More Efficient Organization Summary

for

Medical and Dental Equipment, Biomedical Engineer and Repair of Other Equipment, Clinical Center at the National Institutes of Health

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Table of Contents

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More Efficient Organization

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1 Executive Summary

The National Institutes of Health (NIH) developed a More Efficient Organization (MEO) as the government's organizational entity for performing the scope of work and tasks required for Clinical Center Medical Dental Equipment, Biomedical Engineer and Repair of Other Equipment services. The NIH Clinical Center serves as the nation's premier research hospital for conducting clinical research to improve the health of human kind. It also serves as a national resource for clinical research by developing diagnostic and therapeutic interventions, enhancing systems to ensure the safe, efficient, and ethical conduct of clinical research, training clinical researchers, and leading the response to the nation's public health needs. Activities included in the Requirements Document (RD) are performed by the following areas of the Clinical Center:

- Biomedical Engineering and Property Section
- Diagnostic Radiology
- Nuclear Medicine
- Positron Emission Tomography

The primary departments that are affected by this MEO are the Diagnostic Radiology Department, Materials Management Department, Nuclear Medicine Department, and the Positron Emission Tomography (PET) Department. Within the Materials Management Department, the Biomedical Engineering and Property Section (BEPS) is the organization where the majority of MEO positions reside. Each of these entities mentioned are involved with the management, tracking, diagnostics, and repair of medical and dental equipment in some form.

Development of the MEO was accomplished through review of the Requirements Document, analysis of workload and process flows, and evaluation of the requirements by staff currently associated with the required functions. Emphasis was placed on identifying areas that might lead to improving efficiency, gaining effectiveness, introducing standardized best practices, or re-engineering business processes.

The proposed MEO will continue to be located within the current Clinical Center operations area. The MEO will have four functional areas: Biomedical Engineering and Property Section, Diagnostic Radiology Department, Nuclear Medicine Department, and Positron Emission Tomography Department. The Director of the Clinical Center is not in the scope of the MEO but is integral to the success of the MEO, and will continue to provide the overall guidance and leadership.

The MEO will require 10.755 Full Time Equivalent (FTE) government employees to conduct the individual tasks and meet the requirements of the RD. This represents a reduction of 1.270 FTE from the organization currently performing these tasks. A position will be added during the second performance period (first option year). The position will begin as a partial position (0.300 FTE) in Performance Period 2 and

increase to 0.600 FTE in Performance Period 3. In Performance Period 4, the position will be 1.000 FTE.

2 Introduction

The purpose of this document is to describe the government's MEO that will conduct the functions specified in the RD. This document describes assumptions made, the approach utilized, the analyses conducted, and rationale employed in the development of the MEO.

2.1 Functions Under Review

The RD defines multiple functions applicable to the Clinical Center that encompass Medical and Dental Equipment Repair. The main functions that have been identified are supported by biomedical engineers, biomedical technicians, physicists, and other medical related professionals. Each of these functions includes numerous sub-functions or sub-requirements that must be performed in order to successfully fulfill the mission of the Clinical Center. Numerous functions that are integral to the success of the Clinical Center are not within the scope of the Requirements Document. The MEO has made every effort to maintain the relationship with management, tracking, diagnostics, and repair of medical equipment as necessary elements in providing integrated quality service.

3 Current Organization

The Clinical Center's ability to perform its mission as the premier clinical research center in the country is critically dependent on the Biomedical Engineering and Property Section and Imaging Sciences Program (ISP). The BEPS is responsible for providing and maintaining safe, functional, and effective medical equipment that is used in patient care. The ISP provides imaging resources for quality patient care, provides training, and performs basic and clinical research sponsored by NIH and the Clinical Center.

3.1 Mission

The mission of the NIH is to uncover new knowledge and translate it in a manner that will lead to better health outcomes for everyone. The NIH accomplishes that mission by (1) conducting research in its own laboratories; (2) supporting the research of non-federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; (3) helping in the training of research investigators; and (4) fostering communication of medical information.

As the nation's clinical research center, the NIH Clinical Center is dedicated to improving human health by providing an outstanding environment that facilitates the following:

- Development of diagnostic and therapeutic interventions;
- Training of clinical researchers; and,
- Development of processes to ensure the safe, efficient, and ethical conduct of clinical research.

In part, the Clinical Center achieves this mission through a culture that fosters collaboration, innovation, diversity, and the highest ethical standards. The functions under Medical and Dental Repair are an integral part of supporting the mission of Clinical Center.

3.2 Organization and Staffing

The current organization and staffing represents the applicable structure of the Clinical Center as it pertains to Medical and Dental, Biomedical Engineer and repair of Other Equipment. Figure 1 is a high-level organization chart detailing the reporting structure of the Clinical Center as it relates to these functions. A detailed organizational chart for the Clinical Center can be found at http://www.cc.nih.gov/external/org/index.html. Figures 2 through 5 illustrate organizational charts for each of the functions detailed in the Requirements Document. Table 1 shows the staffing levels of the current organization.

Figure 1: Current Clinical Center organization: Areas not covered by the RD are delineated by broken lines. This organizational chart is to provide a high level view of the entities that have staff that currently perform requirements specified in the RD.

Table 1: Current Clinical Center organizational FTE distribution for those functions identified in the RD.

Branch	Budget	On Board	Vacant
Biomedical Engineering and Property Section	9.330	9.330	0
Diagnostic Radiology Department	1.475	1.475	0
Nuclear Medicine Department	0.640	0.640	0
PET Department	0.580	0.580	0

3.2.1 The Imaging Sciences Program

The Imaging Sciences Program is part of the Clinical Center and is comprised of several departments. The departments within ISP that have duties specified by the Requirements Document are as follows: Nuclear Medicine, PET, and Diagnostic Radiology.

3.2.1.1 Nuclear Medicine Department

The Nuclear Medicine Department performs diagnostic nuclear medicine and PET procedures and specialized state-of-the-art nuclear medicine procedures to serve the NIH research community. In addition, new approaches introduced by its imaging physics and molecular imaging investigators or by other NIH groups are tested and clinically evaluated in this department.

The clinical scans are performed by fully qualified and certified technologists under the guidance of the staff physicians and a physicist; when required by a protocol, the scans

are analyzed with numerical algorithms designed by the investigator and the physicist. All the scans are read by the staff physicians. Because of the size and research scope of many of the procedures and the quality of the studies, the performance of departmental scanners often need to exceed those of ordinary nuclear medicine departments and requires a team of highly qualified and trained physicists as well as software engineers.

A full-time imaging physicist experienced in both medical and physics research is part of both the research and clinical teams. This full-time imaging physicist collaborates with institute investigators in protocol design, the analysis of data and implementing new tools for both data analysis, and image-acquisition. Investigators from various institutes approach imaging physicists to request, or explore the feasibility of using nuclear medicine procedures to provide the physiologic information needed for their clinical studies. It is the physicist's role to evaluate the merits, appropriateness, and potential challenges of the concept from the instrumentation and physics viewpoint. The physicist thoroughly investigates the physics and medical scientific literature and identifies or proposes solutions. The physicist may either implement the solution or direct others to do so. The physicist designs the appropriate acquisition and analysis protocols, typically with the participation of the investigator. The physicist follows through with clinical or quantitative evaluation of the procedure and, if merited, a publication.

The physicist is also involved in the efficient operation of the department by setting standards and Standard Operating Procedures (SOP) for all Quality Assurance (QA) procedures for seven scanners. Those seven scanners consist of six Gamma Single Photon Emission Computed Tomography (SPECT) scanners and one PET with an in-line computed tomography (CT) scanner. The standards that are set by the physicist must meet or exceed those set by Joint Commission on Accreditation of Health Care Organizations (JCAHO) and National Electrical Manufacturers Association (NEMA). The physicist is also responsible for overseeing QA and the Picture Archiving and Communications System (PACS) connectivity. This physicist participates with other physicists in the Nuclear Medicine (NM) and the PET Departments in the continuous upgrading of the NM/PET imaging computer network. This network, designed to quickly deploy novel visualization or quantitative-analysis tools and to facilitate the statistical analysis of data, is also the infrastructure for the automation and efficiency of current operations. QA and other routine maintenance activities are designed around this backbone under the guidance of the imaging physicist.

Figure 2: Nuclear Medicine Department – Only the area depicted by a solid line performs functions stipulated in the RD.

3.2.1.2 PET Department

Positron Emission Tomography is a nuclear medicine imaging method. Rather than providing anatomic or structural images such as with CT, PET images provide information about the function of body organs. There are several steps involved in performing research PET scans: producing compounds labeled with radioactive atoms that emit positrons; administering these radioactive compounds (called radiopharmaceuticals) to humans or animals; imaging the distribution of the radiopharmaceutical with a specialized scanner to obtain images in the form of "slices" through the body; and applying mathematical models that describe the behavior of the radiopharmaceutical so that physiological measurements can be made from the images. PET radiopharmaceuticals have been developed to study many aspects of physiology and biochemistry, including: the blood flow and blood volume of organs; the rate of use of sugar, oxygen, lipids and protein; the neuroreceptor-neurotransmitter systems used by brain cells to communicate with each other; and the concentration of drugs labeled with radioactivity.

The NIH PET facility is in the forefront of this field and is the largest facility in the country devoted solely to research. It includes three cyclotrons, radiochemistry laboratories with 10 hot cells, labs for radiopharmaceutical Quality Control (QC) and blood metabolite analysis, four PET scanners, and computers for image processing and databases.

The PET Department works in a unique research environment. All PET scans performed in the PET Department are done for scientific research on human subjects and large animals. In this regard, scans in the PET Department differ from those done in other large hospitals where PET is typically used as a diagnostic tool in cancer patients. Studies are performed in the NIH Clinical Center to obtain a better understanding of the mechanisms and treatment of human disease. The images produced are typically quantitative, i.e., they depict organ functions as numerical values, such as the amount of sugar consumed per minute per unit weight of tissue. Image analysis to generate research conclusions is based on numbers extracted from these images, not on simple visual inspection.

The department operates its cyclotrons to produce radioactive, positron-emitting isotopes; synthesizes PET radiopharmaceuticals; performs research PET scans in Clinical Center patients; develops and implements new PET procedures; conducts basic research in PET methodology; and collaborates with NIH physicians and scientists in the design and execution of their research protocols. There are approximately 60 active research protocols supported by the PET Department. Eighteen different radiopharmaceuticals are available for research use in humans and there are several others for use in animals.

The PET Department is divided into five operational groups.

The Cyclotron Group – operates and maintains three medical cyclotrons; develops new cyclotron targetry; and designs and fabricates specialty equipment items such as O-15 water synthesis modules.

The Radiochemistry Production Group – prepares Investigational New Drug and Radioactive Drug Research Committee (RDRC) research radiopharmaceuticals; maintains units used to synthesize PET radiopharmaceuticals; and designs and implements new methods for preparing radiopharmaceuticals.

The Radiopharmaceutical QC Group – dispenses all PET radiopharmaceuticals; performs QC procedures prior to dispensing; analyzes the level of metabolites of radiopharmaceuticals in blood; and keeps records for compliance to Food and Drug Administration regulation.

The PET Imaging Group – operates four scanners for human and animal PET imaging; schedules the scanners; provides medical supervision of scans; performs image processing and archiving; provides consultation to the NIH investigators in the design and implementation of PET protocols; and performs preclinical and collaborative clinical PET research.

The Modeling and Physics Group - provides physics and instrumentation support for the four scanners and accessory instrumentation; provides consultation to NIH scientists in the design and implementation of PET protocols, especially with regard to instrumentation and mathematical modeling; develops and implements new methodology for PET studies; and performs modeling research studies to evaluate new radiopharmaceuticals.

Figure 3: PET Department – Only the Modeling and Physics Group have duties specified in the RD.

The activities in the RD related to the PET Department are performed by two members of the Modeling and Physics Group. The Group's responsibilities include:

- Primary support of four PET scanners including QC, troubleshooting scanner hardware and software problems, and all interactions with manufacturers and service personnel.
- Procurement and acceptance testing of PET imaging systems, and design of related facilities.
- Addressing hardware and software problems with Automatic Blood Counters (ABC) and gamma counters.
- Support and maintenance of NIH-written software for image processing.
- Development of new methodology including complex acquisition protocols, image reconstruction methods, and image post-processing such as motion correction and image registration; implementation for routine use and support of same.
- Blood input function and metabolite correction development, including evaluation of Thin Layer Chromatography and High Pressure Liquid Chromatography methods and results.
- Creation of functional images from dynamic sequences of PET scans.
- Implementation and testing of image processing methods described in scientific publications.
- Collaboration with NIH scientists on research protocol development and implementation, design and execution of image and model analysis, and troubleshooting of problematic studies, such as those with missing or incomplete scanner or blood data, or those with image artifacts.
- Research in biomathematical modeling to perform physiological measurements with PET, image processing, and the physical aspects of PET imaging.

The PET scanners and other equipment delineated in the RD are not standard "off-the-shelf" items nor are they used in a standard, clinical fashion. QC is done to standards defined by the types of studies being performed, and is typically evaluated at levels more stringent than generally practiced at clinical sites. These measurements include weekly calibration checks that cross-calibrate all of our devices (scanners, gamma counters, ABC, and dose calibrators). Additional measures are performed and evaluated quarterly (spatial resolution, scanner count rate performance, accuracy of scatter correction, and intrinsic scatter).

There are three General Electric Advance whole body scanners that can scan in many different ways to suit research needs. These include 2-dimensional or 3-dimensional imaging; with or without bed motion; static mode (to obtain single "snap-shot" like images) or in dynamic mode (to obtain a time sequence of many images). They are used with 18 different radiopharmaceuticals and 60 research protocols, each of which has different scripts (in-house written protocols) to drive the scanner. Frequently, more than one radiopharmaceutical is administered during a study. The High Resolution Research Tomograph PET is a new, high resolution and sensitive state-of-the-art

scanner designed for brain research studies. It has very sophisticated hardware and image reconstruction software. The software is frequently upgraded (in-house or by the manufacturer) to further improve image quality and the associated computer cluster to reconstruct image is frequently modified. The ABC devices used to withdraw and count radioactivity in blood from patients were uniquely designed and fabricated in-house. These devices require specialized knowledge to maintain and repair. Many PET studies involve measuring radioactivity in discrete blood samples. The balances and radioactivity counters used are connected via the Local Area Network (LAN) to central computers. In-house written software combines the PET images and blood measurements and generates physiologic images of organ blood flow, sugar metabolism, etc.

The equipment and software are highly integrated and connected to produce the final "product", quantitative images representing the physiology of body organs. All equipment must operate accurately and reliably. Failures can occur at many levels; with the hardware (which is proprietary or in-house fabricated); with the software (proprietary or in-house written); with the LAN and computers used to transmit and store images and other data; or by user error. The Modeling and Physics Group must be able to maintain all equipment, diagnose malfunctions, and restore equipment to working order promptly or determine that a manufacturer service call is required. This work must often be done immediately, at times while the patient is in the scanner, so data for the study will not be lost.

It should be noted that information concerning the design and operation of the hardware and software of the four PET scanners is proprietary. Access requires permission from the manufacturers and appropriate confidentiality arrangements. Access is readily granted to government employees, but may not necessarily be granted to industrial competitors.

Staff members that currently perform the functions described in the RD have close interactions with the PET Imaging Group, and with numerous NIH scientists and physicians. Weekly meetings with the Imaging Group are required to discuss QC; new procedures and software; implementation of different clinical research protocols; and problems with equipment and image processing. There is daily interaction with technologists and physicians concerning scheduling the scanners, scanner QC, maintenance and repair, equipment malfunctions, images with artifacts, and other data that appear erroneous. Decisions must be made jointly regarding the severity of problems to determine whether scanning can proceed or whether studies must be delayed for equipment diagnosis and repair. There are ongoing discussions with the Imaging Group about equipment procurement, modifications to existing devices, and implementation of new methods. The Modeling and Physics staff are also involved in consultations, often detailed and ongoing, with NIH physicians and scientists. This is to help in the design of clinical research protocols that use PET, including selection of scanner, mode of scanner operation, imaging protocols, mathematical models used to generate functional images, and image processing.

The work is complex, and requires a high level of knowledge and skills. Knowledge is required with regard to computer languages and software, computer networks, electronics, design and operation of nuclear medicine imaging and counting devices. A broad knowledge in the field of PET is specifically required, including; PET scanner design, performance characteristics, and performance testing; PET image reconstruction and methods to correct for physical effects such as scatter, random counts; biomathematical models used to generate physiologic PET images; image processing; and clinical research areas in which PET is used. Data acquisition and processing is performed across multiple computer platforms and environments. Maintenance of this software requires proficiency in multiple operating systems (Sun, Unix, Linux, VAX, Windows 2000 and Windows XP), programming languages (IDL, Tcl, Perl, PHP, Java), communications standards (LAN, terminal servers, serial comm.) and databases (Informix and MySQL). This comprehensive knowledge base is typically obtained by someone with an advanced degree (PhD, or Masters Degree) in areas such as bioengineering or imaging physics, often supplemented by extensive on-the-job-experience.

Knowledge is required about the design and operation of the PET Department's equipment and associated software, both proprietary and in-house designed. For example, evaluation of scanner operations require not only a thorough knowledge of the physical principles of PET in general but also detailed knowledge of NIH scanners' operational design. Maintenance of the ABC requires an understanding of the principles of nuclear spectroscopy and the operation of Nuclear Instrumentation Modules, as well as the operation of the acquisition software that is used to obtain the blood concentration data. The staff must have the ability to diagnose equipment and software malfunctions, make the required repairs or modifications, or determine that a service call from the manufacturer is required. These types of knowledge and skills are typically obtained by on-the-job experience. This experience must be in a PET research facility, but must also be specific to NIH specialized or unique equipment and software. The NIH staff must have the ability to provide consultative services with regard to research applications of PET and the design of PET research protocols, including areas of instrumentation, methods, data analysis, and image processing. These consultations are with research physicians and scientists, and must be at a high level.

PET scans of the brain, heart, and tumors are integral components of clinical research protocols in several NIH Institutes: National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Child Health and Human Development (NIDCD), National Human Genome Research Institute (NHGRI), National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Child Health and Human Development (NICHD), and National Institute on Alcohol Abuse and Alcoholism (NIAAA). These are typically complex research protocols, involving patient recruitment and careful screening, extensive other testing (e.g., medical and/or psychiatric evaluations, neuropsychological tests, Magnetic Resonance Imaging (MRI) scans, blood tests), and use of new experimental treatments. It is critical that the Department's scanners operate at a very high level of reliability. The required PET scans must be performed during the time-

lines specified in each protocol, and the scans must be performed accurately and completely so that the research data collected are not compromised in any way.

3.2.1.3 Diagnostic Radiology Department

The mission of the Diagnostic Radiology Department (DRD) is to provide imaging resources for quality patient care and perform clinical research studies sponsored by the NIH and the Clinical Center. The department also maintains excellence in the delivery of patient imaging services and continues to be recognized as a preeminent center for the training and performance of biomedical imaging research.

This department maintains a state-of-the-art clinical imaging facility and subspecialty trained radiologists to assist collaborators in research design and analysis. The DRD is responsible for clinical procedures such as angiography, computed tomography (CT scan), interventional radiology, magnetic resonance imaging (MRI), mammography, ultrasound, and conventional radiographs (X-rays). This department is responsible for overseeing all the approved Institutional Review Board protocols that include imaging at the CC. The department has four state of the art high field strength MR scanners, three helical CT scanners, two radiography rooms, two combined rooms with fluoroscopic and radiographic capabilities, one mammography unit and one LORAD prone biopsy table. This is a very active department with the procedure volume for the entire DRD in 2004 of 112,000 exams.

The expanded Digital Imaging Program is being implemented and will result in a completely electronic clinical and research imaging environment within the CC and on the NIH campus. The core of the new system is a new Radiology Information System (RIS)/ Picture Archiving and Communications System (PACS) that will completely “digitize” the department. This infrastructure is not research per se but provides critical support for the digital image analysis research currently being performed by the MEDX group, other departmental investigators. The program has emphasis on computer assisted, quantitative image analysis that will be applied to clinical data. DRD has extended its technical support of quantitative digital image analysis by adding more advanced computer resources and technologists trained in advanced image analysis.

DRD has a lead role in the new image guided therapy which takes advantage of collaborations with other NIH Institutes and Centers. A new Image Guided Surgical Suite will open this year with access to MRI, CT/Fluoroscopy, nuclear probes and associated robotic devices.

Figure 4: Diagnostic Radiology Department – Only Medical Physics functions are called for in the RD.

The staff performing the functions described in the RD has close interactions with the Imaging Groups, and with numerous NIH scientists and physicians. There is constant communication with technologists and radiologists, regarding QC, maintenance and repair, equipment malfunctions, images with artifacts, and other data that appear erroneous.

3.2.2 Biomedical Engineering and Property Section

The BEPS is responsible for implementing the Medical Equipment Plan (MEP). The purpose of the MEP is to assure the selection of proper medical equipment for clinical care and treatment of patients, effective preparation and competencies of staff responsible for the use or maintenance and repair of the equipment, and continual availability of safe, calibrated equipment. BEPS is vigorous in performance monitoring and measurement which is a key component of assuring the MEP is effective. The MEP describes processes for planned maintenance, timely repair, ongoing education and training, and evaluation of all events that could have an adverse impact of the safety of patients or staff.

This section is also responsible for applying criteria to determine if new equipment bought by different institutes qualifies to be entered into the Clinical Center inventory database. Coordination with equipment managers, Capital Resource Committee, Standardization Committee, other Materials Management sections, and others may be needed when the BEPS is identifying and locating new equipment. This inventory is maintained in a computerized database that is audited by JCAHO and other regulatory agencies. This section is responsible for overseeing that all equipment maintenance, testing, and inspections are performed on all applicable clinical equipment that resides in the Clinical Center or is intended for patient care on campus. The Equipment Maintenance Database System contains all work history and other pertinent data on

clinical equipment. This information is used to determine any risk that may be associated with the use of clinical equipment. The Occurrence Reporting System is also used to assess the risk of using clinical equipment. Occurrence Reporting System reports are tracked and trended by the BEPS to reduce patient and staff safety risk.

This section works with other Institutes and Centers that have clinical equipment to ensure that their representative is providing inspection completion rates to the BEPS. The frequency of inspections is determined by the BEPS. Factors such as suggested maintenance cycle, professional judgment, manufacturer's recommendation, failure rate, and current organization experience using a particular piece of equipment are considered when determining the frequency.

The BEPS is also responsible for monitoring equipment hazard notices and recalls. These activities are acted upon when received and are reported to the Safety Committee. This section is also responsible for monitoring and reporting incidents of equipment failure. It is the BEPS's responsibility to secure the equipment and take out of service. An investigation is typically conducted if required. Any investigation conducted by the BEPS is sent to or worked in conjunction with the Safety Officer.

The BEPS is responsible for generating and prioritizing a capital equipment replacement list for all departments within the Clinical Center. This list includes a five year replacement plan for clinical and non-clinical equipment. Factors like age, obsolescence, technology change, significance of repair cost and downtime are scored and prioritized. This is a very labor intensive procedure requiring the following data to be processed; equipment age, model number, serial number, property number, location, account, and cost for each device in relation to capital equipment replacement. This information has a potential financial impact on the Clinical Center. BEPS also conducts trials and evaluations for potentially new Clinical Center equipment and accessories.

The BEPS, along with the Safety Committee, is responsible for establishing a performance improvement standard that measures the effectiveness of the MEP. This section is also responsible for maintaining an emergency procedure manual that specifies actions that must be taken during an equipment failure and must respond to all NIH red alert critical activities. An Equipment Failure Response Document is maintained to describe whom medical device users should call in the event of equipment failure.

Figure 5: Biomedical Engineering and Property Section – Functions in the Property Management area are not specified in the RD.

3.3 Analysis of Current Operations

3.3.1 Current Procedures

The Biomedical Engineering and Property Section is part of the Materials Management Department located within the Clinical Center of the National Institutes of Health. This section is responsible for the repair and maintenance of all JCAHO regulated equipment. The BEPS is responsible for approximately 4,000 pieces of clinical medical equipment as well as 8,000 pieces of other general patient care-related equipment. Examples of clinical patient care related equipment: physiological monitoring, dialysis, ventilators, intravenous pumps, etc. General equipment typically includes patient televisions, nurse call systems, wheelchairs, medication refrigerators, wall suction and air gauges. BEPS utilizes the EMDBS to track maintenance history on all JCAHO regulated equipment in the Clinical Center including all imaging devices. The BEPS uses the Medical Equipment Management Plan to ensure that all clinical equipment meets prudent standards in procurement, maintenance, and level of knowledge by the employee.

Some of the positions that perform the requirements of the RD are from the Nuclear Medicine, Positron Emission Tomography, and the Diagnostic Radiology Departments. These three departments are under the Imaging Sciences Program. Although the preponderance of their duties is in imaging, each position has some of their activities specified in the RD.

3.3.2 Workload Analysis

Table 2 shows the staffing currently performing the duties specified in the RD.

The positions performing the functions of this RD are distributed among the organizations as listed in Table 2. Positions in the Diagnostic Radiology Department, Nuclear Department, and PET Department dedicate portions of their time to performing the functions specified in the RD. After further analysis by the MEO development team, it was determined that the positions in these departments adequately perform the functions specified in the RD. Therefore, no changes need to be made to the current manner in which these functions are being performed.

Table 2: Current Clinical Center staffing for those functions specified in the RD.

Branch	Budget	On Board	Vacant
Biomedical Engineering and Property Section	9.330	9.330	0
Diagnostic Radiology Department	1.475	1.475	0
Nuclear Medicine Department	0.640	0.640	0
PET Department	0.580	0.580	0

The Biomedical Engineering and Property Section will perform the preponderance of the medical and dental equipment management, tracking, diagnostics, and repair. After detailed analysis, the MEO development team determined that efficiencies can be gained by making adjustments to the section.

4 Methodology and Approach to Develop the MEO

The MEO development team began its challenge by carefully reviewing the RD, the current organization and its performance. Representatives from each of the involved departments reviewed workload measures and outcomes from their respective areas to identify organizational structures, cost reductions, and process improvements associated with performance of activities required by the RD.

The MEO development team then trended workload measures compared to requirements over time, taking into consideration changes in technology that impacted efficiency. Workload measures stipulated in the RD were factored into the trending to arrive at the number of positions that will be needed to fulfill the requirements by area.

The Imaging Sciences Program and Clinical Center Materials Management Departments, as dynamic organizations, have effectively changed its business practices over the past several years to adapt to the changing environment of clinical research. As evidenced by the analysis of current operations in Section 3.3, these areas can meet the increasing demands of the business area with improved and more efficient operations while successfully reducing staff. As a result, the MEO will not implement any major changes to the current organizational structure and recognizes the importance of interacting with other sections of the Clinical Center including those sections that do not have functions specified within Medical Dental Equipment Repair RD. However, continuing with the historical trend and based upon projected and actual improvements and conditions, the MEO will allow for a further reduction in staff.

The MEO will provide all management, supervision, consultation, administration, materials, supplies, equipment, and labor as identified in the RD. In keeping with this responsibility, the MEO development team has concentrated on the mission of this organization to ensure the quality standards set forth in the RD are met.

4.1 Assumptions Used to Develop the MEO

A key component of the MEO structure is the ability to meet the demands of services for the Clinical Center Medical Dental Equipment Repair functions in an ever-changing environment.

The following assumptions of the development team, including those of interest to the government, were addressed in response to the RD:

- The MEO development team will ensure sufficient support for the new organization.
- Involvement of the MEO development team will ensure government furnished information is supplied as needed.

- Equipment, materials, and facilities will be furnished by the government. This includes office equipment such as personal computers, printers, and copiers.
- Identified recommendations will be implemented within the period of performance.

The MEO will provide all services specified and required in the RD at standards of quality and timeliness that meet or exceed the specified requirements. The MEO will incorporate concepts, practices, and processes to gain organizational effectiveness and efficiency, and to promote further accountability. In addition to the key component, the MEO will be:

- An NIH customer service-focused organization that accepts, performs, and completes support services professionally and efficiently, with an emphasis on customer satisfaction.
- An organizational structure that allows for rapid response to critical and urgent requests while effectively interlacing planned and scheduled operations.
- A workforce that responds to the workload in an efficient and pro-active manner.
- A quality driven organization with continuous monitoring of activities by supervisors and staff.

4.2 Fundamental Changes and Justification

The RD outlined the magnitude of the work to be performed by the MEO. Each section of the RD was reviewed in detail by subject matter experts from the four functional areas with affected positions. Combined with this analysis was a review of historical workload measures and technology and process improvements that were used to develop a trend analysis. This provided the MEO with the ability to extrapolate staff requirements to the workload for the performance period.

After gathering information from appropriate sources and documents, the workflow process was assembled and the organization structures identified. The MEO development team reviewed and refined the approach and subsequent results. Fundamentally, it addresses the nine core performance areas of the RD. The MEO will maintain a fully integrated role within the current organization.

The current organizational structure (which includes areas not discussed in the RD) was found to meet the mission for the Clinical Center as defined by the RD and was an excellent basis for the development of the MEO. The MEO is structured to maintain the relationships with activities and organizations outside the scope of the RD and to continue to strike a balanced and effective work environment.

The primary change is a reduction in workforce of approximately one position. This was a justifiable reduction in part due to:

- Improvements in area support systems
- Ongoing business process improvements
- Improvements and expansions in the use of existing technologies
- The creation of new technologies and programs

In addition, upon review of the salary structure of the MEO staff, it is the conclusion of the MEO development team that the incumbent General Schedule (GS) grades as well as the Title 42 pay schedule positions are appropriate for the positions and the functions performed in the Medical and Dental Equipment function. This determination is supported through review of the information provided in the RD, which underscores appropriate levels of work that is commensurate with these salaries. It is recognized that for these affected positions to retain their cross sectional integrated approach to patient care and to carry on its commitment to the mission and vision of the organization, it is critical to retain these highly trained and seasoned staff and maintain fluid transition to the MEO implementation.

The changes in the BEPS section accommodate the current changes in technology and management philosophies by having only one GS-802-12 position in the MEO. In Performance Period 2, the MEO will add a GS-856-09 position at 0.300 FTE. In Performance Period 3, the MEO will increase that position to 0.600 FTE. In Performance Period 4, that position will be 1.000 FTE. The additional position is to accommodate the work associated with the new Clinical Research Center (CRC). The CRC, which opened in 2005, is a new, state of the art research, hospital with approximately 250 beds dedicated to clinical research. The CRC has large systems with thousands of discrete components. These systems, such as the highly sophisticated integrated nurse call system which incorporates cordless phones, television, DVD, computer with internet access and nurse call interface, requires hands on technical expertise. It is expected that these CRC medical equipment items will be problematic with age and would require an additional technically suitable position (see Figure 6).

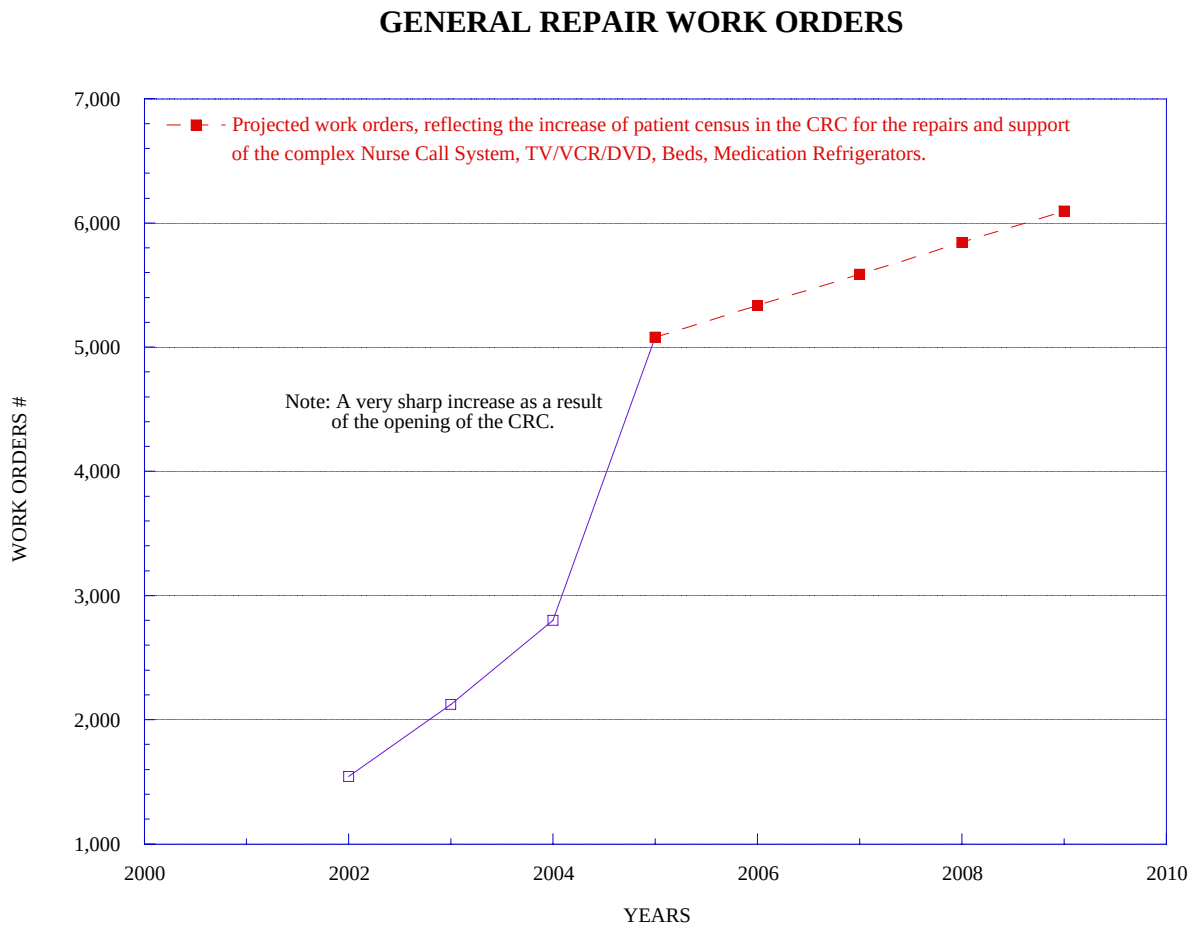

Figure 6: BEPS General Repair Work Orders

In the PET Department, both the staffing level and the level of expertise of the staff (Ph.D. physicist; Masters level biomedical engineer) will remain the same for the MEO.

The work performed by this staff is extremely varied, involving multiple different activities, each one contributing a relatively small amount to the individual's overall workload. Therefore, it is not possible to simply rearrange the pattern of work so that these tasks are accomplished with less staff. Also, the time of day when these tasks are performed is variable, and may depend on when an equipment malfunction develops. The two positions are made available throughout their entire workday to respond to urgent situations immediately, even if the response that is required takes a short period of time. Thus, we have a rapid response throughout the day. Therefore, currently staff members operate at a very high level of efficiency with regard to the tasks specified in the RD.

A very high level of knowledge and expertise is involved and must be maintained. This is because of the following:

- The unique research environment of the NIH PET Department. Most applications and quality control procedures are much more advanced than those found in the usual clinical environment
- The complex, state-of-the-art nature of the hardware and software involved, much of it in-house written or designed, or proprietary
- The fact that our equipment and software is highly integrated. Failures can occur at many levels with hardware, software, LAN, computers used to transmit and store images, or user error. The staff must be able to maintain all equipment, diagnose malfunctions, and restore equipment to working order or determine that a service call is required. This must often be done immediately, while the patient is in the scanner, so that the study will not be lost.
- The high level of interaction required, with other members of the PET Department, and with NIH physicians and scientists to providing consultations about the design of clinical research protocols that use PET.

Similar to the PET Department, the staffing level for DRD will remain the same for the MEO. The work performed by the current staff is critical to the safe operation of the diagnostic imaging equipment in the Clinical Center. This staff has a high level of expertise in the tasks they perform and are extremely efficient.

The areas of expertise for this staff include the following:

- Vast knowledge base from experience in acceptance testing many complex and varied types of equipment including CT, Radio Frequency, Fluoroscopy, Mammography, and Angiography units.

- Ability to complete thorough and rapid testing and documentation of existing equipment including radiation protection devices. Because we have in house support this can be done throughout the work week. This is accomplished during the work day but never impedes work flow and patient care.

- Ability to coordinate installation, renovations and upgrades of equipment between many different groups within DRD, NIH and industry. Although time consuming, this process is essential to keep the department at the cutting edge of technology for the CC patients.

- Ability to communicate well with individuals at many levels of training in DRD; administrative staff, technologists, scientists and radiologists, and with NIH physicians and scientists about clinical protocols and imaging examinations.

In the Nuclear Medicine Department, it was determined that it would be possible to perform the functions outlined in the RD with a lower level of staffing. The Nuclear Medicine Department provides services to a very demanding clientele within the Clinical Center and the other institutes and centers. In addition to the complex work flow of the

typical nuclear medicine facility, the department has to support specialized needs of research protocols, in-house developed systems and unique instrumentation tools.

The department is very mindful of the importance of efficiency and is constantly evaluating and putting into place new ideas. This year, the Nuclear Medicine Department automated a number of QA procedures and implemented a more effective image transfer and data-base systems. SOP's are constantly reviewed to seek better ways to achieve current or new goals. The physicist in this department keeps a detailed data-base to track operational failures and the physics support is essential in designing and implementing the necessary modifications. The NM and PET Departments have pooled many of their software development resources to achieve its current efficiency. There is a stream of new ideas that are constantly, tested and tuned. The department interacts with the Radiology Department in combining their resources to deal with contractors/subcontractors both to increase our bargaining power and, when standards are not met, to put effective pressure to resolve the relevant issues. The MEO development team's analysis indicated the functions for this area specified in the RD can be carried out by 0.300 FTE in the Nuclear Medicine Department.

5 More Efficient Organization

The proposed MEO will be located within the current Clinical Center operations area. Within the MEO are four areas: Biomedical Engineering, Diagnostic Radiology, Nuclear Medicine, and Positron Emission Tomography Departments.

The Clinical Center is the epicenter for all clinical research within NIH. The four areas are required to interact with other departments within the Clinical Center as well as other Institutes and Centers within NIH to accomplish their missions. For example, the BEPS is required to interact with other Clinical Center departments as well as other Institutes and Centers who may have custody of clinical equipment that this section is accountable for.

The design of the MEO will enable it to conduct the individual tasks and meet the requirements of the RD. There will be a change to the current organization performing these requirements. A partial position will be added and assigned to BEPS in the second performance period of this proposal. This partial position will grow into a full-time position by the fourth performance period.

5.1 Management Approach

The MEO will provide the managerial, supervisory, administrative, and direct workforce personnel to accomplish all requirements. The MEO management approach fully addresses and comprehends the philosophy and operational concerns of an organization as unique and talented as the NIH. The MEO management approach addresses numerous key organization requirements and considerations including the ability to:

- Implement a highly responsive and service oriented organization that efficiently and effectively delivers services that support the NIH mission
- Quickly adapt to changing workloads and environmental dynamics
- Efficiently and quickly move workforce to the workload
- Optimally balance cost and service
- Work within the scope of government operations
- Provide for employee satisfaction and development

Underlying the management approach of the MEO is the realization that the uninterrupted performance of the Clinical Center is of prime importance. The MEO is predicated, in part, on the belief that the Medical and Dental Equipment Repair staff is an integral part of the Clinical Center mission.

5.1.1 Management Organization

The MEO will implement an organizational structure that will administer performance of the requirements in a way that will minimize cost and maximize service to the

customers. The structure will utilize the same functional management approach as the current organization. Figure 7: “The Proposed MEO”, presents the proposed organizational structure.

Figure 7: The Proposed MEO (including the dotted lines not contained within the proposed MEO)

Figure 8 presents the proposed organizational structure for the Biomedical Engineering and Property Section. Property Management, delineated by the broken lines, is not covered by the RD therefore no positions are affected. The Electronic Technician carrying the “future” indicator at the bottom of this organizational chart is the position that will be added during the second performance period.

Figure 8: Proposed Biomedical Engineering and Property Section of the MEO

The MEO will replicate the current management organization. Therefore the proposed MEO will not be a completely stand-alone entity with its own management structure. As

a result, the MEO will maintain a close relationship with the Continuing Government Activity (CGA) and will provide detailed reporting.

5.1.2 MEO Operation

The proposed MEO will be located in the NIH Clinical Center. The MEO fully understands that Medical Dental Equipment Repair functions require a unique set of knowledge, skills, and abilities. Understanding and expertise of biomedical engineering, radiology, PET, and nuclear medicine is imperative in performing these functions. Understanding the specific requirements that each department must follow is paramount.

The current organizational operation structure was the basis for the development of the MEO. The MEO is structured to maintain the relationships with activities that are not specified within the RD to continue to strike a balanced and effective work environment.

The MEO will continue with integrated services that touch all aspects of Clinical Center Medical and Dental Equipment Repair. The MEO is committed to creating best value for its customers and developing customer centered partnerships that deliver results. This approach and structure promotes efficiencies among Medical and Dental Equipment Repair sections and facilitates the provision of seamless service that focuses on the customer's requirements. This "integrated" aspect of the Medical and Dental Equipment Repair operation is core to the organization's successes. For these reasons, the Medical and Dental Equipment Repair MEO is structured as a similar organization maintaining the highest quality and effectiveness and will continue to operate in the manner of the current Clinical Center.

5.1.3 Staffing

Staffing for the MEO was developed from the "As-Is" organization, but has been adjusted to meet the requirements of the RD.

Table 3 displays the MEO staffing details. Position 16 will be added to the MEO during the second performance period as indicated earlier

Table 3: Initial Composite MEO FTE Staffing

1	Health Systems Specialist	CC	Diagnostic Radiology	0601	GS-12	1.000
2	Physicist (Medical)	CC	Diagnostic Radiology	1310	GS-13	0.300
3	Senior Medical Physicist (Tech Mgr)	CC	Diagnostic Radiology	1306	Pay Cluster 1 Pay Band 3	0.175
4	Physicist	CC	Positron Emission Tomography	1310	GS-13	0.300
5	Electronic Technician (Biomedical Engineer)	CC	Positron Emission Tomography	0856	Pay Cluster 1 Pay Band 2	0.280
6	Physicist	CC	Nuclear Medicine	1310	Band 2 Tercile 1	0.300
7*	Electronic Technician	CC	Biomedical Engineering	0856	GS-7-8	0.950
8*	Electronic Technician	CC	Biomedical Engineering	0856	GS-9-10	0.900
9	Biomedical Engineer Tech	CC	Biomedical Engineering	0802	Pay Cluster 3 Pay Band 1	1.000
10	Supervisory Biomedical Engineer	CC	Biomedical Engineering	0858	Pay Cluster 1 Pay Band 2	0.700
11	Lead Biomedical Engineer Tech	CC	Biomedical Engineering	0802	GS-12	0.900
12	Biomedical Engineer Tech	CC	Biomedical Engineering	0802	GS-11	1.000
13*	Supply Technician	CC	Biomedical Engineering	2005	GS-6-7	0.950
14	Program Support Specialist	CC	Biomedical Engineering	0301	GS-09	1.000
15	Biomedical Engineer Tech	CC	Biomedical Engineering	0802	Pay Cluster 3 Pay Band 1	1.000
16**	Electronic Technician	CC	Biomedical Engineering	0856	GS-09	-
TOTAL						**10.755**

* These positions may require a change in series to accommodate the performance of the MEO.

** A GS-0856-09 Electronic Technician will be added in the second performance period (Option Year 1) as a partial FTE (0.300) and grow to full FTE (1.000) in the fourth performance period (Option Year 3).

Glossary

A
ABC – Automatic Blood Counters

B
BEPS – Biomedical Engineering and Property Section

C
CIPS - Clinical Imaging Processing Service
CGA – Continuing Government Activity
CRC – Clinical Research Center
CT – Computed Tomography

D
DRD – Diagnostic Radiology Department

F
FDA – Food and Drug Administration
FTE – Full Time Equivalent

G
GS – General Schedule

I
ISP – Imaging Sciences Program

J
JCAHO – Joint Commission on Accreditation of Health Care Organizations

L
LAN – Local Area Network

M
MEO – More Efficient Organization
MEP – Medical Equipment Plan
MRI – Magnetic Resonance Imaging

N

NCI – National Cancer Institute
NEMA - National Electrical Manufacturers Association
NIAAA – National Institute on Alcohol Abuse and Alcoholism
NIAID – National Institute of Allergy and Infectious Diseases
NICHD – National Institute of Child Health and Human Development
NIDCD – National Institute on Deafness and Other Communication Disorders
NIH – National Institutes of Health
NHGRI – National Human Genome Research Institute
NIMH – National Institute of Mental Health
NINDS – National Institute of Neurological Disorders and Stroke
NM – Nuclear Medicine

P

PACS - Picture Archiving and Communications System
PET – Positron Emission Tomography

Q

QA- Quality Assurance
QC – Quality Control

R

RIS - Radiology Information System
RD – Requirements Document

S

SOP – Standard Operating Procedures
SPECT - Single Photon Emission Computed Tomography