Addis Ababa University, Addis Institute of Technology (AAiT)

Centre of Biomedical Engineering

Reengineering the Medical Equipment Management system- The Provider- Regulator – Purchaser Aspect

A Thesis Submitted to Addis Ababa University, Addis Ababa Institute of Technology, and Centre of Biomedical Engineering in Partial Fulfillment of the Requirement for the Degree of Master of Science in Biomedical Engineering

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Addis Ababa University

School of Graduate Studies

Certificate of Examination

This is to certify that the thesis prepared by ***Ashenafi Hussein Ababu*** entitled: ***Reengineering the Medical Equipment Management system- The Provider- Regulator – Purchaser Aspect*** submitted in partial fulfillment of the requirements for the degree of **Master of Science in Biomedical Engineering** complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Acronyms

AAiT - Addis Ababa institute of Technology

BEMIS -Biomedical Equipment Management Information System

DBMS -Database Management system

ER -Entity Relationship

FMoH - Federal Ministry of Health

HEAC - Healthcare Equipment Application Cycle

HTM - Healthcare Technology Management

ISO - International Standard Organization

MIS - Management Information System

MS - Microsoft

NGO - Non Governmental Organization

PMA - Pre Market Approval

SCM - Supply Chain Management

SQL -Structured Query Language

TIC -Technology Innovation Cycle

WHO - World Health Organization

Abstract

A very poor management of healthcare equipment results wastage of valuable limited resources. A well designed and properly implemented Medical equipment management system can help not only managing the financial resources but also improves the quality of life. Different kinds of models are used in many developed countries to reengineer system. Although conceptual model is easy to understand with less accuracy and simulation model is more accurate modeling; neither of them are good to model the strategic implication. The new design is developed based on the concept of input output mechanism engineering model. The thesis evaluated the existing Medical equipment management practices and processes and reengineers the system and come up with a new design to solve the existing problems. In order to properly assign the main inputs in the system design, a preliminary study was implemented in Addis Ababa, Ethiopia to assess the main challenges in healthcare providing organizations. In this preliminary study a total 243 number of healthcare providers were selected including hospitals, health centers and health clinics. Healthcare professionals from those major health facilities were interviewed and asked to full a questionnaire on existing healthcare technology management. The data collected from the facilities indicates there is a poor performance in provision (did not have system to forecast equipment demand based on available budget that was 67.8% of hospitals and 61.1% of health centers), acquisition (68.8% of hospitals, 77.8% of health centers and clinics, 63.6%were found out to be without guideline for procurement), utilization (75.0% of hospitals and 50.0% of health centers in Addis Ababa, are not properly installed), donation (83.3% of them reported that they do not have system to track the donation) and decommissioning (56.2% of hospitals, 66.7% of health centers and 56.9% of clinics reported that they have a problem in decontaminating devices before use and after removal) of medical equipment. The results offered the opportunity to appraise a reengineering the system design of the overall healthcare technology system and design a system to reduce the problem that exists to show improvement for increased efficiency and more effective utilization of available resources. An input output model, the provider regulator purchaser model is used to construct the detail design of the healthcare technology system. MIS and desktop software application is developed for the new designed system. The challenges encountered in this thesis included limited number of samples, difficulty to collect questionnaires and testing the system in the real world. As the thesis includes designs from the strategic planning until decommissioning, it can be used as a blue print from where health facilities, regulatory authorities, purchasing entities can implement.

Acknowledgment

I would like to take this opportunity to express my deepest and sincere gratitude to my advisor, Ato Birhanu Assefa, for his unreserved and priceless advices, remarks, suggestions and guidance, proposed with an extreme kindness, without him my thesis work would never be achieved.

I would also like to extend my profound gratitude and thanks to the biomedical engineering staffs of Addis Ababa institute of technology for their valuable contributions, which are indispensable for the success of the course I have been attending during the last two years.

I owe all of my friends, classmates and colleagues at the center of biomedical engineering during these past years.

Last, but not least, I would like to express my deepest gratitude to my family, especially my wife, my parents, who always believed in me and supported me. I would have achieved for less without their continuous support. They have been my greatest mentors, and I owe all my success to them. My special love goes to my daughter Fikir Ashenafi who has come to the world by the time I began my MSc. My daughter has been inspirational support for my all life activity and I dedicate this thesis to her.

Background on Ethiopian Health System Organization

The recently implemented BPR of the health sector has introduced a three-tier health care delivery system which is characterized by a first level of a Woreda/District health system comprising a primary hospital (with population coverage of 60,000-100,000 people), health centers (1/15,000-25,000 population) and their satellite health posts (1/3,000-5,000 population) that are connected to each other by a referral system. A primary hospital, health center and health posts form a Primary Health Care Unit (PHCU) with each health center having five satellite health posts. The second level in the tier is a general hospital with population coverage of 1-1.5 million people; and the third a specialized hospital that covers population of 3.5-5 million. The Ethiopian health care system is augmented by the rapid expansion of the private for profit and NGOs sector playing significant role in boosting the health service coverage and utilization thus enhancing the public/private/NGOs partnership in the delivery of health care services in the country. Offices at different levels of the health sector from the Federal Ministry of Health (FMoH) to Regional Health Bureaus (RHB) and woreda health offices share decision making processes, decision powers, duties and responsibilities. The FMoH and the RHBs focus more on policy matters and technical support while Woreda Health Offices have basic roles of managing and coordinating the operation of a district health system under their jurisdiction. Regions and districts have RHBs and district health offices respectively for the management of public health services at their respective levels. The devolution of power to regional governments has resulted in the shifting of decision making for public service deliveries from the centre to largely under the authority of the regions and down to the district level. Under FMoH, other than hospitals, health centres and health posts, there are four major organizations that offer services to the public; The Ethiopian Public Health Institute (EPHI) which mainly focuses on health related research and emergency preparedness; the Federal HIV/AIDS prevention and Control office which mainly focuses on HIV prevention; the Pharmaceuticals Fund and Supply Agency (PFSA) mainly focus on availing pharmaceuticals at affordable price to the public; the Ethiopian Food Medicine and Healthcare Administration and Control Authority (EFMHACA) majorly focusing on regulation of manufactures, products and health professionals.

Introduction

The provision of equitable, high-quality and efficient health care requires an extraordinary array of properly balanced and managed resource inputs (Bastiaan L. R.,1997). Physical resources such as fixed assets and consumables, often described as health care technology, are among the principal types of those inputs. Required equipment may range from sophisticated life-support equipment in a tertiary hospital setting to simple equipment needed for effective diagnosis and safe treatment of patients in a primary health care setting (Andreas L., Willi K. and Manjit K., 2000). However, the basic requirements are the same across all settings: clear policies, technical guidance, and practical tools for effective and efficient management of health care technology (David H. W., 2001).

Identification of appropriate technology, and its acquisition and utilization, require massive investment, and related decisions must be made carefully. To ensure the best match between the supply of technology and health system needs, the appropriate balance between capital and recurrent costs, and the capacity to manage technology throughout its life must be maintained. (Bloom G. and Temple-Bird C.,1990).

Developing countries account for about $5-billion (or 7%) of the $ 71-billion spent each year on medical equipment world-wide (this includes medical and dental supplies, surgical instruments, electro medical and X-ray equipment, diagnostic tools and implanted products) (David H. W., 2001). Nevertheless, developing countries are under heavy pressure to acquire healthcare technologies: externally from technology providers and donor agencies, and internally from rising healthcare expectations of their populations (Andreas L., Willi K. and Manjit K., 2000). Many developing countries are characterized by poor management of healthcare equipments that results in wastage of valuable limited resources (Bloom G. and Temple-Bird C., 1990). The efficiency losses from poor selection and maintenance of medical equipments in developing countries can be very large. The world Health Organization (WHO) estimates that less than half of all medical equipment in developing countries is usable. WHO (2010) also accounted the loss due to inability to correctly specify and foresee total needs when tendering and procuring equipment for 10-30%, for extra cost purchase of sophisticated equipment which remains unused due to lack of skilled technical staff for 20-40%, and for equipment extra modifications or additions to equipment initially unchecked due to lack of staff expertise 10-30%. Maltreatment by operating and maintenance staff accounted for 30-80%, lack of standardization 30-50%, for extra spare parts cost down-time due to inability to repair, or no spare parts or accessories. The other major scenario was 25-35% of equipments fail prematurely in part because maintenance budgets are inadequate. In many cases, improving maintenance to increase operating life and reduce equipment downtime would be more efficient than buying new equipment.

While examining the situational analysis of developing countries health care technology is far from satisfactory. This can be attributed to the inefficient use of equipment and facilities and unstructured need assessment (Chang T., 1997). Due to the absence of data on equipment in the public health system, procurements are often made in unscientific and ad-hoc manner resulting in the import of wide variety of equipments. For developing countries WHO (2010) showed glaring example of equipment diversity for instance, different models of the same machines are found in use in hospitals. Reports also revealed that most of the machines were not installed and commissioned even after their receipt at the facilities (David H. W.,2001).

Generally, no improvements can be made unless there is effective action to adopt and implement appropriate national policies regarding health care technologies. Specifically, these policies must influence, inter alia: the levels of equipment appropriate to the country, the standardization, procurement, and installation and commissioning of equipment, the staffing structure for both management and maintenance, and the introduction of supporting information systems. Therefore, the purpose of this thesis is to study the potential use of reengineering as applied to the medical device innovation and management process.

The thesis is organized into three parts where the preliminary assessment mainly focuses on identifying major problems and to prove existing problems in Ethiopian context. The second part is composed of designing from clean sheet (Reengineering) the medical equipment management system and the final part discusses implementation of the design using MIS and development of a desktop software.

Literature Review

This section aims to review main topics in medical device management, current knowledge and consensus in the world about medical devices and issues related with reengineering.

Reengineering/ Process Approach

Origin of process approach and reengineering concepts dates back to 1911(Tylor, 1911) when it has been described as a system where each work and process is broken down to detail parts and carefully studied, then reassembled in the most efficient way possible. From the scientific management points of view process approach has been explained into a much broader range of activities.

The current set up of quality assuring and controlling organization has also supported process approach (Basler and Pizinger, 2004). International Standards Organization (ISO) especially *ISO 9001:2000* has mandated the adoption of a process approach (ISO, 2000). ISO introduced *ISO 13485:2003,* which explicitly requires a process approach toward quality management for medical device manufacturing (ISO, 2003). Even though not implemented ISO 13485 establishes guidelines for a quality management system in a medical device firm. Basler and Pizinger (2004) have emphasized the importance of a process approach, versus a procedural approach, to quality management, and have argued that risk management is integrated into the process-based approach to quality.

Process Mapping

Marrelli (2005) describes process mapping as “the step-by-step description of the actions taken by workers as they use a specific set of inputs to produce a defined set of outputs”. However, process mapping has been used on a wide range of scales and different levels of detail, and has been established as a tool that creates greater understanding and potential for improvement. Biazzo (2002) has established that using process mapping techniques is crucial to improving processes. Closer to the subject of medical devices, Terziovsky and Morgan (2006) have identified “innovation cycle maps” as one of 10 tools for accelerating the medical device management process.

Cross-Organizational Links

For medical devices to be implemented in the grass root level, organization linkages are vital. Cross organizational communication and processes are a main importance to a firm's well-being, especially in the medical device industry and in the process of medical device management. Hammer (2001) has maintained that a great amount of waste is created by lack of communication between different organizations, for example, by the same exact work being performed by an organization and its supplier. Hammer (2001) has argued that "Streamlining cross-company processes is the next great frontier for reducing costs, enhancing quality, and speeding operations".

Development and Management of Medical Devices

A number of perspectives were found that describe the actual development process for new medical devices. These can be grouped into two main categories. Some, such as Kaplan *et al*. (2004) have looked at the individual events that take place in medical device development process. Others have described the process on a more abstract level, at risk of neglecting the individual events that may take place. Kaplan *et al*. (2004) maintain that most new types of devices are developed by start-up companies, rather than large, established medical device firms. The development time up until clinical testing takes around 2-3 years and costs around 10 to 20 million dollars. Panescu (2009) has recognized a common pattern of six phases that occur in this development process: funding phase, concept phase, development phase, verification and validation phase, product phase, and market release phase.

Regulation and Approval Process

Regulation of medical devices begins from research and development until post marketing surveillance. Classifying medical devices into different levels and classes is critical for premarket notification and use. According to Monsoein (1997), there are three main routes to market, depending on whether the device falls within the three tier class system. The classification assigns each device to Class I, II or III accordingly. Some class I and II devices are exempt from this process (Medical Device Classification Procedures, 2009). Class III devices must usually have a Premarket Approval (PMA), which is sufficiently more complex process, involving large randomized clinical trials. According to Kaplan et al. (2004), "The specifics regarding study design may have profound impact on the time and cost of bringing a new device to market." Kaplan *et al*. (2004) have also stressed that clinical testing is the greatest financial risk to a new device developer.

Public procurement is an important function of government, aiming to satisfy requirements for goods, works, systems, and services in a timely manner. Ideally, public procurement should meet the basic principles of good governance: transparency, accountability, and moreover, should ensure value for money (Wittig, 2003).

Public procurement systems can be considered as a bridge between public requirements and private sector providers when the government decides to outsource the activity (Wittig, 2003). In terms of size and procedural systems, public sector procurement is large and complex (Rasheed, 2004), accounting for between twenty and thirty percent of gross domestic product (Thai & Grimm, 2000).

The management of medical equipment yields a better productivity which means a state of efficiency or the rate and quality of output based on the rate and quality of input (Kirkland, 1985). As it relates to hospital facilities management, higher productivity can mean safer and more reliable equipment, less service cost, less equipment downtime, more revenue and more effective use of man power (Hashem and Al-Fadel, 1986).

The medical equipment management professionals ensure that equipment used in the patients care are operational, safe, properly configured to meet the mission of the medical treatment facility and continue to function effectively in a good working condition. Human factors engineering is frequently being cited as an important method to reduce medical error and adverse events and to increase patient safety, when it is applied to the design and evaluation of medical equipment (Gill Ginsburg, 2004).

Periodic training on medical equipment maintenance will normally involve the manufacturer or supplier initially and the in-house technical service thereafter (McKie, 1987:50). Previous studies in developing countries show that a high percentage of equipment malfunctions is caused by operator mishandling. As equipment maintenance includes much more than just repair activities it will be useful to give an outline of what an effective maintenance system should look like. Equipment maintenance has been described as any action or combination of actions carried out to retain an item, or restore it to, an acceptable condition (Metha, 1983)

Objectives

General Objectives

To reengineer a healthcare technology management system (medical equipment management system).

Specific Objectives

- To assess the current scenario of medical equipment management system in Ethiopian healthcare facilities.
- To redesign a healthcare technology system for regulatory aspects of the medical equipment.
- To redesign an integrated medical equipment management system for procuring/logistics aspects of the medical equipment.
- To design an integrated system for utilization and decommissioning of the medical equipment.
- To redesign a system for donation of medical equipment.
- To develop an integrated medical equipment system for provider regulator purchaser using MIS.
- To propose areas of improvements.

Significance of the Study

This thesis attempts to solve the major problems in the Ethiopian healthcare technology system by designing a system for the medical equipment management and implementing of software to solve the current issues related to provision, acquisition, utilization and decommissioning including donation. This thesis will serve as a blue print for decision makers, regulatory authorities, procuring agencies and service providing health facilities. The medical equipment management system is supported by MIS software that can resolve major problems in communication, data management as well as providing information for decision making.

Material and Methods

Description of the Study Area

This study was conducted in Addis Ababa. It is the largest city in Ethiopia, having a population of 3,104,000 according to the 2007 population census with annual growth rate of 3.8%. Addis Ababa is located at 9.02497 [latitude in decimal degrees], 38.7469 [longitude in decimal degrees] at an elevation of 2405 meters above sea level. In this research, hospitals, health centers and private clinics are investigated regarding their medical equipment management system. In the current study hospitals were classified as governmental and nongovernmental. Clinics were classified as lower, medium and higher to collect a more resolved data.

Sampling and Data Analysis

This cross sectional study was applied on government hospitals, private hospitals, health centers, and private clinics (higher, medium and lower). The study sampling frame is listed as number of organizations which provide different kinds of health care services. These are listed as governmental hospitals (no. 11), private hospitals (no. 34), health centers (no. 50), private clinics (higher clinics: 206, medium clinics: 226 and lower clinics: 143). As the capacity and level of health care services between the different health care providers were different, stratified sampling technique was used to collect data. Stratified sampling technique considers there is heterogeneity among strata and homogeneity within strata.

For each health care service providers, the sample size was determined by stratified sampling formula which is shown in equation below (Cochran, 1967). Then, the sampling unit is determined by lottery method in each strata.

$$n = \frac{\sum_{i=1}^{L}\left(\frac{N^2{}_i p_i q_i}{W_i}\right)}{\frac{N^2 d^2}{Z^2} + \sum_{i=1}^{L} N_i P_i q_i} = \frac{N * \sum_{i=1}^{L} N_i p_i q_i}{\frac{N^2 d^2}{Z^2} + \sum_{i=1}^{L} N_i p_i q_i}$$

where: **p** is the proportion of medical equipment management system among different health care providers. Due to limited number of research that has been done in this field, the p value is taken as 0.5, **q** can be found simply by subtracting the p value from one, N is the total number of health care providing organizations, L is the maximum number of health facilities, d is the margin of error which is selected often by the investigator (the margin of error is taken as 0.05.) The standard normal random variable (**Z**) is taken as 1.96. Based on the sample size formula, 243 number of health care giver organizations were selected. The stratification technique allocated the number of hospitals for each strata.

Table 1: The sample size for each strata.

Government hospital	Non-Government-hospital	Health center	Lower-clinic	Medium clinic	Higher clinic
n1=4	n2=12	n3=18	n4=52	n5=82	n6=75

The results are presented in cross tabulation tables, percentiles and pareto charts. A pareto diagram is a simple bar chart that ranks related measures in decreasing order of occurrence.

Data Collection Process

With the support letter from the Center of Biomedical Engineering, AAiT, the questionnaire was distributed to the selected health facilities. Briefing about the questionnaire and overall aim of the thesis is done face to face with the respondents. The respondents of the questionnaire were doctors, pharmacists, biomedical engineers, biomedical technicians, nurses, laboratory technologists as well as the health facility managers.

Study Design and Period: The preliminary assessment was done between November to December 2013.

Inclusion and Exclusion Criteria: In the current set up of the Ethiopian health care system only professionals who are working on medical equipment management are included. Since there are no enough biomedical engineer professionals, related information are not found from these professionals.

The input-output model (purchaser-provider-regulator models) concept is where input , output , regulators and providers are inserted with feedback system to make the system complete. In the real world , one output of a system can be input , regulator for the next system and will continue in the overall loop of the system .

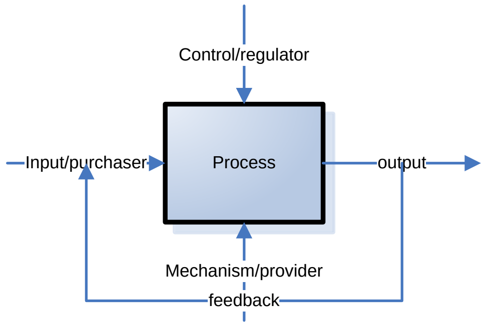

Figure 1 Input/output – purchaser provider regulator model

Medical Equipment Management System Design Tools

Microsoft MS Visio was used to design systems, engineering tools, process and mapping tool for different activities. It is user friendly, easily accessible and applicable in all Microsoft products.

Results and Discussion

Major challenges in the Health Care Service

Preliminary Study: **assessment of the Medical equipment management system in healthcare providing organizations found in Addis Ababa Ethiopia**. The main aim of this preliminary study was to assess the quality of Health care Technology management (HTM) system in the major health care providing organizations. Based on this study, the main challenges were identified, and system design was developed in order to reengineer the existing ad-hoc HTM system.

Moreover, the study aimed to justify the importance of HTM System in healthcare service providing organizations. The analysis mainly focused on identifying major challenges in developing Medical equipment management system. The study included 243 healthcare service providers in Addis Ababa. Out of 243 healthcare service providers, 16 were hospitals, 18 were health centers, and 209 were private clinics (lower, medium and higher). The major challenges were broad and wide from the basic in hand use of the medical devices to decommissioning. In utilization of medical devices, healthcare providers were asked to respond regarding the major challenges they faced. After analysis of the data it was found that the main challenges were medical equipment management system, scarcity of skilled manpower, and medical device market. However, surprisingly equipment management challenge showed in Table 2 is higher in hospitals than health centers and clinics.

Table 2: Major challenges encountered by healthcare service providers

	Hospital	Health Center	Clinic
No challenge	1 (6.2%)	2 (11.11%)	10 (4.8%)
Maintenance	10 (62.5%)	9 (50.0%)	114 (54.5%)
Skilled human power	4 (25.0%)	7 (38.9%)	82 (39.2%)
Market	1 (6.2%)	0 (0%)	3 (1.4%)
Total	16 (6.6%)	18 (7.4%)	209 (86.0%)

The major problem of hospitals in utilization of healthcare technology was skilled manpower and equipment management system. Out of the total, 10 (62.5%) hospitals reported lack of efficient equipment management system as the main problem. It was also found out that 4 (25.0%) hospitals faced challenges in skilled human power. The major problem reported by health center and clinics were equipment maintenance (50.0% and 54.5%) respectively (Table 2). Similar equipment management system results were reported previously by other preliminary studies carried on medical equipment management systems (Free M J ,1992).

Improving Medical equipment management System

Improvement of the medical equipment management was assessed based on seven curtail questions that are answered from strongly agree to strongly disagree. Questions were asked based on “how do you agree if your organization fulfills the following ideas”. Hence, when the organization agrees to these questions, it does mean the organization needs those activities to enhance the healthcare technology. The first pareto chart plotted showed if these organizations selected appropriate technology for medical equipment or not. As we can see from the plot most of organizations have selected appropriate technology system to be implemented. Out of 243 organizations, 132 organizations agreed positively to the questions if they correctly specify medical instruments or not. In addition, most organizations agreed that they appropriately store and distribute medical equipment and do inspection of medical instruments. Other studies also suggested similar findings were also observed in other developing countries (Racoveanu N.T and Johansn K.S, 1995).

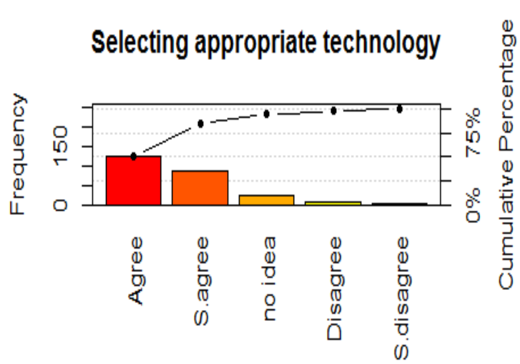

Figure 2: Selecting appropriate technology

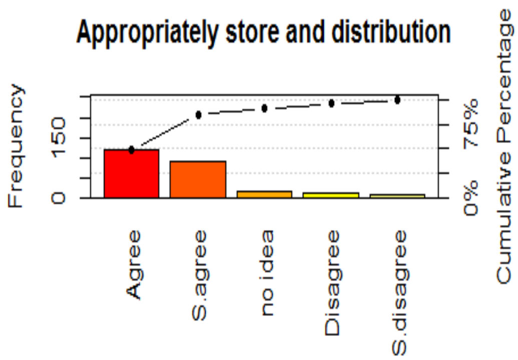

Figure 3: Appropriate storage and distribution of medical equipment.

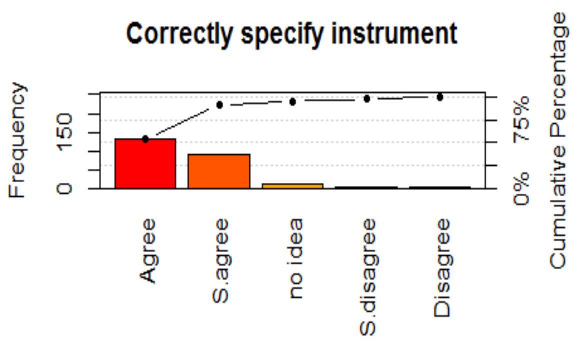

Figure 4: Correct specification of medical equipments

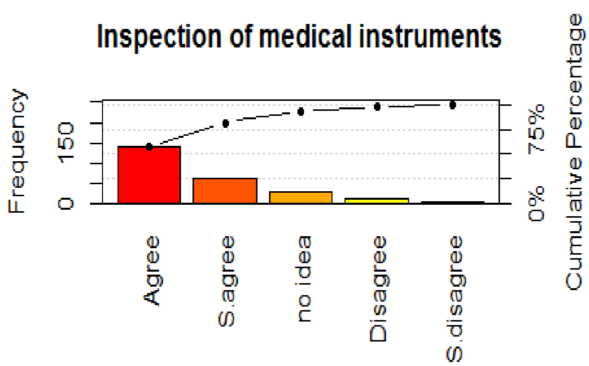

Figure 5: Inspection of medical instrument

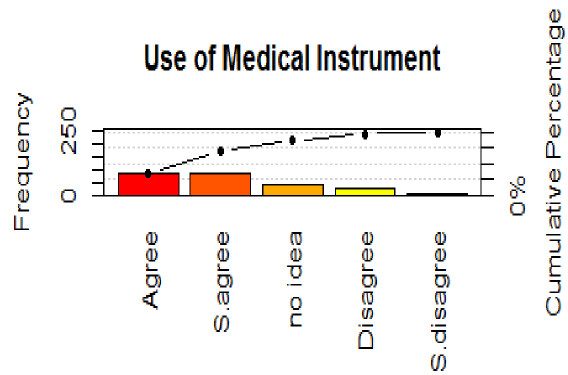

Figure 6: Use of medical instrument

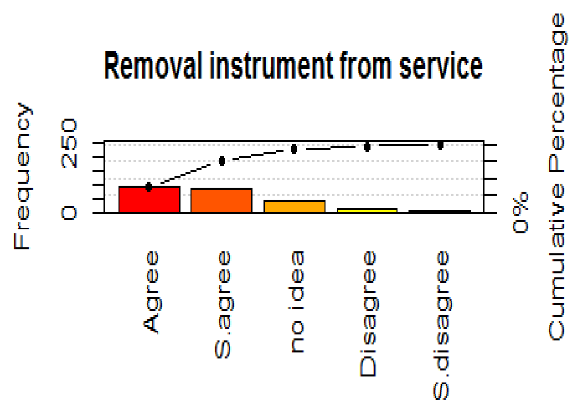

Figure 7: Removal instrument from service.

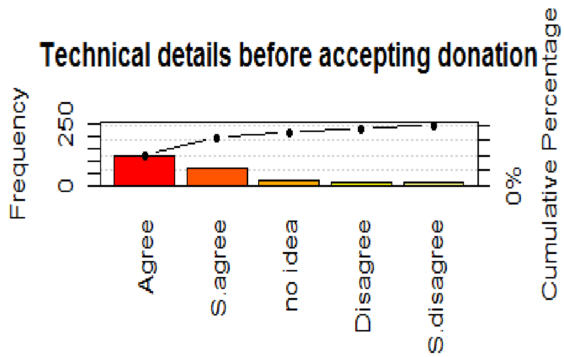

Figure 8: Technical details before approving acceptance of donation

Forecasting and Quantification of Medical Instruments

The main parameters used to forecast and quantify medical instruments in healthcare organization were listed (Table 3). Hospitals and health centers showed similar pattern. The majority of hospitals and health centers reported that they did not have system to forecast equipment demand based on available budget that were (67.8%) and (61.1%) respectively. Standards for quantifying medical instruments were very low in hospitals and health centers. Quantifying instruments based on standard and available budget was not common in hospitals (37.5%) and health centers (38.9%). However, more than 50% of clinics have system to forecast and quantify medical equipment based on standard and available budget. The current data showed a serious lack of medical equipment quantification as compared to other studies conducted elsewhere (J. Tobey Clark, 2004).

Table 3: Forecasting and quantification of medical instruments

Measurements		Hospital	Health Center	Clinic	Total
Adequate health facility equipment	Yes	6 (37.5%)	7 (38.9%)	115 (55.0%)	128 (53.9%)
	No	10 (62.5%)	11 (61.1%)	94 (45.0%)	115 (46.1%)
Standards for Quantifying medical instruments	Yes	5 (37.5%)	5 (27.7%)	133 (63.6%)	143 (59.3%)
	No	10 (62.5%)	13 (72.3%)	76 (36.4%)	99 (40.7%)
Do you forecast your demand based on budget	Yes	6 (31.2%)	7 (38.9%)	139 (66.5%)	152 (62.1%)
	No	10 (67.8%)	11 (61.1%)	70 (33.5%)	91 (37.9%)
Quantify based on standard and budget	Yes	6 (37.5%)	7 (38.9%)	117 (56.0%)	130 (53.5%)
	No	10 (62.5%)	11 (61.1%)	92 (44%)	113 (46.5%)
Monitor your inventory	Yes	7 (43.7%)	11 (61.1%)	124 (59.3%)	142 (60.9%)
	No	9 (56.3%)	7 (38.9%)	85 (40.7%)	101 (39.1%)

Procurement

68.8% of hospitals, 77.8% of health centers and 63.6% of clinics were found out to be without guidelines for procurement. Among all of the health service providers, (66.7%) of them have no guideline for procurement. This suggests that guideline for procurement was uncommon in all organizations. Availability of clear and viable procurement specifications was another main problem. Most of the hospitals (62.5%) and the health centers (61.1%) have no clear and viable specifications to equipment procurement. Most of the health service providers have no established system to select appropriate technology in procurement 25% for the hospitals, 22.2% for the health centers, 40.29% for clinics (see Table. 4). Results found here revealed a lack of system in procurement of medical equipment in Ethiopia as compared to other studies conducted in countries with a similar condition as here (Kachiengna, M.O. (1992).

Table 4 : Medical equipment procurement

Measurements		Hospital	Health Center	Clinic	Total
Guideline for procurement	Yes	5 (31.2%)	4 (22.2%)	76 (36.4%)	85 (33.3%)
	No	11 (68.8%)	14 (77.8%)	133 (63.6%)	158 (66.7%)
Specifications clear and viable to procurement	Yes	6 (37.5%)	7 (38.9%)	112 (53.6%)	125 (53.1%)
	No	10 (62.5%)	11 (61.1%)	97 (46.4%)	118 (46.9%)
Procurement of medical instrument after sales	Yes	7 (43.7%)	5 (27.7%)	65 (31.1%)	77 (34.6%)
	No	9 (53.3%)	13 (72.3%)	144 (68.9%)	166 (65.4%)
Get the procured within short period of time	Yes	8 (50.0%)	8 (44.4)	69 (33.0%)	85 (31.7%)
	No	8 (50.0%)	10 (55.6%)	140 (67.0%)	158 (68.3%)
System of selecting appropriate technology	Yes	6 (25.0%)	4 (22.2%)	84 (40.2%)	94 (40.2%)
	No	10 (75.0%)	14 (77.8%)	125 (59.8%)	149 (59.8%)

Storage and Distribution

As it can be observed from Table 5, majority of hospitals (68.8%) and health centers (61.1%) had no safe storage to their equipment. Transportation and storing of medical equipment were uncommon in the majority of hospitals. Of the total hospitals (62.5%) reported that they have problem in transportation and storage of medical devices. However, this problem was not as significant in the health center (38.9%) and the clinics (46.9%).

Table 5: Storage and distribution of medical equipments.

Measurements		Hospital	Health Center	Clinic	Total
Instruments are received as per the specification	Yes	9 (56.2%)	13 (72.2%)	111 (53.6%)	133 (53.1%)
	No	7 (43.8%)	5 (27.8%)	96 (46.5%)	108 (46.9%)
Is there safe storage	Yes	5 (31.2%)	7 (38.9%)	100 (47.8%)	112 (50.2%)
	No	11 (68.8%)	11 (61.1%)	109 (52.2%)	131 (49.8%)
Instruments transported and stored?	Yes	6 (37.5%)	11 (61.1%)	111 (53.1%)	128 (54.7%)
	No	10 (62.5%)	7 (38.9%)	98 (46.9%)	115 (43.3%)

Medical equipment Utilization

Utilization of medical equipment was measured by six main parameters. Installation and proper use of medical instruments was found to be the main problem. Most hospitals (75.0%) and health centers (50.0%) in Addis Ababa, do not properly install and use medical instruments. The main problem reported by hospitals was the lack of personnel to operate on the machines, and that accounted for 68.8%. In addition, more than half of the hospitals (56.2%), health centers (72.2%) and clinics (55.5%) in Addis Ababa have no written procedure for the use of all equipment. Maintenance is the critical issue in all healthcare providers. It was found out that most of the healthcare service providers do not have proper maintenance workshop and records. Most hospitals (62.5%), health centers (83.4%), and clinics (83.3%) do not have maintenance workshop. Results found here revealed a lack of system in utilization of medical equipments in Ethiopia as compared to other studies conducted in countries with a similar condition as here (Ngara N., 2000).

Table 6: Utilization of machine

Measurements		Hospital	Health Center	Clinic	Total
Instruments installed and work properly?	Yes	4 (25.0%)	9 (50.0%)	127 (60.8%)	140 (57.6%)
	No	12 (75.0%)	9 (50.0%)	82 (39.2%)	103 (42.4%)
Enough personnel to operate the machine?	Yes	5 (31.2%)	5 (27.8%)	73 (34.9%)	83 (34.2%)
	No	11 (68.8%)	13 (72.8%)	136 (65.1%)	160 (65.8%)
Log book for equipments?	Yes	7 (43.2%)	8 (44.4%)	58 (27.8%)	73 (30%)
	No	9 (56.3%)	10 (55.6%)	151 (72.2%)	170 (70.9%)
Written procedures for the use of all equipments?	Yes	7 (43.8%)	5 (27.8%)	93 (44.5%)	105 (43.2%)
	No	9 (56.2%)	13 (72.2%)	116 (55.5%)	138 (56.8%)
Do you have maintenance record for device	Yes	5 (31.2)	7 (38.8%)	68 (32.5%)	80 (32.9%)
	No	11 (68.8)	11 (61.1%)	141 (67.5%)	163 (37.1%)
Do you have maintenance workshop	Yes	6 (37.5%)	3 (16.6%)	35 (16.7%)	44 (17.7%)
	No	10 (62.5%)	15 (83.4%)	174 (83.3%)	199 (83.3%)

Donation

Around 50% of all hospitals and health centers, in Addis Ababa received donated medical equipment not based on their demand. In addition to this, most of them do not have system to track the donations. Among the health centers and hospitals, (55.6%, 56.3%) of them reported that they don't have system to track the donation respectively. As in other reports donation of these equipment were a common practice in developing countries as also shown in other related works (Dyro J. , 2004).

Table 7: Medical equipment donation

Measurements		Hospital	Health Center	Clinic	Total
Are Instruments donated as per your demand	Yes	6 (37.5%)	9 (50.0%)	94 (45.0%)	109 (44.8%)
	No	10 (62.5%)	9 (50.0%)	115 (55.5%)	134 (51.2%)
Do you have system to track donation	Yes	5 (31.2%)	8 (44.4%)	35 (16.7%)	48 (19.7%)
	No	11 (68.8%)	10 (55.6%)	174 (83.3%)	195 (80.3%)

Decommissioning

This study assessed decommissioning in hospitals, health centers and clinics, to examine how and when decommissioning takes place to decontaminate devices before use and removal. Majority of the hospitals reported that they have no established system on how and when decommissioning should take place. The result was also consistent for the health centers and clinics. Especially, most health centers do not have a system how and when decommissioning should be carried out. Occupational safety and hazard is different between hospitals and clinics. As indicated in Table 8, majority of the hospitals do not have occupational safety and hazard; this covers 56.2% and, around 72.3% of the health centers. In the contrary, most clinics have occupational safety and hazard, this accounted 51.2%. Healthcare service providers including most hospitals (56.2%), health centers (66.7%) and clinics (56.9%) reported that they have a problem in decontaminating devices before use and after removal. Medical equipments have a very low rate of decommissioning in Ethiopia which might be the case in other African countries as reports suggested (Madani, M.A. 1995).

Table 8: Equipment decommissioning

Measurements		Hospital	Health Center	Clinic	Total
Do instruments removed as per the lifetime	Yes	6 (37.5%)	5 (27.8%)	67 (32.1%)	78 (32.1%)
	No	10(68.5%)	13 (72.2%)	142 (67.9%)	165 (67.9%)
System how and when decommission	Yes	7 (43.8%)	4 (22.2%)	51 (24.4%)	62 (25.5%)
	No	9 (56.2%)	14(77.8%)	153 (73.2%)	176 (74.5%)
Occupational safety and hazard	Yes	7 (43.8%)	5 (27.7%)	107 (51.2%)	119 (48.9%)
	No	9 (56.2%)	13 (72.3%)	102 (48.8%)	124 (51.1%)
Occupational safety guideline	Yes	6 (50.0%)	6 (33.3%)	74 (35.4%)	88 (36.2%)
	No	10 (50.0%)	12 (66.7%)	135 (64.6%)	155 (63.8%)
Do you have mitigation program	Yes	6 (37.5%)	6 (33.3%)	97 (46.4%)	109 (44.8%)
	No	10(68.5%)	12 (66.7%)	112 (53.6%)	134 (45.2%)
Do you have waste management system	Yes	4 (25.0%)	7 (38.8%)	104 (49.8%)	115 (47.3%)
	No	12 (75.0%)	11 (61.2%)	105 (51.2%)	128 (52.7%)
Decontaminate devices before use and removal	Yes	7 (43.8%)	6 (33.3%)	90 (43.1%)	103 (42.3%)
	No	9 (56.2%)	12 (66.7%)	119 (56.9%)	140 (57.7%)
Guideline for used medical device	Yes	3 (18.8%)	5 (27.7%)	70 (33.5%)	78 (32.1%)
	No	13 (81.2%)	13 (72.3%)	139 (66.5%)	165 (67.9%)

Conclusion on Preliminary Assessment

Results found here revealed a higher gap in procurement of medical equipments in Ethiopia as compared to other studies conducted in countries with a similar condition as here (Gill G. (2004) ; Harding G. H. and Epstein A.L. (2004)). Most of the healthcare service providers do not have proper maintenance workshops and records. With hospitals (62.5%), health centers (83.4%) and clinics (83.3%) do not have maintenance workshops as indicated on other studies conducted previously (Zhou X, Xi L and Lee J, 2006 ; Wang B; Furst E; Cohen T, Keil O. R; Ridgway M and Stiefel R ,2006). 80.3% of health facilities reported that they do not have system to track donations. Donation of equipments was a common practice in most developing countries as also shown in other related works (Dyro J. 2004). This has come to a conclusion that the problems found in this preliminary assessment are in compliance with the problems indicated by WHO in 2010. Although some interventions such as quick fix were implemented, no major improvements have been obtained so far. Thus designing an integrated system from a clean sheet will result in fundamental and dramatic changes of the system.

Re-engineering the Medical Equipment Management System

Based on the findings obtained from the preliminary study, it can be clearly seen that the disintegrated medical equipment management system cannot fulfill the customer need. It is observed that a disintegrated system which in effect has a poor outcome has been used in the current situation. Thus, this thesis tries to address the issue by constructing a new system design that incorporates as many details relevant to the problem at hand. According to Pugh S., 1991, system design is defined as the process of defining the architecture, components, modules, interfaces, and data for a system to satisfy specified requirements. Such a design could be seen as the application of systems theory to product/system development. Engineering design process involves a series of steps that lead to the development of a new product or system (Fries R C , 2005). It consists of the following basic steps: problem identification, setting up criteria and constraints, brainstorm possible solutions, generate ideas, explore possibilities, select an approach, build a model or prototype and refine the design (Brooks F.P., 2000). The current study also employed the outline suggested in the aforementioned studies to reengineer the medical equipment management system for healthcare centers in Ethiopia. In order to reengineer the healthcare technology, the work employed preliminary study using questioners and observation to identify major problems as with the findings set as also in other reports (Yadin D., Thomas M. J., 2000).

According to Gunasekaran and Kobu (2002), study on 45 samples using the model commonly used in reengineering they found that 31.1 % found conceptual model as easy to understand with less accuracy, 24.4 % found simulation model more accurate modeling but difficult to model the strategic implication, 15.6% found object oriented model difficult to understand by the end users, 13.3% of the total sample found IDEF model as easy to understand but does not include implication, 8.88 % of the total sample indicates network model as more accurate but less friendly , 6.46 % of the total sample knowledge base models intelligence system as user friendly but limited in its application which is in contrary to the current study.

However, input output model engeneered in this study has advantage in that it can show inputs, outputs, mechanism, controls, linkage between system, scalable by inserting new components, support for a series of methodologies and notations, can solve strategic issues, potential to automatically translate a system process to code, integration with other system process tools, user friendly, users management, privacy and access rights and maturity.

Medical equipment life cycle

The study considers addressing the management interventions that facilitate the availability of appropriate healthcare technologies before designing the system as it was the initiation phase of previous studies (File W T , 1991). This served as a point of departure for the formulation of a new Medical equipment management system approach. The medical device life-cycle is considered to have four distinct phases. The first phase, research and development, is in the domain of industry, which also concerns itself with innovation and the product life cycle (Richard C. F., 1997). This extends from R&D to market diffusion, product/range refinement, and finally product/range maturation (David H. W. 2001). Technology is made available in the technology innovation Cycle (TIC) and transferred to the healthcare equipment application cycle (HEAC). The next three phases, viz. assessment, regulation and management, are usually the responsibility of the healthcare purchaser, provider, and regulator and can be considered as part of the user Equipment Management Cycle. This cycle is seldom fully functional in a developing country. The situation is compounded by lack of healthcare technology system, management skills and adequate resources for training, maintenance, consumables as also suggested by (Free M J ,1992).

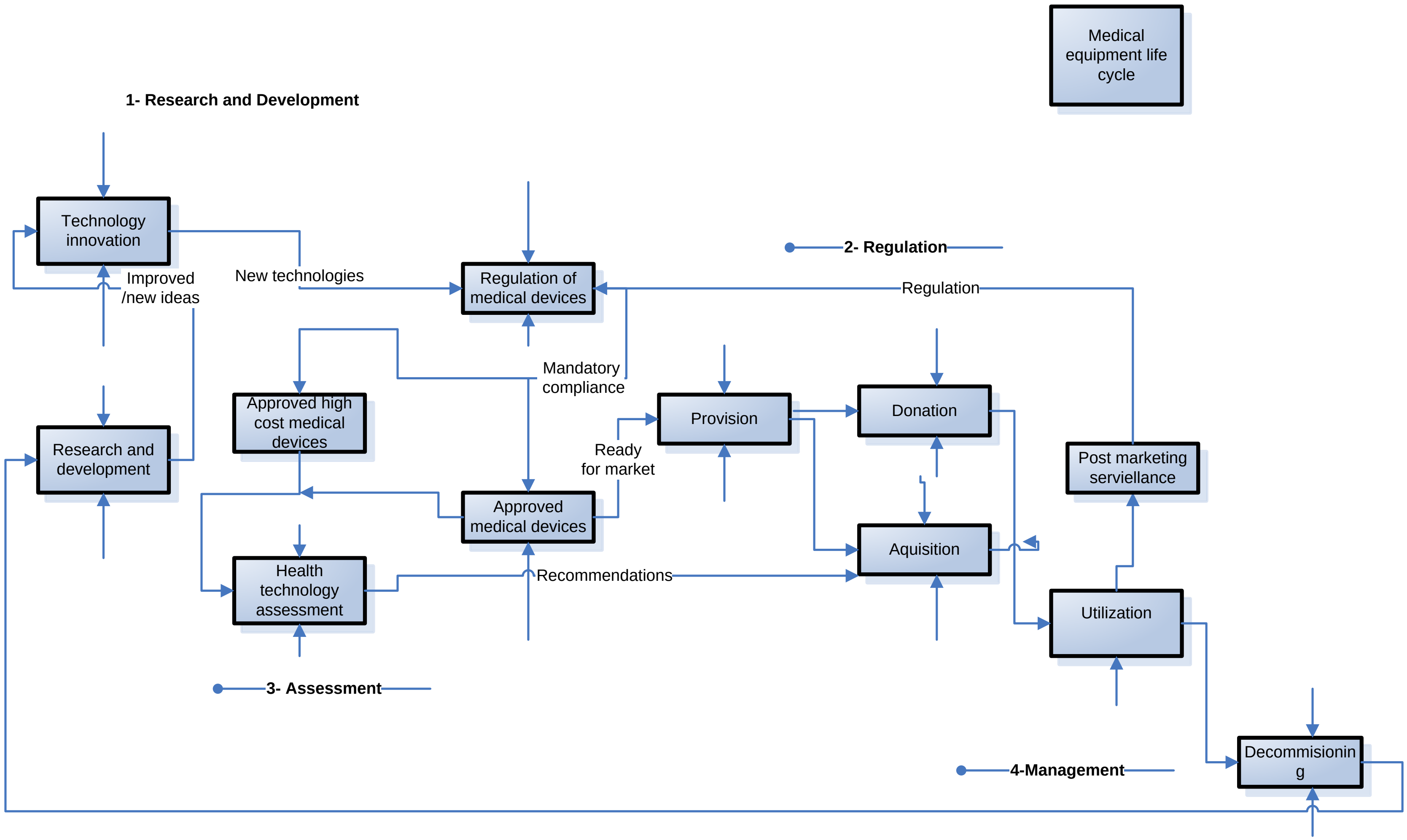

Figure 9: Medical equipment life cycle

Overall Design

The study also considered the activities listed in the medical equipment management system essential for the successful implementation and the cost-effective and sustained utilization of healthcare technologies (Cheng M and Dyro J F , 2004). Other models may be narrower or wider in scope, but few focuses- as this one does- on the Medical equipment management process. This model can therefore also be used to identify shortcomings in existing capacity/competencies at all levels; specifically, individuals involved with any phase of the system can be provided with a “value-added layer” or “package of technology competencies”, appropriate to their own needs other reports also suggested a similar idea (Wang B, Furst E, Cohen T, Keil O R, Ridgway M and Stiefel R , 2006).

Provision and acquisition, in terms of healthcare delivery needs, may or may not be conducted and even if it is, this is seldom comprehensive (Harding G H and Epstein A L ,2004). Moreover, important issues relating to strategic planning are often bypassed. The net result is that equipment is introduced into a sub-optimal target environment with significant mismatches between the needs for effective equipment utilization and support, and what the environment can provide. In the worst case, equipment is never used because it has not been properly installed or commissioned (Andreas L., Willi K. and Manjit K. ,2000).

When equipment is removed from service, it is often not properly disposed of (for example, it could be used in a health facility at a lower level or for training purposes) and no life-cycle analysis is conducted. Life-cycle analysis would serve as valuable input to on-going assessment of the technological needs and their impact on healthcare delivery. It is important, at this point, to stress that healthcare equipment is but one component of effective healthcare delivery. The equipment management cycle, therefore, is part of a larger management cycle which extends over all levels of the whole health system, from ministerial departments to individual institutions as also described in previous studies (Baretich M ,2004). Equipment management activities extend across these levels. Healthcare equipment management interventions address missing links in the management process, or act to strengthen existing links. In order to be truly effective, however, the interventions must be integrated with other healthcare delivery management processes and there should therefore be strong intersectional links, and these issues were also reported in previous studies by Andreas L., Willi K. and Manjit K., 2000.

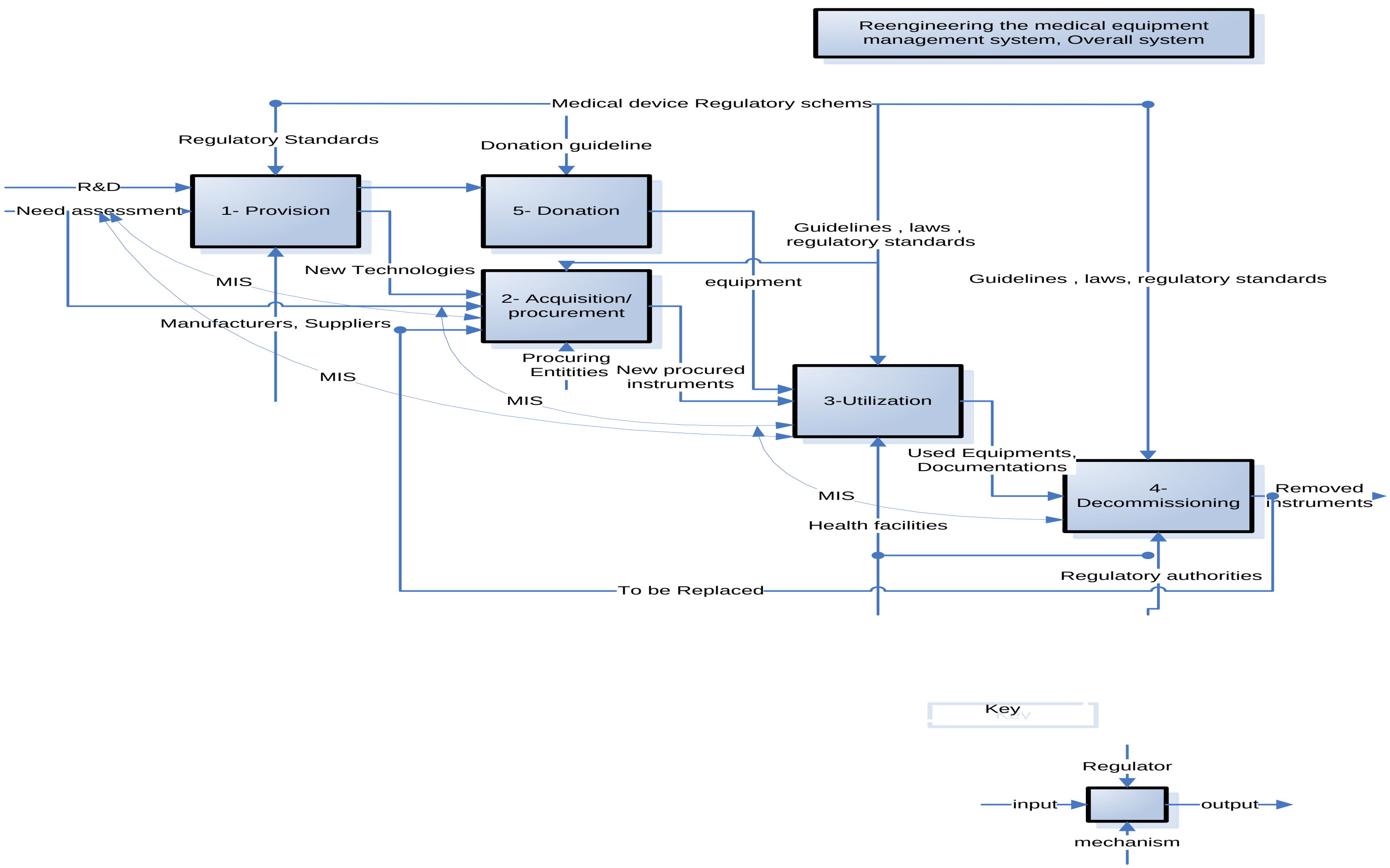

Figure 10: Overall design

Provision

As many other studies suggested (Heimann, P. and Poluta, M.A. ,1997) this study also considered all healthcare equipment management interventions are limited by resources available; most industrialized country scenarios have an existing infrastructure with policy, procedures and processes in place. In contrast, many developing countries have no infrastructure to begin with. Management interventions ideally should be subjected to an appropriate "technology transfer" filtering process, where a proper match is made to the local environment. Provision of the medical instrument from technology transfer begins with technology strategic planning and other components as described below.

Strategic Technology Planning

Leading health care organizations have begun to combine strategic technology planning with other technology management activities in a program that effectively integrates new technologies with their existing technology base (Wang B, Furst E, Cohen T, Keil O R, Ridgway M and Stiefel R, 2006). This has resulted in high-quality care at a reasonable cost. A proper technology strategic plan is derived from and supports a well-defined clinical strategic plan. When the clinical strategic planning process has started and hospital management has begun to analyze or reaffirm what clinical services they want to offer to the community, the hospital can then conduct efficient technology strategic planning (J. Tobey Clark , 2004). As suggested by previous articles (Cheng M ,2004) the current study also employed the key elements of this planning which involve: performing an initial audit of existing technologies, conducting a technology assessment for new and emerging technologies for fit with current or desired clinical services, planning for replacement and selection of new technologies, setting priorities for technology acquisition, and developing processes to implement equipment acquisition and monitor ongoing utilization.

Essential Health Technology Packages

This approach is currently gaining favor, especially within developing countries and emerging economies, as issues of sustainability in a climate of limited resources come to the fore (Free M J ,1992). The process of arriving at an Essential Technology package is as follows: establish epidemiological profiles/presenting cases , identify health services package (including levels at which these will be delivered), specify clinical interventions and procedures, identify technology packages needed to provide these interventions and procedures, establish affordability and sustainability, priorities technology packages using criteria of policy/constraints/health outcomes (Yadin D., Thomas M. J. ,2000).

Technology Assessment

According to (Racoveanu N.T and Johansen K.S ,1995), technology assessment refers to any process which examines and reports on healthcare equipment (and specifically medical technology) properties such as safety, efficacy, feasibility, indications for use, cost and cost-effectiveness and social, economic and/or ethical consequences. A primary technology assessment is one that seeks new data through research, typically employing long-term clinical studies. A secondary technology assessment is usually based on published data, interviews, questionnaires, surveys and/or discussions (Cheng M and Dyro J F ,2004). As in the current study increasing importance is being attached to macro-assessments which address the constraints of specific environments – these constraints may significantly dampen the promise offered by results of micro-assessments.

Quality Assurance

To design the system the study considered quality service that meets specified requirements and, given current knowledge and resources, fulfils expectations for maximizing benefits and minimizing risks to the health and well-being of patients. Health care of good quality is thus characterized by: a high degree of professional excellence, efficiency in the use of resources, minimal risk to patients, patients' satisfaction and a favorable impact on health which was also the main issue in previous studies (Zhou X, Xi L and Lee J ,2006).

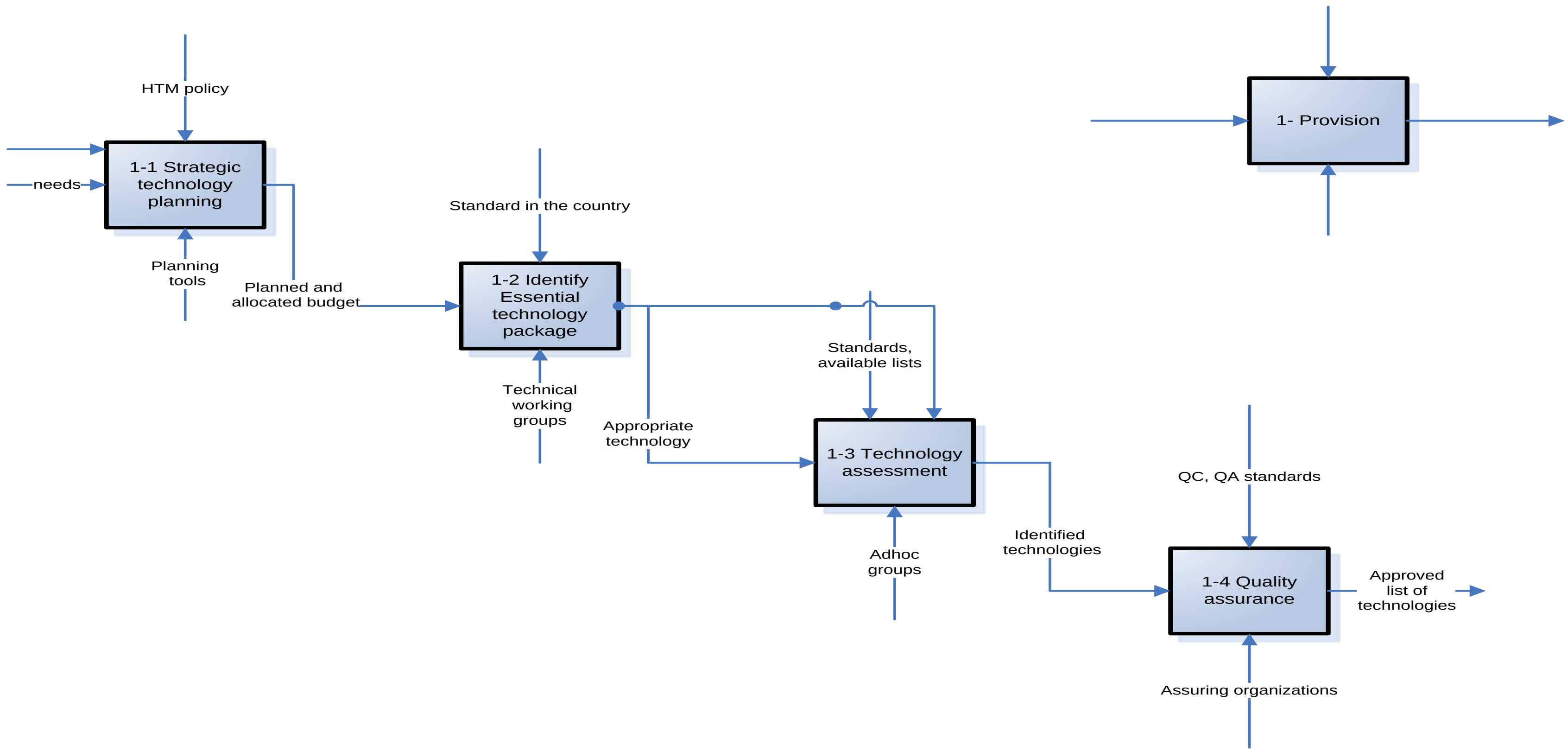

Figure 11: Equipment provision design

Procurement

According to (Kachiengna, M.O. ,1992) procurement is a vital element of equitable access to health care. It can be defined as "the acquisition of Medical equipment, goods, works or services through purchase, hire, lease, rental or exchange" and is taken to include "all actions from planning and forecasting, identification of needs, sourcing and solicitation of offers, evaluation of offers, review and award of contracts, contracting and all phases of contract administration until delivery of the goods, the end of a contract, or the useful life of an asset. When procurement includes installation and commissioning, the process can be termed "technology incorporation"(Harding G H and Epstein A L ,2004).

Effective procurement system allows providing satisfactory quality, service and price within a timely delivery schedule. Basic principle of procurement is to describe the right product or service of the right quality and right price, and the right quantity, at the right place and time. Although this formula is simple, it involves questions of accountability, integrity and value, with effects far beyond the actual buyer/seller and obtain the right product or service, with a generic description within a clear required specification. Four "pillars" are required for a good procurement system: legislative framework, integrity and transparency, institutional and management capacity, operations and markets. The current study also included above mentioned procedure as in (Kaur M et al. 2005).

Decision Making for Procurement

In the present study this mainly involves current and required technology assessment, budget allocation to effect the procurement, and decisions to select the method of procurement until approving procurement plan. Decision in procurement is the critical part to affect the procurement activities to be performed as in earlier studies (Gill G. (2004) ; Harding G H and Epstein A L (2004)).

Preparation

Demand /request from the end user or program items are collected for quantification in which the quantities and type of the product to be procured are identified with the available fund. Budget analysis should always include the actual procurement budget and other related costs in the overall delivery of the equipment to the health facility which has also been suggested by previous studies (Temple-Bird C. et al., 2005).

Managing the Tender Process

This process where the actual procurement package is performed consists of activities done procedurally. Identifying the right supplier/manufacturer is done with the support of the registration profile from the regulatory authorities (Lee P, 1995). After receiving bids , the critical part of procurement is selection of the machine: clinical need, clinical efficacy, expected lifespan of equipment, maturity of technology (and if the technology used in the equipment likely to change in the near future (up to 2 years), estimated life-cycle costs , user training , training of maintenance personnel (if relevant) (Kachiengna, M.O. 1992). Award of contract and contract management in procurement will be done if all the procurement principles, procedures and appropriate selection of the machine is performed. This thesis also tried to include all of the aforementioned facts.

Getting Ready for Arrival

In this study activities related to the placing of the order until arrival would be monitored by consolidating lead time the procurement has been taken. Site preparation for the installation of the machine including identifying the sites, the layout diagram and some pre installation activities will be done before delivery as also been seen in other guidelines (Rushton A, Oxley J and Croucher P, 2001).

Delivering

Depending on the nature of the product, the urgency, the volume of the product, transportation, custom clearance, proper storage for the medical equipment would be ready before distributing the items to the health facility where they are going to be installed and be functional as also suggested by (Lysons K, 2000).

Acceptance

Before accepting the machines physical check, labelling check, documentation check and machine completeness check shall be performed. If any discrepancy to the inspection and checking is found, the machines will not be delivered to the health facilities. Final acceptance to the machines is done after installation and commissioning. Similar issues were also put forward by previous studies (Harding G H and Epstein A L 2004).

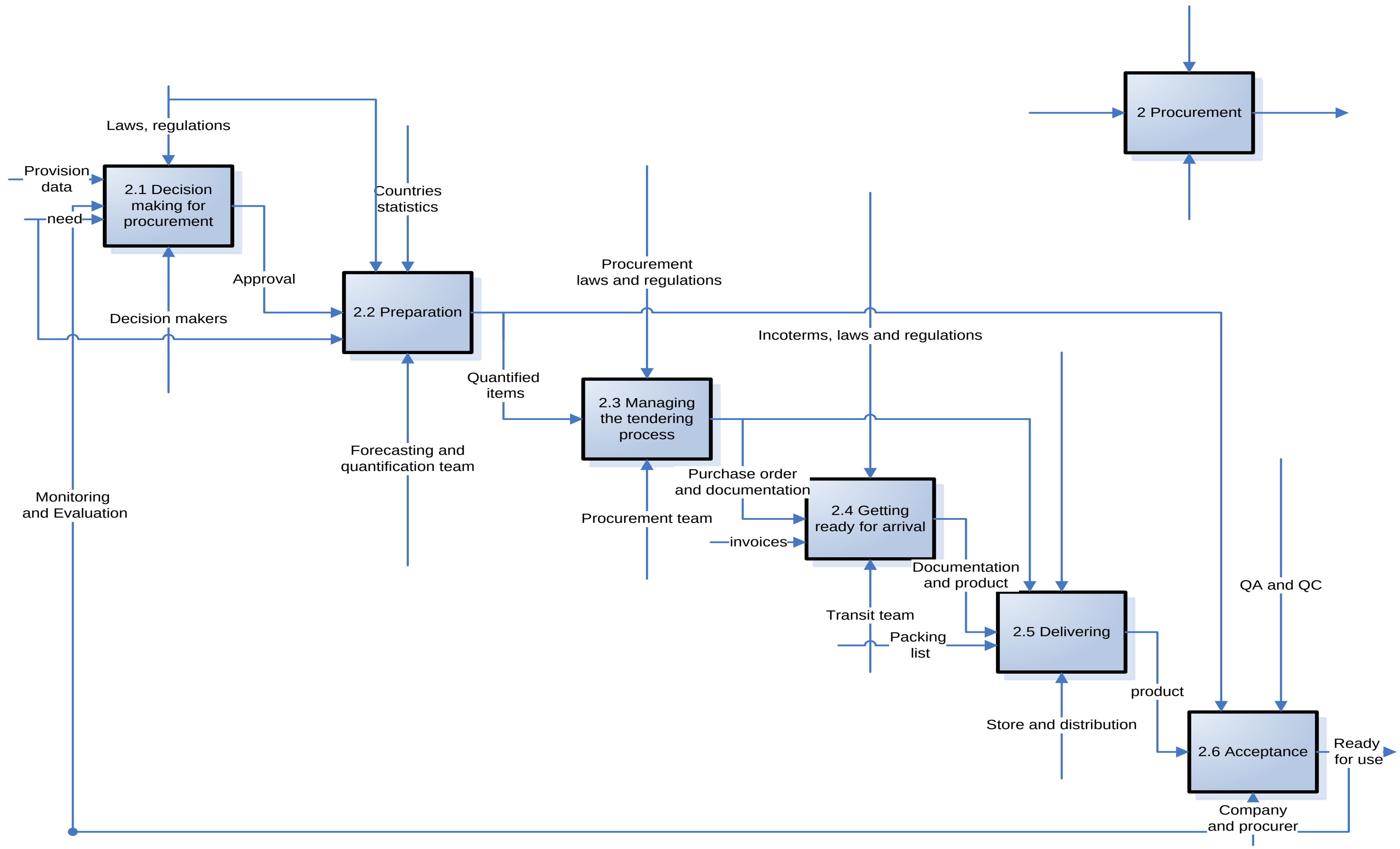

Figure 12: Medical equipment procurement design.

Donation

The current study found out that, healthcare technologies in Ethiopia are seen as peripheral to healthcare delivery and subsequently receive little attention from healthcare planners as elsewhere (Heimann, P. and Poluta, M.A. ,1997). Similarly, donor aid in the form of equipment is seen merely as an addition to the peripheral aspects of healthcare delivery and seldom as part of an integrated healthcare plan which is in agreement with former studies (IMDG. ,1992). The examples of inappropriate donations in terms of medical equipment constitute ample reasons to develop international guidelines for medical equipment donations. The first and paramount principle is that medical equipment donations should benefit the recipient to the maximum extent possible (Plymouth Meeting, PA, 1995).

Pre-donation Assessment and plan

It is not enough for the recipient to adopt and publish the general guidelines on the selection, quality, presentation and management of medical equipment donations. Administrative procedures need to be developed by the recipient to maximize the potential benefit of medical equipment donations. As much as possible such arrangements should be linked with existing medical equipment supply systems, but there are several questions which apply to donations only. This is also in accordance with other reports which came out before (WHO Guidelines, 2000).

Donation Criteria and Requirement

As in the previous studies (Chang, T.,1997) pre-donation plan, installation requirement, operational requirement, and maintenance requirement should be identified and communicated to the recipient. These include but are not limited to air or water cooling electrical power, water quality mechanical layout or radiation or acoustic shielding requirement. Sometimes specialized software may be required to install, operate, or maintain equipment. The above scenarios were also a concern in this thesis work.

Identifying Donor Need and Criteria

As suggested in earlier studies (Madani, M.A. ,1995) this study also tried to illustrate that donors should always respect the four core principles: a donation should benefit the recipient to the maximum extent possible; a donation should respect the wishes and full authority of the recipient; there should be no double standards in quality; and there should be maximum communication between the donor and recipient. Donors should also respect the national guidelines for medical equipment donations and respond to the priority needs indicated by the recipient. Although they are a reality of life, unsolicited donations should be discouraged as much as possible.

Identifying Recipient Need and Criteria

The important action by the recipient is to specify the needs for donated medical equipment as much as possible. This puts the onus on the recipient to carefully prepare such requests, indicating the required quantities and prioritizing the items. The more information given, the better. Information on donations that are already in the pipeline, or anticipated, is very helpful to other potential donors. Full information from the side of the recipient is greatly appreciated by donors and pays off in the long run as also described in other studies (Chang, T.,1997).

Donation Implementation

This study has tried to show prior to packaging the equipment to be donated as in WHO Guidelines, 2000 the donor should ensure that it is safe and performing within manufacture's specifications. This can be accomplished by performing an operational verification procedure found in most operating manuals. In addition, all accessories and supplies should also be checked. Installation should be performed according to the instructions received from the donor. After the installation verification of proper and safe operation must be performed prior to clinical use. After verifying that the equipment received is working properly, the recipient should implement a program of periodic inspection, maintenance and calibration to assure that the equipment is maintained in a safe and effective operating condition for its remaining useful life.

Follow-up and Evaluation

After installation and operation, the donor and the recipient should assess the level of operational success or failure of the medical equipment donated. This assessment fosters communication between donor and recipient, encourages the continued support of the donor, and allows both parties to learn to improve from previous experience. These were also one of the common practices reported by (Chang, T.,1997; Dyro J. 2004).

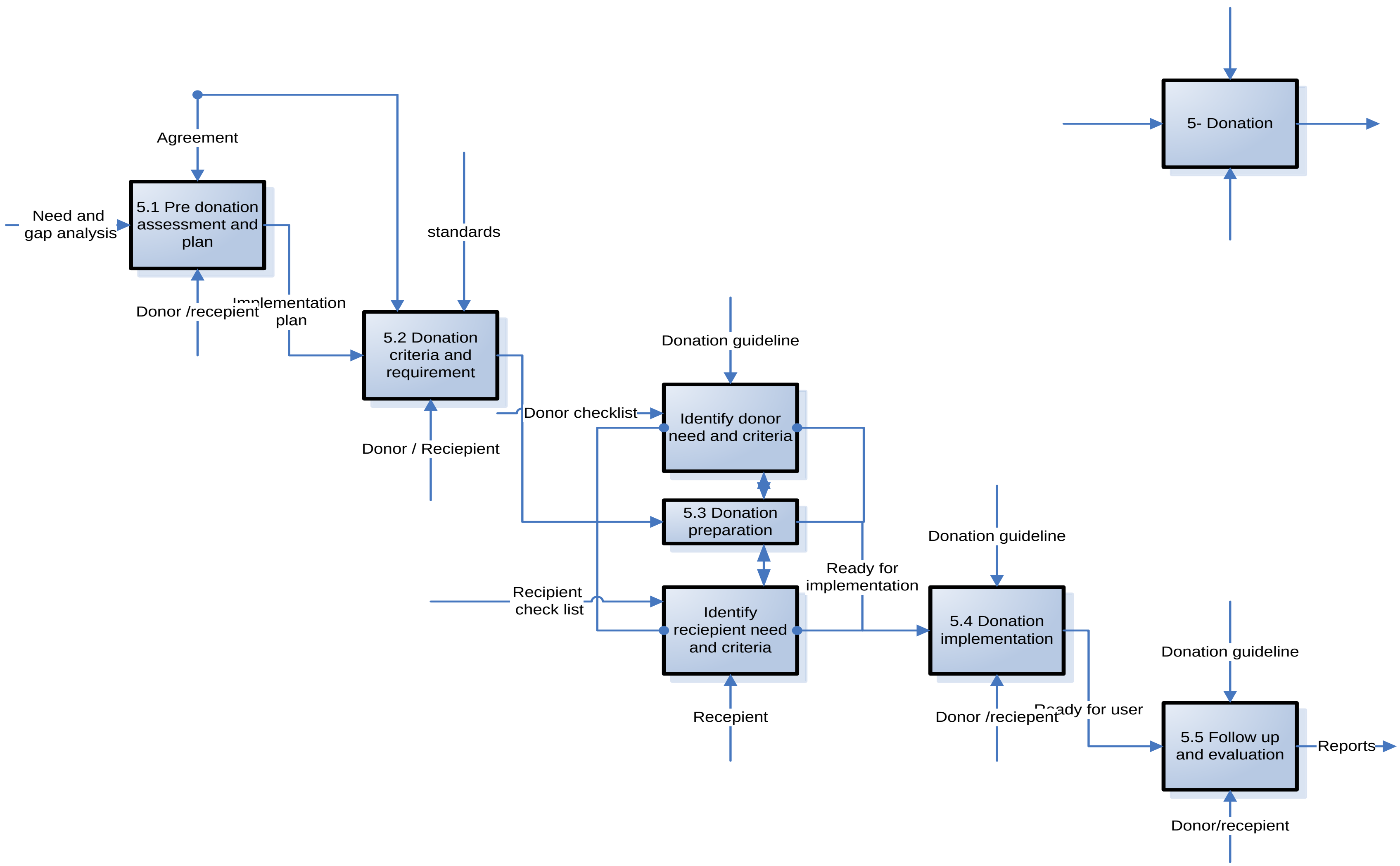

Figure 13: Deign for equipment donation.

Utilization

The current study believed in the importance of collecting baseline information on the utilization of the health technology that is in use, as it can greatly influence the expected lifetime of the equipment as also reported by former studies (Michael L. G. ,2000). Incorrect utilization may negatively influence healthcare delivery and the expected lifespan of the equipment, and must be rectified with user training. Over-utilization, compared to the design capacity of equipment, will often reduce the expected lifespan significantly (Yadin D., Thomas M. J. ,2000). Under-utilization may not adversely influence the lifespan, but investment cost may have been saved if the design capacity of the equipment were closer to the actual use. Correct utilization rates reduce the capital investment costs and care must be taken to make as accurate calculation as possible. Besides information on lifespan and maintenance requirements, utilization also determines the rate at which consumables are used to which other studies conducted by (Zhou X, Xi L and Lee J ,2006 ; Wang B, Furst E, Cohen T, Keil O R, Ridgway M and Stiefel R ,2006) agreed upon.

First Use and Check

This study included safety checks pertinent to the electrical, environmental hazard and other related safety issues that must be critically addressed before performing calibration and use the machine. Accuracy of physiological measurements, precision, dose delivery, energy delivery, accuracy of other outputs and other calibration issues recommended by the manufacturer must be addressed which is in agreement with previous studies (Marv S. ,2004; Michael L. G. 2000).

Operational and Monitoring

While the machines are operating, the biomedical engineers, the professionals who are operating on the machine must always monitor the status of the machine before using. Day to day records of the measurement must be taken to understand and follow up continuous functioning of the machine, and this is in a good agreement with previous findings (Ngara N. ,2000).

Maintenance

Most maintenance and repair work is done as a response to operator request for help and is therefore unplanned. However, the maintenance and repair service should include a planned preventive maintenance design; this comprises a predetermined schedule of simple maintenance procedures to be undertaken at regular set intervals. In this way potential problems can be detected early and corrected; this will diminish the amount of time the equipment could be out of service (John K., Stephen M. and David M. ,2012). Keeping equipment in good running order will require adequate funds throughout the life of the equipment. International guidelines suggest that maintenance and repair costs ought to be around: 5-6% of stock value per year for medical equipment, 2-3% of construction costs for buildings per year, 3-4% of purchase and installation costs per year for service supplies and plant (Walters N.M and Bunn A.E ,1995).The current study considered to meet the best requirements. It is necessary to document, monitor, and review maintenance expenditure; then it will be possible to undertake effective forward forecasting of budgetary requirements, as well as undertake cost-benefit analyses of maintenance interventions. As equipment grows old it becomes uneconomical to maintain and a point will be reached when it is more cost effective to replace it than to try and repair it (Jardine A K S and Tsang A H C ,2006).

Planned Maintenance Design

Planned maintenance design is undertaken with the aim of preventing breakdowns and ensuring that equipment is operational and safe. This is the implementation of a timetable of scheduled maintenance activities, in order to diminish the amount of time equipment is out of service. There is a point where decision must be made if the machine actually needs maintenance by monitoring the functionality of the machine. Management of equipment is sustained by proper management of spare parts. It can be said that achievement of medical equipment management depends on whether the spare parts management (or spare parts control) can be properly done. Spare parts management requires a broad range of technology, experience and knowledge of medical equipment. In addition to this, it requires the ability to estimate necessary spare parts , this scenario has also been reported by other studies (J. Tobey Clark ,2004).

Equipment Maintenance Cycle

Equipment placed under routine preventive maintenance must be recorded and checked every time maintenance is performed. Equipments in the range of therapeutic, intensive care units and lifesaving equipments should always be in preventive maintenance. Also, inspection and check must be performed after each preventive maintenance

Maintenance Initialization

As in the current study previously conducted researches suggested a relative measure of the importance of equipment based on some factors considered in a particular context should be addressed in prioritization of maintenance (Gulati R and Smith R , 2009). The importance or criticality of a failure mode depends on the combined influences of several factors such as severity, probability, detectability, cost and timing, and all these factors play a part in determining the amount of attention that a failure mode requires. Tools to perform maintenance must be kept before performing the actual maintenance. After performing the actual maintenance operational check for functionality checkup should be done before clearance for use. Former studies also revealed similar findings (Cui L, Xie M and Loh H 2004).

Unscheduled Maintenance

Many reports revealed that unscheduled maintenance usually initiate with sudden breakdown or malfunctioning of the machine. At this moment the biomedical engineers must have a decision proposal to identify where to maintain – in the workshop or where the machines are installed. The machine must be removed from the workshop to identify defects and to perform the actual repair. Evaluation must always be done to actually provide green light for the functioning of the machine (Campbell J D and Jardine A K S ,2001). These issue were considered in the current study.

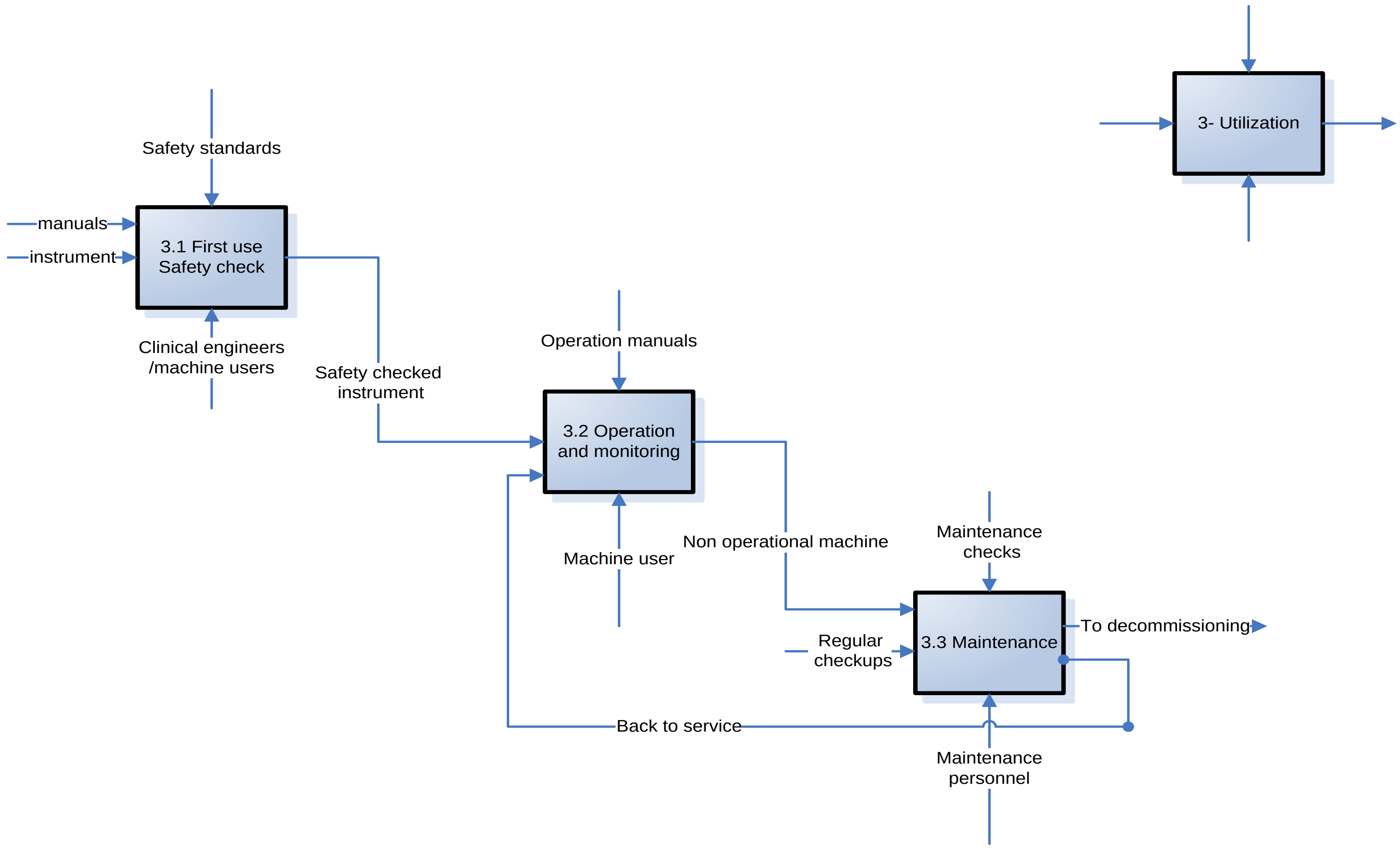

Figure 14: Medical equipment utilization design.

Decommissioning

Decommissioning of healthcare technology refers to decommissioning for the purpose of upgrade and removal from service (disposal/resell/donation) of medical equipment and/or devices, their accessories and any component(s) and/ or system which may provide link between equipments and/or devices which is used in healthcare for the purpose of preventing, diagnosing, or treating diseases as well as for monitoring and rehabilitation. Other guidelines also state a similar concept regarding decommissioning (Cheng M and Dyro J F , 2004).

Decommissioning should include transfer of ownership, decontamination, making safe, making unusable and disposal. This is to ensure that an inappropriate person does not use the equipment and expose themselves to potential hazards. It is advisable to contact the manufacturer at this stage for information on decommissioning. The manufacturer should be able to provide details of any environmental, disposal, recycling or structural requirements. Decommissioning larger installations often involves removal from a purpose-built room or surroundings. When removing equipments from service the followings should be conducted: final test and calibration (certificate should be issued for filing), equipment service records and acceptance certificates, removal (migration) and erasing of patient information, equipment decontamination, equipment has to be marked as being out of service and removed from asset registered as being sold/donated/trade-in or scraped with its current value. Other similar studies also described the same procedures in decommissioning healthcare equipment (Chien Y H, Sheu S H and Chang C C , 2009).

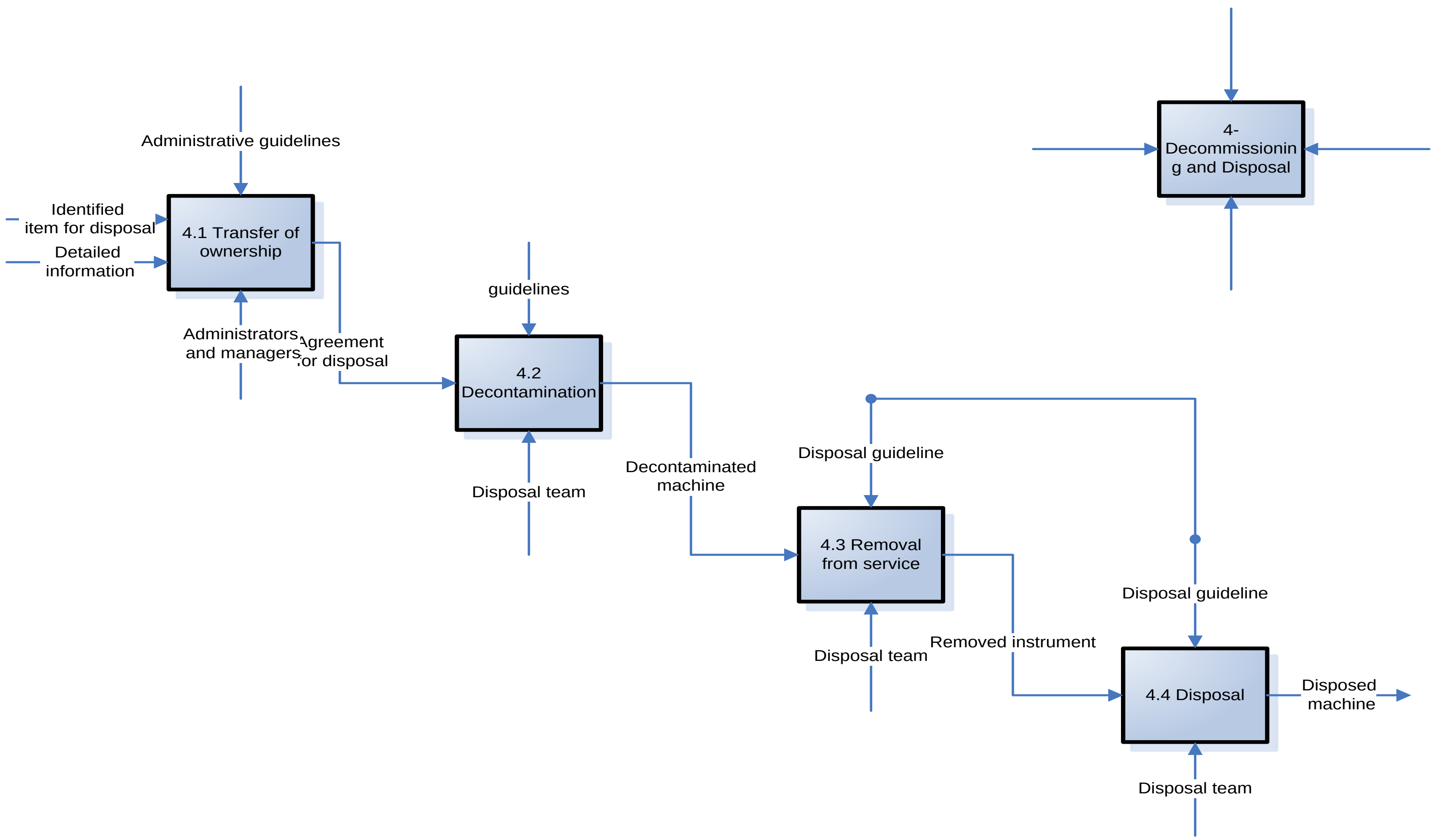

Figure 15: Equipment decommissioning design.

Regulation

Regulation is primarily concerned with enabling patient access to high quality, safe and effective medical devices, and restricting access to those products that are unsafe or have limited clinical use. When appropriately implemented, regulation ensures public health benefit and the safety of patients, health care workers and the community. This step also incorporates evaluation of technical dossier - evaluating technical documentation of the medical device and the manufacturer, collaboration on acceptance criteria and clinical trials/testing (David W. Feigal, Susan N. Gardner, and Mark McClellan, 2003 ; Baretich M , 2004); Identifying compliance with standards depending with the level of risk as Class A (very high), Class B (high), Class C (medium), Class D (low); compliance with international/national standards and collaboration on international quality systems and product specific standards and there should be agreement on systems for conformity assessments (Tran, Eushiuan, 2009 ; Harding G H and Epstein A L ,2004). Registration of the product and the manufacturer, a national database on manufacturer and products is essential for effective control of medical devices.

Marketing issues related to misleading advertisement, failing to fulfill the after sales obligation must be dealt as regulatory issues. Post-market surveillance mainly focuses on correct use is the ultimate determinant of safety and effectiveness. Important activities like training of user before use, regular maintenance of devices in accordance with operation and service manuals, user networks and medical device vigilance systems to facilitate alert notification, adequate management and disposal of discarded devices (Jardine A K S and Tsang A H C , 2006).

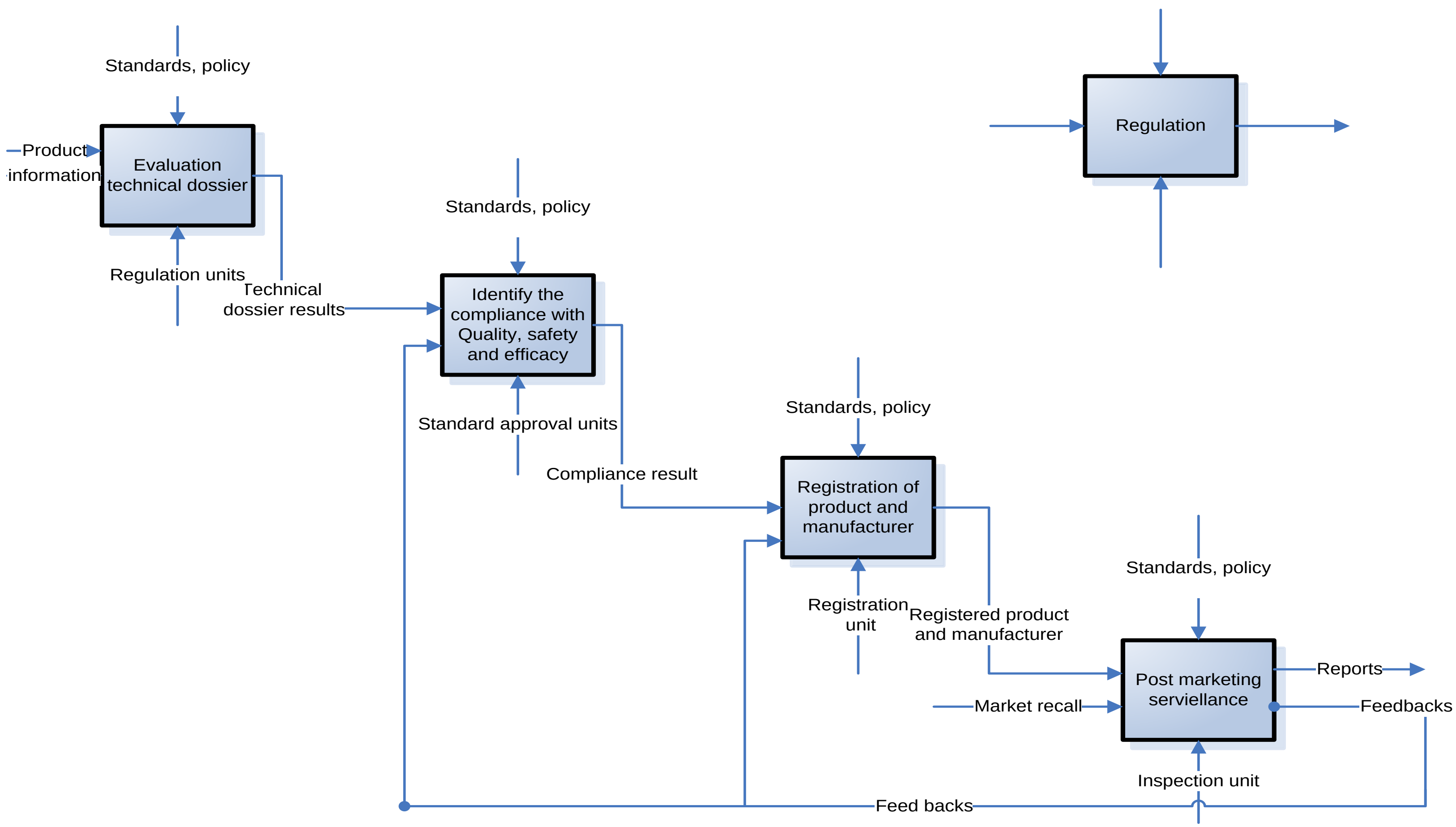

Figure 16: Equipment regulation

Biomedical Equipment Management Information System (BEMIS)

Technology plays a key role in the effective delivery of health care (Joseph J. C., John M. B. ,1998). The selection of appropriate medical technology and the organization of keeping that technology in good working order fall under the remit of health-care technology management (HTM) programs (Andreas Lenel, Caroline Temple-Bird, Willi Kawohl, Manjit Kaur , 2009). HTM is often the responsibility of the clinical engineering (or medical equipment) department, which tests, repairs and maintains diagnostic and therapeutic clinical equipments to ensure that it can be used safely and effectively (Cheng M and Dyro J F ,2004).

Management information systems (MIS) have evolved to provide support to HTM managers to maintain medical equipment and monitor their associated costs automatically (Cohen T ,2008). A MIS is a software package that contains a computer database of information about a Medical equipment management system. In HTM, the MIS is used to automate the documentation of all activities relating to medical devices, including equipment planning, inventory management, corrective and preventive maintenance procedures, spare parts control, service contracts, and medical device recalls and alerts. The collected data can be analyzed and used for technology management, quality assurance, work order control and budgeting of medical equipment (Cohen T and Cram N ,2004).

The decision to automate a HTM system or replace an existing MIS depends on the individual circumstances of the health facility, including working procedures, information technology (IT) infrastructure and available budget. In order to effectively assist in the management and maintenance of medical equipments, a MIS must comprehensively meet the needs of the user (Cram N ,1998). Although major vendors strive to develop a system that universally meets the needs of all HTM managers, no available system presents a complete solution. Most, however, can be customized to meet the specific needs of the health facility. Alternatively, an IT firm can be contracted to develop a MIS package tailored to local requirements. A customized MIS package is generally more expensive but if well designed and maintained will often produce a more satisfactory solution that meets local needs (Mobarek I et al. 2005).

BEMIS is a system for managing all aspects of biomedical equipments. It is a windows application, enabling the data to be stored centrally by MS Access. BEMIS is designed to be used by personnel at all levels, and provides a full range of functions for the effective management of healthcare technology. BEMIS helps users to record equipment history and maintain standard processes associated with each biomedical device. The system provides a complete resource for managing equipment inventory information, calibration results, purchasing and stock-control, utilization and donor information in a single, secure, comprehensive yet easy-to-use package. The "valid data" concept, which is embedded throughout all components, creates a database of consistent data for valuable analysis. The "valid data" requirements on key fields throughout the system require that data be selected from pre-defined choices in the BEMIS Data Managers. To ease data entry and speed "valid data" selection, there are lookup tables and smart fill for each field. For instance, users are not required to enter the same manufacturer name every time when new equipment is registered. They can do so by selecting from a dropdown combo box. Other comparable packages were also developed by other researchers (Staker T. 2003).

The System Network Architecture

The system network architecture displayed under considered; date integration flow of information, data safety and work performance. This was divided into three parts. First, the intranet in a health facility connects the overall operating computers of hospital and the health facility information system. It sends some basic information of medical equipments (such as budget, purchase, and property information) to the MIS. The inner users can also access MIS through the intranet. Second, the MIS is set up in the intranet of Biomedical/clinical engineering database and connected to the intranet of the health facility through a router. The architecture will increase the work performance for the inner users of Biomedical/clinical engineering data input or query data to MIS and system maintenance. In addition to MIS, the local network also includes a Web server of Biomedical/clinical engineering database. Third, the Web server of Biomedical/Clinical engineering data connects to the internet through a firewall and provides a service for supporting outside branch member to access the database of Biomedical /clinical engineering database, which shares related information like the procurement, maintenance, and contract related. This and other related components were shown in previous studies (Cohen T 2008).

The software developed in this thesis is desktop based applicable in the local intranet. But future works can extend to make the software web based application using internet. Reengineering the medical equipment management software: Front End Application tool used:- C# .Net is used to program the software of the medical equipment management system as C# is a multi-paradigm programming language encompassing strong typing, imperative, declarative, functional, generic, object-oriented (class based), and component oriented programming disciplines. Its cutting edges, powerful features for maximum reuse, advanced runtime in memory management and reliability to make it faster and easier makes it much better than other programming languages.
Back End Application used: - MS access is used as a back end application database because SQL server and other advanced database management systems do run as separate processes, cache results and are RAM intensive even when not being queued. The developers of the Biomedical Equipment Management System chose MS Access as the back end application to overcome those overheads. This very fact, not only increases performance but will also insure the accessibility of the system almost on every machine without the need to install huge DBMS apps such as MS SQL server and others. Entity relationship diagram, also called an entity-relationship (ER) model, is a graphical representation of entities and their relationships to each other, typically used in computing in regard to the organization of data within databases or information systems. An entity is a piece of data-an object or concept about which data is stored. A relatively comparable concept were also seen in other reports (Mobarek I. et al. 2006).

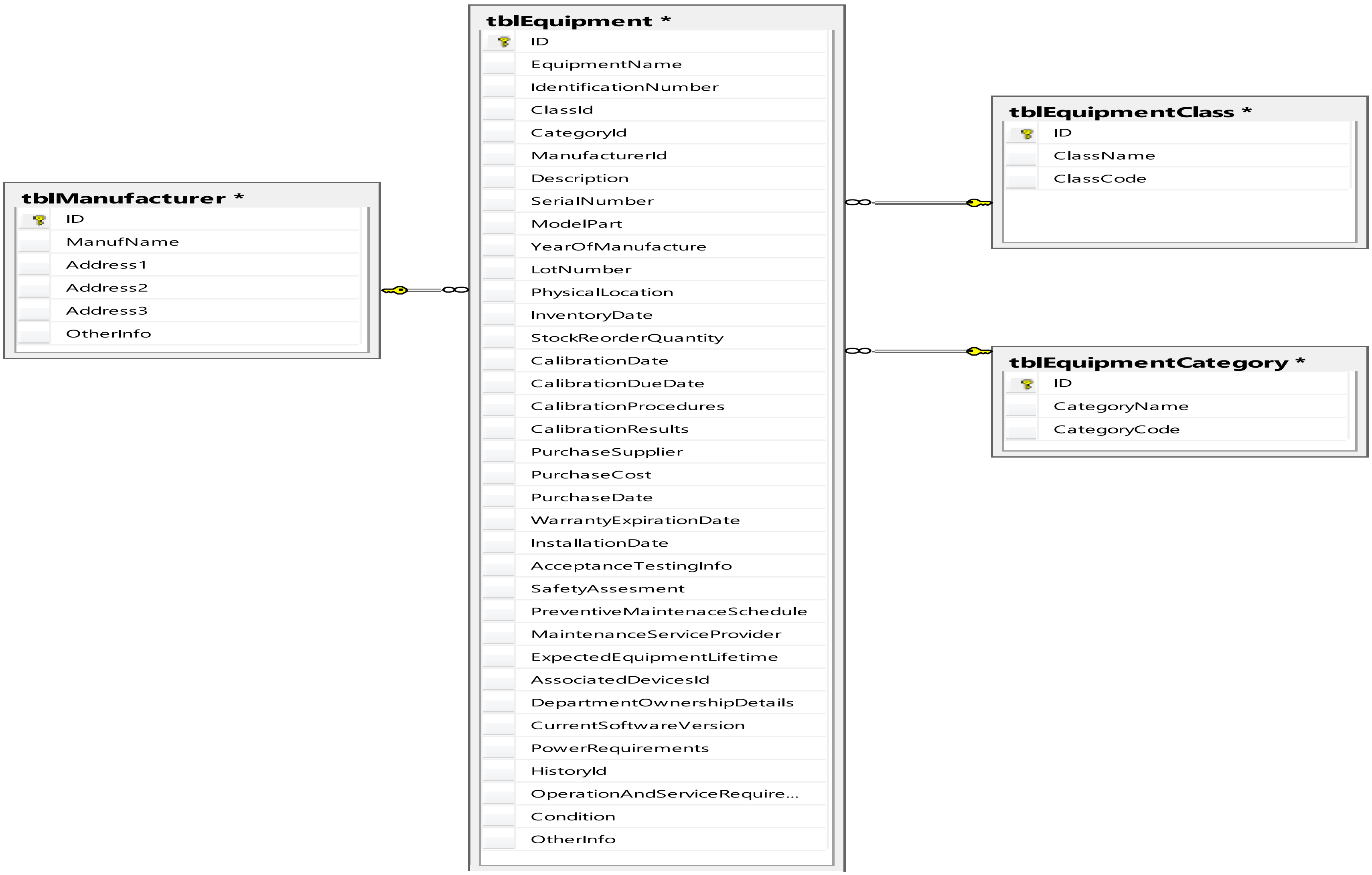

Figure 17: Entity relationship diagram for reengineering equipment management system

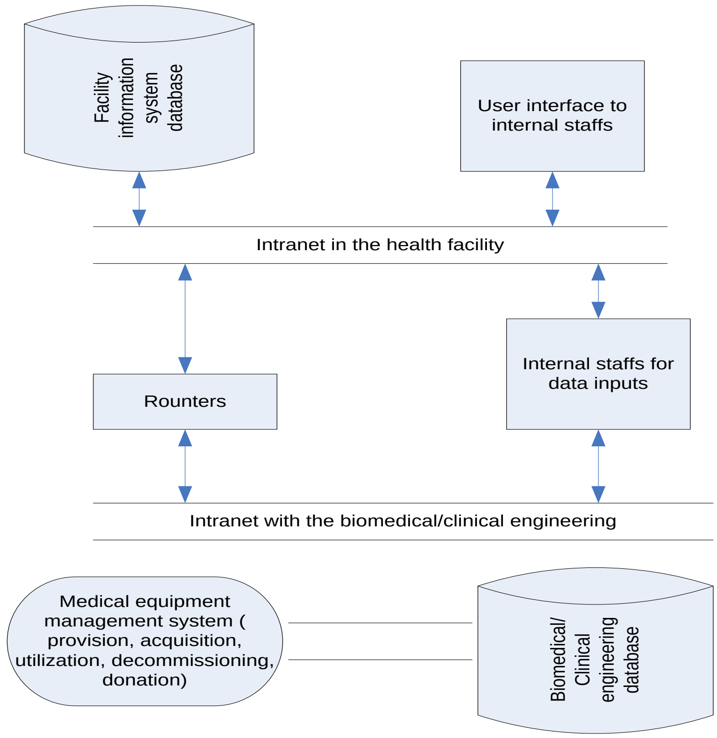

Figure 18: Network architecture.

Biomedical Equipment Management Information System Basic Components and Features

Reengineering the medical equipment system software of the MIS has basic information as

Equipment Information

In this work equipment information provides users with relevant information to manage equipment history. The list is long. Examples are: equipment history, class, category, manufacturer and model specific details, department ownership details, contract detail, and operation and service requirements.

Calibration Information

Calibration Information provides users information regarding calibration results for a particular equipment. Important fields may include calibration date, calibration due date, calibration procedures and calibration results.

Purchase Information

Relevant information related with purchasing of equipments is maintained in this section. This includes supplier information, equipment cost, installation date, warranty expiration date, purchase date etc.

Utilization Information

This is the core section of the system. It provides information regarding safety checks. Normal operation and maintenance schedules of a particular equipment are dealt here.

Safety Check

This consists of parameters like Electrical Check, Mechanical Check and Quality check. If particular equipment fails to pass all these safety measures the next process, which is, 'Normal Operation' will be automatically disabled for that equipment.

Normal operation

This part specifies whether a particular equipment is operational or not. If that same equipment requires maintenance, the next process, 'Maintenance schedule' will be automatically enabled.

Maintenance schedule

Once this option is enabled, users may specify parameters like safety assessment results, preventive maintenance schedule and maintenance service provider.

Donor Information

All information related with donors is maintained here. This includes donor name, donation date, equipment status (new or used) and type of equipment.

Report

Reports turn data into information that helps users respond to daily issues and provides the big picture to help make timely decisions. Reports can be arranged easily through a variety of filters, sorts, sub-sorts and other parameters such as Equipment Class (Class A, Class B, Class C, Class D) , Category (diagnostic, therapeutic, imaging, rehabilitation, assistive) , Manufacturer and Donor Information.

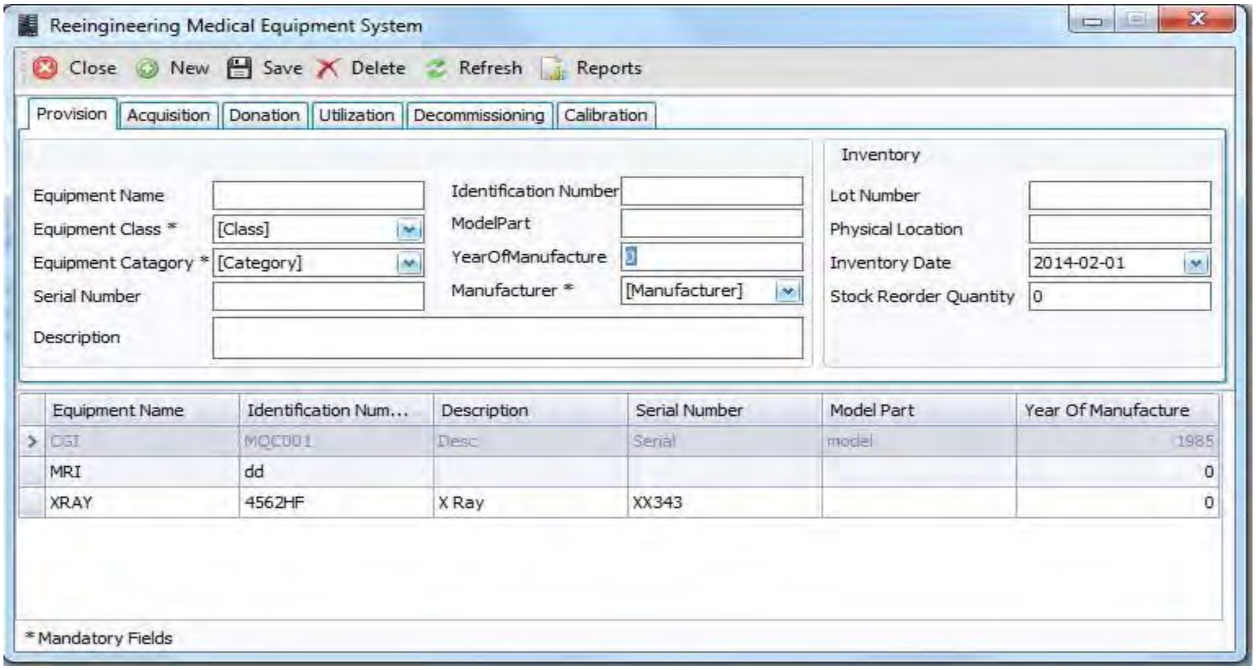

Figure 19: Biomedical Equipment Management Information System basic windows.

In this study relatively different components were included to design the information system as compared to the previous studies by (Staker T. 2003 ;Cohen T and Cram N ,2004; Mobarek I et al. , 2005)

Table 9: Reengineering Summary

Problem	Waste as indicated by WHO (2010)	Issues addressed with the design enabled by MIS	Expected outcomes
Inability to correctly specify & foresee total needs when tendering & procuring equipment	10-30% extra cost	Provision and procurement design	Improvement, incremental, time, cost, quality of service
Purchase of sophisticated equipment which remains unused due to lack of skill of operating and technical staff	20-40% of equipment	Procurement and sub design installation, training	Improvement, incremental, time, cost, quality of service
Extra modifications or additions to equipment and/or building unforeseen at the initial tender stage due to lack of staff expertise	10-30% of equipment	Procurement and sub design initial assessment	Improvement, incremental, time, cost, quality of service
Maltreatment by operating and maintenance staff	30-80% of lifetime	Utilization design and sub design maintenance cycle	Fundamental, time, cost , quality of service
Lack of standardization	30-50% extra spare parts cost	Regulator design and sub design selection of appropriate technology	Fundamental time, cost , quality of service
Down-time due to inability to repair, or no spare parts or accessories.	25-35% of equipment	Utilization , donation, decommissioning and sub designs	Improvement, incremental, time, cost , quality of service

Conclusion

Proper management of medical equipments which includes selection, purchase, installation and maintenance are important for ensuring continued readiness of the service, positive impact on the safety and effectiveness of health services. It increases the lifetime of the equipment and provides information essential for equipment management. The findings from the data collected revealed that most of the health provider organizations in Ethiopia do not have proper management of their medical equipments.

As indicated in the preliminary study, the organizations fail to assess the new technology when selecting new equipment thus compromising the healthcare and patient safety. The findings from the data collected revealed that the health provider organizations do not have proper and clear systems for management of their medical equipments.

The reengineered system design has brought integration within different components of the system. Detail design parts of each component of the healthcare technology system are designed using input output model so that major components the provider-regulator-purchaser aspect - of the system are identified and integrated and clearly seen in the design where they can be implemented. Thus this system will serve as a blueprint for decision makers in a radical and fundamental ways to increase efficiency and effectiveness. It is supported by information system that can show integration of the system. MIS for the reengineered system will enable the system data management, data communication and system integration.

Recommendations

- This thesis has a study area performed in Addis Ababa and can in the future be expanded to the other regions of the country so that a more refined data can be obtained.
- This system should be implemented on the ground so that the result can be analyzed.
- This generic system design which can be applicable in any country taking into consideration of policy, guidelines and manuals pertinent to the system can be customized and be implemented.
- The system presents a holistic view and is designed for all health facilities but can be modified in each level of health service activities such as design for hospitals, for health centers and other health institutions.
- The software developed is a desktop application and can be expanded to web based application in future.

Limitation of the thesis

- Collecting the questionnaires from the end users was the major bottle neck
- Geographically dispersed nature of the health facilities makes the study difficult.
- Lack of enough knowledge from the end users makes some questionnaires incomplete and not correctly filled.
- Lack of awareness on the medical instrument makes life difficult to perform the brainstorming session with some stakeholders.
- System design not tested at the grass root level.

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Annex A: Questionnaire for the preliminary study

Addis Ababa University, Institute of Technology
Centre of Biomedical Engineering

Questionnaire for
Healthcare Technology System

Aim:

To investigate the current situation and future prospect of the healthcare technology of medical instruments in Ethiopia.

Objectives:

- To identify major challenges and developments for healthcare technology system and related issues in Ethiopia
- To understand the impact of healthcare technology system in the overall healthcare delivery.

Theme 1: Healthcare technology practices and performance
Theme 2: the cycles of healthcare technology system

Part 1 – Person filling the form Profile

1. ID No ____________________

2. City ____________________

3. Country ____________________

4.Adress____________________ 5. Fax ________________ 6. E-mail: ____________________

5. Age
A)18-23 B)24-29 C) 30-35 D) >=36

6- Organization you work at :

A) Government, B) Non-government C) Your own business D) unemployed

7- Profession.
A) Nurse B) Pharmacist C) Director D) Biomedical Engineer E) Biomedical Technician F) Other , please specify …………………………

8. Educational level
A. Grade 12 complete B) Diploma C) Bachelor degree D) Masters E) PhD and above

9. Work experience in this organization ____________year

10. Total work experience in your current discipline ____________year

11. Health facility Types: ☐ Hospital ☐ Health centre ☐ other, specify
☐ Health post ☐ Other (define) ____________________

[______] [__________________]

Theme 1

1 What is your role in healthcare technology? *Tick all that apply*

☐ Supplier of medical device

☐ Regulatory of medical devices

☐ User of medical devices

☐ Maintenance of medical devices

☐ Quantifying and selecting of appropriate technology

☐ Other, please specify

____

2- How successful do you think is your Health facility in healthcare technology in general?

Not successful at all	Not successful	Somewhat successful	Successful	Very successful
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3- What are your health care technology basic challenges?

4- Do you take remedial soon when your healthcare technology gets trouble?

5- How much are you satisfied by your employer solution when your healthcare technology gets trouble?

6- The following are measuring the improvement of healthcare technology,
Tick all that apply.

	agree	Strongly agree	Disag ree	Strong ly	No idea
Selecting appropriate technology					
Correctly specify medical instrument					
Appropriately store and distribution					
Inspection of medical instruments					
Appropriate use of medical instruments					
Overview the technical details before accepting					
Removal of medical instrument from service					
Other (*specify)*					

7- Does your health facility have a separate health care technology department? ☐ YES ☐ NO

7.1 if no, Why ? ________________
If your answer is No , Jump to Theme 2.

8- Does your health facility have a clear healthcare technology system? ☐ YES ☐ NO

If Yes, Please specify
____
____
____

9- Has health care technology direct or indirect impact on you healthcare activity ? (yes /No)

If yes ,

How?……………………..

If No,

Why ?

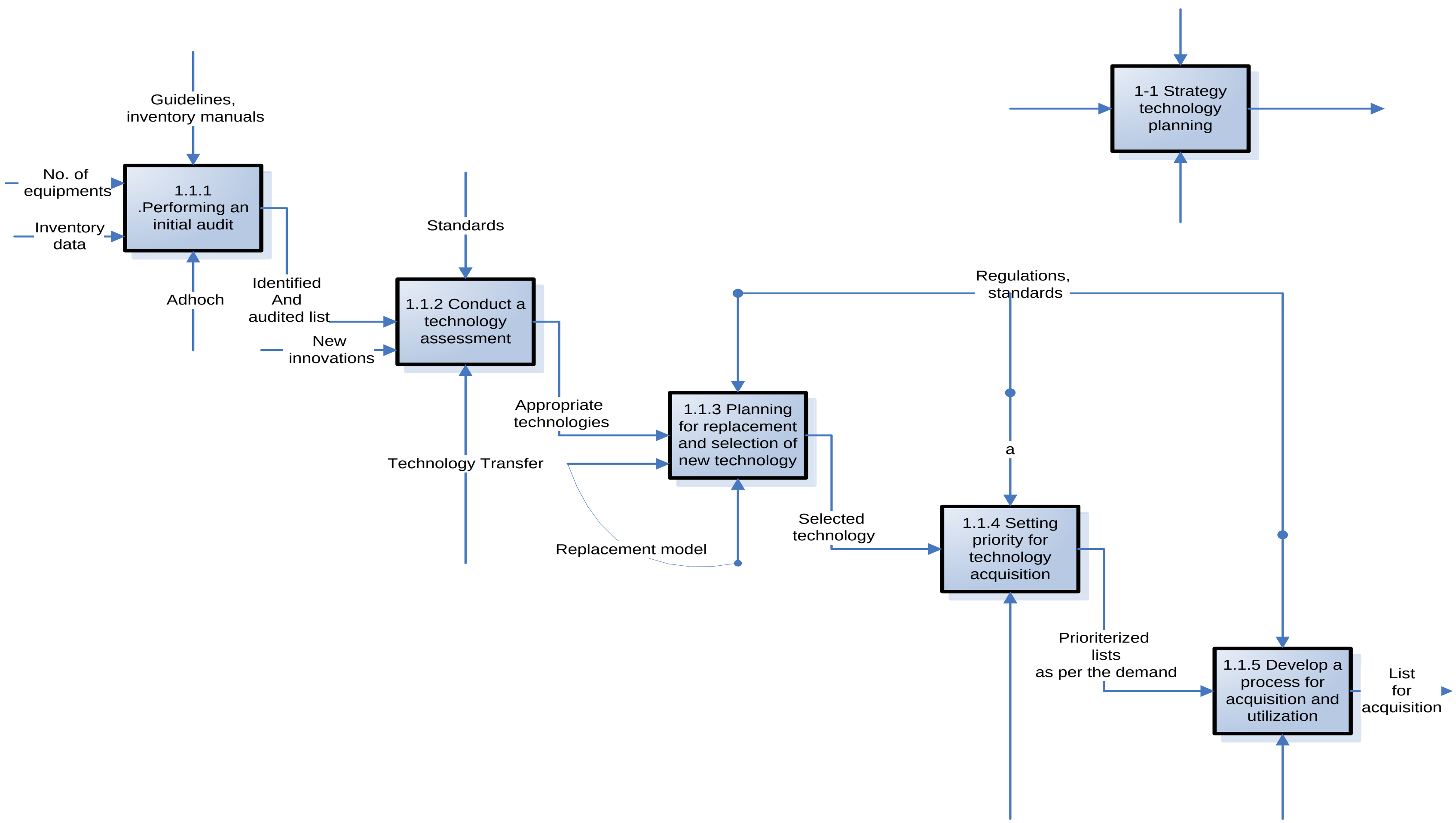
Theme 2

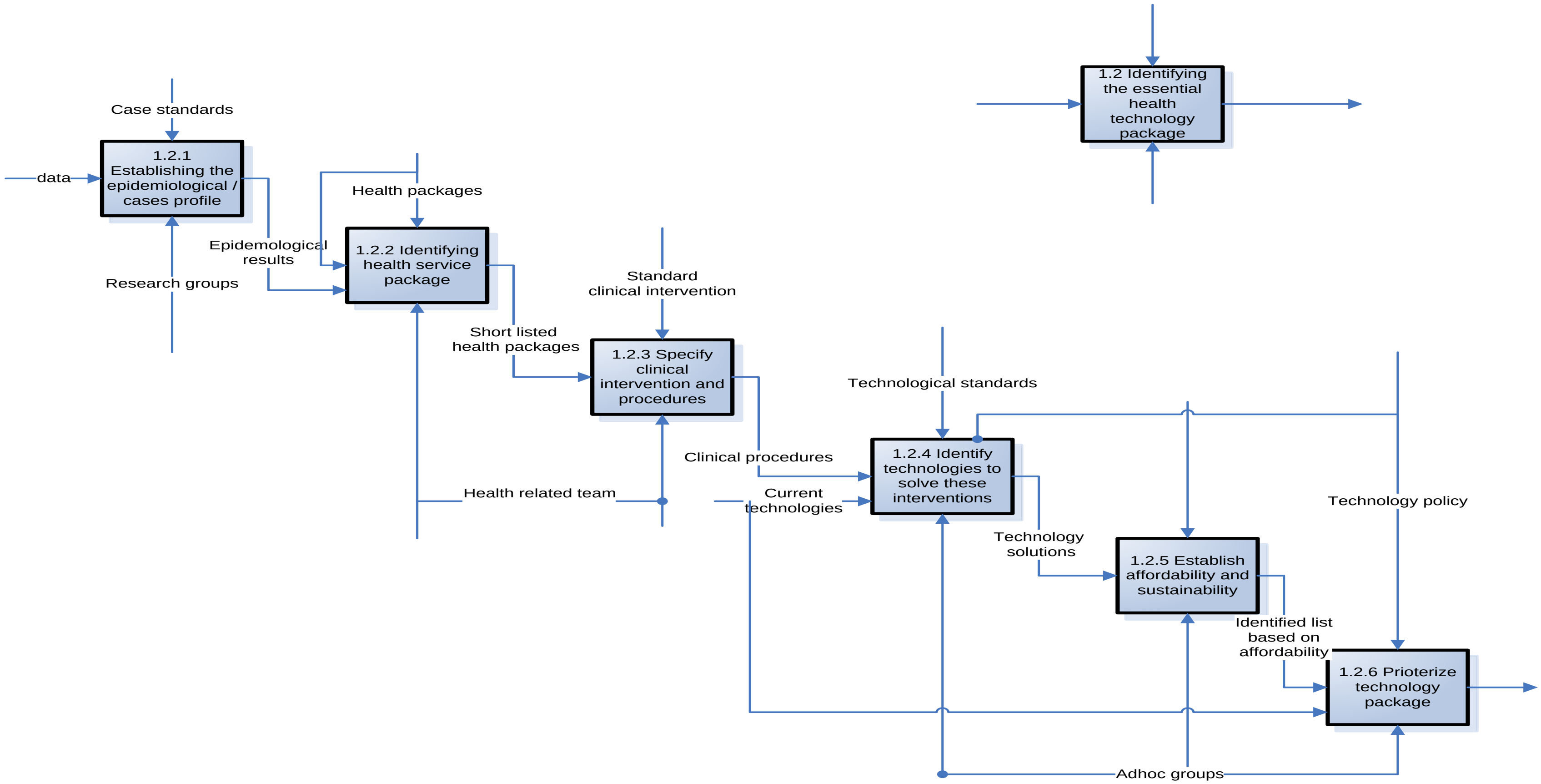
	Questioner on healthcare technology system			
Sr.No.		**Yes**	**No**	**Remark**
6	**Forecasting and Quantification of medical instrument**			
6.1	Do you have adequate health facility equipment? (To fulfill your mission?)			
6.2	Are there standards for quantifying medical instruments?			
6.3	Do you forecast your demand based on your budget?			
6.4	Do you quantify your demand based on the standard and budget ?			
6.5	Do you monitor your inventory for quantification and forecasting?			
7	**Procurement**			
7.1	Is there a clear guideline for procurement of medical instruments?			
7.2	Are the specifications clear and viable to procurement?			
7.3	Does you procurement of medical instrument include after sales service?			
7.4	Do you get the medical instruments procured within short period of time?			

7.5	Do you have a system of selecting appropriate technology ?			
8	**Storage and Distribution**			
8.1	Are the instruments received as per the specification and the order?			
8.2	Is there a good storage practice for medical equipments?			
8.3	Are the instruments transported and stored as per the manual recommended by the manufacturer/supplier?			
9	**Use (utilization)**			
9.1	Do the instruments procured /donated installed and work properly?			
9.2	Do you have enough personnel to operate the machines?			
9.3	Do you have log book for equipments, list of important spare parts and consumables?			
9.4	Do you have written procedures for the use of all equipment?			
9.5	Do you have a maintenance record, for each device and central record archives?			
9.6	Do you have a maintenance workshop equipped with testing devices			
10	**Donation**			
10.1	Are the instruments donated as per your demand?			
10.2	How many of the instruments donated are functional			
10.3	Do you have a system to track donation of medical equipment			
11	**Decommissioning**			
11.1	Are the instrument removed as per the lifetime of the instruments			
11.2	Do you have a system how, and when to decommission medical instruments?			
12	Occupational safety and Hazard			
12.1	Do you have occupational safety guideline			
12.2	Do you have risk mitigation program in health care technology system			
12.3	Do you have waste management system			
12.4	Do you decontaminate devices before use and removal			
12.5	Do you have guideline or procedure for used medical device /chemical removal in your health facility?			

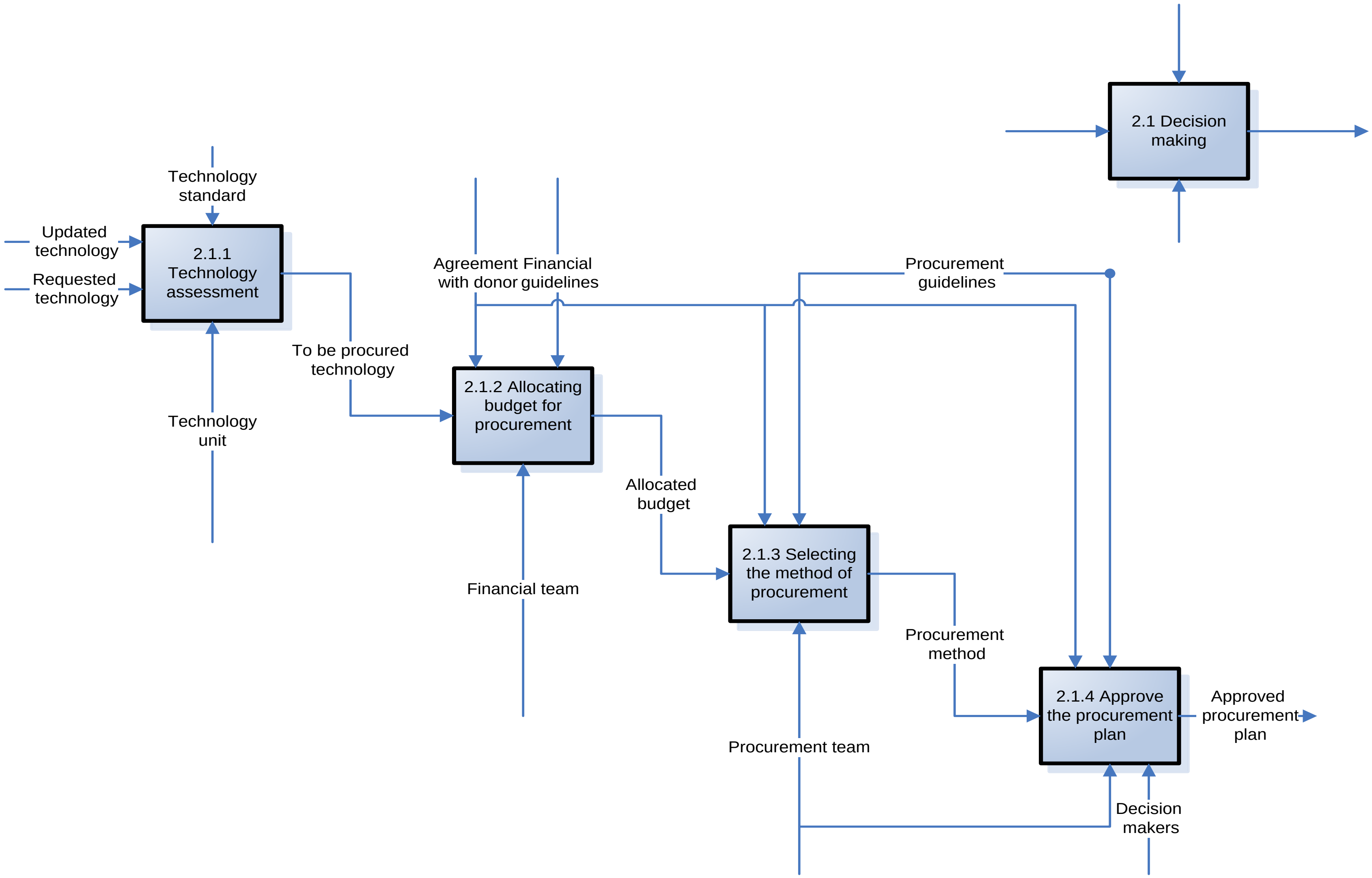
Annex B: Detailed Parts of the Medical equipment management System Design

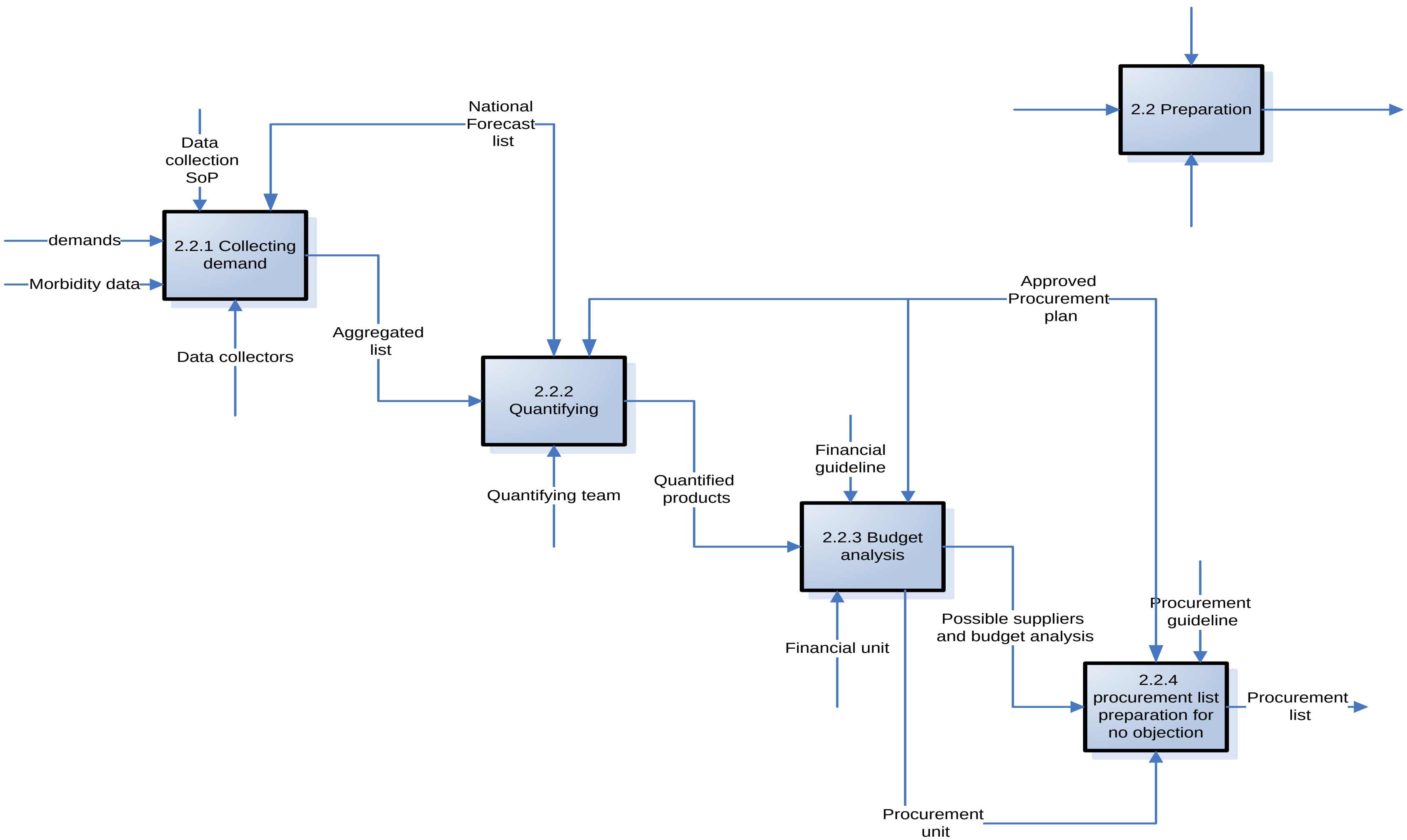
Provision

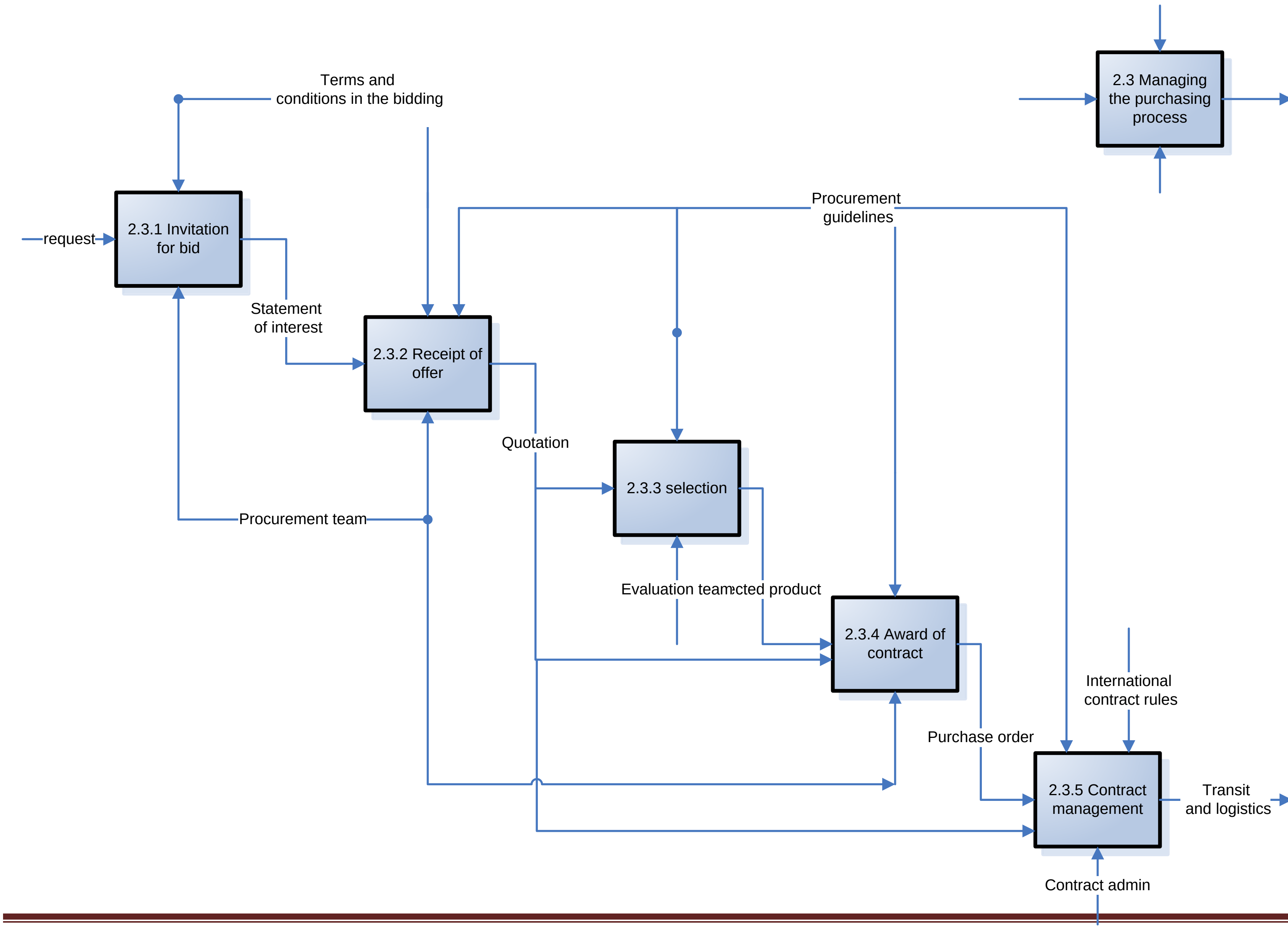


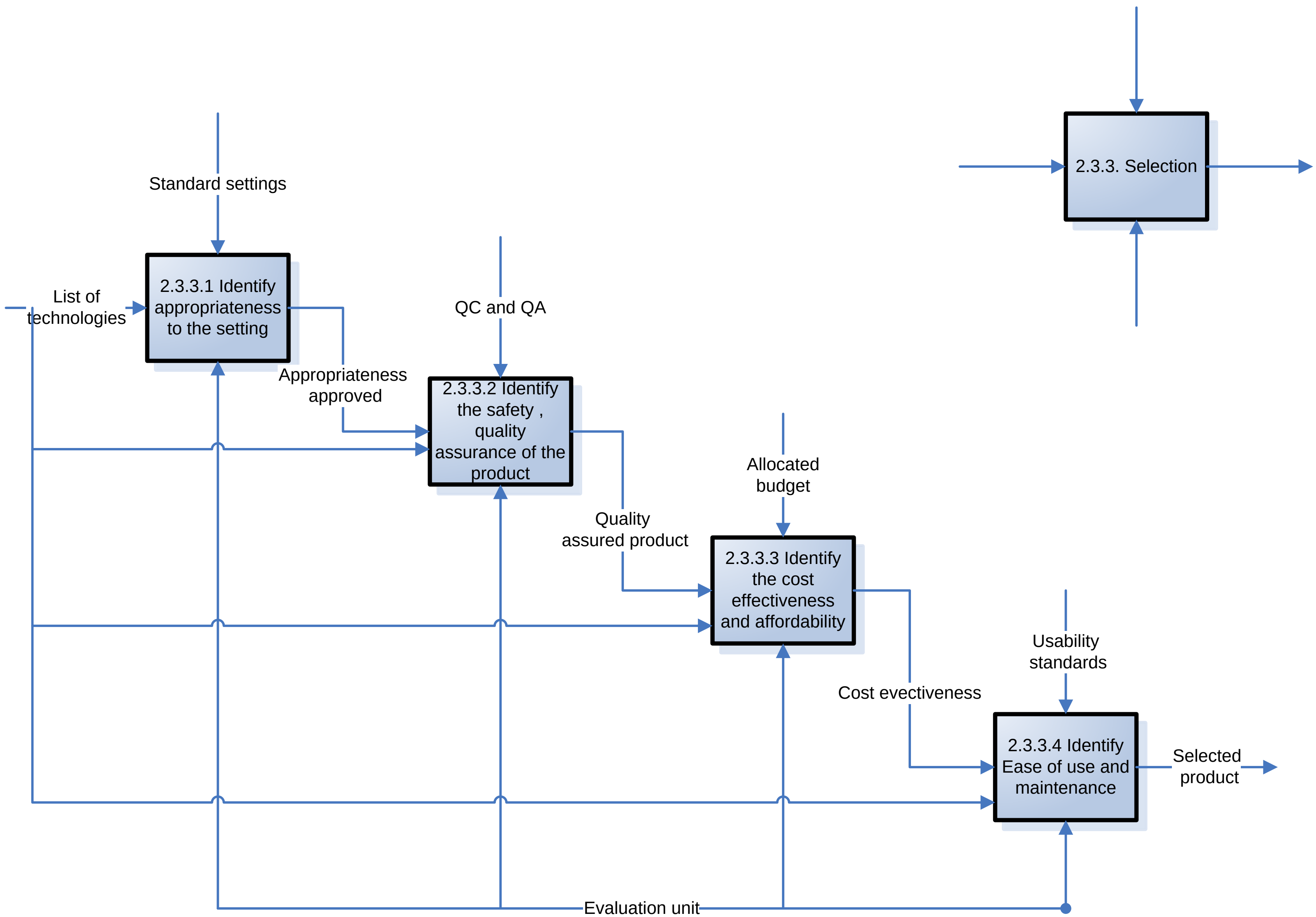

1.2 Identifying the essential health technology package
Case standards
data
1.2.1 Establishing the epidemiological / cases profile
Research groups
Health packages
Epidemiological results
1.2.2 Identifying health service package
Standard clinical intervention
Short listed health packages
1.2.3 Specify clinical intervention and procedures
Technological standards
Clinical procedures
1.2.4 Identify technologies to solve these interventions
Health related team
Current technologies
Technology policy
Technology solutions
1.2.5 Establish affordability and sustainability
Identified list based on affordability
1.2.6 Priorize technology package
Adhoc groups

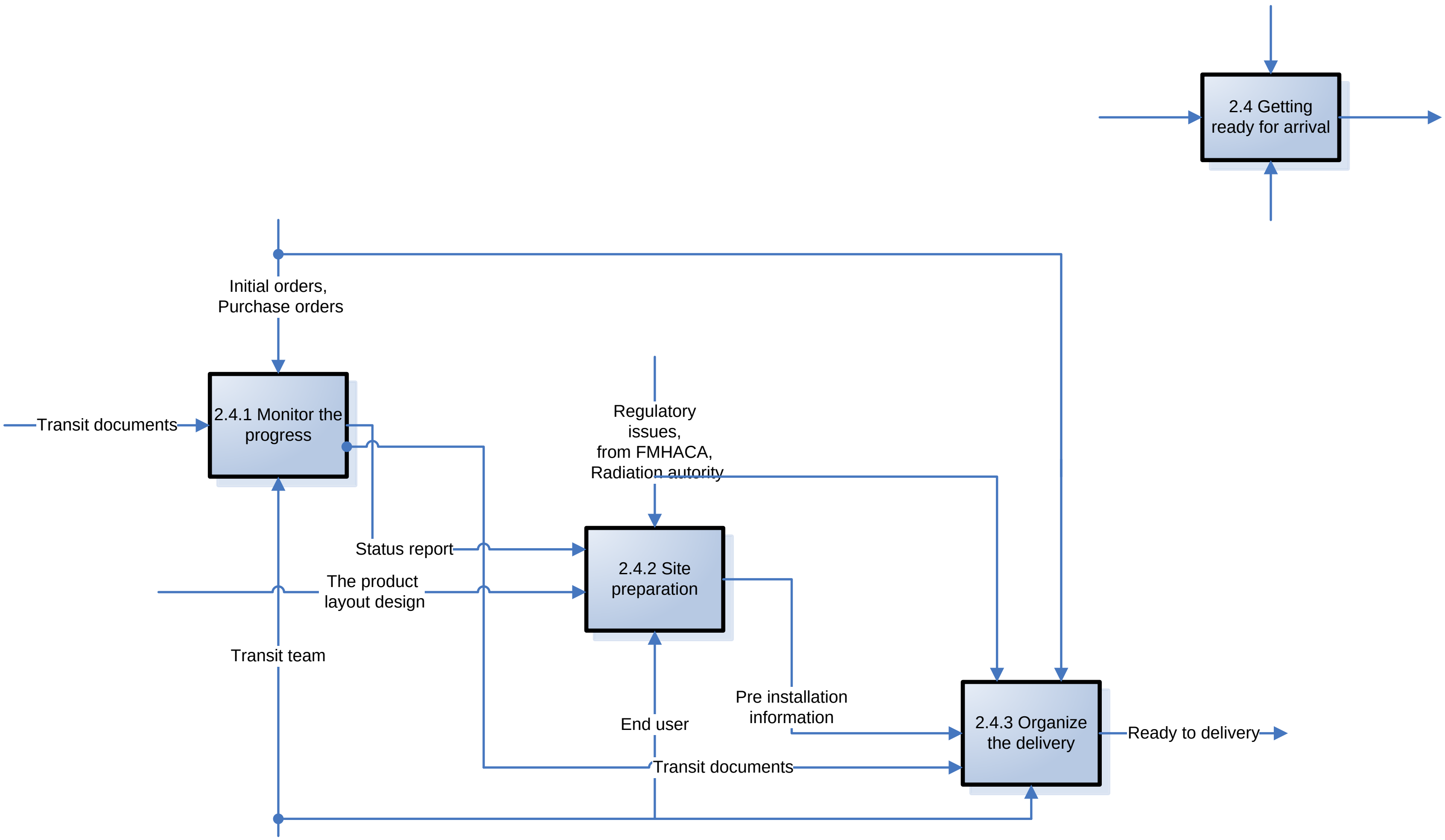
Procurement

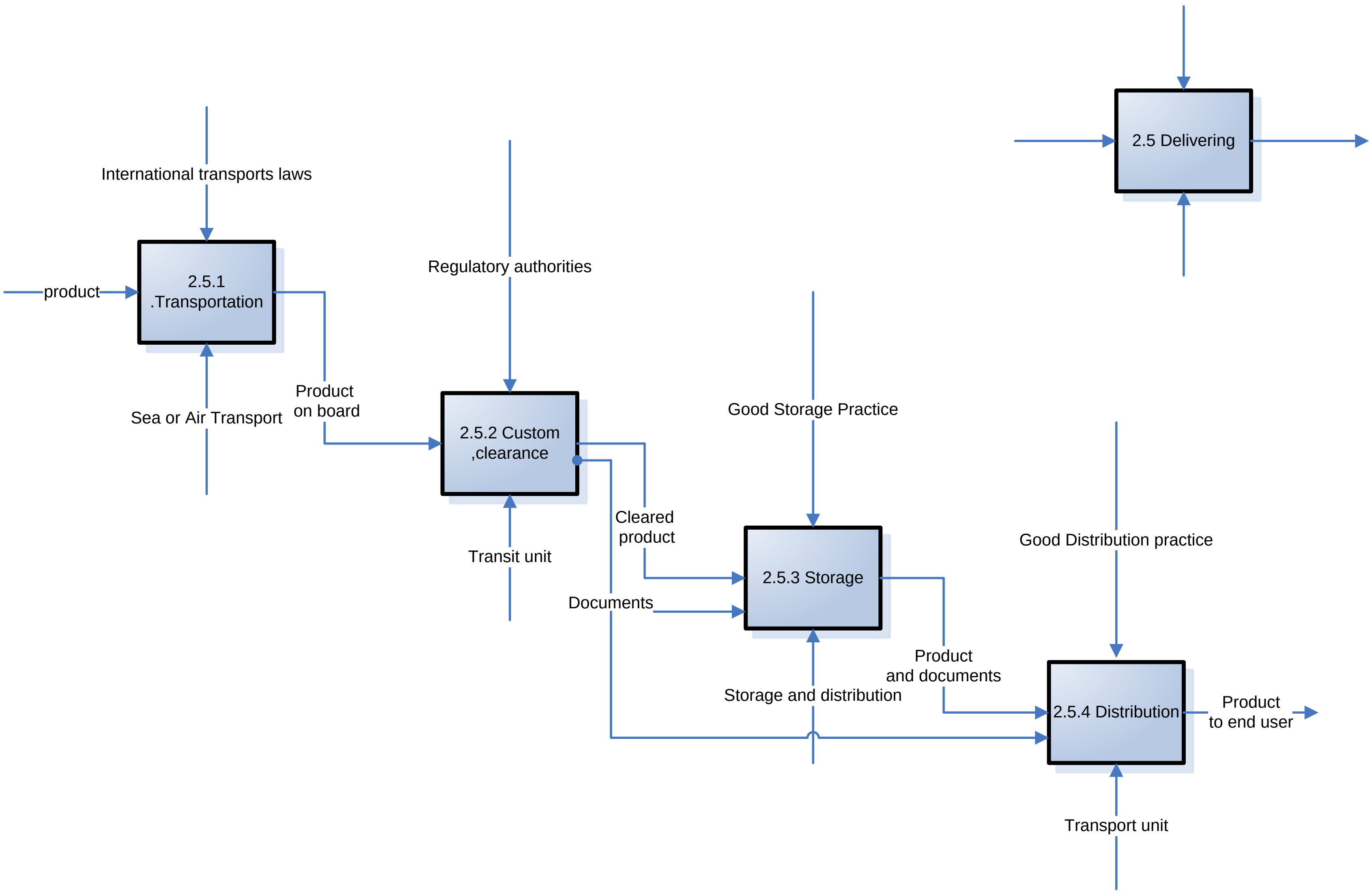


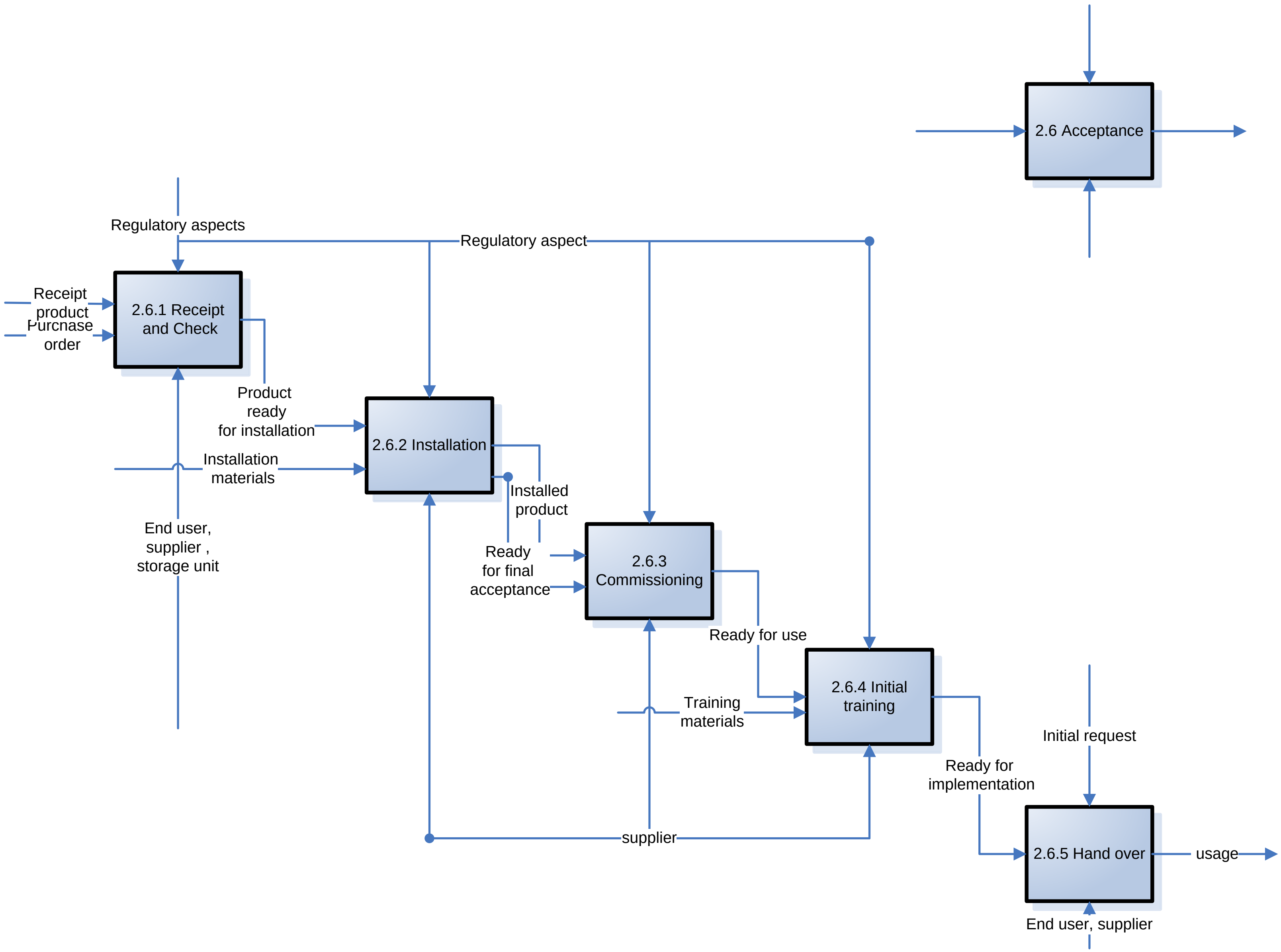

2.2 Preparation
Data collection SoP
National Forecast list
demands
Morbidity data
2.2.1 Collecting demand
Data collectors
Aggregated list
2.2.2 Quantifying
Quantifying team
Approved Procurement plan
Quantified products
Financial guideline
2.2.3 Budget analysis
Financial unit
Possible suppliers and budget analysis
Procurement guideline
2.2.4 procurement list preparation for no objection
Procurement list
Procurement unit

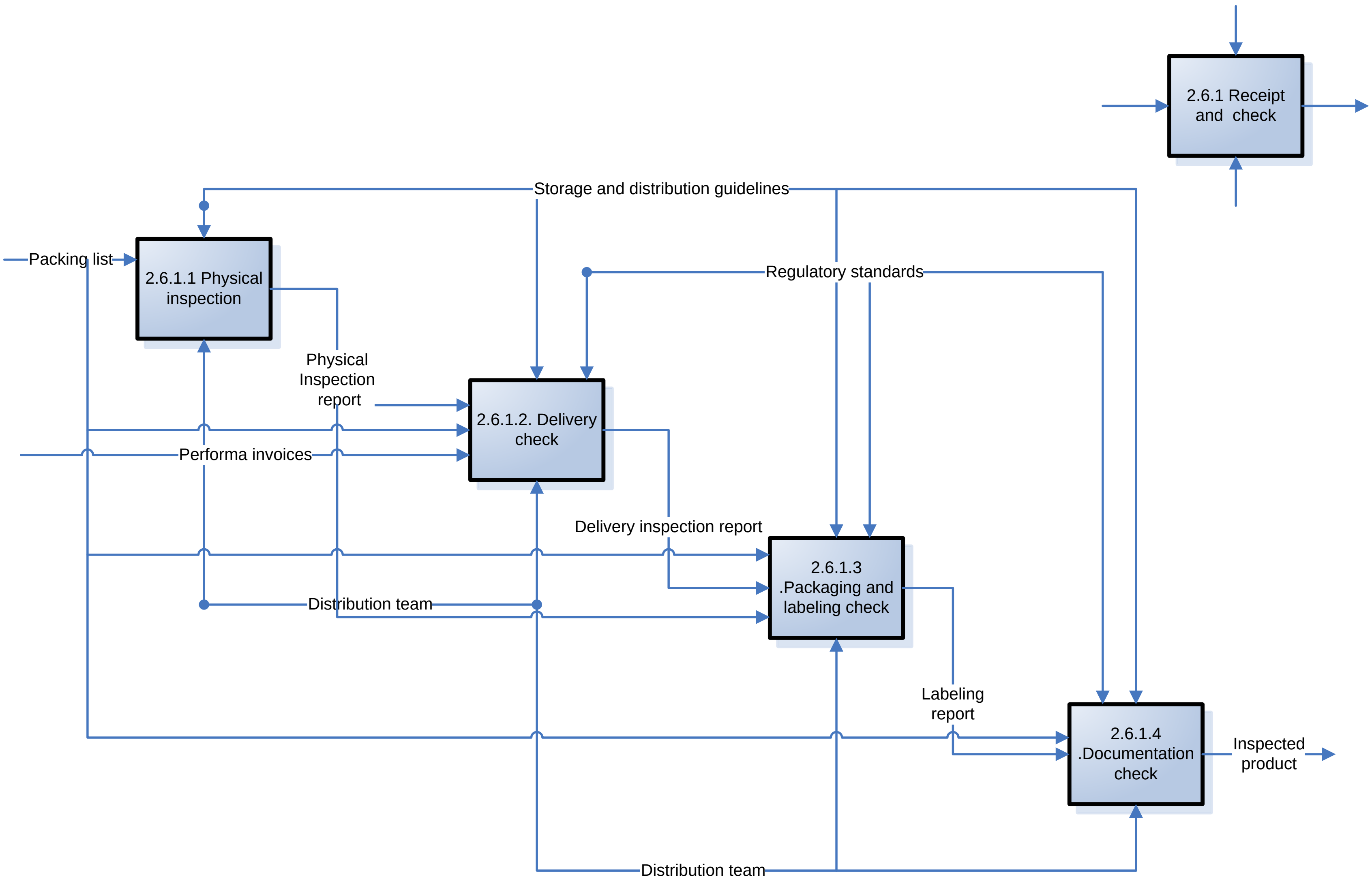

2.3 Managing the purchasing process
Terms and conditions in the bidding
request
2.3.1 Invitation for bid
Procurement guidelines
Statement of interest
2.3.2 Receipt of offer
Quotation
2.3.3 selection
Procurement team
Evaluation team
cted product
2.3.4 Award of contract
International contract rules
Purchase order
2.3.5 Contract management
Transit and logistics
Contract admin

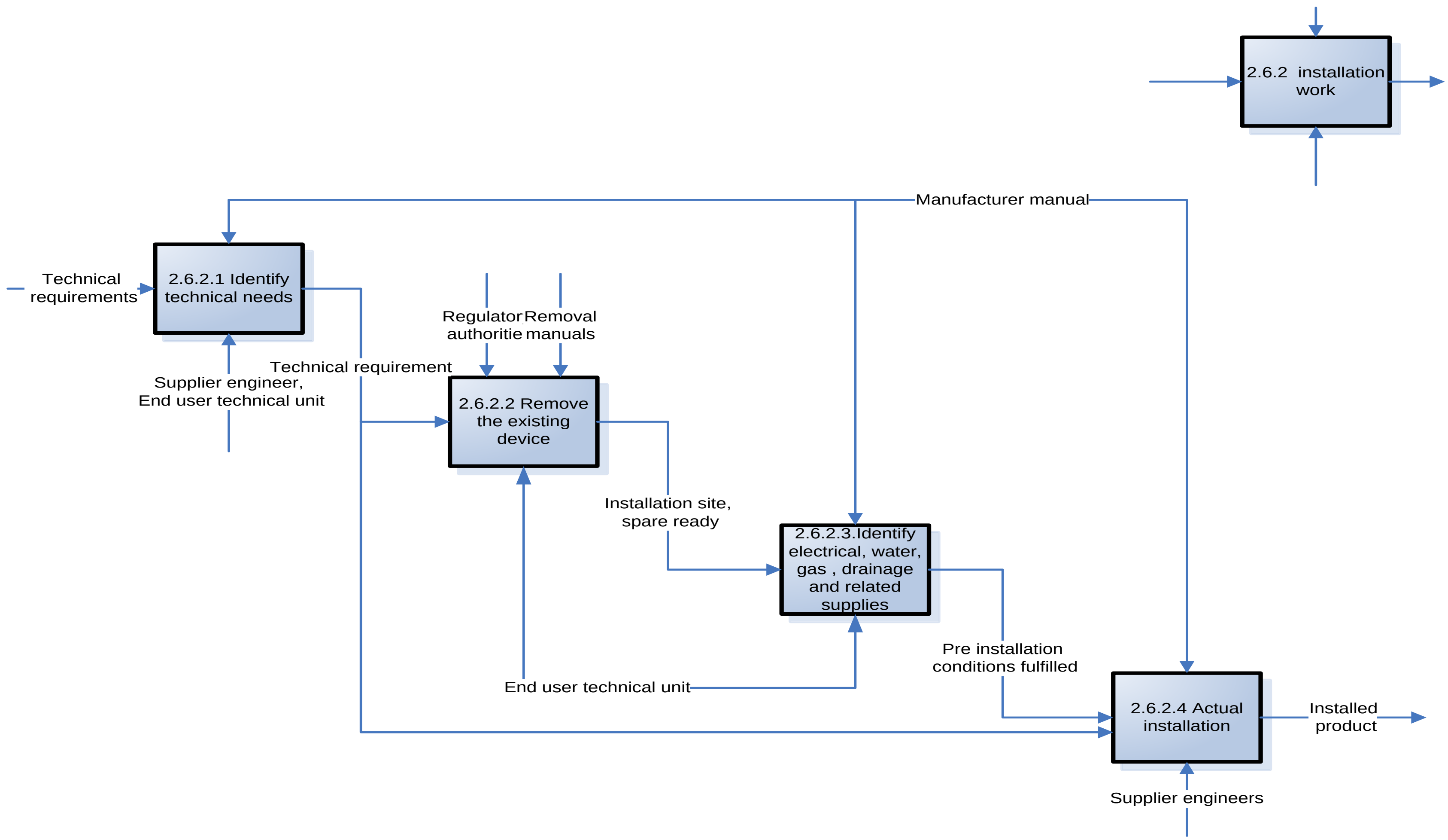

2.3.3. Selection
Standard settings
List of technologies
2.3.3.1 Identify appropriateness to the setting
Appropriateness approved
QC and QA
2.3.3.2 Identify the safety , quality assurance of the product
Quality assured product
Allocated budget
2.3.3.3 Identify the cost effectiveness and affordability
Cost evectiveness
Usability standards
2.3.3.4 Identify Ease of use and maintenance
Selected product
Evaluation unit


2.4 Getting ready for arrival
Initial orders,
Purchase orders
Transit documents
2.4.1 Monitor the progress
Regulatory issues, from FMHACA, Radiation autority
Status report
The product layout design
2.4.2 Site preparation
Transit team
Pre installation information
End user
2.4.3 Organize the delivery
Ready to delivery
Transit documents

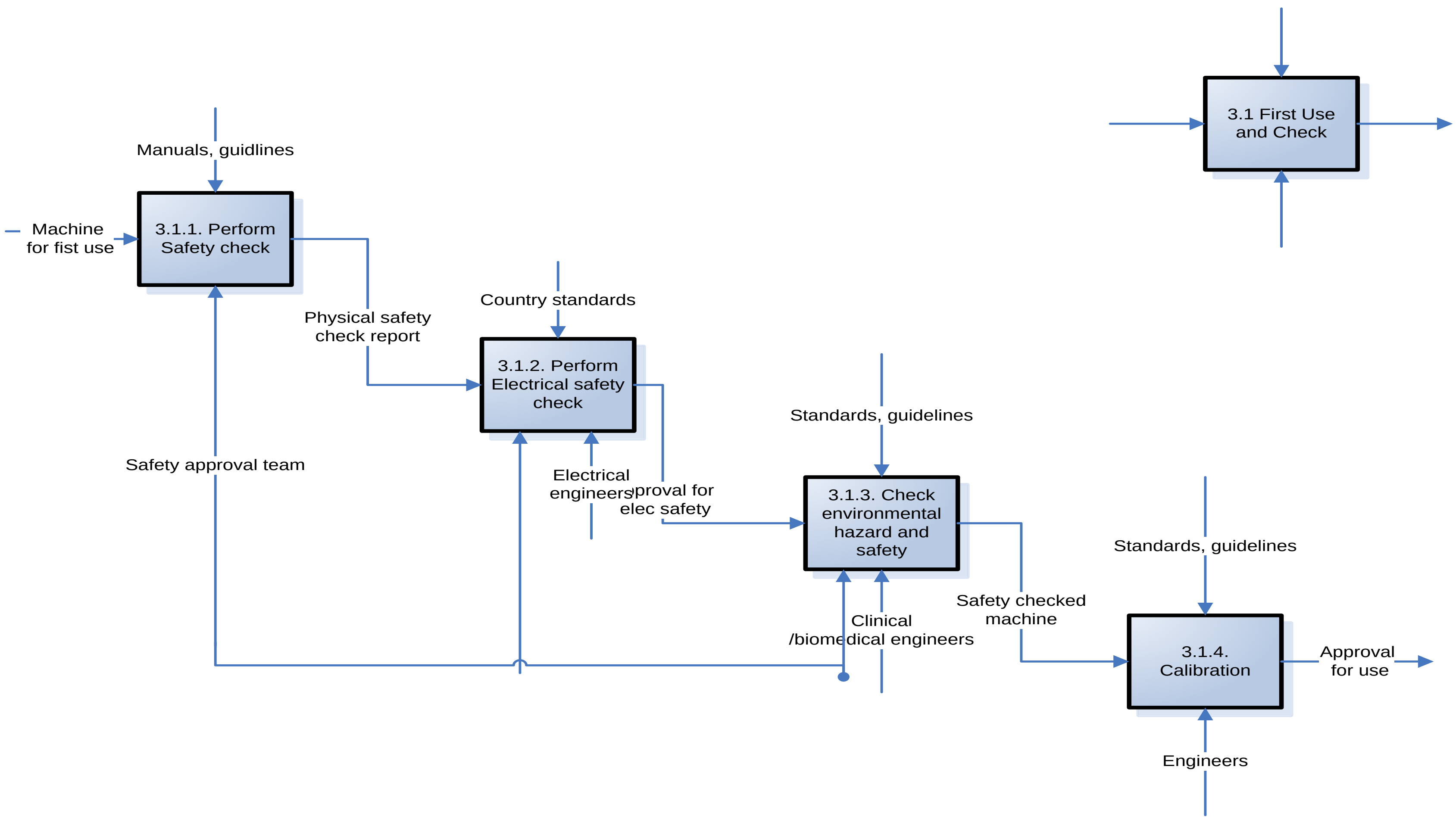

2.5 Delivering
International transports laws
product
2.5.1 .Transportation
Sea or Air Transport
Product on board
Regulatory authorities
2.5.2 Custom ,clearance
Transit unit
Cleared product
Documents
Good Storage Practice
2.5.3 Storage
Storage and distribution
Product and documents
Good Distribution practice
2.5.4 Distribution
Product to end user
Transport unit

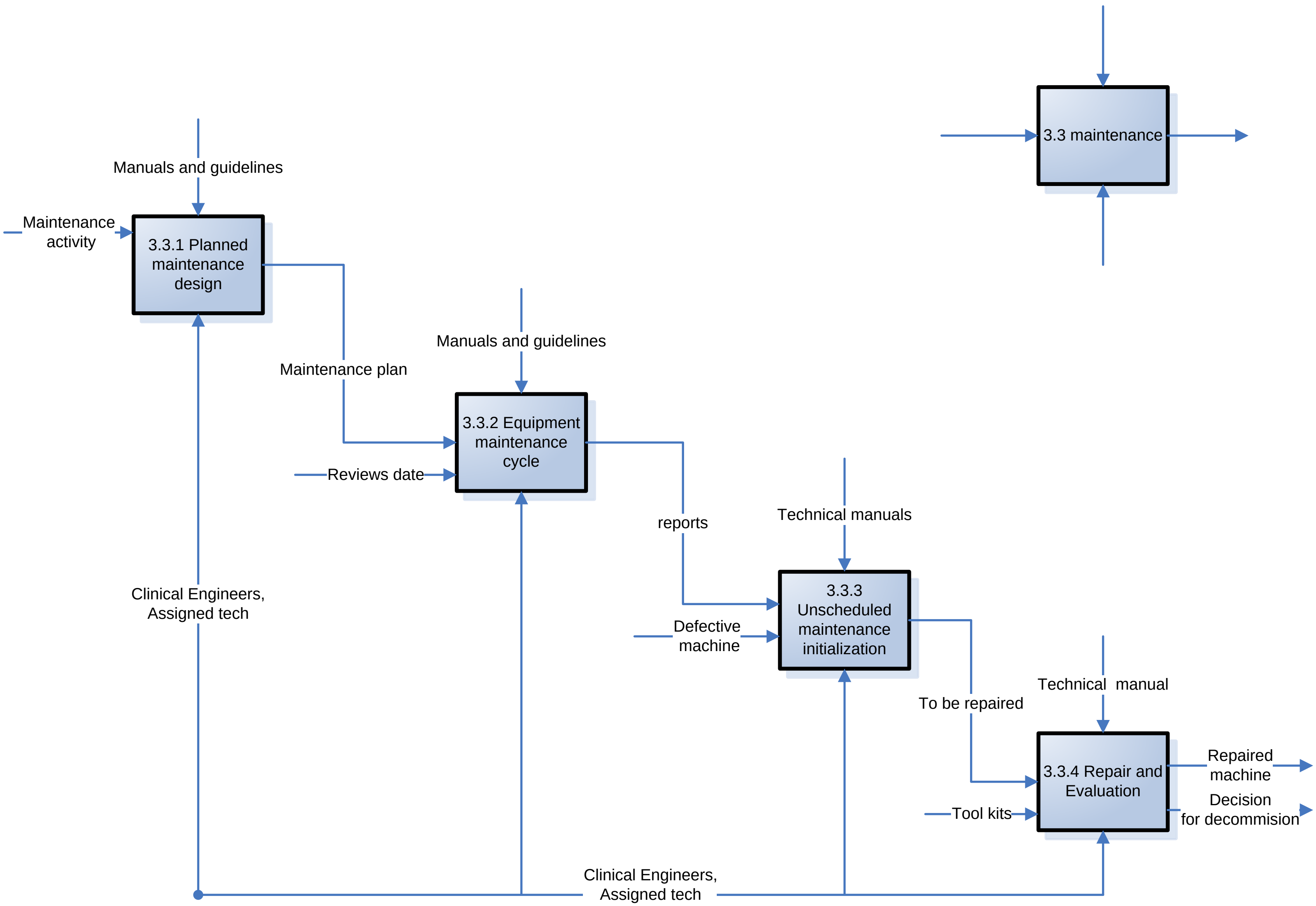

2.6 Acceptance
Regulatory aspects
Regulatory aspect
Receipt product
Purchase order
2.6.1 Receipt and Check
Product ready for installation
Installation materials
2.6.2 Installation
End user, supplier , storage unit
Installed product
Ready for final acceptance
2.6.3 Commissioning
Ready for use
Training materials
2.6.4 Initial training
Initial request
Ready for implementation
supplier
2.6.5 Hand over
usage
End user, supplier


2.6.1 Receipt and check
Storage and distribution guidelines
Packing list
2.6.1.1 Physical inspection
Regulatory standards
Physical Inspection report
2.6.1.2. Delivery check
Performa invoices
Delivery inspection report
2.6.1.3 .Packaging and labeling check
Distribution team
Labeling report
2.6.1.4 .Documentation check
Inspected product
Distribution team

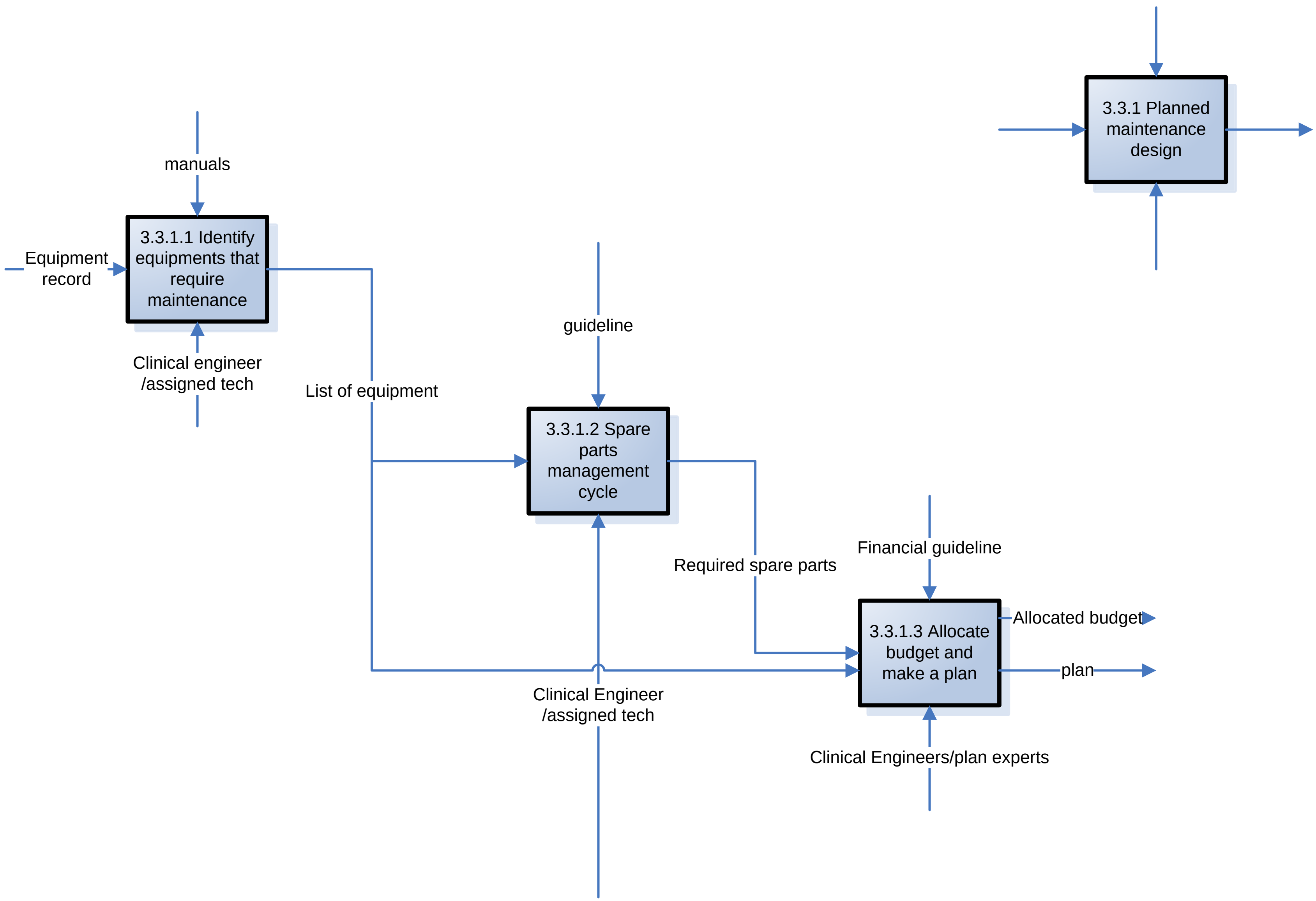


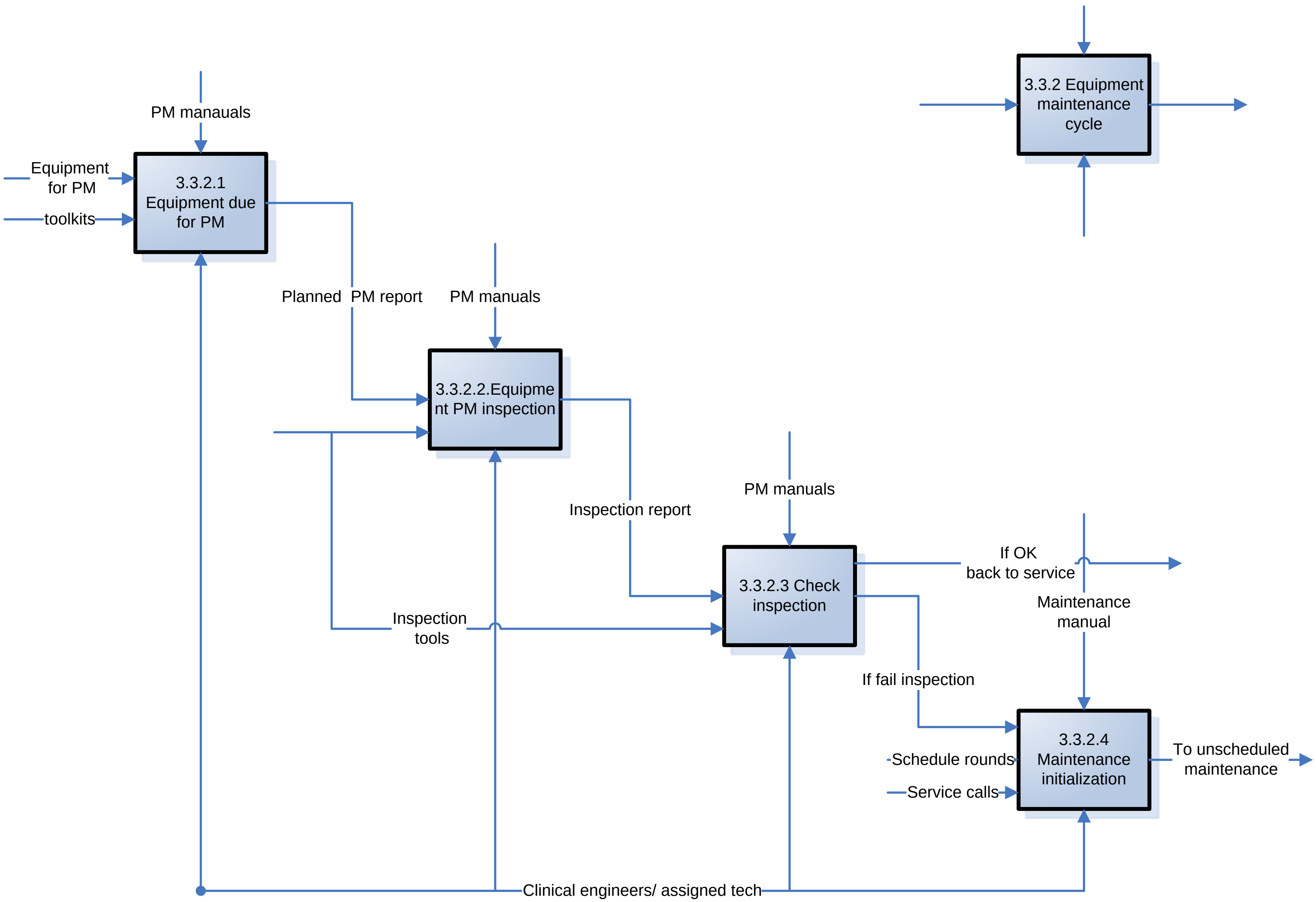
Utilization

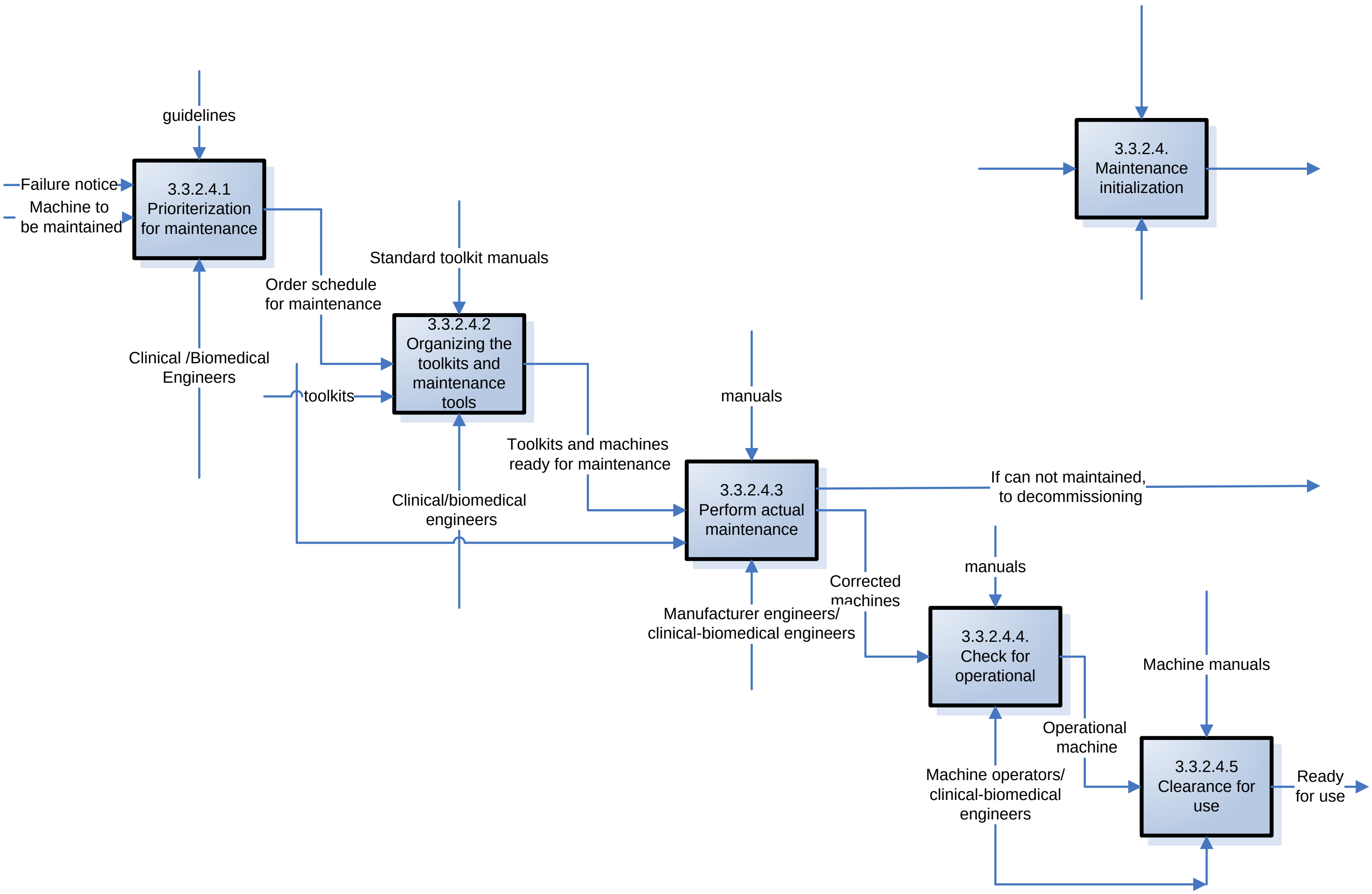

3.1 First Use and Check
Manuals, guidlines
Machine for fist use
3.1.1. Perform Safety check
Physical safety check report
Country standards
3.1.2. Perform Electrical safety check
Safety approval team
Electrical engineers
Approval for elec safety
Standards, guidelines
3.1.3. Check environmental hazard and safety
Clinical /biomedical engineers
Safety checked machine
Standards, guidelines
3.1.4. Calibration
Approval for use
Engineers

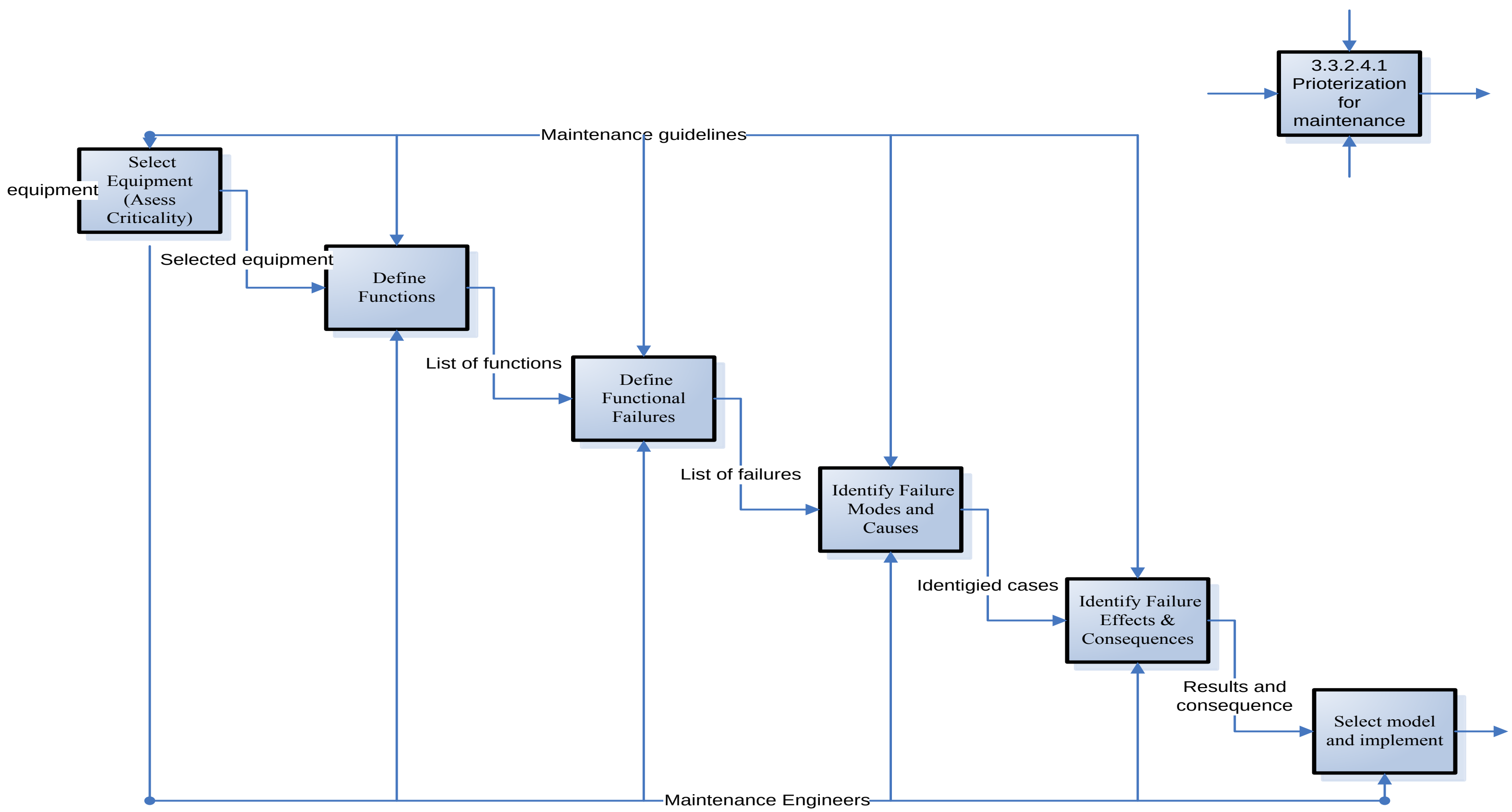


3.3 maintenance
Manuals and guidelines
Maintenance activity
3.3.1 Planned maintenance design
Maintenance plan
Manuals and guidelines
3.3.2 Equipment maintenance cycle
Reviews date
reports
Technical manuals
3.3.3 Unscheduled maintenance initialization
Defective machine
Clinical Engineers, Assigned tech
To be repaired
Technical manual
3.3.4 Repair and Evaluation
Repaired machine
Decision for decommision
Tool kits
Clinical Engineers, Assigned tech

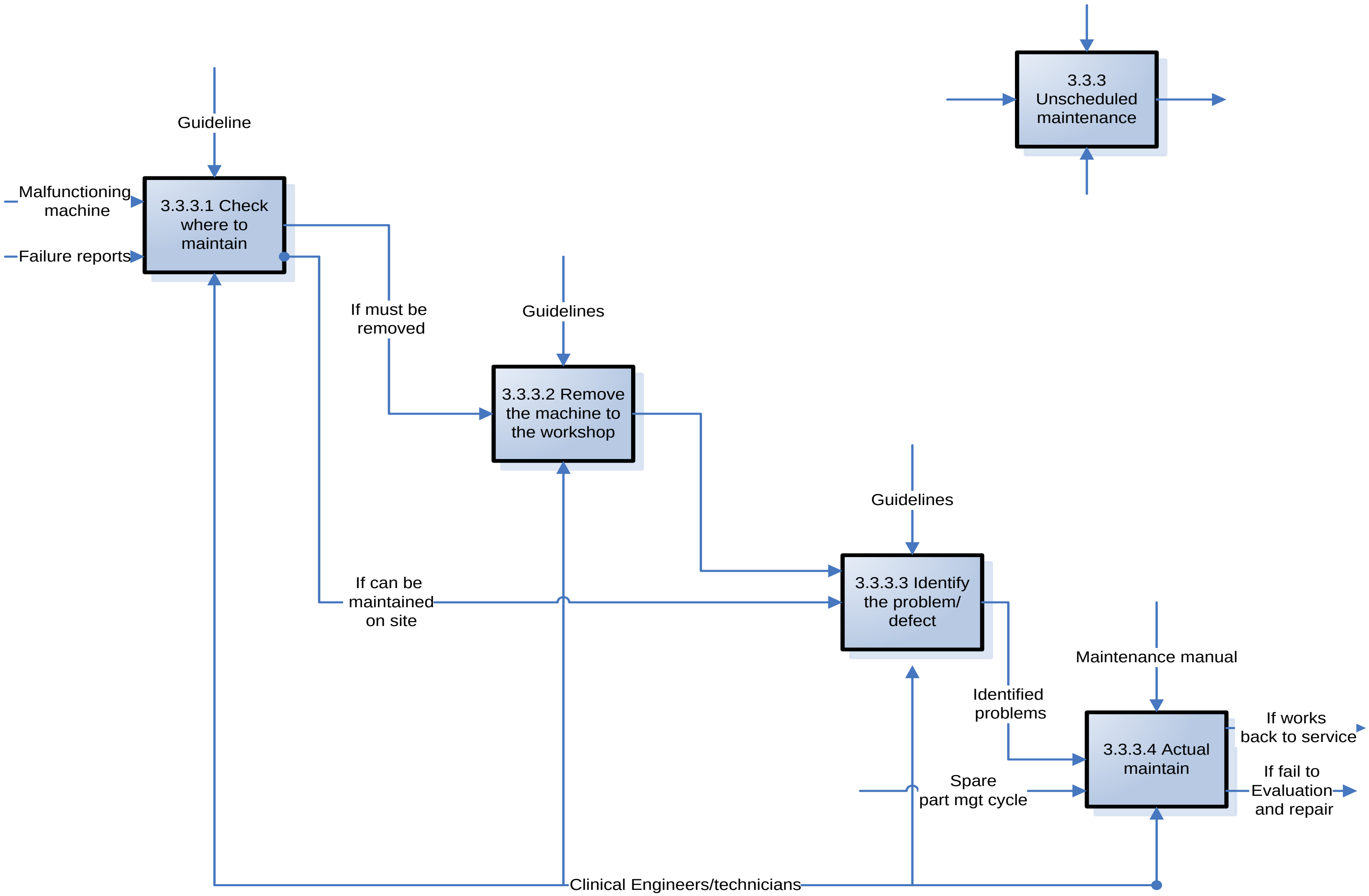

3.3.1 Planned maintenance design
manuals
Equipment record
3.3.1.1 Identify equipments that require maintenance
Clinical engineer /assigned tech
List of equipment
guideline
3.3.1.2 Spare parts management cycle
Required spare parts
Financial guideline
3.3.1.3 Allocate budget and make a plan
Allocated budget
plan
Clinical Engineer /assigned tech
Clinical Engineers/plan experts

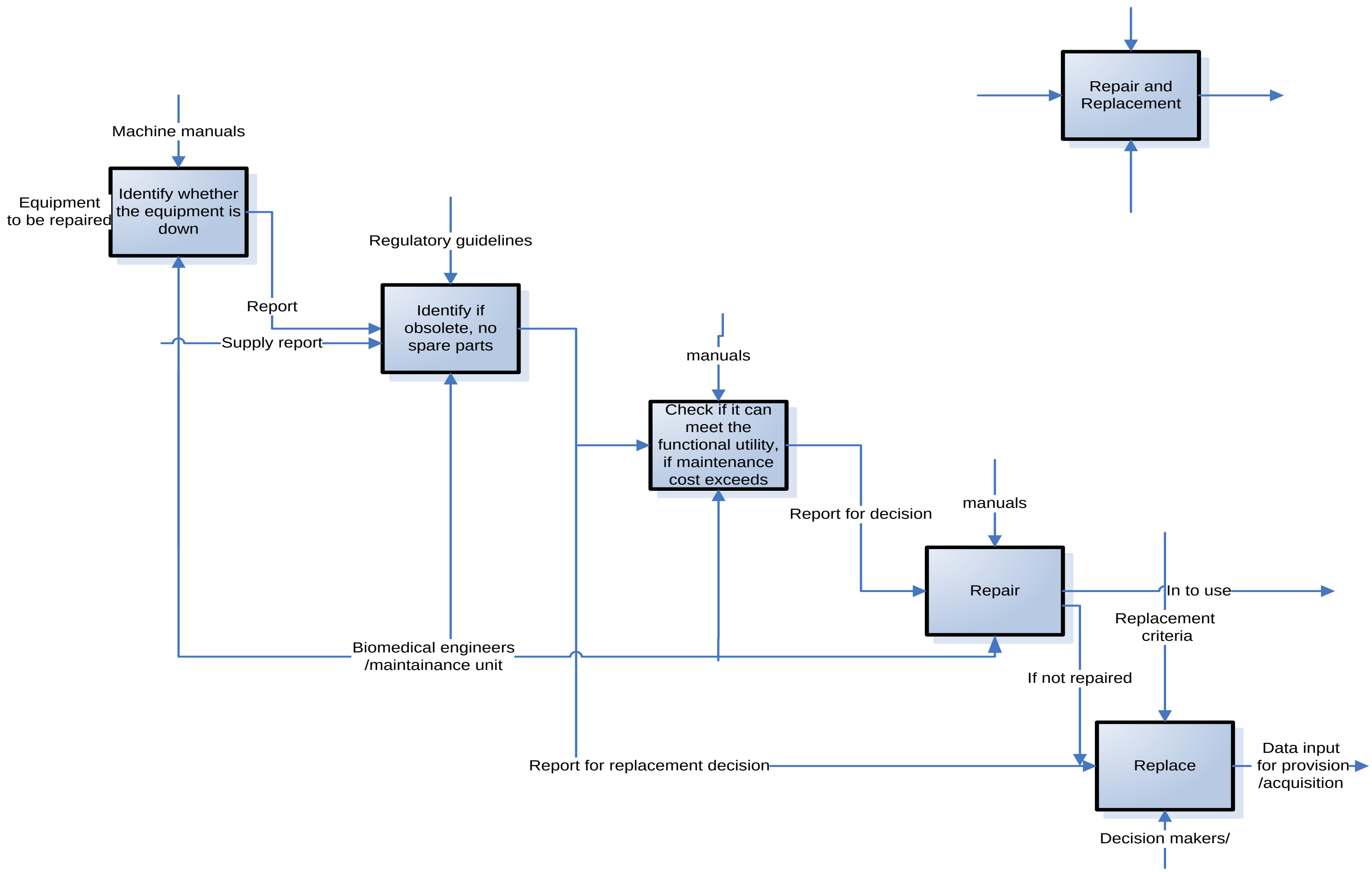

3.3.2 Equipment maintenance cycle
PM manauals
Equipment for PM
toolkits
3.3.2.1 Equipment due for PM
Planned PM report
PM manuals
3.3.2.2.Equipment PM inspection
Inspection report
PM manuals
3.3.2.3 Check inspection
If OK back to service
Maintenance manual
Inspection tools
If fail inspection
3.3.2.4 Maintenance initialization
Schedule rounds
Service calls
To unscheduled maintenance
Clinical engineers/ assigned tech

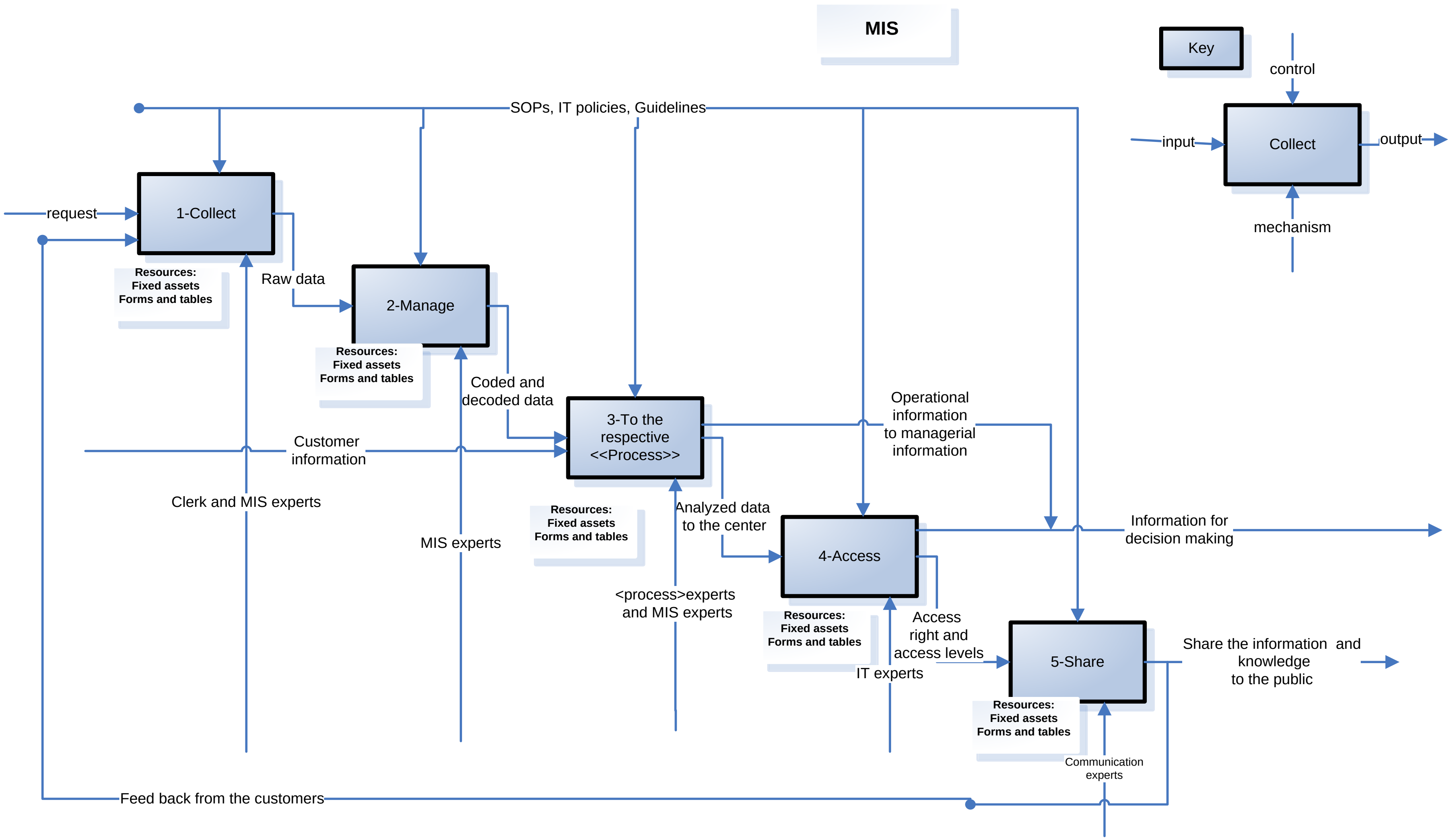

3.3.2.4.
Maintenance
initialization
guidelines
Failure notice
Machine to
be maintained
3.3.2.4.1
Prioriterization
for maintenance
Standard toolkit manuals
Order schedule
for maintenance
3.3.2.4.2
Organizing the
toolkits and
maintenance
tools
Clinical /Biomedical
Engineers
toolkits
manuals
Toolkits and machines
ready for maintenance
3.3.2.4.3
Perform actual
maintenance
If can not maintained,
to decommissioning
Clinical/biomedical
engineers
manuals
Corrected
machines
Manufacturer engineers/
clinical-biomedical engineers
3.3.2.4.4.
Check for
operational
Machine manuals
Operational
machine
Machine operators/
clinical-biomedical
engineers
3.3.2.4.5
Clearance for
use
Ready
for use



3.3.2.4.1 Prioterization for maintenance
Maintenance guidelines
equipment
Select Equipment (Asess Criticality)
Selected equipment
Define Functions
List of functions
Define Functional Failures
List of failures
Identify Failure Modes and Causes
Identigied cases
Identify Failure Effects & Consequences
Results and consequence
Select model and implement
Maintenance Engineers


3.3.3 Unscheduled maintenance
Guideline
Malfunctioning machine
Failure reports
3.3.3.1 Check where to maintain
If must be removed
Guidelines
3.3.3.2 Remove the machine to the workshop
Guidelines
If can be maintained on site
3.3.3.3 Identify the problem/ defect
Maintenance manual
Identified problems
3.3.3.4 Actual maintain
If works back to service
Spare part mgt cycle
If fail to Evaluation and repair
Clinical Engineers/technicians


Repair and Replacement
Machine manuals
Equipment to be repaired
Identify whether the equipment is down
Regulatory guidelines
Report
Identify if obsolete, no spare parts
Supply report
manuals
Check if it can meet the functional utility, if maintenance cost exceeds
Report for decision
manuals
Repair
In to use
Replacement criteria
Biomedical engineers /maintainance unit
If not repaired
Report for replacement decision
Replace
Data input for provision /acquisition
Decision makers/


MIS
Key
control
input
Collect
output
mechanism
SOPs, IT policies, Guidelines
request
1-Collect
Resources:
Fixed assets
Forms and tables
Raw data
2-Manage
Resources:
Fixed assets
Forms and tables
Coded and
decoded data
3-To the
respective
<<Process>>
Customer
information
Clerk and MIS experts
MIS experts
Resources:
Fixed assets
Forms and tables
Operational
information
to managerial
information
Analyzed data
to the center
<process>experts
and MIS experts
4-Access
Resources:
Fixed assets
Forms and tables
Information for
decision making
Access
right and
access levels
IT experts
5-Share
Resources:
Fixed assets
Forms and tables
Share the information and
knowledge
to the public
Communication
experts
Feed back from the customers

Annex C: Source Code

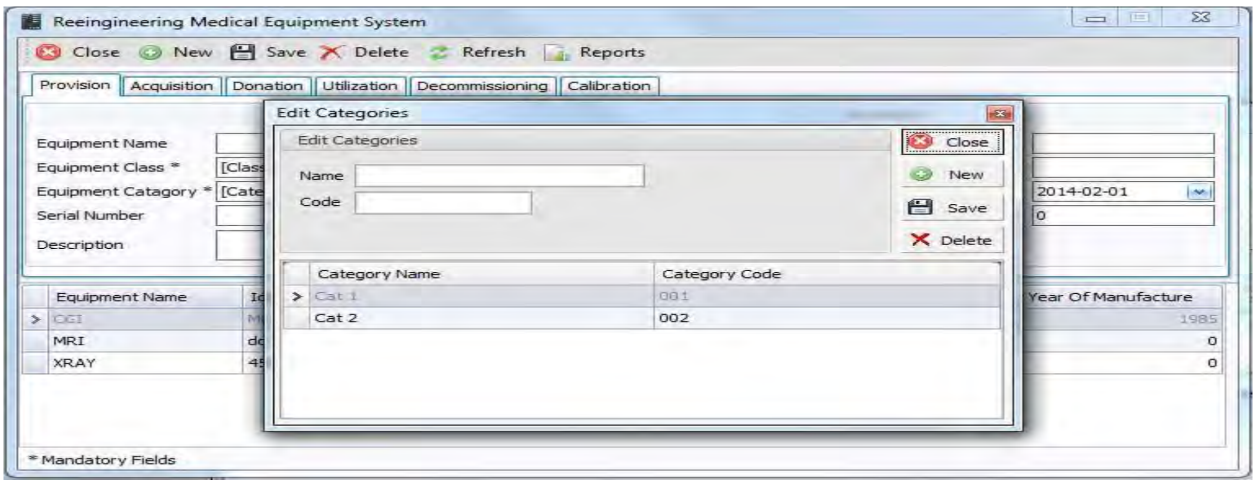
Form Opener Class

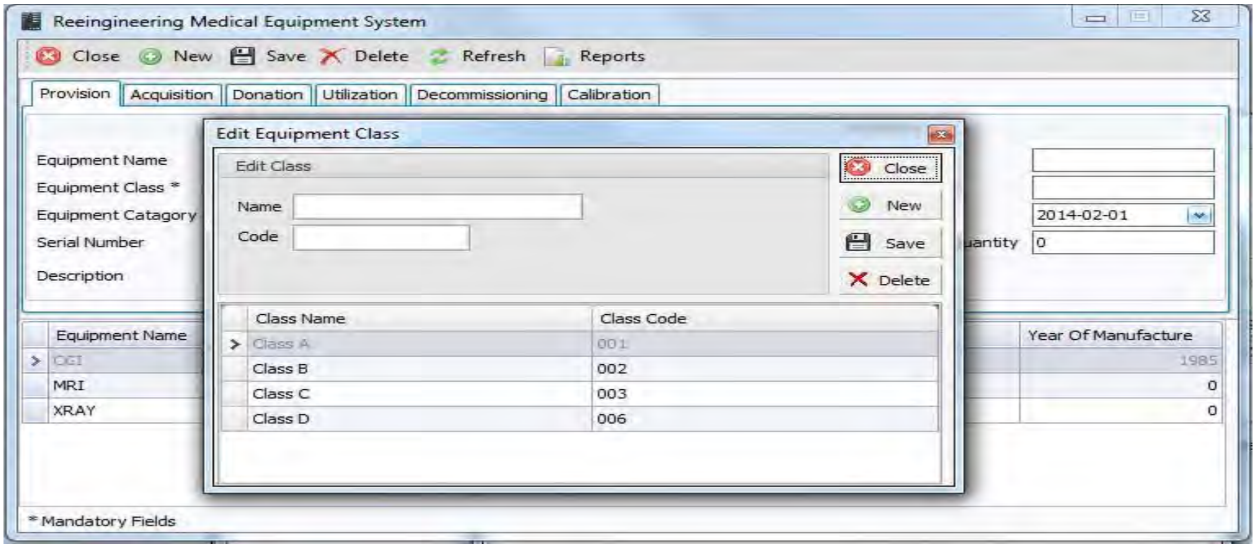
```
//The source code is only a small portion of the software code
using System;
using Enterprise.Framework;
using Enterprise.Framework.UserInterface;
using Enterprise.Framework.UserInterface.Controls;
using System.Windows.Forms;
using System.Drawing;
using System.Drawing.Drawing2D;

namespace HTS
{
    /// <summary>
    /// Contains  methods that enable to Open or display Forms
    /// in the current Application.
    /// </summary>
    public class HTSAppFormOpener : FormOpenerObject
    {
        #region Members
        private Point m_currentLocation;
        #endregion

        #region constructors
        /// <summary>
        /// Creates and initializes a new instance of HTSAppFormOpener class.
        /// </summary>
        /// <param name="application"></param>
        protected internal
HTSAppFormOpener(Enterprise.Framework.UserInterface.UIApplication application) :
            base(application)
        {
        }
        #endregion

        #region properties

        /// <summary>
        /// Gets the reference to the Application that owns the current instance.
        /// </summary>
        public new HTSUIApplication Application
        {
            get { return (HTSUIApplication)base.Application; }
        }


        /// <summary>
        /// Gets the reference to the inner Application object of the current UI
Application.
        /// </summary>
        public new HTSBusiness.HTSApplication InnerApplication
        {
            get { return HTSBusiness.HTSApp.Application; }
        }
```

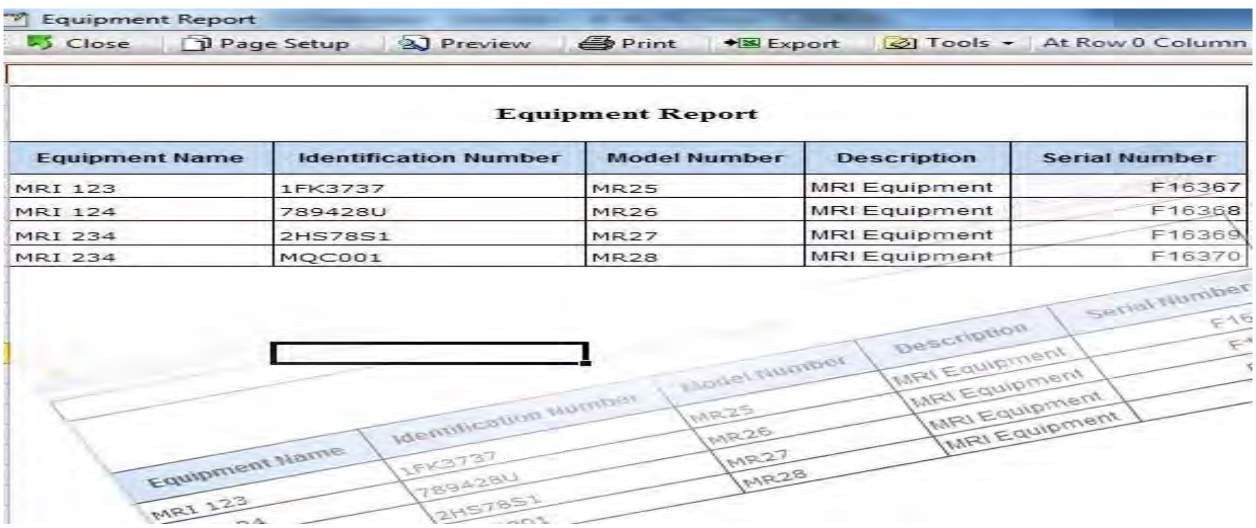
```
        #endregion

        ,,,,,,,,,,,,,,,,,,
tblEquipment";
                        loadDataGrid(queryString);
                    }
                    else
                        MessageBox.Show("One or more mandatory fields are empty. Please fill
all the required fields.", "Error", MessageBoxButtons.OK, MessageBoxIcon.Error);
                }
                catch (Exception ex)
                {
                    MessageBox.Show(ex.Message);
                }
        }

        private void radioButton4_CheckedChanged(object sender, EventArgs e)
        {
            if (radioButton4.Checked == true || radioButton2.Checked == true ||
radioButton6.Checked == true)
            {
                xtraTabControl2.TabPages[1].PageEnabled = true;
            }
            else
            {
                xtraTabControl2.TabPages[1].PageEnabled = false;
            }
        }

        private void radioButton2_CheckedChanged(object sender, EventArgs e)
        {
            if (radioButton4.Checked == true || radioButton2.Checked == true ||
radioButton6.Checked == true)
            {
                xtraTabControl2.TabPages[1].PageEnabled = true;
            }
            else
            {
                xtraTabControl2.TabPages[1].PageEnabled = false;
            }
        }

        private void radioButton6_CheckedChanged(object sender, EventArgs e)
        {
            if (radioButton4.Checked == true || radioButton2.Checked == true ||
radioButton6.Checked == true)
            {
                xtraTabControl2.TabPages[1].PageEnabled = true;
            }
            else
            {
                xtraTabControl2.TabPages[1].PageEnabled = false;
            }
        }

        private void radioButton10_CheckedChanged(object sender, EventArgs e)
        {
```

```
            if (radioButton10.Checked == true )
            {
                xtraTabControl2.TabPages[2].PageEnabled = true;
            }
            else
            {
                xtraTabControl2.TabPages[2].PageEnabled = false;
            }
        }

        private void MainForm_FormClosing(object sender, FormClosingEventArgs e)
        {
            Application.Exit();
        }
    }
}
```

Annex D: Medical Information System Windows Snapshots




Reeingineering Medical Equipment System
Close New Save Delete Refresh Reports
Provision Acquisition Donation Utilization Decommissioning Calibration
Equipment Name
Equipment Class *
Equipment Catagory
Serial Number
Description
uantity
2014-02-01
0
Edit Equipment Class
Edit Class
Name
Code
Close
New
Save
Delete
Class Name
Class Code
Class A 001
Class B 002
Class C 003
Class D 006
Equipment Name
Year Of Manufacture
CGI 1985
MRI 0
XRAY 0
* Mandatory Fields


Equipment Report
Close Page Setup Preview Print Export Tools At Row 0 Column
Equipment Report
Equipment Name
Identification Number
Model Number
Description
Serial Number
MRI 123 1FK3737 MR25 MRI Equipment F16367
MRI 124 789428U MR26 MRI Equipment F16368
MRI 234 2HS78S1 MR27 MRI Equipment F16369
MRI 234 MQC001 MR28 MRI Equipment F16370