

- License from Ministry of Health: Minimum legal standards
- ISO: System
- Accreditation:
 - Services
 - Products
 - Employees

DR. ALİ IRAVUL

Legal Requirements Ministry of Health

Ministry of Health administrates legislations, in order to determine minimum level of standards in Health Institutions.

- Employee Standards
- Infrastructure Standards
- Required Divisions/Departments (Minimum Level)
- Work standards for Institutions
- Emergency Room Services
- Advertisement and PR Services

DR. ALİ IRAVUL

- Only % 1 of failures result from incompetent employees.
- Remaining % 99 results from competent employees that are hardworking with good intentions.
- Processes themselves are main reason of failure.*

*Dr.Lucian Leape, Harvard School of Public Health

DR. ALİ IRAVU

International Standards for Healthcare Institutions

- ISO 9001:2008 Quality Management System
- ISO 15189 Laboratory Accreditation
- Hospital Accreditations (JCI, HKS)
- ISO 14001 Environment Management Systems
- OHSAS 18001 Standards of Safety & Health At Work
- HACCP Safety of Food

DR. ALİ IRAVUL

International Organization for Standardization(ISO)

Quality Management System:

Required management system for an institution to manage and organize quality within.

DR. ALİ IRAVUL

ISO

ISO, is an acronym for an international organization that publishes standards for products, services and systems.

ISO has been established in 1947, with membership of 146 countries. Headquarters of ISO is based in Geneva/Switzerland

What does ISO mean?

- "International Organization for Standardization" acronym for name in English is "IOS",
- In French "Organisation internationale de normalisation" therefore with acronym "OIN"
- but actually derived from Greek word "ISOS" that means equal.

Source: www.iso.org

DR. ALİ IRAVUL

- ISO 9000 standards were prepared in 1979 with participation of 20 members and 10 observers by using standards in UK, Canada, US and Japan.
- Published in 1987
- ISO 9000 standards are widely in use in Health Industry of Turkey.

DR.ALİ IRAVUL

4.4

ISO 9001:2008 Quality Management System

DR. ALİ IRAVUL

Quality Management System

- 4.1. General Requirements
- 4.2. Documentation Requirements
 - 4.2.1. General
 - 4.2.2. Quality Handbook
 - 4.2.3. Documentation Check
 - 4.2.4. Registry Check

DR. ALİ IRAVUL

Management Responsibility

- 5.1. Managerial Obligation
- 5.2. Customer Focus5.3. Quality Policies
- 5.4. Planning
- 5.4. Planning 5.4.1. Quality Targets
- 5.5. Accountability, Authority and Communication
 - 5.5.1. Accountability and Authority
 - 5.5.2. Management Representation 5.5.3. Internal Communication
- 5.6. Managerial Review
 - 5.6.1. General
 - 5.6.2. Review Input
 - 5.6.3. Review Output

DR. ALİ IRAVUL

Resource Management

- 6.1. Resource Supply
- 6.2. Human Resources
 - 6.2.1. General
 - 6.2.2. Competency, awareness and training
- 6.3. Infrastructure
- 6.4. Workplace

Product Realization

- 7.1. Planning phase
- 7.2. Customer Related Processes
 - 7.2.1. Determination of product related requirements
 - 7.2.3. Customer Communication
- 7.3. Design and Development
 - 7.3.1. Planning of design and development
 - $\ \, 7.3.3.\ Output\ of\ design\ and\ development$
 - 7.3.4. Review of design and development
 - 7.3.5. Confirmation of design and development
 - 7.3.6. Applying design and development
 - 7.3.7. Review of changes on design and development

DR. ALİ IRAVUL

Purchasing

- 7.4.1. Purchasing Processes
- 7.4.2. Purchasing Data
- 7.5 . Production and Services Supply
 - 7.5.1. Inspection on Production and Services
 - 7.5.2. Validation of Production and Service Processes
 - 7.5.3. Determination and Traceability
 - 7.5.4. Customer Ownership
 - 7.5.5. Product Care/Cover
- 7.6. Inspection of Observation and Measurement Tools

DR. ALİ IRAVUL

Measurement, analyses and improvement

- 8.1. General
- 8.2. Observation and Measurement
 - 8.2.1. Customer Satisfaction
 - 8.2.2. Internal Inspection
 - 8.2.3. Observation and Measurement of Processes
 - 8.2.4. Observation and Measurement of Products
- 8.3. Inspection of inadequate products
- 8.4. Data Analyses
- 8.5. Improvement
 - 8.5.1. Continuous Improvement
 - 8.5.2. Adjustment activities
 - 8.5.3. Preventive activities

DR. ALİ IRAVUL

Principles of Quality Management

- Customer Focus
- Leadership
- Employee Participation
- Process Approach
- System Approach in Management
- Continuous Improvement
- Realistic Approach in Decision Making
- Supplier Relations with Mutual Benefits

DR. ALİ IRAVUL

- Customer Focus: Institutions depend on their customers therefore
 they need to well understand and meet current and future needs of
 customers and strive for going beyond customer expectations.
- 2. Leadership: Leaders organize, design shared route and objectives.
 Leaders should settle and sustain an environment where employees would be able to participate actions necessary to reach goals and focus on objectives.

DR. ALİ IRAVUI

- **3. Employee Participation:** Employees in all levels should be valued within institution and their participation would enable using their skills most productively for company interests.
- **4. Process Approach:** When activities and related resources are managed as a process, effective successful results can be achieved.

Plan .. Determine Objectives & Processes

Apply.. Apply Processes

Control .. Observe and Measure

Improve.. Supply Continuous Improvement

- **5. Management System Approach:** Defining related processes as a system, enables productive management of meeting goals and efficiency within organizations.
- **6. Continuous Improvement**: Institution should have permanent objectives in order to improve performance continuously

Improvement: Increase in features and characteristics of products and/or increase productivity and efficiency of processes to produce and distribute this products.

DR. ALİ IRAVUL

- **7. Realistic Approach in Decision Making:** Effective decisions should be based on data and analyses of information.
- **8. Supplier Relations with Mutual Benefits:** An institution and its supplier are co-dependent and should establish productive relationships with each other that are based on mutual benefits and values.

DR. ALİ IRAVUL

External Benefits:

- 1. A strong addition to reputation and image,
- 2. Increase in customer satisfaction,
- 3. Increased in customer numbers,
- 4. Increase in competition skills,
- 5. Improvement in supplier relationships.

DR. ALİ IRAVU

Internal Benefits:

- 1. Effective Management
- 2. Improvement in Organizational Culture
- 3. Increase in Quality Awareness
- 4. Better Documentation
- 5. Systematization
- 6. Standardization and Consistency
- 7. Improvement in efficiency, productivity and data gathering
- 8. Within time decrease in costs
- 9. A forward step in Institutionalization

DR. ALİ IRAVUL

- ISO 9001 does not publish features of services as a standard.
- ISO is a certificate for Management System, does not confirm perfection of services or products.

"ISO focuses on system quality rather than product or service quality."

DR. ALİ IRAVU

- ISO is a tool to reach goals not an objective.
- ISO certificate is a first step in road to quality.
- But ISO Quality Management Certificate is very useful to establish quality culture within organization and gather knowledge on documentation principles.

ISO REQUIREMENTS

- QUALITY MANAGEMENT SYSTEM
- MANAGERIAL ACCOUNTABILITY
- RESOURCE MANAGEMENT
- PRODUCT REALIZATION
- MEASUREMENT, ANALYSES AND IMPROVEMENT

DR. ALİ IRAVUL

How to establish Quality Infrastructure?

- Determine/appoint manager(leader)
- Full time visible office to be set
- Quality Council and Audit Committee to be appointed.
- Improved quality plan for hospital
- · Quality becomes a part of Hospital Budget
- Set trainings
- · Appoint workgroups.

DR. ALİ IRAVUL

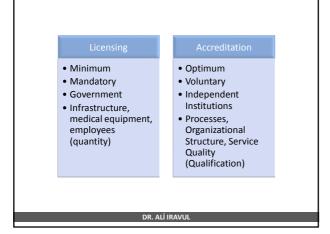
Accreditation

DR. ALİ IRAVUL

ACCREDITATION

Accreditation is an official process of an institution to be acknowledged as suitable with established and published standards by a legal entity that is agreed by all parties. *

*Rooney - vanOstenberg 1999



| First Inspection Year | Programme | # of Program s |
|-----------------------|--|----------------|
| 1951 | USA (JCAHO) | 1 |
| 1958 | Canada | 1 |
| 1974 | Australia (ACHS) | 1 |
| 1979 | USA (AAAHC) | 1 |
| 1986 | Taiwan | 1 |
| 1987 | Australia (QIC) | 1 |
| 1989 | New Zealand | 1 |
| 1990 | UK(HAP) | 1 |
| 1991 | UK (HQS), US (NCQA) | 2 |
| 1994 | South Africa | 1 |
| 1995 | Finland, Korea, Indonesia | 3 |
| 1996 | Argentine, Spain | 2 |
| 1997 | Check Republic , Japan | 2 |
| 1998 | Australia(AGPAL), Brazil, JCI, Poland, Switzerland | 5 |
| 1999 | France, Malaysia, Holland, Thailand, Zambia | 5 |
| 2000 | Portugal ,England (CSBS), Filipinos | 3 |
| 2001 | Bulgaria, Germany , Italy, Ireland | 4 |
| Not available yet | Colombia, Slovakia, Mongolia, Bosnia | 4 |
| Total | | 39 |

Practices regarding accreditation in countries differs in;

- whether being mandatory,
- whether being issues by government offices,
- whether being focused on optimum or basic requirements,
- whether based on outputs or processes,
- whether to improve processes or result in punishments,
- whether detailed accreditation results to be published publicly or to be kept confidential. (Silimperi and Rooney 2003).

DR. ALİ IRAVUL

Accreditation

 Accreditation is a process in which an independent institution evaluates whether a health organization have necessary requirements to improve service quality. Institution which does the evaluation should be independent from health organization to be evaluated, also might be independent from the government authorities.

DR. ALİ IRAVUL

Accreditation

Is a method to commit in

- improving service quality,
- creating secure environment for patients,
- reducing risks that are faced by patients and employees
 with help of an independent organization.

DR. ALİ IRAVU

Accreditation

- Provides a process to evaluate healthcare service organization within specific standards.
- Aim of the programme is to promote continuous and sustainable progress in healthcare services by applying international consensus standards.

DR. ALİ IRAVUI

Accreditation

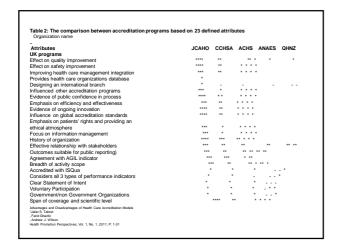
- Logic behind standards depends on quality management and continuous quality improvement.
- Accreditation process is designed to adopt legal, religious or cultural factors within different countries.
- Even though there would be one type of high standards of patient care, country specific factors will be included in accreditation process.

DR. ALİ IRAVUL

Table 1: Frequency of citation of different accreditation programs

| The program name | Frequency | Percent |
|---------------------------|-----------|---------|
| JCAHO and JCI (USA) | 76 | 91.56 |
| CCHSA (Canada) | 17 | 20.48 |
| UK accreditation programs | 16 | 19.27 |
| ACHS (Australia) | 15 | 18.7 |
| QHNZ (New Zealand) | 9 | 10.87 |
| ANAES (France) | 8 | 9.63 |
| COHSASA (South Africa) | 5 | 6.02 |
| Other programs | 11 | 13.25 |
| Total | 83 | 100 |
| | | |

7



Categories of JCI Standards

- Patient Focused Functions
- Healthcare Organization Management Functions

DR. ALİ IRAVUL

Functions that directly satisfy patient needs

- Patient Rights
- Evaluation of patients
- Patient Care
- Training/Education of Patients and their Families
- Sustainable Care

DR. ALİ IRAVUI

Patient Focused Functions

- Access to Services and Sustainability of the Services
- Rights of Patients and their Families
- Evaluation of Patients
 - Clinical Laboratories
 - Radiology
- Patient Care
 - Drug Use
 - Surgery and Anesthesia
- Training/Education of Patients and their Families

DR. ALİ IRAVUL

Healthcare Organization Management Functions

- Quality Improvement and Patient Safety
- Prevention and Control of Infections
- Governance, Leadership & Direction Facility Management and Safety
- Qualification and Education of Employees
- Information Management

DR. ALİ IRAVUL

Organizational Support Functions for Patient Care Functions

- Leadership (inc. strategic planning, policies and strategy.)
- Human Resources Management
- Information Management (inc. medical records and information analyses)
- Environment Management and Security
- Prevention and Control of Infections
- Performance Improvement (inc. process management, customer satisfaction and recovery results)

Standards

- Functions are grouped in whether they are related to safe and trustworthy healthcare provided to patients or effective and well management of organization
- This separation should be done for organization as a whole but also for each division and department.
- Inspection process provides information whether standards are met in this step.
- But accreditation result depends on harmony of function swithin organization as a whole.

DR. ALİ IRAVUL

Access to Care and Continuity of Care (ACC)

Standard

ACC.2.2. Information regarding patient care and patient responses are ought to be shared between doctors, nurses and other healthcare employees between division transfers and shift changes.

Aim of ACC.2.2.

Share of information between healthcare employees is very critical for a continuous healthcare service. Information can be shared orally, written or in electronic devices. All organizations determines how information will be shared.

Shared information includes, Health condition of the patient, A summary of care services given,

Patients response to services

When a patient is transferred within divisions, reason of the transfer must be shared between employees.

Measurement Tools of ACC.2.2

Measurement 100Is of ALL.A.Z.

There is a process to share customer related information throughout service period.

Shared information includes health status of the patient.

Shared information includes a summary of care services given.

Shared information contains recovery status of the patient.

When a patient is transferred within divisions, reason of the transfer is known between employees.

DR. ALİ IRAVUL

Patient and Family Rights (PFR)

- PFR.1 Organization is responsible for providing processes that support patient and family rights.
- PFR.3 Organization is responsible to inform patients and families on options regarding body and tissue donations.
- PFR.4 Organization is responsible to inform patients and families how and why to participate if possible participations in clinical trials are available.
- PFR.10 Organization provides healthcare services considering patient rights, financial, ethical and legal norms.

DR. ALİ IRAVUL

Assessment of Patient (AOP)

- AOP.1 All healthcare needs of patients within the organization are assessed through an organized and pre-determined evaluation process.
- AOP.2 All first examinations of all patients includes physical, social and psychological factors that require physical examine and information gathering regarding health history.

DR. ALİ IRAVUL

Care of Patients (COP)

- **COP.1** Policies and procedures, available legislations guides that all patients should receive same level of care services
- COP.1 Clinic and administrative leaders within the organization co-operate in order to give one type of care process

Even though several different facilities are used care services should be in same level and way

Patient and Family Education (PFE)

- PFE.1 Training supports patient and the family in order to understand and decide on care processes.
- PFE.3 Patient and family education includes subjects that are suitable for patient care;
- Safe use of drugs
- Safe use of medical equipment
- Potential interactions of certain drugs and foods
- Guidance on diet
- Rehabilitation techniques

Quality Management & Improvement (QMI)

- QPS.3.2 Clinical observation includes laboratory and radiology safety and quality control programs
- QPS.4 Individuals who have suitable experience, knowledge and qualifications analyses and gathers organizational information.

DR. ALİ IRAVUL

Prevention and Control of Infection (PCI)

 PCI.1.1 Organization should include all patients, employees and visitors to infection control programme.

DR. ALİ IRAVUL

Governance, Leadership & Direction (GLD)

 GLD.1 Managerial responsibilities are explained by procedures and documents, published legal papers.

DR. ALİ IRAVUL

Facility Management & Safety (FMS)

- Reduction of threats and risks
- Prevention of accidents and injuries
- All staff should be trained about the facility, how to eliminate risks and observation and reporting of situations that might cause risks.

DR. ALİ IRAVUI

Staff Qualifications & Education (SQE)

- Employee recruitment, evaluation and determination are possible to be done effectively and coordinated only by using one type of process. Also it is important to well document qualifications, experience, education and information. It is very important to examine historical data regarding doctors and nurses as this employees are working at core of healthcare services being with interaction to patients all the time.
- Healthcare organizations should provide necessary conditions and opportunities to their employees to improve themselves.

DR. ALİ IRAVU

Management of Information (MOI)

- Providing patient care is a complex effort mostly based on information.
- In order to provide ,co-ordinate and integrate services , health organizations depends on information such as data regarding individual patients, scientific methods of healthcare, list of services that are provided and output and performance results.

ISO-JCI

- ISO standards focuses on specific requirements and ability to meet those requirements. ,
- JCI standards focuses to promote continuous improvement for institutional performance and optimum results.





