

ANNUAL CONFERENCE : QUALITY IMPROVEMENT IN THE MEDICAL SCHOOL
THE ASSOCIATION OF MEDICAL SCHOOLS IN EUROPE (AMSE)

ACCREDITATION OF RESEARCH LABORATORIES
ACCORDING TO ISO – UNE 9000 - 9001

AMSE ANNUAL CONFERENCE
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THE MANAGEMENT OF THE QUALITY IN THE RESEARCH

GENERAL FRAME

THE U.E. CONSIDERS OF VITAL IMPORTANCE THE CONFIDENCE IN THE RESULTS OBTAINED BY THE LABORATORIES OF THE U.E.

STANDARD UNE-EN ISO / IEC 17025 : 2005

ESTABLISHES THE GENERAL REQUIREMENTS RELATIVE TO THE TECHNICAL COMPETITION OF THE LABORATORIES OF TEST AND CALIBRATION THAT E.N.A.C. USES AS CRITERIA FOR THE ACCREDITATION.

STANDARD UNE-EN ISO / IEC 9000 : 2000

DESCRIBES THE FOUNDATIONS OF THE SYSTEMS OF MANAGEMENT OF THE QUALITY AND SPECIFIES YOUR TERMINOLOGY.

THE MANAGEMENT OF THE QUALITY IN THE RESEARCH

GENERAL FRAME

ANY ORGANIZATION THAT TO CARRY OUT THE REQUIREMENTS OF THE STANDAR ISO 17025, BUT NOT INVERSELY.

“IS HERE AN EVIDENCE THAT IS ALSO A NORM”

(Santiago Ramón y Cajal)

THE MANAGEMENT OF THE QUALITY IN THE RESEARCH

GENERAL FRAME

THE LABORATORY OF TEST, CALIBRATION AND MEASUREMENT DEMONSTRATES YOUR TECHNICAL COMPETITION.

YOUR RESULTS ARE SUPPORTED BY NATIONAL ORGANIZATIONS (ENAC) AND INTERNATIONAL (AE).

“SOMETIMES THE DIFFERENCE BETWEEN TRANQUILITY AND RESTLESSNESS CAN SEEM SMALL, BUT INDGED IT IS VERY BIG”.

- ENAC : NATIONAL ENTITY OF ACCREDITATION.
- AE : EUROPEAN COOPERATION FOR ACCREDITATION.

WHAT IS A QUALITY MANAGEMENT SYSTEM?

ISO 9000 DEFINES A QUALITY MANAGEMENT SYSTEM (QMS) AS:

“MANAGEMENT SYSTEM TO DIRECT AND CONTROL AN ORGANIZATION WITH REGARD TO QUALITY”.

IMPLEMENTATION PLAN

- QUALITY COORDINATOR.
- DISCIPLINE TASK TEAMS.
- QUALITY TEAM.
- DEVELOP POLICIES.
- MAP PROCESSES.
- QUALITY MANUAL \Rightarrow PROCEDURES.
- COMMUNICATE, EDUCATE, TRAIN.
- AUDIT.
- ACREDITATION.

STRUCTURE FOR A QUALITY SYSTEM

QUALITY SYSTEM ESSENTIALS (QSE)

- ORGANIZATION.
- PERSONNEL.
- EQUIPMENT.
- PURCHASING / INVENTORY.
- PROCESS CONTROL.
- DOCUMENTS / RECORDS.
- INTERNAL ASSESSMENT.
- PROCESS IMPROVEMENT.
- SERVICE AND SATISFACTION.
- FACILITIES AND SAFETY.
- INFORMATION MANAGEMENT.

STRUCTURE FOR A QUALITY SYSTEM

PATH OF WORKFLOW

- PRE – ANALYTIC.
- ANALYTIC.
- POST – ANALYTIC.
- INFO

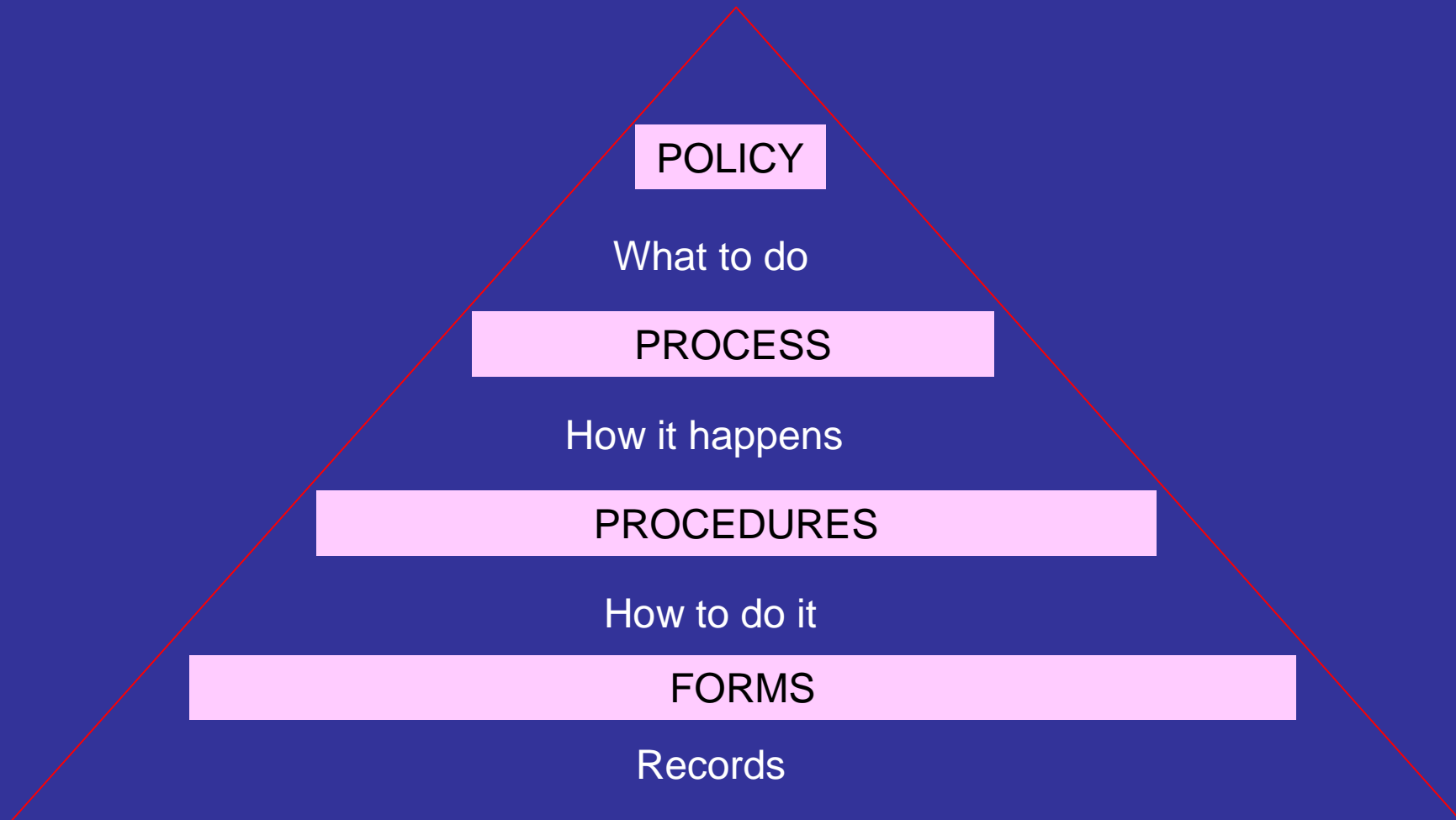
QUALITY SYSTEM ESSENTIAL APPLY TO ALL OPERATIONS IN THE PATH OF WORKFLOW.

QUALITY SYSTEM ESSENTIALS

DOCUMENTS AND RECORDS

- CREATE.
- IDENTIFY.
- CHANGE.
- APPROVE.
- FILE.
- DISTRIBUTE.
- ARCHIVE.

HIERARCHY OF DOCUMENTS



PROCESS MAPPING

- ADDRESS THE PATH OF WORKFLOW.
- DESCRIBE HOW THINGS HAPPEN HERE.
- FLOW CHARTS OR TABLES.

PROCEDURE DEVELOPMENT

- IDENTIFIED FROM PROCESS MAPPING.
- TEMPLATES DEVELOPED BASED ON GUIDELINES.
- USED FOR ANALYTICAL AND NO ANALYTICAL PROCEDURES.

PROCEDURES

- ACCESSIBLE.
- UP TO DATE.
- USER FRIENDLY - ACCURATE.

QSE : PROCESS CONTROL

- LABORATORY PROCESSES AND PROCEDURES.
- VALIDATION.
- ESTABLISHING REFERENCE INTERVALS.
- QUALITY CONTROL.
- INTERNAL AND EXTERNAL QA.
- METHOD COMPARABILITY.
- ACCREDITATION.

QSE : OCCURENCE MANAGEMENT

- QUALITY CONTROL : CORRECTIVE ACTION.
- EXTERNAL AND INTERNAL QUALITY ASSURANCE.
- TURN AROUND TIME DELAY.
- DISCREPANT RESULTS.
- CORRECT RESULTS.
- SPECIMEN REJECTION CRITERIA.

QSE : INFORMATION MANAGEMENT

- RESULTS REPORTING.
- RELEASE OF RESULTS.
- COMPUTER PROCEDURES.
- CHANGE APPROVAL.
- COMPUTER QA.
- COMPUTER SECURITY.
- COMPUTER VALIDATION.

QSE : PURCHASING AND INVENTORY

- INVENTORY CONTROL SYSTEM.
- EXTERNAL SERVICES.
- PURCHASING DOCUMENTS.
- MATERIAL RESOURCES.

QSE : SAFETY

- SAFETY OFFICER, SAFETY COMMITTEE.
- SAFETY MANUAL.
- AUDIT AND INSPECTIONS.
- REPORTING INCIDENTS, ACCIDENTS, ILLNESS.
- TRAINING.
- PERSONNEL RESPONSIBILITIES.

QSE : FACILITIES

- LOCATION AND DESIGN.
- ENVIRONMENTAL CONDITIONS.
- ACCESS.
- COMMUNICATION SYSTEMS.
- STORAGE.
- COMPUTER ENVIRONMENT.

QSE : EQUIPMENT

- EQUIPMENT SELECTION.
- CALIBRATION.
- VERIFICATION.
- VALIDATION.
- INVENTORY.
- EQUIPMENT OPERATION MAINTENANCE AND RECORDS.
- DEFECTIVE EQUIPMENT.

QSE : PERSONNEL

- JOB DESCRIPTION.
- QUALIFICATIONS.
- TRAINING.
- COMPETENCE.
- CONTINUING EDUCATION.
- PERSONNEL RECORDS.
- PERFORMANCE APPRAISAL.

QSE : ORGANIZATION

- LICENSE.
- MISSION STATEMENT.
- ACCREDITATION.
- ORGANIZATIONAL STRUCTURE.
- RESOURCE ALLOCATION.
- REFERRAL LABORATORIES

QSE : ASSESSMENT

- QUALITY INDICATORS.
- INTERNAL AUDITS.
- MANAGEMENT REVIEW.

QSE : PROCESS IMPROVEMENT

- QUALITY IMPROVEMENT ACTIVITIES.
- OCCURRENCE MANAGEMENT.
- PROBLEM SOLVING.

QSE : SERVICE AND SATISFACTION

- CUSTOMER SATISFACTION.
- INTERNAL AND EXTERNAL.

RESOURCE MATERIAL

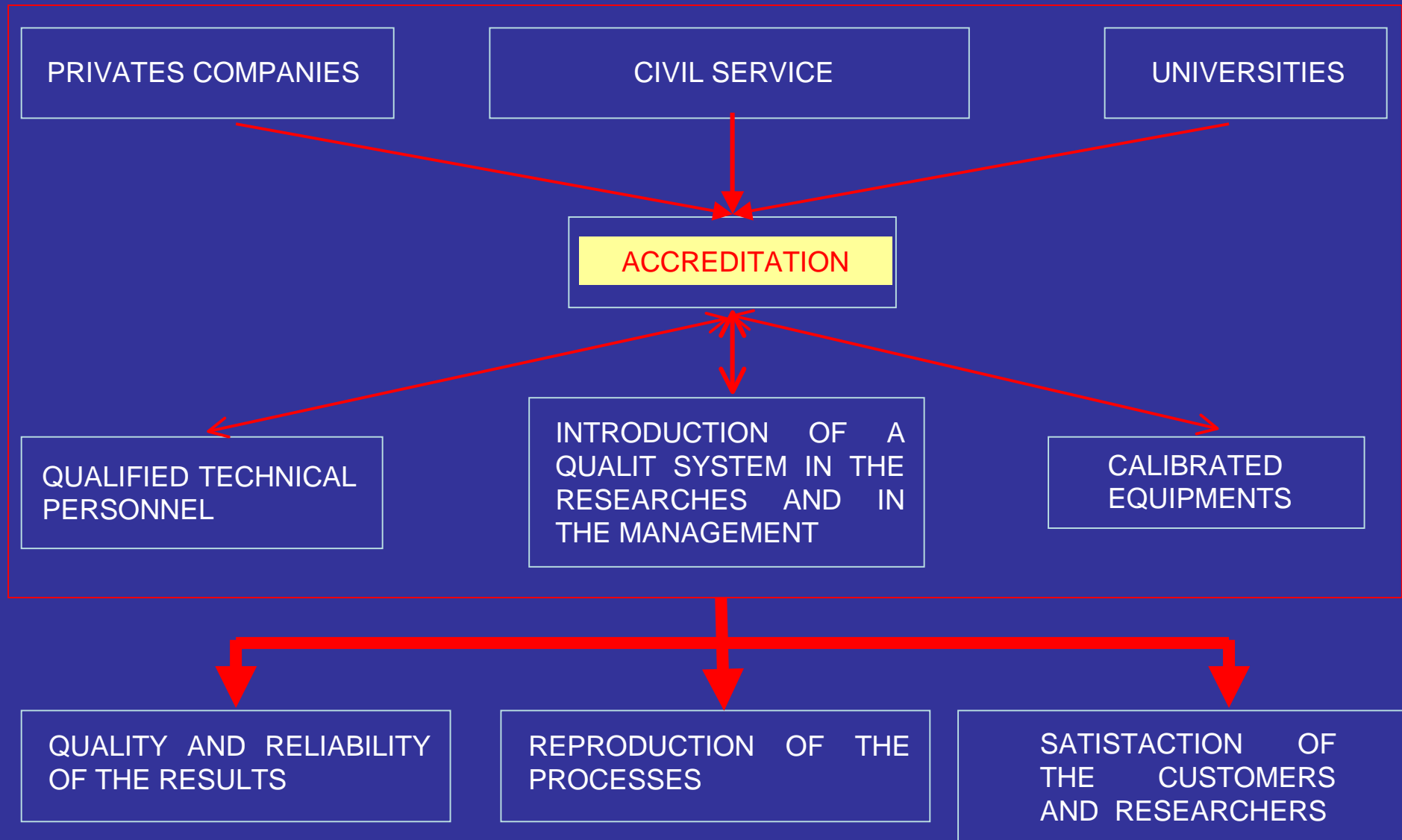
- ISO DOCUMENTS :

9001 : 2000

PHASES OF THE ACREDITATION

1. THE LABORATORY IMPLEMENTS YOUR QUALITY SYSTEM.
2. ENAC FIXES THE PROCEDURE.
3. THE LABORATORY DELIVERS YOUR QUALITY MANUAL.
4. ENAC EVALUATES THE DOCUMENTATION.
5. THE LABORATORY EVALUATES THE REPORT OF THE AUDIT.
6. ENAC AUTHORIZES / REJECTS THE ACCREDITATION.

THE WAY OF THE ACCREDITATION



TO ERR IS HUMAN : BUILDING A SAFER HEALTH SYSTEM

HEALTH CARE IN THE UNITED STATES(*) IS NOT AS SAFE AS IT SHOULD BE AND CAN BE

AT LEAST 44,000 PEOPLE, AND PERHAPS AS MANY AS 98,000 PEOPLE, DIE

IN HOSPITALS EACH YEAR AS A RESULT OF MEDICAL ERRORS

THAT COULD HAVE BEEN PREVENTED, ACCORDING TO ESTIMATES FROM TWO MAJOR STUDIES.

EVEN USING THE LOWER ESTIMATE, PREVENTABLE MEDICAL ERRORS IN HOSPITALS EXCEED ATTRIBUTABLE DEATHS TO SUCH FEARED THREATS AS MOTOR – VEHICLE WRECKS, BREAST CANCER, AND AIDS.

(*) To Err Is Human: Building a Safer Health System”. National Academy Press. (2000) The full text of this report is available www.nap.edu

TO ERR IS HUMAN : BUILDING A SAFER HEALTH SYSTEM

MEDICAL ERRORS CAN BE DEFINED AS THE FAILURE OF A PLANNED ACTION TO BE COMPLETED AS INTENDED OR THE USE OF A WRONG PLAN TO ACHIEVE AN AIM.

RESULT IN TOTAL COSTS (INCLUDING THE EXPENSE OF ADDITIONAL CARE NECESSITATED BY THE ERRORS, LOST INCOME AND HOUSEHOLD PRODUCTIVITY, AND DISABILITY) OF BETWEEN:

\$ 17 BILLION AND \$ 29 BILLION PER YEAR IN HOSPITALS NATIONWIDE.

TO ERR IS HUMAN : BUILDING A SAFER HEALTH SYSTEM

ERRORS ALSO ARE COSTLY IN TERMS OF LOSS OF TRUST IN THE HEALTH CARE SYSTEM BY PATIENTS AND DIMINISHED SATISFACTION BY BOTH PATIENTS AND HEALTH PROFESSIONALS:

1. PATIENS WHO EXPERIENCE A LONG HOSPITAL STAY OR DISABILITY AS A RESULT OF ERRORS PAY WITH PHYSICAL AND PSYCHOLOGICAL DISCOMFORT.

2. HEALTH PROFESSIONALS PAY WITH LOSS OF MORALE AND FRUSTRATION AT NOT BEING ABLE TO PROVIDE THE BEST CARE POSSIBLE.

3. SOCIETY BEARS THE COST OF ERRORS AS WELL, IN TERMS OF LOST WORKER PRODUCTIVITY, REDUCED SCHOOL ATTENDANCE BY CHILDREN, AND LOWER LEVELS OF POPULATION HEALTH STATUS.

PROGRESS UNDER WAY

IN DECEMBER 2000 CONGRESS OF US IT APPROPRIATED \$ 50 MILLION TO THE AGENCY FOR HEALTH CARE RESEARCH AND QUALITY (AHRQ) TO SUPPORT A VARIETY OF EFFORTS TARGETED AT REDUCING MEDICAL ERRORS.

THE AHRQ ALREADY HAS MADE MAJOR PROGRESS IN DEVELOPING AND IMPLEMENTING AN ACTION PLAN. EFFORTS UNDER WAY INCLUDE:

1. DEVELOPING AND TESTING NEW TECHNOLOGIES TO REDUCE MEDICAL ERRORS.
2. CONDUCTING LARGE-SCALE DEMONSTRATION PROJECTS TO TEST SAFETY INTERVENTIONS AND ERROR-REPORTING STRATEGIES.

PROGRESS UNDER WAY

3. SUPPORTING NEW AND ESTABLISHED MULTIDISCIPLINARY TEAMS OF RESEARCHER AND HEALTH-CARE FACILITIES AND ORGANIZATIONS, LOCATED IN GEOGRAPHICALLY DIVERSE LOCATIONS, THAT WILL FURTHER DETERMINE THE CAUSES OF MEDICAL ERRORS AND DEVELOP NEW KNOWLEDGE THAT WILL AID THE WORK OF THE DEMONSTRATION PROJECTS.
4. SUPPORTING PROJECTS AIMED AT ACHIEVING A BETTER UNDERSTANDING OF HOW THE ENVIRONMENT IN WHICH CARE IS PROVIDED AFFECTS THE ABILITY OF PROVIDERS TO IMPROVE SAFETY.
5. FUNDING RESEARCHERS AND ORGANIZATIONS TO DEVELOP, DEMONSTRATE, AND EVALUATE NEW APPROACHES TO IMPROVING PROVIDER EDUCATION IN ORDER TO REDUCE ERRORS.

PLAN OF IMPLANTATION OF THE QUALITY SYSTEM IN A PUBLIC ORGANISM OF RESEARCH

1. QUALITY MANUAL.
2. MANAGEMENT OF THE DOCUMENTATION OF THE QUALITY.
3. INTERNAL AND EXTERNAL COMMUNICATION.
4. MANAGEMENT OF THE INTERNAL TRAINING.
5. RESOURCE MANAGEMENT.
6. EVALUATION, FOLLOW-UP AND CLOSING OF THE PROJECTS.
7. EXECUTION AND PROJECT CONTROL.
8. RENDERING OF TECHNICAL EXTERNAL SERVICES.
9. R&D AGREEMENTS.
10. MANAGEMENT OF THE CLIENT'S SATISFACTION.

PLAN OF IMPLANTATION OF THE QUALITY SYSTEM IN A PUBLIC ORGANISM OF RESEARCH

11. DESIGN AND DEVELOPMENT.
12. MANAGEMENT OF THE PURCHASES.
13. EVALUATION OF THE SUPPLIERS.
14. INSPECTION OF RECEIPT.
15. MANAGEMENT OF STORAGE AND DISTRIBUTION.
16. CONTROL OF EQUIPMENT OF MEASUREMENT AND FOLLOW-UP.
17. MANAGEMENT OF THE EXTERNAL DOCUMENTATION.
18. INTERNAL AUDITS.
19. MANAGEMENT OF NOT CONFORMITIES.
20. CORRECTIVE AND PREVENTIVE ACTIONS.

QUALITY MANAGEMENT – ISO 9001

WORLD BALANCE OF IMPLANTATION OF THE STANDARD ISO 9000 : 2000 AND ISO 9001 : 2000.

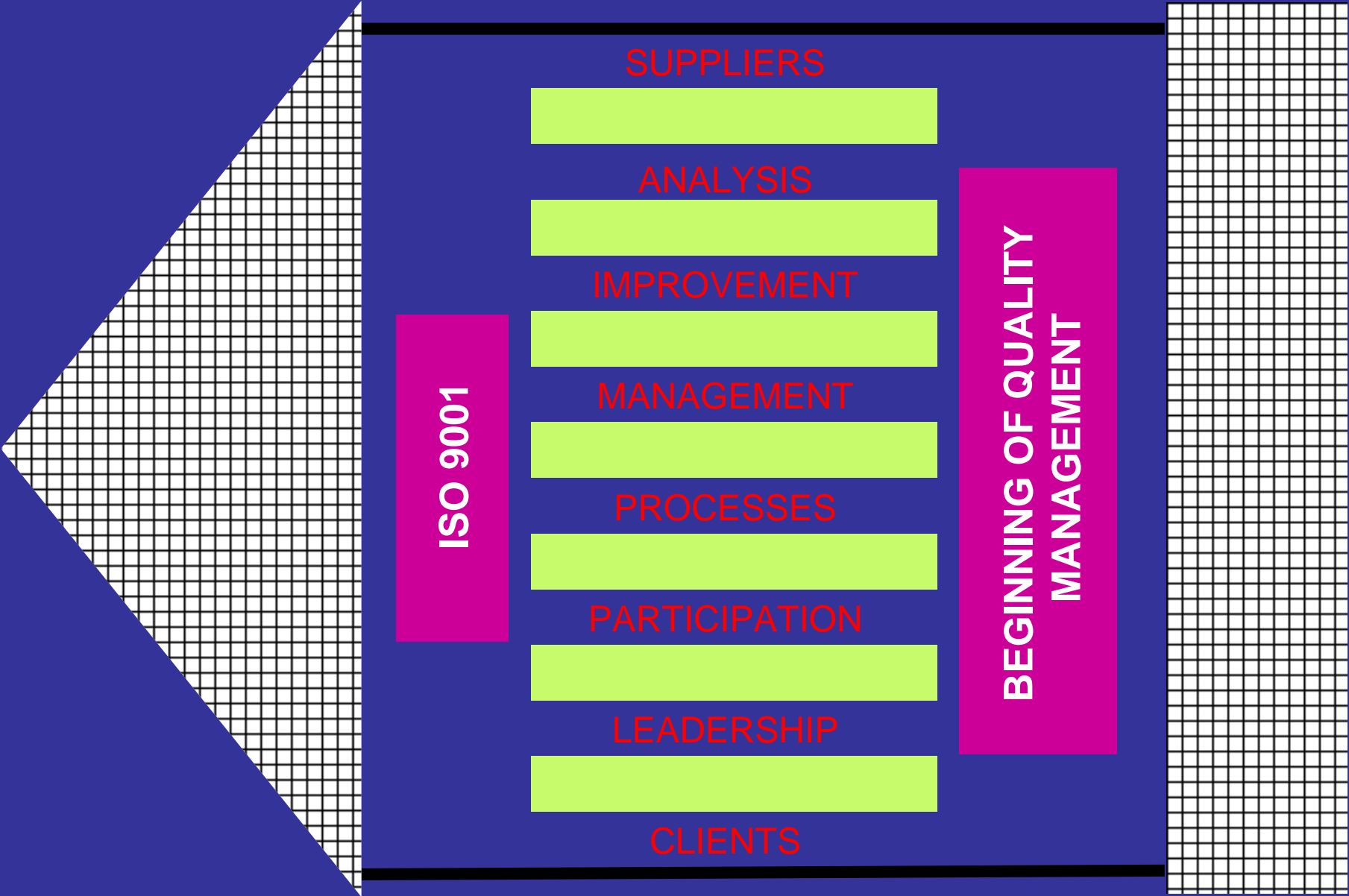
2001 : 510.616 ACCREDITATIONS (161 COUNTRIES) ⇒ INCREASE 25% (101.985) WITH REGARD TO 2000.

SOME EXAMPLES

COUNTRY	CERTIFICATIONS
UNITED KINGDOM	66.760
ITALY	48.109
GERMANY	41.629
UNITED STATES	37.026
JAPAN	27.385
AUSTRALIA	26.750
FRANCE	20.901
SPAIN	17.749

TOTAL: 286.309

SCHEME OF THE PRINCIPLES OF MANAGEMENT OF THE QUALITY



CONCLUSIONS

1. IT IS NECESSARY THAT THE DIRECTION ENDOWS OF THE SUFFICIENT RESOURCES FOR THE IMPLANTATION AND LEADS THE PROJECT.
2. THE IMPLANTATION OF A SYSTEM OF MANAGEMENT BASED IN STANDARD ISO 9001 IT'S A CHAIN, IF IT TRUMPS A LINK, BREAKS.
3. IT DOES NOT HAVE FELT THE IMPLANTATION OF THE SYSTEM BEGINS IF NOT THIS ONE DEFINED THE AREA OF THE CERTIFICATION.

CONCLUSIONS

4. THE PERSON OR GROUP OF PERSONS IN WHOM DELEGUE THE IMPLEMENTATION AND MANAGEMENT OF THE QUALITY SYSTEM HAVE THAT REPORT OF THE DIRECTION OF THE COMPANY.
5. TO CREATE THE CIRCUIT OF DRAFT, REVIEW AND APPROVAL OF THE DOCUMENTATION.
6. IN THE ACTIVITIES, ONE HAS TO GIVE ATTENTION IN THE WAY OF IMPROVING THE CIRCUITS AND MANAGEMENT OF THE QUALITY.

REFERENCES

INTERNATIONAL STANDARDS

1. UNE-EN-ISO 9000 : 2000. QUALITY MANAGEMENT SYSTEM IN PRODUCTION ENVIRONMENTS.
2. UNE-EN-ISO 9001 : 2000. QUALITY MANAGEMENT
3. ISO 10006. QUALITY MANAGEMENT – GUIDELINES TO QUALITY.
4. ISO 19011 : 2002. STANDARD PROVIDING GUIDELINES FOR QUALITY AND ENVIRONMENTAL MANAGEMENT SYSTEMS AUDITING.