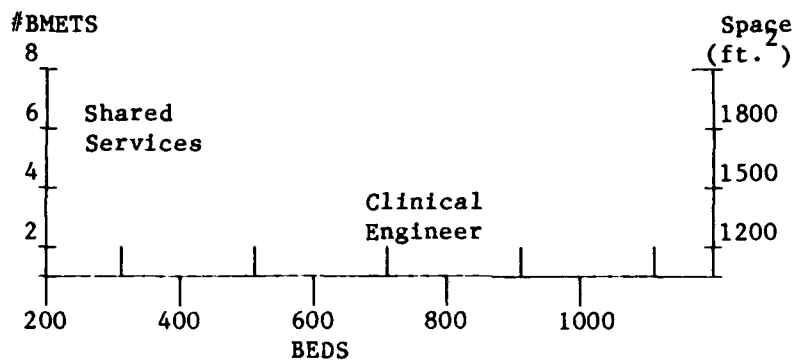
Source: Lee E. Ostrander, "Presentation of the Clinical Engineering Role to Hospital Administrators," Journal of Clinical Engineering, Vol. 4, No. 1 (January-March 1979): 15.

Table III shows that the annual maintenance cost as a percentage of equipment costs varies by as much as a factor of 20, and the annual maintenance cost-per-bed varies by a factor as large as 50.

The Veterans Administration Hospital system has developed a set of guidelines for staffing and facilities in support of a biomedical equipment maintenance and repair program. The basic guidelines are graphically represented in Figure 2.

FIGURE 2

Model for Biomedical Equipment Maintenance Departments in Veterans
Administration Hospitals



Source: Lee E. Ostrander, "Presentation of the Clinical Engineering Role to Hospital Administrators," Journal of Clinical Engineering, Vol. 4, No. 1 (January-March 1979): 16.

to complete preventive maintenance procedures on medical equipment can provide staffing requirements by converting the time requirement into man hours per annum for all units of that particular medical equipment. The man hours per annum are then added for all items of medical equipment to ascertain the estimated annual work load.²⁷ One preventive maintenance program was found to also include, by equipment item, accessories to be kept with equipment item, repair parts to be kept with item, and recommended stock of additional repair parts.²⁸

The literature review yielded only one source of a documented process by which to evaluate an existing in-house biomedical maintenance and repair program. The program consists of determining productivity levels as the measurement standard to evaluate either an individual's work performance or that of the entire department. Productivity is determined by using the following formula:

$$\text{Productivity (\%)} = \frac{\text{time worked}}{\text{time available}} \times 100$$

where time worked is charged to productive activities of scheduled

The literature is replete with well documented preventive maintenance programs of medical equipment. All are similar in nature and contain what and when maintenance is to be accomplished. Most include the average time required to complete the maintenance procedure. The average time required maintenance, repairs, and direct labor of clinical engineering, and time available is the total hours labor paid.²⁹

The productivity figure provides key information about the relationship between direct labor (time worked or production time) and indirect labor (time available minus time worked or nonproductive time). This method enables the user to measure performance efficiency of the entire organization or that of an individual. The difference between direct and indirect labor is whether the activity falls into a developed list of productive or nonproductive activities. "In a typical 200-bed to 250-bed hospital, productive clinical engineering activities, other than repairs and scheduled maintenance, should require 0.25 to 0.5 full-time equivalent."³⁰ The productivity percentage is then applied to a grading scale which will be addressed in detail in the following chapter.

In general, the literature went a long way to support the idea that an efficient, well-managed internal biomedical maintenance program can provide most hospitals with some cost savings and other additional benefits. The challenge is in maintaining the consistently high level of management oversight needed to keep the program running in optimum fashion.

Research Methodology

Overview

The lack of explicit standards developed by Naval Medical Command, Washington, D.C., for maintenance and repairs of medical equipment required that standards considered to be appropriate by the civilian professionals be used in answering the research question. The methodology developed was based upon the evaluation techniques suggested in the literature and also upon those described in Medical Equipment Management in Hospitals, published in 1982 by the American Society for Hospital Engineering of the American Hospital Association.

Objectives

While the main objective was to answer the research question, several secondary goals were also included in developing the research methodology in order to present a comprehensive study of the NRMC Camp Pendleton program of medical equipment maintenance and repair, and to indicate problem areas with appropriate recommendations for program improvement. The goals of this research were to:

1. Examine the present system which provides maintenance and repair for biomedical equipment at the command;
2. Analyze the existing method for decision making of whether to contract out or perform in-house maintenance and repair on individual medical equipment items;
3. Establish and discuss the major factors affecting the decision process;

4. Develop a decision model to answer the research question;
5. Evaluate the advantages and disadvantages of the present method as well as the alternatives of the decision model.

Included in each section of the research was information not considered necessary for answering the research question but added to meet the above secondary objectives.

Research Process

The methodology of the study was comprised of five facets: survey, delphi questionnaire, personal interviews, observation and a literature search.

In carrying out the objectives of this graduate research project, initial data collection was accomplished using general analytical techniques to include the already presented literature search, inquiry technique to identify the present systems of decision making, and a questionnaire to establish the major factors affecting the decision process. A copy of the questionnaire is provided as Appendix B. The analytical approach will be to complete the operations research quantitative method to management decision making. The steps in this procedure are to include analyzing and defining the problem, developing a decision model, selecting the inputs, solving the model with sensitivity analysis, and presenting the finished model for application.

To further delineate this approach, the inquiry technique employed a questionnaire to establish the existing decision process used at the three major naval medical centers located with the Naval Medical Command, Southwest Region. An on-site visit to each of the activities was conducted to

observe the Medical Repair Departments and complete the questionnaire. The Directors of Hospital Administration, Comptrollers, and Heads of Medical Repair Departments were asked to identify their activities' current process in deciding whether or not to contract out maintenance of medical equipment. In addition, to the above people, all medical repairman at the facilities were asked to identify what they feel should be the important factors in deciding whether or not to contract out the maintenance and repair of medical equipment. The questionnaire also asks that the developed factors be weighed using a scale of one to 10, with 10 being the highest value, and using the same weighted value for more than one factor was permissible. For this project, the use of the Churchman-Achoff method was considered the best methodology to convert subjective variables to a value assignment.

The question concerning development of weighted decision factors was subjected to delphi analysis. That is, upon return, the weighted factors were compiled and fed back to respondents for refinement. The ultimate aim was to reconcile diverging views of individual experts in order to come to a consensus of opinion. Time limitations preclude more than one iteration of this procedure.

In developing the decision model, the task was to produce a model which is able to forecast the effect of factors crucial to the solution of the problem. A combination of methods will be used to answer the research question. The developed mathematical model will be based on cost-effectiveness analysis.

Once the model is constructed, data required by the model will be col-

lected on several pieces of medical equipment in order to test the model.

The final resulting model is presented for application, along with a statement qualifying when the model should be utilized. This will include the conditions under which the solution can be used, point out any identified weaknesses, provide the limits within which the results are considered valid, and the conditions under which the model will not work.

Chapter I Footnotes

1. American Society for Hospital Engineering, Medical Equipment Management in Hospitals, American Hospital Association, AHA Publication No. 190105, Chicago, Illinois, 1982, p.19.
2. Ibid.
3. Gerald L. McNair, C. E. Brown, and Roy Wolharsht, "Analysis and Recommendations for a Medical Engineering Department," Jornal of Clinical Engineering, Vol.6, No.4 (October-December 1981): 293-99.
4. U.S. Department of the Navy, Bureau of Medicine and Surgery, Medical and Dental Equipment Maintenance and Repair Manual, BUMED Instruction 6700.36B, 25 June 1982, p.1-1.
5. Ibid., p. 1,2.
6. Ibid., p. 2-2.
7. Ibid., p. 4-1.
8. Ibid., p. 3-1.
9. Hospital Survey Profile83, Chicago, Illinois, Joint Commission on Accreditation of Hospitals, 1982, p. 51.
10. Accreditation Manual for Hospitals83, Chicago, Illinois, Joint Commission on Accreditation of Hospitals, 1982, p. 43.
11. HSP, P. 51-2.
12. Program on Hospital Accreditation Standards Manual, Chicago, Illinois, Joint Commission on Accreditation of Hospitals, 1981, p. FSS/8.
13. HSP, p. 54.
14. AMH, p. 6.

15. Ibid., p. 31.
16. Ibid., p. 112.
17. Ibid., p. 126.
18. Ibid., p. 158.
19. Ibid., p. 164
20. Ibid., p. 175.
21. Ibid., p. 186.
22. Interview with Comptroller for the NRMCC, Camp Pendleton on 21 February 1983.
23. Warren D. Berryman and W. Sanford Topham, "Present Use of Clinical Engineering in Hospitals: A Nationwide Survey," Journal of Clinical Engineering, Vol. 4, No. 2 (April-June 1979): 107.
24. Thomas L. Robertson, "Clinical Engineering Services at the VA Medical Center, Los Angeles," Journal of Clinical Engineering, Vol. 5, No. 2 (April-June 1980): 130.
25. Ernest Guignon, "Setting Up a Clinical Engineering Department," Journal of Clinical Engineering, Vol. 5, No. 1 (January-March 1980): 71.
26. Lee E. Ostrander, "Presentation of the Clinical Engineering Role to Hospital Administrators," Journal of Clinical Engineering, Vol. 4, No. 1 (January-March 1979): 16.
27. Ibid, p. 14.
28. Gary Lee Stanley, Hospital Bio-Medical Engineering Policy and Procedure Manual (Marion, Illinois: Hospital and Physician Consulting Service, Inc., 1982), Chapter IX.
29. American Society for Hospital Engineering, p. 5.
30. Ibid., p. 6.

CHAPTER II

DISCUSSION

Introduction

The data collection for the research on the Naval Regional Medical Center (NRMC), Camp Pendleton, Biomedical Equipment Maintenance and Repair Program began in November 1982 and ended in June 1983. Despite the volume of information, data collection was successful in all sections with only minimal problems encountered by the researcher. To facilitate a complete understanding of findings, each component of the research was analyzed separately before any general conclusions were drawn. Presentation of findings in the same manner seemed the most logical format for this section. Consequently, only findings and results specific to each research component are presented in this Chapter. General conclusions and recommendations were reserved for the final chapter of the project.

Structural Review of the NRMC Biomedical Equipment Maintenance and Repair Program

The existing control system for medical equipment maintenance and repair comes under the administrative control of the Medical Equipment Repair Division of the Facilities Engineering Department.

The medical equipment maintenance and repair program is designed for an IBM 1401 Computer System with core storage and contains advanced programming, high-low-equal compare, and sense switch special features.

The system also requires a 1402 card reader punch, a 1403 printer with 132 print positions and four 729 tape drives. Auxillary equipment required includes a keypunch, verifier, sorter, interpreter, and a reproducer with mark sense capability.

All new medical equipment delivered to the receiving dock is taken directly to the Medical Repair Division for entry into the medical equipment preventive maintenance program. A preventive maintenance number is assigned to the new equipment, and this number is affixed to the equipment by means of a gummed label. At the same time, additional gummed labels are placed on the medical equipment for the completed safety check, warranty expiration date, and electrical leakage condition for equipment going to sensitive patient areas. The sensitive patient areas are the intensive care units, operating rooms, and nursery.

Each piece of medical equipment is assigned a preventive maintenance schedule in accordance with local requirements or as prescribed in Section III of NAVMED P-5009.

In order to get medical equipment into the automated preventive maintenance program, a program manager master code sheet, NRMC/CP6770/2, is completed and submitted to the Data Processing Department. After entry into the system, any maintenance or repairs performed on medical equipment is fed into the system by completing a coded history file sheet, NRMC CAMPEN 6770/3, and submitting same to the Data Processing Department.

Once the above has been accomplished, the medical equipment preventive maintenance program is driven by automated reports done on a monthly basis. Appendix E depicts this process in flow chart form.

On the first of each month, Medical Repair receives from Data Processing

a 10301-M02 printout which lists the preventive maintenance scheduled for that month. At the same time, a deck of mark sense cards, one for each line item on the 10301-M02, is produced by Data Processing and delivered to Medical Repair. The preventive maintenance supervisor assigns each equipment item scheduled for preventive maintenance to a shop Biomedical Equipment Repairman (BMER) and gives him the corresponding mark sense card. The BMER returns the cards to the preventive maintenance supervisor when the preventive maintenance has been completed. The returned cards reflect the type of preventive maintenance, who performed the preventive maintenance, cost of any parts, and time expended to complete the preventive maintenance. There are provisions on the card to reflect medical equipment not found at the specified location. BMER's are not to spend more than 15 minutes looking for an equipment item scheduled for preventive maintenance.

The returned cards are then submitted to Data Processing, along with completed code sheets, and at the end of the month Medical Repair receives from Data Processing a 10301-M03 report. This Preventive Maintenance Status Report is checked by the preventive maintenance supervisor and action is taken on each line item that appears on the report. Scheduled preventive maintenance that was completed does not appear on the 10301-M03 report. Medical equipment to be surveyed has a preventive maintenance master card work sheet completed to change the equipment status. Medical equipment shown as scheduled preventive maintenance not performed is completed by the BMER's within five working days. Department Heads receive a memorandum for any medical equipment charged to their department which is reflected as equipment not at location specified. When the medical equipment in question is located by the department, medical repair personnel then perform the

required preventive maintenance. For those items not found by the departments, Medical Repair requests the Plant Account Officer to conduct an investigation on the proposed lost item of medical equipment.

Also, at the end of each month, a Preventive Maintenance Work Performed and Updated Master File, 10301-M01 report, is produced by Data Processing and delivered to Medical Repair. This report is a listing of all work, scheduled and unscheduled, performed by medical repair personnel since the last 10301-M01 report. The report also includes any work performed under contract or warranty. The report updates the master file information by making the changes necessitated by the performed maintenance listed on the 10301-M01 report.

The Preventive Maintenance Master File Listing 10301-M04 report is run by Data Processing after the Work Performed 10301-M01 report. The report is a complete and current listing, by preventive maintenance number, of all medical equipment presently enrolled and requiring routine maintenance on a scheduled basis. The report reflects the latest bottom line totals on all medical equipment enrolled in the program and updates the bottom line totals of all equipment serviced in any way since the last printout of the report.

Finally, a Preventive Maintenance History File is produced yearly and represents a complete listing of all maintenance functions, scheduled and unscheduled, detailing methods required to effect repairs, dates of repairs and inspections, as well as all parts used and down time. Medical equipment items are listed by preventive maintenance numbers and maintenance performed is recorded in chronological order from date of acquisition.

This completes the major components of the preventive maintenance and repair program at the NRMC, Camp Pendleton, CA. After interviewing the

managers for the same programs at the Naval Hospital, San Diego and the Naval Regional Medical Center, Long Beach, it was determined that the differences existed in how the programs were carried out.

Current Program Evaluation

Measuring the performance of a biomedical equipment maintenance and repair program is a difficult task and currently the Navy Medical Department has not made any serious attempts to do so. A proper assessment of the program requires evaluation of a combination of factors. It cannot be confined to cost or user satisfaction. Program evaluation must consider scope, effectiveness, and efficiency. Scope will determine if the program provides all of the necessary or desired services. Effectiveness will show how well the program accomplishes its goals, and efficiency will provide comparison of present program cost which can be compared to other ways of meeting the same objective.

To examine the current program at the NRMC, the nine part full-service evaluation program developed by the American Society of Hospital Engineering of the American Hospital Association was employed by the researcher and the results are displayed in Table IV.

Appendix D is provided for a better understanding of the weighted value assigned to each of the nine areas addressed in Table IV. Appendix D identifies the weak points in the current program at NRMC for the maintenance and repair of medical equipment.

TABLE IV
Nine Part Program Evaluation

- | | | |
|----|--|-----------|
| 1. | Check all biomedical equipment for safety and proper performance. Provide systems for the efficient documentation of the testing, according to the schedules required by the regulating agencies. Verify adequacy of the test procedures, proper calibration of the test equipment, and competency of the testing personnel | 15 points |
| 2. | Provide prompt and competent repair of all biomedical equipment. Document repair costs. Provide a system to monitor repair competency and equipment downtime | 15 points |
| 3. | Provide methodology and technical assistance for the evaluation of potential cost-effectiveness of new biomedical equipment. Provide proper legal and fiscal safeguards when equipment is purchased. Keep staff informed on current advances in biomedical equipment | 7 points |
| 4. | Check the electrical safety of potentially hazardous areas of the facility. Provide systems for the efficient documentation of the facility testing, according to the schedules required by the regulating agencies. Verify adequacy of the test procedures, proper calibration of the test equipment, and competency of the testing personnel | 7 points |
| 5. | Provide administration with periodic reports on the cost and effectiveness of the program. Perform management analyses to ensure that the mix of in-house and outside resources is optimum. Keep current information on the cost of outside resources to support these analyses. Provide competent technical supervision for any in-house biomedical staff. Evaluate all biomedical service agreements | 7 points |
| 6. | Define the current biomedical safety regulations and standards. Provide an efficient program documentation system, including appropriate policies and procedures on how to document work performed by both in-house and outside service personnel | 7 points |
| 7. | Provide an adequate system for continuing in-service training of the clinical staff on electrical safety and the safe and proper use of the hospital's clinical equipment | 6 points |
| 8. | Provide an adequate system with written policies and procedures for handling equipment hazard notifications. Distribute equipment hazard notifications to the appropriate clinical staff | 4 points |
| 9. | Provide technical support to the hospital's safety committee. Provide a system for investigation of equipment-related incidents. Provide technical liaison with the loss control specialists from the hospital's liability insurance underwriters | 5 points |

OVERALL SCORE: (possible 100 points)

73 points

Existing Decision Process

The personal interviews and responses to question one of the questionnaire revealed a heterogeneous mixture of approaches to the decision of whether or not to contract out maintenance and repair of medical equipment. None of the three programs that were examined had an established methodology for the decision process. Although each Director of Hospital Administration (DHA) had a list of questions that once answered served as the basis for the decision. With only one exception, the DHA's questions appeared as part of the list of primary factors included in the responses received to the second question of the questionnaire. The consideration listed by only a DHA was the availability of TAD funds to train BMETS.

The actual decision to contract out or to perform the work in-house is usually made at a level of management below the DHA, except when training dollars are requested in order to accomplish in-house maintenance and repair. Generally speaking, a review of the equipment history is performed, before warranty expires, by both the user's department and the Medical Repair Department. When both parties agree on the way to complete maintenance and repair, upper levels of management usually do not question the soundness of or reason for the decision, and the joint decision is executed. When there is a disagreement between the two parties on whether or not to contract out the maintenance and repair, the command supply, comptroller and DHA officers may become involved prior to a final decision.

All three programs that were examined used availability of existing manpower to take on the added workload as a major factor in the decision

process, yet none of the programs had any set procedures to determine desired productivity levels or established performance criteria with which to evaluate the current workload situation. In the final analysis, cost was considered in the decisions of all three programs, but here, too, there were no developed standards to evaluate decisions based on an established cost-benefit analysis. No program exhibited a set format for a decision process that was used regularly for the decision of whether or not to contract out the maintenance and repair of individual units of biomedical equipment.

Primary Factors

The primary factors of consideration were developed by using the responses to question two of the questionnaire and a delphi analysis approach. This systematic solicitation and collation of informed judgment was confined to the medical centers in the Naval Medical Command, Southwest Region. Rather than a group response, the characteristic of anonymity was employed in factor development and refinement. The professionals in this field were considered to be all the BMETS, civilian and military, employed by the Navy in the southwest region, and the supply, comptroller and DHA officers of the three major medical commands. The laboratory and radiology department heads were also solicited for responses. The responses totaled 42 in number and represented 100 percent of the professionals in the original field of consideration.

The first responses produced a list of 32 separate items as possible primary factors. The original list contained 15 items that received three or fewer responses. These were combined with other broader listings or eliminated from further consideration. After a singular iteration, items

that obtained a final average value of five or less were also discarded from the final field of consideration. This eliminated five items. The average score was obtained by using the value assessments - one to ten - assigned to the primary factor by the respondent. The final list of 12 primary factors for consideration, along with their average value score, is reflected in Table V.

The answers to the 12 items listed in Table V are, then, considered necessary to a developed systematic approach to decision making. Therefore, the methods used to acquire the answers to the primary factors become the key elements to model development.

Mission Essential: This subjective value is important. Critical support equipment and critical equipment involved in direct patient care are identified and the length of acceptable downtime due to maintenance and repair is quantified in hours or days. This information can then be used later when comparing the anticipated repair times when done by in-house or contract services. This allows the individual hospital to evaluate and prioritize its mission essential equipment. This also allows the individual hospital to take into account its particular situation as to availability of back-up units or system, cost and availability of alternative services, and any legal responsibilities.

Resident Staff Skills: The intent here is to ascertain if the skills reside in the present staff to perform maintenance and repair of the equipment in question. This is meant to be as simple as a "yes" or "no" determination. The determination is made by the Medical Repair Department.

TABLE V

Primary Factors

<u>Factor</u>	<u>Average Value</u>
1. Mission Essential: Critical Equipment Critical to Direct Patient Care Downtime value	9.4
2. Resident Staff Skills	8.6
3. Resident Staff Time	7.8
4. Training	8.5
5. Personnel Turnover	7.3
6. Equipment Sophistication/Complexity	7.9
7. Cost-Effectiveness	7.9
8. Parts: Availability Cost Storage Usage Rate	6.5
9. Required Testing/Calibration Equipment: Special Tools Service Manuals/Schematics	8.4
10. Equipment History: Age Condition Replacement Timeframe Repair History	5.6
11. Contract Cost: Company Reputation Multiple Units of Equipment	6.2
12. One-Time Repair Cost	6.8

Resident Staff Time: The answer to this question requires a lengthy process that starts with a complete medical equipment inventory list. The second step is to compile the annual labor time required to complete periodic preventive maintenance, calibration, performance checks and periodic electrical safety checks on the equipment and other potentially hazardous components of the hospital environment. These times are available from manufacturers' literature or any of the several marketed medical equipment

management systems for hospitals. Currently, the Navy uses NAVMED P-5009, Procedures and Serviceability Standards for Medical Equipment. The determined annual man-hours for each instrument in the inventory can then be totalled to acquire the anticipated man-hours per year. It is rare that any one person would possess all the work skills needed to work on any piece of equipment. So, the annual man-hours are then broken down into the basic work skill areas of electronics, electromechanics, laboratory, x-ray and clinical engineering. This breakdown can be expanded or retracted to fit the individual hospital. For example, a large hospital might want to add a skill area for Nuclear Medicine or Ultrasound. With equipment charged to a particular department, the information day work skill can be recorded by department. There also has to be an allotted time for incoming inspections, in-service training maintenance management (admin time). The corresponding developed annual man-hours can be converted into full-time equivalents (FTE). This method can be used to support staffing patterns and identify the availability or nonavailability of time for current staff to take on the added responsibility for maintenance and repair of certain items of medical equipment.

As a check on this system, the completion of a semi-annual productivity evaluation will indicate whether or not staff members are using their time appropriately on productive activities. This is composed of a list of items that are considered productive activities (equipment maintenance, repairs etc.) and a list of what is considered nonproductive activities (meetings, inventory maintenance, training, etc.) When time used on productive activities is divided by the total time available, the result is a productivity percentage when multiplied by 100. The published industry

standard for the levels of productivity are expressed in Table VI.

TABLE VI
Productivity Levels

<u>Level</u>		<u>Rating</u>
More than 85%	=	Questionable
75-85%	=	Excellent
60-74%	=	Acceptable
55-59%	=	Borderline
Less than 55%	=	Unacceptable

Source: American Society for Hospital Engineering, Medical Equipment Management in Hospitals, American Hospital Association, AHA Publication No. 190105, Chicago, Illinois, 1982, P.6.

Training: In the event that the staff does not have the skills to maintain and repair certain medical equipment, it is important to find out if the training is available through military or commercial sources. While cost is a factor, it will be considered later. Sometimes training for maintenance and repair can be a part of the purchase agreement. When multiple units are in the equipment inventory, the training can receive a higher usage rating. Acquired training can also be passed along as part of the in-service training programs.

Personnel Turnover: Military BMET'S are subject to transfer every three years and this must be kept in mind when managing a Medical Repair Department. Often new people will have to be trained because equipment manufacturers are multiple for the standard equipment items found at all naval hospitals throughout the United States and on foreign shores. This only increases the importance of an in-service training program to pass

along maintenance and repair skills.

Equipment Sophistication/Complexity: Certain medical equipment items have reached a level of such sophistication and complexity that it is considered economically infeasible to train in-house staff, purchase testing and calibration equipment, and maintain expensive repair parts. For the most part, these medical equipment items are high-dollar and usually the hospital will have only one such medical device. Often, these items will have high technology components and the manufacturers will not provide service manuals or schematics of such internal parts.

Cost-Effectiveness: Cost-effectiveness is employed here instead of cost-benefit because in cost-benefit both inputs and outputs are variable and in this project the output remains the same in either alternative to (contracting out or performing maintenance and repair or medical equipment in-house). Cost-effectiveness was also seen as appropriate because the benefits of alternatives are measured in the same units. Cost-effectiveness, as opposed to cost-benefit analysis, may be used in this instance because the output (maintenance and repair) is the same across approaches. Cost-effectiveness analysis is employed to estimate the approach to use an effective tool for management decision making, planning and resource allocation.

For the individual unit of medical equipment, the approach is to identify the anticipated cost related to maintenance and repair as opposed to the cost of contracting out the same work. The dollar and non-dollar values in the developed decision model are listed in Table VII.

In reviewing Table VII, the reader needs to be mindful of the following:

1. Total for equipment life expectancy would not reflect inflation and are intended to average out start-up cost.
2. Labor is based on annual time required to do preventive maintenance average hour wage for Medical Repair Department.
3. In-house total for equipment life expectancy would include the cost to do the three most common repair procedures for equipment item.
4. Back of form would have a place for any additional remarks.
5. Review of process done annually for adjustments.

Three examples of completed cost-effective analysis are provided as Appendix E.

The remaining five primary factors: parts, required testing/calibration equipment, equipment history, contract cost, and one-time repair cost are all part of the presented cost-effective model.

Advantages/Disadvantages of Decision Alternatives

The potential pros and cons for the four possible decisions are as follows:

ALTERNATIVE: CONTINUE PRESENT METHOD.

- | | | |
|---------------|---|--|
| Advantages | - | No change in procedures is required |
| Disadvantages | - | Not cost effective |
| | - | May result in legal liability exposure |
| | - | No developed productivity levels |
| | - | No productivity evaluation |

- No staffing analysis
- JCAH requirements may not be met

ALTERNATIVE: Use developed model and select in-house program.

- Advantages
- Total hospital control
 - Reduced legal liability exposure
 - Improved department efficiency
 - JCAH and other controlling bodies satisfied
 - Responsive maintenance service
 - Reduced sources of service
 - Cost savings

- Disadvantages
- Hospital administration must provide total management for functions on a daily basis
 - Overhead cost to equipment department
 - Space requirement for function
 - Recruiting, selecting and other personal functions
 - Narrow information base to work from with all technical know-how internally generated

ALTERNATIVE: - Use developed model and choice in-house maintenance and one-time repair contracts.

- Advantages
- Moderate operation cost
 - Contract out low cost repairs while staff perform more expensive procedures

- Disadvantages
- Not appropriate for mission essential equipment
 - Frequent repairs of equipment under such approach can liquidate cost savings
 - Downtime may be lengthy

ALTERNATIVE: - Use developed model and select to contract out

- Advantages
- No cost for support equipment to perform maintenance and repair
 - Minimal management requirements for hospital
 - No additional staffing or space requirements
 - Manufacturer's can sometimes perform repairs quicker because of total familiarity with equipment
- Disadvantages
- Can be the most expensive way to do business
 - Hospital control last to commercial contractor
 - Multiple sources of service

III CONCLUSIONS

Research Question

The research was conducted to provide a comprehensive study that would evaluate the Navy's medical equipment maintenance and repair program to determine the optimal method for a cost effective management system for deciding whether individual medical equipment items are to be contracted out for maintenance and repair or maintained and repaired in-house by staff Biomedical Equipment Technicians. The examination included program organization; implementation, and results at the NRMCC, Camp Pendleton, California. The research methodology was composed of five parts which investigated the local program in terms of structure, process and outcome, and also provided the method to collect data and support model development to answer the finite research question. The research was also designed to determine whether or not the local program met the requirements of the Naval Medical Command and the Joint Commission on Accreditation of Hospitals.

Related Research Findings

In addition to the research findings related to the primary research question, other discoveries were made in conducting the data collection and analysis to accomplish the project objectives. Program analysis and evaluation yielded the following problems and resulting recommendations.

Problems

1. Medical equipment in use, but not enrolled in preventive maintenance program.
2. Preventive maintenance performance labels being removed or missing from medical equipment.
3. At scheduled time for preventive maintenance, subject medical equipment not at specified location.
4. Missing operator instruction manuals.
5. Automated preventive maintenance reports that do not reflect:
 - a. equipment condition code
 - b. recommended replacement time frame
 - c. No history of repair parts used that includes cost of said repair parts.
6. Maintenance contracts without a clause specifying that work performed is to meet JCAH standards.

Recommendations

The following recommendations are made:

1. Market the program and educate the department staffs that preventive maintenance is a joint responsibility of medical repairmen and equipment operators.
2. Develop a local instruction that delineates the duties and responsibilities of departments managing medical equipment and medical repair.
3. Ensure command awareness that medical equipment is not to be used without safety check label affixed to the equipment.

4. Departments should be required to maintain one copy of the operator's manual for each piece of medical equipment under their control. If the operational instructions are part of a technical manual maintained in medical repair, place a label on the equipment that states the location of the operational instructions. This label would only be required when the operational guidelines are not within the general location of the equipment.

5. Departments should be required to inventory their medical equipment semiannually for the purpose of count, location, preventive maintenance labels, and estimated replacement date.

6. Departments should be required to notify Medical Repair when medical equipment, under their cognizance, changes its location of use.

7. Departments should be required to appoint a responsible individual to coordinate or perform the department's functions under the medical equipment preventive maintenance program. This individual will act as liaison between the department and Medical Repair.

8. Departments should insure that requests for the purchase of new medical equipment include TWO copies of the operator's manual.

9. Medical Repair should be required to condition code medical equipment at time of repairs or scheduled preventive maintenance. This information would be recorded on the mark sense card and added to the automated reports that reflect the information submitted on the mark sense card.

10. Medical Repair should be required to list the cost of all repair parts used on the preventive maintenance history file submission form and this information should be added to only the history file report.

11. Medical Repair should be required to evaluate medical equipment semiannually for the specific purpose of recommending replacement based upon repair histories and life expectancies. This information would be recorded on the preventive maintenance history file and incorporated into the history file. There should also be a requirement to provide this information to the department involved. This evaluation could be done in conjunction with regularly scheduled preventive maintenance.

12. A second copy of each equipment instruction booklet be kept in a master file located in medical repair.

13. Medical repair survey departments annually to establish compliance with the program. Reports of surveys conducted should be submitted to the Director of Hospital Administration and departments in non-compliance with program elements be required to respond in writing within 30 days.

14. Medical repair discontinue the use of the Defective Do Not Use label and replace it with a Hazard Warning label.

15. Acquire and attach to all radiographic system control panels a DD Form 2163, Medical Equipment Verification/Certification.

16. That contracts governing the provision of preventive maintenance and repair services by outside sources require that the provider meet JCAH standards for such services.

Research Findings

Before implementation and use of the developed cost effectiveness model, the medical facility in question must complete an extensive and time consuming list of preliminaries. All Navy hospitals have existing biomedical programs' so the economic feasibility of an internal biomedical

maintenance and repair program is not necessary, but the evaluation of the existing program is a must. The necessary data collection and evaluation considered as preliminaries is as follows:

1. Complete and validate an equipment inventory by department.
2. Determine the annual man-hours for each instrument in the equipment inventory, using the manufacturer's guidelines or procedure manuals. Separate data into that contracted-out and that performed in-house. Further separate hours by work skills.
3. Total the resulting annual workload to determine how many FTE's are considered necessary to complete that workload.
4. Determine the productivity level of each employee and the department as a whole by using the formula provided in Chapter I.
5. Evaluate the existing program by completing the nine components of the performance effectiveness checklist for a full-service program developed by the American Society for Hospital Engineering and published by the American Hospital Association.

Granted, completing the five items listed above will be costly and time consuming, but the information gained places management in a much better position to make a decision over an area that is rapidly increasing in annual operating cost. Simply by adding the acquisition cost of equipment on maintenance and repair contracts, and computing what percent the total cost of the contracts are of the acquisition cost will inform the manager if he is within the industry average of 10 to 12 percent. The same process can be applied for each individual contract. By using the total operating budget for the Medical Repair Department, the manager can compare the cost to what has been spent on outside service. The information now available

can be used to perform technical and fiscal evaluation, produce program cost, measure efficiency, provide comparison of alternates and produce cost savings.

It is important to a manager to find a consistent, quantitative method for assessing the elements of any given program. There are no absolute scales by which programs in different hospitals can be compared, but the primary requirement here is that the assessment method provide a consistent way of (1), checking progress toward stated goals, and (2), evaluating the impact of switching to alternate resources.

Recognizing that the biomedical repair program is not usually a hospital administrator's highest priority obligates the program manager to communicate with hospital administration as effectively as possible. The program manager must strive to project complete understanding and control of the program in order to gain the desired level of recognition and trust from administration. On the other hand, administration must also recognize that it needs to give the program adequate amounts of attention and resources. Therefore, the final step would be to complete the aforementioned five items on an annual basis and present to management a summary of the overall performance of the current program. Did overall costs increase, decrease, remain about the same? If they increased significantly, were the increases reasonable? Did the overall effectiveness increase or decrease? Where are the strong areas and weak areas as depicted by the analysis? What is the feasibility of improved performance or reduced costs, and what proposed changes might bring these about? If major changes are involved, such as replacing outside services with in-house staff or vice-versa, what aspects of the comparative analysis justify the change?

The only element missing to make this approach whole is a standard methodology with which to accomplish necessary comparative analysis for present decision making and retrospective review. The cost-effective analysis model provided in table VII is intended to provide this missing element and represents the optimal management system for deciding whether individual medical equipment items are to be contracted out for maintenance and repair or maintained and repaired in-house by Biomedical Equipment Technicians. The cost-effective model was developed because it provides management not only the direct cost factors, but also the important non-dollar factors of consideration needed for optimal decision making. When the final decision does not follow the path of least cost, the model provides the reasons to support the necessity for such a decision.

The finished product can be developed into a local command form and produced on standard size paper using both sides of a single sheet of paper. The standard format would first provide the necessary equipment nomenclature, along with the department to which the equipment is assigned. This would be followed by the cost-efficiency analysis developed in Table VII, to include a section for additional remarks. It is recommended that the remaining space be used to develop a section for annual review. This would provide program evaluation to include review of decisions and identify areas for improvement in not only the program, but in the developed decision model as well.

Qualifying Statement

While the model was developed with the Naval Regional Medical Center, Camp Pendleton in mind, there are no known reasons that would preclude its

use in any Navy hospital that has an in-house medical equipment maintenance and repair program. The model is believed to have enough flexibility that it can be modified by the user to fit their particular needs in decision making. Utilization of the model at present is limited to equipment items whose acquisition costs exceed \$3,000; thereby being confined to equipment purchased with Other Procurement Navy (OPN) funds. It is believed that the use of the model could be expanded to provide more detailed information when deciding on what and whose medical equipment is going to be purchased in the future. An identified weakness is that if sufficient funds and manpower are not made available, an optimal program will not be developed to its fullest capacity. However, the use of the developed program will provide maximum utilization of the resources that are made available. Because a value in non-dollar terms is placed in certain factors in the decision process, an individual's bias can weaken an otherwise optimal program. The results are considered valid only after implementation of the program preliminaries discussed earlier and adoption of annual evaluation to modify the program or model if necessary. The only condition that could preclude using this system and model for decision making is when the medical facility is large, with thousands of medical equipment items, and the program lacks the necessary computer support which would make program management from one centered point simply too costly in man-hours and manpower resources.

APPENDIX A

DEFINITIONS

The following definitions have been used throughout the research project:

BIOMEDICAL EQUIPMENT TECHNICIAN: This person is often oriented in much the same way as the clinical engineer. He has, however, directed his attention to instrumentation rather than its application. The BMET must be able to calibrate, repair, and evaluate several hundred different kinds of instruments. He must therefore, be considerably more flexible and analytical than the average technician. He must have extensive experience in a hospital environment, and must be able to interface easily with the medical staff.

CLINICAL ENGINEER: This person is an engineering professional whose focus is on the application of engineering principles and technology to the patient/machine interface. The clinical engineer minimally holds a Master's degree. A bachelor's degree in engineering is the basis for his professional standing, with additional training in anatomy, physiology, and biochemistry, and extra training in instrumentation. Direct experience in a hospital setting is necessary for the development of a fully-functional clinical engineer. The kind of hybrid training described makes a qualified clinical engineer valuable to industry. Consequently, the hospital is often in competition with industry for the services of a well-trained clinical engineer.

REPAIRS: Work performed on a piece of equipment to restore it to proper operating condition. The work is usually furnished on an unscheduled basis following a request from the equipment operator or user.

SCHEDULED MAINTENANCE: Work performed on a scheduled rather than on a user-

demand basis. The purpose of the procedure may be a mix of one or more of the following:

1. Preventive maintenance: To clean, lubricate, adjust, check for wear, and perhaps replace components that might cause total breakdown or serious functional impairment of the equipment before the next scheduled inspection. In addition to improved performance, a major advantage of true preventive maintenance is a reduction of those economic losses associated with demand repair work and loss of revenue while the equipment is nonfunctional.
2. Functional testing, performance verification, and calibration: To verify that equipment is fully operational and performing within reasonable, previously specified limits. Depending on the device, it may be appropriate to specify several different levels of functional testing and performance assurance; for example, the simplest level consists of visual inspection of the device. The term calibration usually implies that the device is compared against a reliable standard.
3. Safety testing: To verify that the equipment is in compliance with one or more specified safety requirements. Such checking is frequently limited to electrical safety testing.

TESTING TECHNICIAN: This person must be technically oriented, but not necessarily technically trained. He must be able to perform repetitive test procedures accurately and reliably. His most important qualities are patience and persistence.

APPENDIX B

QUESTIONNAIRE

BIOMEDICAL EQUIPMENT MAINTENANCE AND REPAIR QUESTIONNAIRE

In order to complete a graduate research project to determine the optimal method for a cost effective management system for deciding whether individual medical equipment items are to be contracted out for maintenance and repair or maintained and repaired in-house by Biomedical Equipment Technicians, you are requested to answer the following questions. Your response will be instrumental in formulating the decision model.

QUESTION #1: After expiration of the warranty, how does your activity decide whether or not to contract out future maintenance and repair of newly acquired medical equipment?

QUESTION #2: What do you consider the primary factors in initially deciding whether or not to contract out maintenance and repair of medical equipment? In addition, your established factors need to be weighted on a scale of 1 to 10. Use of the same weighted value for more than one identified factor is permissible, and the upper value of 10 is to be used for the most important factor or factors.

Because the responses are to be subjected to delphi analysis, it is requested that your name be provided at the top of this page and your completed response be attached to this questionnaire when returned. That is, upon return, the weighted factors will be compiled and fed back to the respondents one time for refinement. The ultimate aim is to reconcile diverging views in order to come to a consensus of opinion prior to developing the decision model. Your participation in this matter is greatly appreciated.

Direct any questions to LT. Chapman at ext. 1543/1580. Please return response to LT. Chapman in room 1056.

APPENDIX C

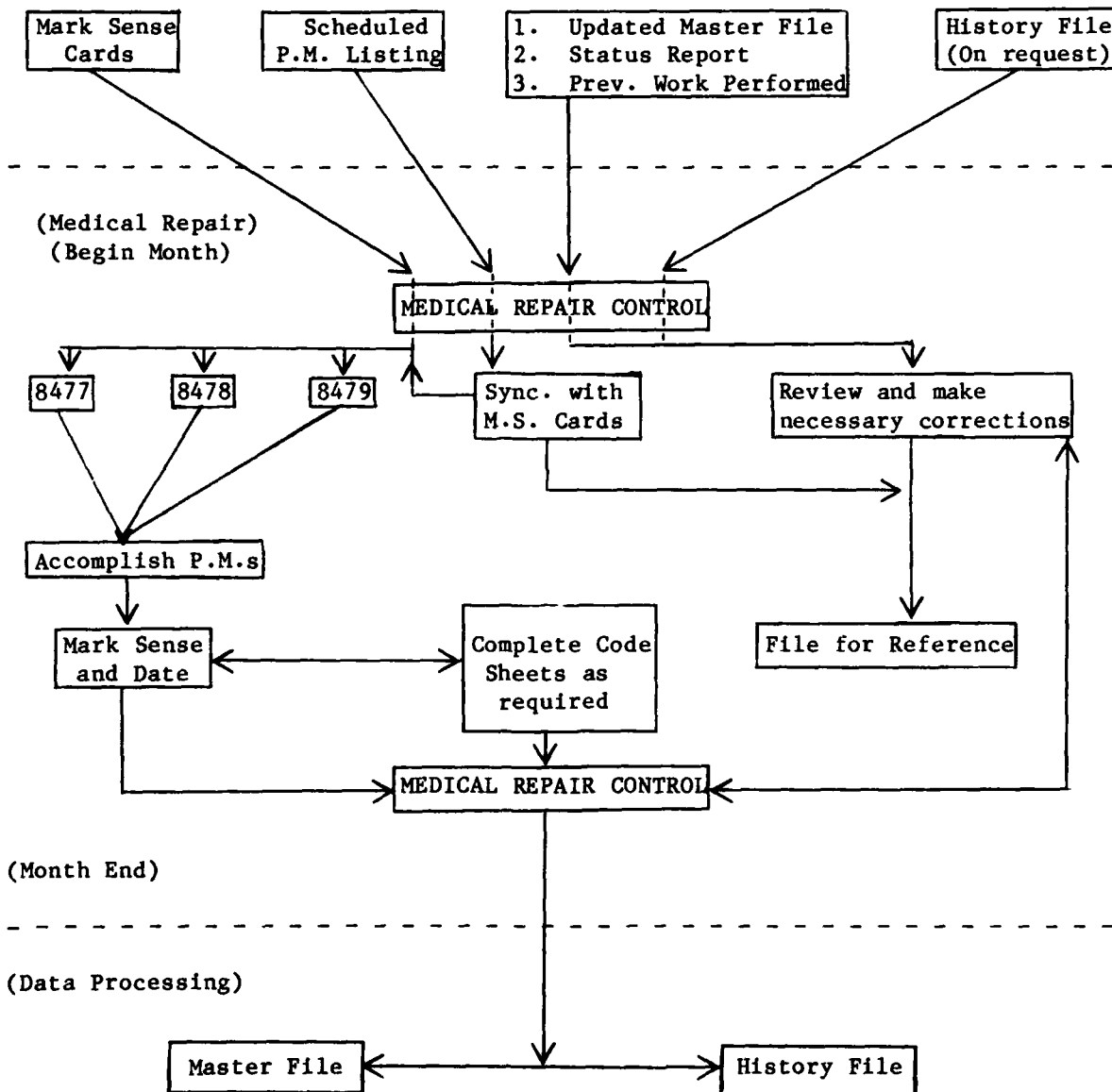
EXISTING SYSTEM FOR PREVENTIVE MAINTENANCE

EXISTING SYSTEM FOR PREVENTIVE MAINTENANCE

MONTHLY PROCESSING

FROM

(Data Processing)



APPENDIX D

NINE PART WEIGHTED CHECKLIST WITH PROGRAM EVALUATION

NINE PART WEIGHTED CHECKLIST WITH PROGRAM EVALUATION

1. Check all biomedical equipment for safety and proper performance. Provide systems for the efficient documentation of testing, according to the schedules required by the regulating agencies. Verify adequacy of test procedures used, proper calibration of the test equipment, and competency of the testing personnel 15 points out of 20

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Is there a complete, up-to-date inventory of all biomedical equipment that indicates the maintenance intervals and who is responsible for the scheduled work on each item?	<u>X</u>	<u> </u>	<u>2</u>
B. Is there a written schedule or some other method of generating timely work orders? Do the frequencies conform to the minimum requirements?	<u>X</u>	<u> </u>	<u>2</u>
C. Is there a written procedure on file in the hospital for every safety and performance or calibration check?			
(1) For work done in-house	<u>X</u>	<u> </u>	<u>1</u>
(2) For work done by outside sources	<u> </u>	<u>X</u>	<u>1</u>
D. Are periodic written summaries of the test results provided to all department heads?			
(1) For work done in-house	<u> </u>	<u>X</u>	<u>1</u>
(2) For work done by outside sources	<u> </u>	<u>X</u>	<u>1</u>
E. Is all of the maintenance completed on time?	<u> </u>	<u>X</u>	<u>2</u>
F. Are efficient check-off report forms used rather than those requiring extensive written responses?	<u>X</u>	<u> </u>	<u>2</u>
G. Is all of the documentation, including that done by outside sources, complete?	<u>X</u>	<u> </u>	<u>2</u>
H. Are notices of defective equipment used to warn users when defective equipment cannot be physically removed?	<u> </u>	<u>X</u>	<u>1</u>

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
I. Does the hospital have on file evidence that the test equipment used is calibrated according to the manufacturer's directions?			
(1) For work done in-house	<u>X</u>		<u>1</u>
(2) For work done by outside sources		<u>X</u>	<u>1</u>
J. Does the hospital have on file for each outside vendor appropriate written assurance of the competency of the personnel performing the testing?		<u>X</u>	<u>1</u>
K. Are there written procedures and a written policy covering the scope and operation of the scheduled maintenance program?	<u>X</u>		<u>2</u>

NOTES:

Item: D - Test Results are on file, but are not provided to department heads in writing. Negative results are conveyed to Head of Department. Points not subtracted for Item D.

Item: H - Equipment decals (HAZARDOUS - DO NOT USE) are used instead of defective notices to Heads of Departments. Points not taken away for Item H.

2. Provide prompt and competent repair of all biomedical equipment. Document repair costs. Provide a system to monitor repair competency and equipment downtime 15 points out of 20

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Is there a simple procedure for staff in all departments to follow in order to notify the proper service source of the need for service?	<u>X</u>		<u>2</u>
B. Are vendors required to log-in and log-out of the hospital/department?	<u>X</u>		<u>2</u>
C. Does the hospital require that replaced parts be left for inspection?		<u>X</u>	<u>2</u>
D. Is there a policy requiring authorization of (estimated) expensive repairs before the repair is made?	<u>X</u>		<u>2</u>
E. Are there written procedures and a written policy covering equipment repair services?	<u>X</u>		<u>2</u>

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
F. Do the departments that depend on equipment for revenues, such as radiology and the clinical laboratory, use equipment downtime log sheets?	(N/A)		-
G. Is downtime performance considered satisfactory in all departments?		X	2
H. Is any substantial attempt made to assess repair competency in some or all departments?	X	(SOME)	2
I. Is repair competency considered satisfactory in those departments?	50%		2
J. Are there individual files in which repair invoices can be kept?	X		2
K. Are all repair invoices filed in an organized and efficient manner?	X		2

3. Provide methodology and technical assistance for evaluation of potential cost-effectiveness of new biomedical equipment. Provide proper legal and fiscal safeguards when equipment is purchased. Keep staff informed on current advances in biomedical equipment 7 points out of 10

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Are there written procedures and a written policy controlling the acquisition of biomedical equipment?	X		2
B. Does the hospital use a "request for new equipment" procedure whenever new biomedical equipment is requested?	X		1
C. Does the hospital use an adequate "General Condition of Purchase" document containing electrical safety, performance, business, and legal requirements for all purchases of clinical equipment?	X		1
D. Is engineering/biomedical engineering alerted whenever new clinical equipment is to be purchased?	Sometimes		1

	<u>Yes</u>	<u>No</u>	<u>Points Value</u>
E. Is there routine input from biomedical engineering during the selection of all items of biomedical equipment?	<u>Sometimes</u>		<u>1</u>
F. Is there a formal acceptance procedure for all new biomedical equipment?	<u>X</u>		<u>1</u>
G. Is all new biomedical equipment checked for safety and proper performance prior to being put into service for the first time? Does the hospital have completed checklists on file?	<u>X</u>		<u>1</u>
H. Does the program provide any information to the hospital staff on current advances in biomedical equipment on a routine basis?	<u>Sometimes</u>		<u>1</u>
I. Does the hospital obtain multiple copies of operating manuals and service manuals when new equipment is acquired?	<u>Sometimes</u>		<u>1</u>

NOTE: 3/4 point removed for each value of sometimes.

4. Check the electrical safety of potentially hazardous areas of the facility. Provide systems for the efficient documentation of the facility testing, according to the schedules required by the regulating agencies. Verify adequacy of the test procedures, proper calibration of the test equipment, and competency of the testing personnel 7 points out of 10

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Is the scope of the program adequate? Is there a written classification of all hospital locations?	<u>X</u>		<u>1</u>
B. Is there a written schedule or some other method of generating timely work orders? Do the testing frequencies conform to the minimum requirements?	<u>X</u>		<u>1</u>
C. Is there a written procedure on file in the hospital for the environmental electrical safety checks?	<u>X</u>		<u>1</u>
D. Is all of the testing completed on time?		<u>X</u>	<u>1</u>

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
E. Are efficient "check off" type report forms, exception reports, or other efficient documentation means used rather than those requiring extensive written responses?	<u>X</u>	<u> </u>	<u>1</u>
F. Is all of the documentation completed?	<u>X</u>	<u> </u>	<u>1</u>
G. Are written summaries of the testing results distributed regularly to the relevant supervisors or department managers?	<u> </u>	<u>X</u>	<u>1</u>
H. Does the hospital have on file evidence that the test equipment used is calibrated according to the manufacturer's directions?	<u>X</u>	<u> </u>	<u>1</u>
I. Are there written procedures and a written policy covering the scope and operation of the facility electrical safety program?	<u>X</u>	<u> </u>	<u>1</u>
J. Were there any citations in this area resulting from the most recent state/JCAH survey? Or any similar survey?	<u>X</u>	<u> </u>	<u>1</u>
K. Is all nonclinical equipment tested on a scheduled basis at an appropriate frequency selected by the director of engineering?	<u> </u>	<u>(N/A)</u>	<u> </u>

5. Provide administration with periodic reports on the cost and effectiveness of the program. Perform management analyses to ensure that the mix of in-house and outside resources is optimum. Keep current information on the cost of outside resources to support these analyses. Provide competent technical supervision for any in-house biomedical staff. Evaluate all biomedical service agreements 7 points out of 10

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Is administration provided with periodic reports on the cost and effectiveness of the program?	<u>X-(Cost)</u>	<u>X</u>	<u>(Effectiveness) 1</u>
B. Are analyses performed regularly to determine the optimum mix of in-house and outside service sources?	<u> </u>	<u>X</u>	<u>1</u>
C. Is any research undertaken to keep informed on the cost of various outside service sources?	<u>Some</u>	<u> </u>	<u>1/2</u>
D. Is the procedure for evaluating the biomedical service agreements adequate?	<u>Some</u>	<u> </u>	<u>1</u>

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
E. Is the technical and administrative supervision provided to the in-house technical staff adequate?		<u>Sometimes</u>	<u>1</u>
F. Is any formal continuing education or in-service training provided for the technical staff? . . .	<u>X</u>		<u>1</u>
G. Are adequate resumes describing the basic qualifications of the technical staff available? . . .	<u>X</u>		<u>1</u>
H. Is the in-house technical staffing level adequate?	<u>X</u>		<u>1</u>
I. Are the equipment, facilities, and support services for the in-house technical staff adequate?	<u>X</u>		<u>1</u>
J. Is there an internal charge-back system for biomedical services?		<u>Partial</u>	<u>1/2</u>
K. Are the efforts of any in-house biomedical staff regularly audited by competent personnel? .	<u>X</u>		<u>1</u>

NOTES:

Items: H/I - The yes response is for current maintenance and repair functions being completed in-house.

1/2 value removed if not in total compliance.

6. Define the current biomedical safety regulations and standards. Provide an efficient program documentation system, including appropriate policies and procedures on how to document work performed by both in-house and outside service personnel 7 points out of 10

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Does the hospital staff have an adequate understanding of the biomedical requirements in the current codes and standards? Do they have convenient access to this information?		<u>Partial</u>	<u>1</u>
B. Is there a complete set of biomedical policies and procedures?	<u>X</u>		<u>2</u>
C. Are they well organized and available in one place, such as a biomedical maintenance manual? .	<u>X</u>		<u>1</u>
D. Are there complete, individual files or listings for each item of biomedical equipment?	<u>X</u>		<u>1</u>

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
E. Is there an adequate technical library? Codes, manufacturers' procedures, and so forth? . . .	<u>Mostly</u>	<u> </u>	<u>1</u>
F. Are the inventories and area classifications complete and up to date?	<u>Mostly</u>	<u> </u>	<u>1</u>
G. Is the reporting paperwork reasonably efficient?	<u>X</u>	<u> </u>	<u>1</u>
H. Does all of the biomedical equipment have a legible, easily visible, identification tag? . . .	<u>X</u>	<u> </u>	<u>1</u>
I. Is all of the equipment labeled to indicate where user information is kept, or is such information readily available within the immediate area of the equipment?	<u> </u>	<u>X</u>	<u>1</u>

7. Provide an adequate system for continuing in-service training of the clinical staff on electrical safety and the safe and proper use of the hospital's biomedical equipment 6 points out of 10

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Is there a written program plan defining the sessions, the personnel, the repeat intervals and the individuals responsible for coordination and actual teaching?	<u>Partial</u>	<u> </u>	<u>1</u>
B. Is the content of the individual sessions documented?	<u>Some</u>	<u> </u>	<u>1</u>
C. Are the content (electrical safety and proper use of critical equipment) and frequency of the sessions adequate?	<u>Mostly</u>	<u> </u>	<u>1/2</u>
D. Is suitable audiovisual material available? . . .	<u>X</u>	<u> </u>	<u>1/2</u>
E. Are all shifts adequately covered?	<u>X</u>	<u> </u>	<u>1/2</u>
F. Does the program cover at least the following personnel: all special care nurses, all OR nurses, general nurses, engineering, and RT, PT, EKG technicians?	<u>X</u>	<u> </u>	<u>1</u>
G. Is individual participation in the programs recorded?	<u>X</u>	<u> </u>	<u>1</u>
H. Are suitable professional books and journals available?	<u>X</u>	<u> </u>	<u>1/2</u>

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
I. Are there adequate written materials for initial electrical safety orientation for the entire hospital staff?	<u>X</u>		<u>1/2</u>
J. Are there adequate follow-up electrical safety tutorial opportunities for the entire hospital staff?		<u>X</u>	<u>1/2</u>
K. Is the biomedical continuing education program for management and supervisory staff adequate?		<u>X</u>	<u>1</u>
L. Is attendance of all staff at external educational sessions documented and summaries generated by the participants for future in-house use?	<u>X</u>		<u>1</u>
M. Is there a mechanism for reviewing in-service training needs as they relate to the use and maintenance of clinical equipment?		<u>X</u>	<u>1</u>
8. Provide an adequate system with written policies and procedures for handling equipment hazard notifications. Distribute equipment hazard notifications to the appropriate clinical staff	<u>4</u> points out of 5		
	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Are there written procedures and a written policy on how equipment hazard notifications are handled?	<u>X</u>		<u>1</u>
B. Is there a good method for seeking out all of the current equipment hazard notifications?		<u>X</u>	<u>1/2</u>
C. Is there a convenient and efficient method for documenting that appropriate corrective action was taken?	<u>X</u>		<u>1</u>
D. Is the file reasonably complete?	<u>X</u>		<u>1/2</u>
E. Are (a sample of) the completed forms properly filled out?	<u>X</u>		<u>1/2</u>
F. Is there a specific individual identified as coordinator for hazard notifications?	<u>X</u>		<u>1</u>
G. Does the designated individual keep a log book of open action items?		<u>X</u>	<u>1/2</u>

9. Provide technical support to the hospital's safety committee. Provide a system for investigation of equipment-related incidents. Provide technical liaison with loss control specialists from the hospital's liability insurance underwriters 5 points out of 5

	<u>Yes</u>	<u>No</u>	<u>Point Value</u>
A. Is there a biomedical program representative on the safety committee?	<u>X</u>		-----
B. Is there an adequate internal system for reporting all accidents, incidents, or potential equipment-related hazards?	<u>X</u>		-----
C. Does the committee ensure that appropriate action is taken to investigate all of these reports?	<u>X</u>		-----
D. Are the accident/hazard reporting forms adequate?	<u>X</u>		-----
E. Is there reasonable interaction with the liability insurance underwriter's loss control specialists?		<u>(N/A)</u>	-----
F. Has the clinical staff been provided with specific instructions on what to do immediately after an accident involving any equipment? . . .	<u>X</u>		-----

APPENDIX E

EXAMPLES OF

COST-EFFECTIVE ANALYSIS

68
INHALATION THERAPY

Instrumentation Laboratory IL System 1303 ph/Blood Gas Analyzer

Cost-Effective Analysis Model

<u>Contract Out</u>	vs.	<u>In-House</u>
\$ Values		
<u>4,828</u> Annual contract cost to include all maintenance and repairs. Contract cost as percentage of equipment cost <u>24%</u> (industry avg. 10 to 12%)	Training to include travel Repair Parts Inventory Test Equipment Special Tools Service Manual/Schematic Calibration Equipment Labor	<u>850</u> <u>3,000</u> <u>N/A</u> <u>N/A</u> <u>60</u> <u>900/year</u> <u>N/A</u>
<u>4,828</u>	1st Year Cost	<u>6,000</u>
<u>48,000</u>	Total for Equipment Life Expectancy (<u>10</u> years)	<u>15,000</u>

NON-\$ Values

<u>yes</u>	Essential to mission	<u>yes</u>
<u>yes</u>	Anticipated repair time meets downtime limitation (<u>8 hours</u>)	<u>no</u>
<u>yes</u>	Equipment user's desires	<u>no</u>
	Repair parts available	<u>yes</u>
	Technical literature available	<u>yes</u>
	Resident staff time available	
	Equipment repair history:	

Replaced Fluid and Heater Board

SINGLE REPAIR CONTRACT
Three Most Common Repairs

<u>Problem</u>	<u>Estimated Repair Cost</u>
1. <u>Fluid and Heater Board</u>	<u>1,779</u>
2. _____	_____
3. _____	_____

SINGLE REPAIR CONTRACT

ANNUAL CONTRACT

DECISION

IN-HOUSE

69
LABORATORY

Electronic Lasaer Technology ELT-8

The ELT-8 Hematology Analyzer (Lasaer-Board) is an automated hematology instrument for in vitro diagnostic use, that proceeds data for RBC, WBC, HGB, HCT, PLT, MCV, MCH, AND MCHC

Cost-Effective Analysis Model

<u>Contract Out</u>	vs.	<u>In-House</u>
\$ Values		
<u>7,073</u>	Annual contract cost to include all maintenance and repairs.	Training to include travel <u>2,000</u> Repair Parts Inventory <u>3,500</u> Test Equipment <u>N/A</u> Special Tools <u>N/A</u> Service Manual/Schematic <u>100</u> Calibration Equipment <u>N/A</u> Labor <u>1,400</u>
<u>7,073</u>	Contract cost as percentage of equipment cost <u>10%</u> (industry avg. 10 to 12%)	<u>1st Year Cost</u> <u>5,500</u>
<u>56,584</u>	Total for Equipment Life Expectancy (<u>8</u> years)	<u>25,200</u>

NON-\$ Values

<u>yes</u>	Essential to mission	<u>yes</u>
<u>X</u>	Anticipated repair time meets downtime limitation (8 hours)	<u>no</u>
<u>-----</u>	Equipment user's desires	<u>-----</u>
<u>-----</u>	Repair parts available	<u>no</u>
<u>-----</u>	Technical literature available	<u>yes</u>
<u>-----</u>	Resident staff time available	<u>yes</u>
<u>-----</u>	Equipment repair history:	<u>-----</u>

Replaced Power Supply
Replaced pump seal in P-6, P-10, P-11
Replaced 8K RAM.

SINGLE REPAIR CONTRACT
Three Most Common Repairs

<u>Problem</u>	<u>Estimated Repair Cost</u>
1. <u>Bad Lasaer Power Supply</u>	<u>400.00</u>
2. <u>Leaking pump seals</u>	<u>200.00</u>
3. <u>Bad 8K RAM Board</u>	<u>800.00</u>

SINGLE REPAIR CONTRACT

ANNUAL CONTRACT	DECISION	IN-HOUSE
-----------------	----------	----------

70
X-RAY UNIT AT BARSTOW

Cost-Effective Analysis Model

<u>Contract Out</u>	vs.	<u>In-House</u>
\$ Values		
<u>2,200</u> Annual contract cost to include all maintenance and repairs. Contract cost as percentage of equipment cost <u>8%</u> (industry avg. 10 to 12%)	Training to include travel Repair Parts Inventory Test Equipment Special Tools Service Manual/Schematic Calibration Equipment Labor	<u>400</u> <u>1,000</u> <u>N/A</u> <u>N/A</u> <u>HAVE</u> <u>N/A</u> <u>1,100/yr</u>
<u>2,200</u>	1st Year Cost	<u>3,500</u>
<u>17,600</u>	Total for Equipment Life Expectancy (<u>8</u> years)	<u>12,000</u>

NON-\$ Values

<u>yes</u>	Essential to mission	<u>yes</u>
<u>X</u>	Anticipated repair time meets downtime limitation (<u>\$/day</u>)	<u>no</u>
<u>yes</u>	Equipment user's desires	<u>yes</u>
	Repair parts available	<u>yes</u>
	Technical literature available	<u>yes</u>
	Resident staff time available	<u>yes</u>
	Equipment repair history:	

Bearing in tube arm replaced

SINGLE REPAIR CONTRACT
Three Most Common Repairs

	<u>Problem</u>	<u>Estimated Repair Cost</u>
1.	_____	_____
2.	_____	_____
3.	_____	_____

SINGLE REPAIR CONTRACT

ANNUAL CONTRACT

DECISION

IN-HOUSE

ADDITIONAL REMARKS

Contract written because

1. Distance from support activity.
2. Only unit available.
3. Company most likely to carry complete line of parts.
4. Corpshospital could provide the general repairs but outweighed by the distance (123 miles) between the two facilities.
5. No history of repair in PM system.
6. Out of warranty March 83

BIBLIOGRAPHY

- Berryman, Warren D., and Topham, Sanford. "Present Use of Clinical Engineering in Hospitals: a Nationwide Survey." Journal of Clinical Engineering, Vol. 4 No. 2 (April-June 1979): 107-111.
- Breed, G.H. "Biomedical Engineering Department in a US 500 Bed Acute Care Hospital." Hospital Engineering 35 (June 1981): 14-7.
- Crosby, P. "Management of High Technology Equipment in a Hospital." Australian Health Review 4 (September 1981): 10-2.
- Crystal, Royal A., and Brewster, Agnes W. "Cost Benefit and Cost Effectiveness Analyses in the Health Field: An Introduction." Medical Economics, Vol. 3, No. 4 (December 1977): 3-13.
- Dodson, Burt. Strategies for Clinical Engineering. Battle Creek, Michigan: W.K. Kellogg Foundation, 1976.
- Emergency Care Research Institute. Health Devices Sourcebook 1982-83. Plymouth Meeting, Pennsylvania: ECRI, 1982.
- Emergency Care Research Institute. Issues in Health Care Technology. Plymouth Meeting, Pennsylvania: ECRI, 1981.
- Guignon, Ernest. "Setting up a Clinical Engineering Department." Journal of Clinical Engineering 5 (January-March 1980): 69-72.
- Hellinger, Fred J. "Cost-Benefit Analysis of Health Care: Past Applications and Future Prospects." Inquiry 17 (Fall 1980): 204-215.
- Hummel, J.C. "The Evolution of an In-House Biomedical Department." Journal of Clinical Engineering 5 (July-September 1980): 145-52.
- Joint Commission on Accreditation of Hospitals. Accreditation Manual for Hospitals 83. Chicago, Illinois: JCAH, 1982.
- Joint Commission on Accreditation of Hospitals. Hospital Survey Profile 83. Chicago, Illinois: JCAH, 1982.
- Joint Commission on Accreditation of Hospitals. Program on Hospital Accreditation Standards Manual. Chicago, Illinois: JCAH, 1981.
- McNair, Gerald L. et al. "Analysis and Recommendations for a Medical Engineering Department." Journal of Clinical Engineering 6 (October-December 1981): 293-9.

- Obeid, S.I. "Maintenance and Repair of Medical Equipment." World Hospital 17 (September 1981): 15-7.
- Ostrander, Lee E. "Presentation of the Clinical Engineering Role to Hospital Administrators." Journal of clinical Engineering 4 (January-March 1979): 11-21.
- Roberts, V.C. "Education and Training for Biomedical Engineers: A Changing Pattern." Journal of Biomedical Engineering 3 (July 1981): 180-2.
- Robertson, Thomas L. "Clinical Engineering Services at the VA Medical Center, Los Angeles." Journal of Clinical Engineering, Vol. 4, No. 2 (April-June 1980): 126-132.
- Shepherd, M.D. "Does the In-House BMET Face Obsolescence." Journal of Clinical Engineering 5 (October-December 1980): 341-3.
- Stankevick, B.A. "4% of Professional Liability Claims Involve Electromedical Equipment." Modern Health Care 10 (December 1980): 74-6.
- Stanley, Gary Lee. Hospital Bio-Medical Engineering Policy and Procedure Manual. Marion, Illinois: Hospital and Physicians Consulting Service, Inc., 1982.
- U.S. Department of the Army, the Navy, and the Air Force. Preventive Maintenance Procedures and Serviceability Standards for Medical Equipment. Navy Publication NAVMED P-5009, 31 May 1977.
- U.S. Department of the Navy. Bureau of Medicine and Surgery. Medical and Dental Equipment Maintenance and Repair Manual. BUMED INSTRUCTION 6700.36B, 25 June 1982.
- Veterans Administration, Department of Medicine and Surgery. Preventive Maintenance Guides for Select Hospital Equipment. VA-G-29 Vol:1 to 5, July 1974.
- Wullaert, I.L. "The Biomedical Engineering Department." Hospital Engineering 35 (March 1981): 5-6.
- Yacoob, E.Y. "Preventive Maintenance and Repair of Medical Equipment and Apparatus: an essential service." World Hospital 17 (August 1981): 17-9.
- _____. Accreditation Manual for Hospitals 83. Chicago, Illinois: Joint Commission on Accreditation of Hospitals, 1982.
- _____. Hospital Survey Profile 83. Chicago, Illinois: Joint Commission on Accreditation of Hospitals, 1982.
- _____. Program on Hospital Accreditation Standards Manual. Chicago, Illinois: Joint Commission on Accreditation of Hospitals, 1981.