

## Fact finding and needs assessment of Medical Equipment Program in the six targeted Governorates

*“Anbar, Al Diwaniyah, Kerbala, Salah Al-Din, Sulaymaniyah and Thi-Qar”*

### PERFACE

Technologies changes in all area including medical devices have proceeded, and will continue to proceed, at a rapid pace. Medical devices usually are associated with diagnostic or therapeutic devices or procedures. With the continuing technology advances, there is a continuously growing gap to efficiently manage the medical equipment activity services in Iraq. National systems for appropriate health technology transfer to local circumstances and conditions in the light of available national resources, infrastructure, knowledge and skills are not in place. Because of a lack of such system and mechanism, precious resources are wasted by introducing technologies and purchasing medical devices that are not appropriate to local conditions, improperly reconditioned or have reduced life expectancies.

Iraq does not have a comprehensive national health care technology policy that maps out national vision and strategy for rational introduction and application of technology, although initial efforts have started in this respect.

This document outline the needs assessment carried out on the medical equipment activity services in the Departments of Health at Anbar, Al Diwaniyah, Kerbala, Salah Al-Din, Sulaymaniyah and Thi-Qar. It summarizes the assessment on managing medical equipment activity services and set guidelines for good management practice (GMtP) for medical devices.



Map of Iraq indicating targeted Governorates

## **1. INTRODUCTION**

Health care systems everywhere face the twin problems of increasing patient needs and expectations and the consequent rising costs. Much of rising expenditure on health is associated with increasing sophistication of the technologies used in diagnosis, treatment and care. A fact finding and needs assessment of medical equipment activity services is needed for each of the 6 targeted governorates to establish the basis for prioritizing activities and allocating resources (physical, financial and human). The needs assessment will provide essential baseline data against which a time-bound plan of action for the implementation of the different project components can be determined.

The term “fact finding” in this instance is defined as the procedures, data collection and assessments necessary to provide a reasonable summary of the current state of medical equipment divisions and physical infrastructure, including its management in the six targeted governorates.

This needs assessment is been conducted as part of the UNDG ITF project “Support to improving Management and Safe Use of medical equipment targeting six governorates in Iraq “Anbar, Al Diwanayah, Kerbala, Salah Al-Din, Sulaymaniyah and Thi-Qar”.

## 2. CONTENT OF ASSESSMENT

The process of fact finding and needs assessment started with familiarization of targeted six DoH's staff on using WHO assessment tool aiming at providing qualitative and quantitative information on the status of medical equipment program at selected DoH's in terms of structure, planning, staffing and sets recommendations for a good management practice.

Iraq is one of the countries in the eastern Mediterranean region in which the management of health care technology is limited by lack of: national policy, suitable organizational structures, Computerized Maintenance Management System, staff with relevant skills; and education and training programmes.

Rational planning of technology for health care has been impossible to achieve, and use of resources has been less than optimal.

Promoting technical support services to deal with maintenance and repair of medical equipment alone without considering the broader focus on health technology management in all aspects would not address the challenges in the domain of management of health care technology.

Standardization of health care technology is essential for improving asset management, maintenance and use. The choice of public health and clinical interventions, and associated technology modalities, should be governed by the health care needs of the population (based on local disease patterns), available health care services, cost, affordability, cost-effectiveness and equity considerations. Therefore health care technology assessment should be concerned with justification of purpose, quality, cost-effectiveness and health outcomes, in accordance with priority needs, effectiveness and impact. Without these considerations standardization is difficult to achieve.

The lack of national policy on medical devices for rational acquisition associated with a formal technology assessment has meant that precious resources has been wasted by purchasing substandard and improperly reconditioned medical devices.

Major investment in expensive equipment is often made without careful assessment and evaluation of the total costs of ownership. The equipment is then not used to its full potential, or not used at all, because necessary consumables have not been provided, or appropriately trained personnel are not available.

The fact finding needs assessment of medical equipment program at country level and targeted DoH's is presented here below:

## 2.1. Country Assessment

The country assessment represents key areas of information and resources for medical equipment management; see attached Annexes I and II.

Annex I shows the assessment on managing Health Care Technologies (Medical Equipment) in terms of resources needed to perform the clinical equipment management services:

Fundamental resources:

(1) Staffing, (2) Space, (3) Test equipment, (4) Tools, (5) Communications equipment, (6) Training, and (7) Computerized maintenance and management system.

Annex II shows the elements for Good Management Practice (GMtP) for Medical Equipment. Successful program on medical equipment depends on access to relevant information, sound criteria for priority setting and national commitment for implementation.

Iraq needs to have a structured review of existing system in place and establish a Medical Equipment Management body to look after the technologies before the time of purchase and lasts through the life of the equipment, including the repair and maintenance process.

An accurate needs assessment is needed to establish the basis for prioritizing activities, improving effectiveness of use, and allocating physical, financial and human resources. Needs assessment can also provide essential baseline data against which policies and actions to bring about desired improvements in the performance of a system can be determined.



### National policy on health technology

**Health Technology (medical device) national policy:** Not available, however development of a national strategy and comprehensive review of all procedures and regulations for management of medical equipment has started and to be completed by end of 2012.



### Regulatory agency

**Name of principal institution:** The State Company for Provision of Medicines and Medical Appliances (KIMADIA) is adapting regulations for procurement circulated by the Ministry of Planning. For regulations and procedures within the MoH the Directorate of Technical Affairs takes the lead.



### National health technology units

National health technology unit(s): Yes

Medical equipment allocation



Technical specification



User training



Health technology assessment



	Medical equipment allocation	Technical specification	User training	Health technology assessment
Unit/department: Directorate of Technical Affairs Contact: Dr. Iman M. Hussein Email: <a href="mailto:consultivedep@yahoo.com">consultivedep@yahoo.com</a>	Yes	Yes	Yes	-
Unit/department: Technical Department / Directorate of Technical Affairs Contact: Eng. Husham J. Khalaf Email: <a href="mailto:h_aljabiry@yahoo.com">h_aljabiry@yahoo.com</a>	-	Yes	-	-
Unit/department: State Company for Provision of Medicines and Medical Appliances (KIMADIA) Contact: Eng. Kadhim D. Sharz Email: <a href="mailto:kimadia_engineering@yahoo.com">kimadia_engineering@yahoo.com</a>	-	-	Yes	-
Unit/department: Directorate of Engineering Projects Contact: Eng. Mohammed Rasheed AL-Mozan Email: <a href="mailto:mohammed_246rk@yahoo.com">mohammed_246rk@yahoo.com</a>	-	Yes	Yes	-



## Medical device incorporation

### Procurement

Policy or guideline: Yes

National level procurement: Yes

### Donations

Policy or guideline: Not available

### List of Approved Medical Devices for Procurement or reimbursement

List available: Yes, but it is only a recommendation

Unit name: Technical Affairs (Department of Medical Equipment Management and Needs Assessment)

### Technical Specifications

Technical specifications to support procurement or donations: Yes, but not publicly available. A comprehensive review of medical equipment specifications are undergoing and once finalized will be posted on MoH website

Reference: Department of Medical Equipment Management



## Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Medical equipment management unit: Yes



### Medical devices

	Public sector	Private sector	Total	Density per 1,000,000 population
Magnetic Resonance Imaging	55	N/A	55	1.7887
Computerized Tomography Scanner	75	N/A	75	2.4392
Positron Emission Tomography Scanner	0	N/A	0	0
Nuclear medicine	5	N/A	5	0.1626
Mammograph	49	N/A	49	1.5936
Linear accelerator	4	N/A	4	0.1301
Telecobalt unit (Cobalt-60)	2	N/A	2	0.065



## List of medical devices

### National Lists of medical Devices for Different types of healthcare facilities

Lists available: Yes

Link to document: [http://www.who.int/medical\\_devices/survey\\_resources/medical\\_devices\\_by\\_facility\\_iraq.pdf](http://www.who.int/medical_devices/survey_resources/medical_devices_by_facility_iraq.pdf)

### National Lists of recommended medical Devices for specific Procedures:

Lists available: No



## Medical device nomenclature system

Official nomenclature system for medical devices: No, however MoH is working on adapting the Universal Medical Devices Nomenclatures System (UMDNS).

## 2.2 Fact finding and needs assessment at targeted Departments of Health

The conducted fact finding and needs assessment of 6 targeted governorates (Anbar, Kerbala, Al Diwaniyah, Salah Al-Din, Sulaymaniyah and Thi-Qar) built the basis to put in place a time-bound draft plan of action for the implementation of the different project components of the UNDG-ITF project titled “Support to improving Management and Safe Use of Medical Equipment.

The fact finding and needs assessment of medical equipment program at 6 targeted governorates

- The 6 targeted governorates have almost same service level and sub-sections. The Medical Equipment Division (ME) is part of the Department of Engineering and Maintenance at the DoH level. In general the ME Division should be made of maintenance and monitoring units, nonetheless officially such structure is not available and staff is assigned to specific tasks on ad hoc basis as deem necessary by the head of division. The maintenance unit consists of small specialized teams’ e.g. imaging, laboratory, dental, and general.
- At least each hospital has an in-house ME unit for maintenance and repair activities.
- At least 355 staff between engineers and technicians is working within at the targeted governorates in the area of management and maintenance of ME to serve 54 Hospitals, 31 districts, and 13 specialized centers.
- At least 99 staff between engineers and technicians is working within the ME Division at the DoH central level.
- At least 12% of staff working at the ME Divisions and units of DoH is female.

DoH's	Anbar	Al Diwaniyah	Kerbala	Salah Al-Din	Sulaymaniyah	Thi-Qar
Staffing	84	34	42	36	51	108

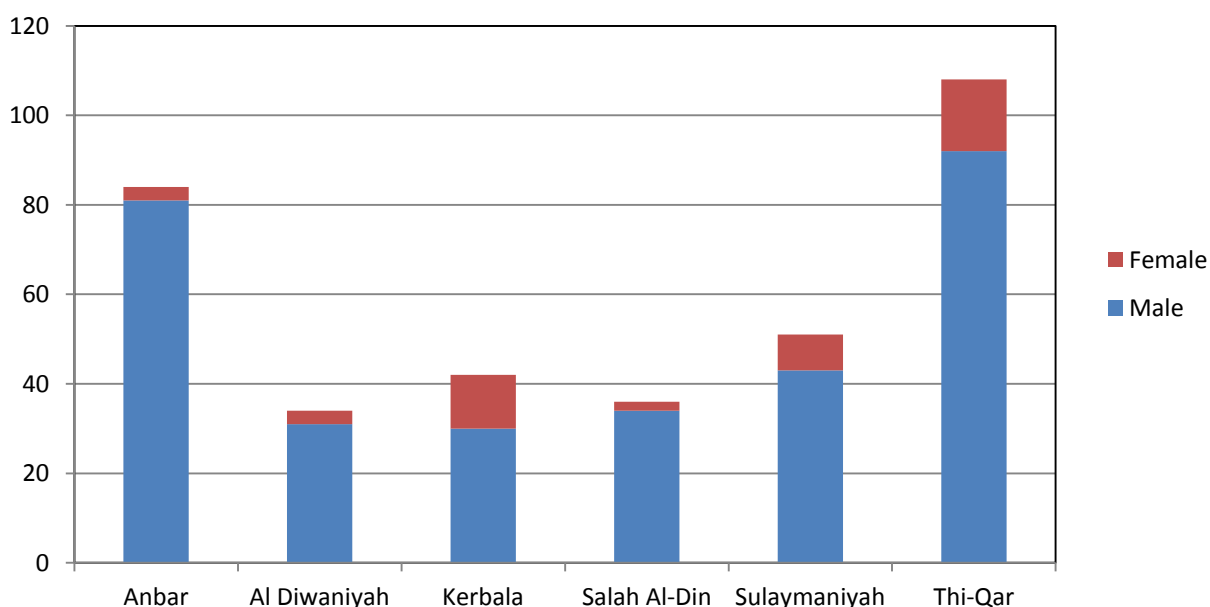


Figure 1- Male and Female staffing

- At least 4 ME Divisions (Anbar, Al-Diwaniyah, Kerbala and Salah Al-Din) do not have official organogram (official administrative structure).
- At least 2 ME Divisions (Sulaymaniyah and Salah Al-Din) are somehow satisfied with the physical building of the maintenance repair shop.
- At least 2 governorates need provision of furniture for the ME division and training hall.
- At least 1 governorate (Anbar) has the need for a separate store.
- At least 1 governorate (Al-Diwaniyah) prefers to keep the location of ME division within the Department of Engineering and Maintenance.
- All governorates do not have biomedical test instruments to ensure accurate measurements and functioning of medical equipment at healthcare facilities.
- All governorates do not have a ME management software used in public institutions. All maintenance activities are recorded manually and mainly 3 special forms are available for this purpose (report on equipment fault, technical inspection and repair accomplished).
- All ME Divisions require provision of informatics equipment.
- At least 4 ME Divisions (Anbar, Al-Diwaniyah, Salah Al-Din and Sulaymaniyah) do not have specified vehicle to facilitate repair and maintenance activities.
- All ME Divisions do not have evidence-based training needs. Training list is been prepared once new equipment is delivered to health care institutions and many remain unimplemented.
- All ME Divisions have maintenance and repair role and management aspects are rarely practiced.
- At least 2 ME Divisions have a role in preparing technical specifications for procuring medical equipment and be part of the committee for analyzing the tenders.

### **3. ABBREVIATIONS AND ACRONYMS**

DoH: Department of Health

Kimadia: State company for Drugs and Medical Supplies and responsible for maintenance of equipment for whole Iraq.

EHT: Essential Health Technology

ME: Medical Equipment

MoH: Ministry of Health

MOU: Memorandum of Understanding

PSC: Project Steering Committee

TOT: Training of Trainers

WHO: World Health Organization

GMtP: Good management practice



## Assessment on managing Health Care Technologies (Medical Equipment):

## Resources needed to perform the clinical equipment management services:

## Fundamental resources:

(1) Staffing, (2) Space, (3) Test equipment, (4) Tools, (5) Communications equipment, (6) Training, and (7) Computerized maintenance and management system

Description	Existing (in place)	Recommendations for proper managing of medical devices
<b>Structure</b>		
	<p>على مستوى مركز الوزارة: الشركة العامة / كيماديا (استيراد و صيانة الاجهزة الطبية) دائرة الامور الفنية (تقدير الحاجة، لجان استشارية لوضع المواصفات و تحليل العطاءات)</p> <p>على مستوى دوائر الصحة: مدير عام دائرة صحة قسم الهندسة و الصيانة (مدير القسم، ...) شعبة خدمية و طبية و مشاريع، صيانة الابنية، المتابعة، مخازن.</p>	<p>استحداث ادارة او جهة رسمية معنية بالعناية الشاملة بكل ما يخص الاجهزة الطبية المستخدمة في العناية الصحية و الطبية للمريض. مما يجعل فعاليات الاجهزة الطبية تحت اطار موحد و يدعم لتنسيق بين اقسام الاجهزة الطبية في دوائر الصحة المختلفة ضعيف جدا.</p>
<b>Staffing</b>		
<p>* Adequate &amp; appropriate staffing (engineers and technicians)</p> <p>* Salaries</p> <p>* Job description (technicians for P and C maintenance; engineers performs pre-purchase evaluation, management of service contracts, risk management, quality control, education and training, and research and development</p> <p>* Job titles</p> <p>* Staff bonus</p> <p>* # of staff / section depends on level of experience and responsibility of section</p>	<p>رفع توصيات هيكلية لأدارة الاجهزة الطبية: هيكلية كانت موجودة سنة 88/89 فيما يخص المستشفيات و المراكز المتخصصة و الورش المركزية. شعبة/وحدة صيانة الاجهزة الطبية تابعة لمعاون اداري في المستشفى لا اطار او هيكلية واضحة</p> <p>الراتب: كسمل اداري، تعيين درجة 7 : 296000 دينار عراقي + مخصصات؟؟؟؟ غير مشمول بها (المهنية=الخطورة ) بحيث لا تزيد عن 200% من الراتب. الاختصاص و الواجبات على الوحدة: واجبات الوحدة (المختبرية) ... هناك لجان الاستشارية الاستيرادية (لجان فنية بالمشتريات تتضمن اطباء، صيادلة و الخ...)</p> <p>تقييم اداء الموظف / تحفيز غير مطبق غير في بغداد، اربيل، الموصل. المواصفات الفنية تضع من قبل دائرة الامور الفنية. جديدا تم اضافة تحديد مواصفات للشعبة الطبية من اجل رفعها لمجلس البلدية</p>	<p>مراجعة شاملة للهيكلية التي كانت قائمة المخصصات تكون مرتبطة بالعمل الوظيفي و ليس الشهادة</p>
<b>Training</b>		
<p>* % of new employee's in biomedical equipment field</p> <p>* Selection criteria for attending Training</p> <p>* Training program (annual plan, within contracts, continuous education: collaboration with Universities</p>	<p>قسم التخطيط في دائرة الصحة يرسل كتاب باحتياجات التدريب على اساس الطلب. التدريب يجب ان يشمل جوانب الصيانة و الاستعمال بعض الدوائر لها خبرات في مجالات معينة (اسنان ، اشعة ، ....) مهم جدا نقل الخبرات خاصة للاجهزة البسيطة و المتوسطة. الدورات الداخلية و الخارجية: يتم الاختيار على معيار الالزام بمتابعة الدورات و نقل الخبرات الى بيقة العاملين اختيار المرشحين للدورات : حاليا الاكبر عمر له اولوية = مكافاة بدل خدمة؟؟ نقص في العناصر الفنية للورش تعاون موجود في بغداد و التواصل بين الكليات (التكنولوجية، المستنصرية، بغداد..) ، تخطيط على مستوى الوزارة (كيماديا) فقط سياقات للدورات: كانت: دورة كل 3 اشهر</p>	<p>تبادل/نقل الخبرات مهم جدا تقسيم العاملين على تخصصات و التدريب على اساس التخصص كل في مجاله تطبيق مناقلة الخبراء المحليين الى المستشفيات و الدوائر من اجل نقل الخبرات الى المهندسين الجدد (تنسيب) بين مدير عام و اخر الترغيب اقامة دورات مدعومة و مفصل و خطة واضحة تحديد مفهوم التدريب و من يتدرب</p>

<b>Clinical Engineering Space</b>		
<ul style="list-style-type: none"> <li>* Provision of service vs. space implications (locations within health insititute)</li> <li>* Space should allow department's ability to fulfil their objectives</li> </ul>	حاليا المساحة غير مناسبة مع الخدمات المقدمة	الحاجة الى تصميم مثالي
<b>Computerized Maintenance and Management System (CMMS)</b>		
<ul style="list-style-type: none"> <li>* Foundation of successful clinical engineering program</li> <li>* CMMS should permit keeing an equipment inventory, generate work orders, parts inventory, financial tracking capability, PM</li> <li>* Support decisions and recommendations relating to equipment management</li> <li>* Organzing the work of department</li> </ul>	غير متوفر حاليا، مراقبة كاملة لكل الفعاليات غير متوفر الاجهزة المنصوبة عبر الشركات لديها ( history card ) كارت/ملف يشمل كل تفاصيل التركيب و الصيانة خاصة الاجهزة العالية التكاليف و التقنية هناك حالات فردية	فترة الضمان يجب ان تضاف على فترة الصيانة
<b>Test Equipment and Tools</b>		
<ul style="list-style-type: none"> <li>* Test equipment inventory depends upon the kinds of equipment supported by the department.</li> <li>* Suggested list: Digital Multimeter, oscilloscope, patient simulator with ECG and presssure capabilities, ES unit tester, defibrillator output tester, electrical safety analyzer</li> </ul>	الاجهزة المتوفرة قليلة و تشمل Oscilloscope Power supply غير متوفرة الا بشكل ضئيل	تحديد الاحتياج من عدد و اجهزة المعايير
<b>Communications Equipment</b>		
<ul style="list-style-type: none"> <li>* Telephones, computers with internet access, network communication..</li> </ul>	حاسبات و شبكة انترنت متوفر بشكل متفاوت	الحاجة الى دراسة الاحتياج

## Good Management Practice (GMtP) for Medical Devices

Successful program on medical devices depends on access to relevant information, sound criteria for priority setting and national commitment for implementation.

Description	Existing	Recommendations for proper managing of medical devices
<b>Information collection, situation analysis and assessment</b>		
	Structure	1-تشكيل لجنة مركزية لاعادة هيكلة الكيان الاداري و الفني المعني بشؤون الاجهزة الطبية على مستوى الوزارة و الدوائر الصحية. و على ان يكون من ضمن اعضاء هذه اللجنة المهندسين العاملين في مجال الاجهزة الطبية و الدوائر المعنية بفعاليات الاجهزة الطبية (تقدير الحاجة و المواصفات الفنية و الاستيراد، العقود و الصيانة و التخطيط و الخ..).
	Legislation and regulation Procurement procedures	2- من اولويات هذا الكيان اعلاه هو: - مراجعة و استحداث المعايير و لوائح الاجهزة الطبية - وضع البات محددة لشراء/استيراد الاجهزة الطبية و المواد الاحتياطية
	Inventory	3-ستقوم منظمة الصحة العالمية بتزويد الوزارة باستمارات بيانات موحدة للاستبيان عن عدد و حالة الاجهزة الطبية في كافة المؤسسات الصحية في العراق.
<b>Gap identification and prioritization of needs</b>		<b>تقدير الحاجة</b>
National standards	national, standards and recommendations	
National objectives and targets	Disease burden, existing technologies, usage and effectiveness, demography, etc	تحويل اللجنة الاستيرادية الفنية دراسة و تعديل الاحتياج قبل احالة العقد بعد ان يتم تزويدها بالمعلومات الخاصة بموقف تلك الاجهزة من حيث العدد و النوعية و كفاءتها الحالية.
Public health priorities and emergencies		
<b>Implementation stage</b>	Using a policy-making or planning tool that converts prioritized needs into policies & action plan	
Regulatory mechanisms	Effective regulatory mechanisms: for new and/or donated equipment	1-وضع المعايير و لوائح الاجهزة الطبية الخاصة بالشراء/الاستيراد. 2-مراجعة الدليل الخاص بتبرعات الاجهزة المعد من قبل منظمة الصحة العالمية و تطبيقه بما يتناسب مع الوضع في العراق.
Details of needed medical devices		1- في حالة رغبة الدوائر الصحية (او وزارة الصحة لاقليم كردستان فيما يخص دوائر صحة الاقليم) بشراء اجهزة طبية فيجب التنسيق مع كيماديا من الناحية الفنية و من ناحية توفير خدمات ما بعد البيع. كما على الدوائر الصحية التي تقوم بشراء اجهزة طبية بشكل مباشر او عن طريق منح اعلام دائرة الامور الفنية و كيماديا و وزارة الصحة بتفاصيل العقد المبرم مع الشركات المجهزة.
Selection and registration	Procurement mechanisms Procurement and donation guidelines Committees, selection criteria, source of equipment specs	1-تشكيل لجنة لاعتماد مواصفات قياسية للاجهزة الطبية و تطبع في كتيب و توزع على دوائر الصحة و تراجع سنويا. (مع الاستفادة من الخبرات الهندسية الموجودة في اللجان الفنية المعتمدة). 2-اعتماد اجراءات الفحص و القبول المعمول بها في كيماديا فيما يخص الاجهزة الطبية المشتراة من قبل دوائر الصحة و التي تتضمن ادخالها مخزنا بعد اصدار قرار فحص و مطابقة للمادة المستلمة مع العقد المبرم. 3-وضع خطة توريدية شاملة متضمنة الاعمال المعمارية و المدنية و الميكانيكية بما يتناسب مع الاجهزة الطبية و توقيت وصولها و متطلبات تنصيبها و تشغيلها. 4-اشراك مهندسي الاجهزة الطبية في لجان المشاريع اثناء مرحلتي التصميم و التنفيذ لضمان تهيئة مكان نصب الاجهزة الطبية بما يتلائم مع السلامة و متطلبات التنصيب. 5-ضرورة تزويد جميع المؤسسات الصحية بنسخة من العقود للاجهزة الطبية التي يتم استيرادها عن طريق الوزارة (لمعرفة الشركة المجهزة و الوكيلة و التزاماتها بخصوص تفاصيل التنصيب و الصيانة و الضمان).
Procurement policies and procedures		
Inventory and preventive maintenance systems	Medical device management systems	1-الصيانة الوقائية: اعادة تفعيل و تحديث نظام الصيانة الوقائية في المؤسسات الصحية لكافة الاجهزة لتفادي الاعطال المفاجئة التي قد تعيق تقديم الخدمات الصحية.

**Good Management Practice (GMtP) for Medical Devices**

**Successful program on medical devices depends on access to relevant information, sound criteria for priority setting and national commitment for implementation.**

Education and training of healthcare personnel	Human resources management	<p>* تحديد معايير ثابتة لاختيار المرشحين للايفاد او التدريب و استحداث قاعدة بيانات باسماء جميع المهندسين و الفنيين العاملين في الوزارة و دوائر الصحة على اساس التخصصات و عدد الايفادات و عدد سنين الخبرة. و على ان يتم الزام المتدرب بصيانة الاجهزة التي تدرب عليها و تدريب كوادر فنية اخرى من اجل نقل الخبرة.</p> <p>* تحديد ميزانية لتوفير فرص تعليمية (زمالات، دراسات، الخ) داخلية او خارجية من اجل رفع مستوى الكادر الهندسي و الفني.</p> <p>* شمول الكادر الهندسي و الفني العامل في مجال الاجهزة الطبية بمخصصات الخطورة.</p> <p>* وضع/مراجعة نظام فيما يخص الحوافز التشجيعية و المكافآت.</p>
Quality assurance and risk management systems		<p>* اتباع المعايير و لوائح الاجهزة الطبية الدولية المعتمدة فيما يخص سلامة و فعالية الاجهزة الطبية قبل و بعد الاستعمال. واطلاع كافة المستخدمين بالاحطار و المشاكل المتعلقة.</p> <p>* اعتماد اجراءات استهلاك الاجهزة الطبية المنتهية مدة حياتها و المعمول بها في كيماديا على دوائر الصح</p>