Establish Quality Standard

Establish quality specifications for product

Quality

- The working definition of 'quality' is the minimum level of performance required to fulfill a specification.
- This in turn underscores the importance of a precise description in terms of an item's specifications.

Standards

- The application of preset standards facilitates the description of item specifications.
- Standardization, by both national and international bodies, aims to facilitate the exchange of goods and services.
- These standards are a reference guide for all parties enabling them
  - to define a required specification
  - to provide a quality standard against which the delivered item can be tested and controlled.

- Most countries, if not all, have national standardization bodies.
- Among the many national standards still in use for international trade the most frequently encountered are
  - BS (British Standard)
  - GOST (Russian Standard)
  - DIN (German Standard)
- However, many countries are also members of the ISO, the International Organization for Standardization.
- All ISO member countries are gradually replacing their national standards with the corresponding ISO standards.

Application

- There are 2 types of standards that are of interest to the Movement in terms of its supply activities:
  - those that define the minimum specifications for a given product, and
  - those that define the control and testing procedures for a given specification.

- Red Cross and Red Crescent Movement Standardization
  - The Movement is well advance in terms of its goal to standardize and harmonize a large part of the equipment and materials used in its operations and projects.
  - facilitates the selection of and Movement-wide familiarization with standard goods supplied to emergency response activities.
  - Consequently, this enables the Movement to
    - pre-planned purchases
    - establish stockpiles
    - ensure equipment compatibility
    - train personnel and volunteers
    - establish spare part needs, etc, and, ultimately, to avoid supplying inappropriate goods.

Specifications

- Red Cross and Red Crescent specifications:
  - These include a list of characteristics that a product should present to ensure that the quality requirements for this product are met.
  - These characteristics must be supported by
    - realistic and applicable control methods.
    - Generally, reference is made to an international or a national control standard, or, more rarely, an in-house procedure.

National specifications:

- Nations impose their own national specifications for all products imported into their markets.
- designed to protect
  - Consumers
  - local markets
  - national producers.
- Nations also require exporters to conform to required specifications
  - helps to promote the production of export-quality products.
- Always ensure that the goods intended for importation conform to
  - the country's national specifications.
  - If this is not possible, contact the appropriate national authorities to have the goods authorized as an exception to the import regulations.

- International specifications:
  - Many products already have internationally-recognized specifications which are set out in the ISO standards.
  - Other internationally-recognized bodies have also established standard specifications:
    - GAFTA for international trade contracts covering cereals
    - CEI for international standards on electrical devices,
    - ECHO for humanitarian food-aid products from the EU, etc.
  - The Movement conforms, wherever possible, to international specifications for all standard products.

Inspection

- Where national and international specifications are respected
  - provided that the inspection company is well chosen, applying specifications against standard control procedures should not be a problem.
- Inspections can be undertaken by external services or internally.

- However, in some instances, legal requirements may impose an inspection by a state-certified company.
  - Certified inspection reports are required for most imports and exports.
  - Certified inspection reports are also essential documents in any arbitration process with a supplier.

- It is important to have:
  - well-defined requirements
  - with clear specifications, checked against the destination country's national specifications
  - based on well-known standards in both the country of purchase and destination.
- This ensures that the supplier's specifications and those used by the inspection company conducting the control are comparable.
- In the catalogue, preference has been given to ISO standards, and, where required, regional or national standards.

- **Facts About Current Good Manufacturing Practices (cGMPs)**
  - Consumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective.
  - Most people, however, are not aware of cGMPs, or how FDA assures that drug manufacturing processes meet these basic objectives.
  - Recently, FDA has announced a number of regulatory actions taken against drug manufacturers based on the lack of cGMPs.

- **What are cGMPs?**
  - cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA).
  - cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.
  - Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control

- This includes
  - establishing strong quality management systems
  - obtaining appropriate quality raw materials
  - establishing robust operating procedures
  - detecting and investigating product quality deviations
  - maintaining reliable testing laboratories.
- This formal system of controls at a pharmaceutical company,
  - if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors.
  - This assures that drug products meet their quality standards.

- The cGMP requirements were established to be flexible in order to
  - allow each manufacturer to decide individually how to best implement the necessary controls by
    - using scientifically sound design
    - processing methods
    - testing procedures
- The flexibility in these regulations allows companies to
  - use modern technologies and innovative approaches to achieve higher quality through continual improvement.
- Accordingly, the "c" in cGMP stands for "current,"
  - requiring companies to use technologies and systems that are up-to-date in order to comply with the regulations.
- Systems and equipment that may have been "top-of-the-line" to prevent contamination, mix-ups, and errors 10 or 20 years ago may be less than adequate by today's standards.

- It is important to note that cGMPs are minimum requirements.
- Many pharmaceutical manufacturers are already implementing
  - Comprehensive, modern quality systems and risk management approaches that exceed these minimum standards.

Why are cGMPs so important?

- A consumer usually cannot detect that a drug product is safe or if it will work.
- While cGMPs require testing, testing alone is not adequate to ensure quality.
- In most instances testing is done on a small sample of a batch
  - for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets.
  - Therefore, it is important that drugs are manufactured under conditions and practices required by
    - the cGMP regulations to assure that quality is built into the design and manufacturing process at every step.

- Facilities that are
  - in good condition,
  - equipment that is properly maintained and calibrated
  - employees who are qualified and fully trained
  - processes that are reliable and reproducible
  - These are a few examples of how cGMP requirements help to assure the safety and efficacy of drug products.

How does FDA determine if a company is complying with cGMP regulations?

- FDA inspects pharmaceutical manufacturing facilities worldwide using
  - scientifically and cGMP- trained individuals whose job it is to evaluate whether the company is following the cGMP regulations.
- FDA also relies upon reports of potentially defective drug products from the public and the industry.
- FDA will often use these reports to identify sites for which an inspection or investigation is needed.
- Most companies that are inspected are found to be fully compliant with the cGMP regulations.

- **If a manufacturer is not following cGMPs, are drug products safe for use?**
- If a company is not complying with cGMP regulations, any drug it makes is considered “adulterated” under the law.
- This kind of adulteration means that the drug was not manufactured under conditions that comply with cGMP.
- It does not mean that there is necessarily something wrong with the drug.

- For consumers currently taking medicines from a company that was not following cGMPs,
  - FDA usually advises these consumers not to interrupt their drug therapy, which could have serious implications for their health.
  - Consumers should seek advice from their health care professionals before stopping or changing medications.
- Regulatory actions against companies with poor cGMPs are taken as a preventive measure because the manufacturing processes do not meet FDA’s regulatory standards.

- By focusing on the procedures and processes used to make these drugs,
  - FDA is working to ensure that drugs meet their quality standards and are safe and effective.
  - The impact of cGMP violations depends on the nature of those violations and on the specific drugs involved.
  - A drug manufactured in violation of cGMP may still meet its labeled specifications, and the risk that the drug is unsafe or ineffective could be minimal.
  - Thus, FDA’s advice will be specific to the circumstances, and health care professionals are best able to balance risks and benefits and make the right decision for their patients.

What can FDA do to protect the public when there are cGMP violations?

- If the failure to meet cGMPs results in the distribution of a defective drug, the company may subsequently recall that product.
- This protects the public by removing these drugs from the market.
- FDA cannot force a company to recall a drug, companies will usually recall voluntarily or at FDA’s request.
- If a company refuses to recall a drug, FDA can warn the public

- Even if the drugs are not defective, FDA can bring a seizure or injunction case in court to address cGMP violations.
  - When FDA brings a seizure case, the agency asks the court for an order that allows federal officials to take possession of “adulterated” drugs and destroy them.
    - This enables FDA to immediately prevent a company from distributing those drugs to consumers.
  - When FDA brings an injunction case, FDA asks the court to order a company to stop violating cGMPs.

- Both seizure and injunction cases often lead to court orders that require companies to take many steps to correct cGMP violations,
  - such as
  - hiring outside experts,
  - writing new procedures, and conducting extensive training of their employees.
- FDA can also bring criminal cases because of cGMP violations, seeking fines and jail time.

- **How would a new drug company learn about cGMPs and about FDA's expectations on complying with them?**
  - FDA publishes regulations and guidance documents for industry in the *Federal Register*.
  - This is how the federal government notifies the public of what we are doing and how we do it.
  - FDA's website, www.fda.gov also contains links to the cGMP regulations, guidance documents, and various resources to help drug companies comply with the law.

Identify hazards and critical control points

- **Seven Principles of Hazard Analysis and Critical Control Point (HACCP) System**
  - In order to enhance food safety, every stage of the food production (from purchasing, receiving, transportation, storage, preparation, handling, cooking to serving) should be carried out and monitored scrupulously.
  - The HACCP system is a scientific and systematic approach to
    - identify, assess and control of hazards in the food production process.
  - With the HACCP system, food safety control is integrated into the design of the process rather than relied on end-product testing.
  - Therefore HACCP system provides a preventive and thus cost-effective approach in food safety.

- The seven principles of a HACCP System are

1. Analyze hazards
2. Determine critical control points
3. Establish limits for critical control points
4. Establish monitoring procedures for critical control points
5. Establish corrective actions
6. Establish verification procedures
7. Establish a record system

Analysis hazards

- A food safety hazard is any biological, chemical or physical property that may cause a food to be unsafe for human consumption.
- We analyze hazards
  - to identify any hazardous biological, chemical, or physical property in raw materials and processing steps
  - to assess their likeliness of occurrence and potential to render food unsafe for consumption.

Determine critical control points

- A critical control point is a point, a step or a procedure in a food manufacture process
  - at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.
- Not every point identified with hazards and preventive measures will become a critical control point.

- A logical decision-making process is applied to determine whether or not the process is a critical control point.
- The logical decision-making process for determining critical control points may include factors such as:
  - whether control at this particular step is necessary for safety;
  - whether control at this step eliminates or reduces the likely occurrence of the hazard to an acceptable level;
  - whether contamination with the hazard identified could occur in excess of acceptable levels;
  - whether subsequent steps will eliminate or acceptably reduce the hazard

Establish limits for critical control points

- Limit for critical control point is a criterion which separates acceptability from unacceptability.
- It is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to
  - prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.
- Examples of limits for critical control point are time, temperature, humidity, water activity and pH value.
- The limits should be measurable.
- In some cases, more than one critical limit is needed to control a particular hazard.

Establish monitoring procedures for critical control points

- Monitoring is a planned sequence of observations or measurements
  - to assess whether a critical control point is under control
  - to produce an accurate record for future use in verification.
- Monitoring is very important for a HACCP system.
- Monitoring can warn the plant if there is a trend towards loss of control
  - so that it can take action to bring the process back into control before the limit is exceeded.
- The employee responsible for the monitoring procedure should be clearly identified and adequately trained.

Establish corrective actions

- Corrective action is an action taken
  - when the results of monitoring at the critical control point indicate that the limit is exceeded, i.e. a loss of control.
- Since HACCP is a preventive system to correct problems before they affect food safety,
  - plant management has to plan in advance to correct potential deviations from established critical limits.
  - Whenever a limit for critical control point is exceeded, the plant will need to take corrective actions immediately.
- The plant management has to determine the corrective action in advance.
- The employees monitoring the critical control point should understand this process and be trained to perform the appropriate corrective actions.

Establish verification procedures

- Verification is the application of
  - methods, procedures, tests and other evaluations,
  - in addition to monitoring, to determine compliance with the HACCP plan.
- Some examples of verification are
  - the calibration of process monitoring instruments at specified intervals
  - direct observation of monitoring activities
  - corrective actions

- Besides, sampling of product, monitoring records review and inspections can serve to verify the HACCP system.
- The plant management should check that the employees are keeping accurate and timely HACCP records.

Establish a record system

- Maintaining proper HACCP records is an essential part of the HACCP system.
- Accurate and complete HACCP records can be very helpful for:
  - documentation of the establishment's compliance with its HACCP plan;
  - tracing the history of an ingredient, in-process operations, or a finished product, when problem arise;
  - identifying trends in a particular operation that could result in a deviation if not corrected;
  - identifying and narrowing a product recall.

- The record of a HACCP system should include
  - records for critical control points
  - establishments of limits
  - corrective actions
  - results of verification activities
  - the HACCP plan including hazard analysis.
- To establish recordkeeping procedures, plant management may:
  - develop forms to fully record corrective actions taken when deviations occur;
- identify employees responsible for entering monitoring data into the records and ensure that they understand their roles and responsibilities

Assist in planning of quality assurance procedures

- hat ‘quality’ actually means will depend on the outputs the project is creating, but is generally related to:
  - Fitness for purpose Jisc expects you to perform quality planning to ensure that project outputs meet quality expectations
  - Adherence to relevant standards and specifications (e.g. to ensure interoperability and accessibility)
  - Use of best practice methods and techniques for development

- Fitness for purpose’ will vary with the project output.
- For example, if you are developing software to enable users to perform a task, the software should enable them to perform it.
- However, it can also relate to *how well* it allows them to perform a task and factors like usability.
- If you’re developing a pilot to demonstrate feasibility, it should obviously demonstrate feasibility, but scalability and reliability might be other factors to consider in fitness for purpose.

Why quality and quality planning are important:

- Each output contributes to the success of the programme.
- Disc shares development outputs with the community.
- They need to be fit for purpose and of value to the community
- Integration and interoperability are increasingly important in ICT.
- Outputs need to meet agreed standards so they work together seamlessly
- Jisc development is publicly funded and must provide value for money
- Disc projects should provide a lasting benefit to the community

Quality planning

- A quality planning process has been developed to improve and assure the quality of project outputs
- 1) **Quality expectations** The programme defines the standards and level of quality expected from the project in the funding call
- 2) **Acceptance criteria** The programme defines acceptance criteria for major project outputs based upon the quality expectations set in the funding call

- 3) **Quality plan** The project develops a quality assurance plan showing how it will achieve the quality expected and the quality assurance processes it will put in place.
- 4) **Implementation** During the project, the outputs are developed in line with the quality plan.
- 5) **Acceptance of outputs** The project submits its outputs, supported by evidence that they meet the quality expectations.
- Outputs are assessed against the acceptance criteria and accepted (or rejected) by the programme.

- **Quality expectations**
  - The programme manager will discuss quality expectations for specific types of outputs with you ;
  - they will relate to fitness for purpose and compliance with agreed standards and best practice.
- **Acceptance criteria**
  - will relate to what you must do to demonstrate that the expected quality has been achieved.
  - For example, the programme manager might ask for a set of interoperability test results to demonstrate that interoperability standards have been adhered to, or
  - they might ask for a report from an external evaluator that assesses fitness for purpose.

Project QA plan

- As Jisc innovation programmes result in a wide range of outputs
  - the programme manager may adapt the template to suit the type of outputs being developed.
- Whatever the outputs, the idea is to think through how you will achieve the quality envisaged. This will involve:
  - **quality assurance**
    - putting in place the policies, practices, and procedures for achieving best practice and complying with standards
  - **quality control**
    - checking that you've done what you expected to do (e.g. by testing).

QA methods

- Define the quality assurance methods/techniques that will be used or reference established ones.
- For example, what processes will you put in place to ensure that software complies with Jisc's open source policy, the best practice and relevant standards.

- ***Evidence of compliance***
  - Indicate the evidence that will demonstrate that you have achieved the quality envisaged.
  - For example, this may involve test results, benchmarking, or successful completion of external peer review.

- ***Quality responsibilities***
  - For example, if you’re developing software, quality responsibilities might be:
    - **Project Manager** Change control, quality of project documentation
    - **Lead programmer** System testing quality, configuration management
    - **Programmer** Unit testing quality
    - **Academic advisor** Usability quality.

Quality control tools

- You are encouraged to use compliance testing tools wherever appropriate
- Effective tools are a valuable way of easing the construction and maintenance of standards compliant applications and data.
- They exist in many areas including
  - HTML compliance
  - metadata maintenance
  - accessibility testing
  - conformance to SCORM standards
  - viewing XML schemas
- You are encouraged to select appropriate tools to assist with software testing and quality control.
- These might include tools for testing functionality, performance, usability, compliance with standards, coding, etc.
- The programme manager can advise.

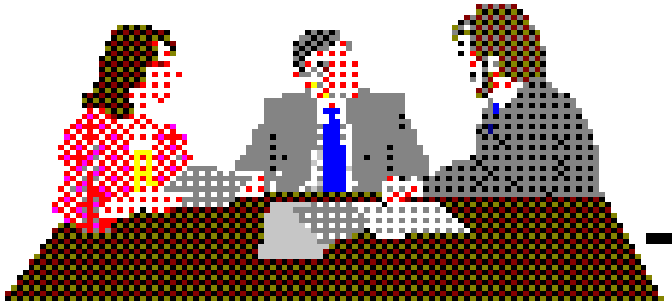
Implement quality assurance procedures

Preventing quality problems

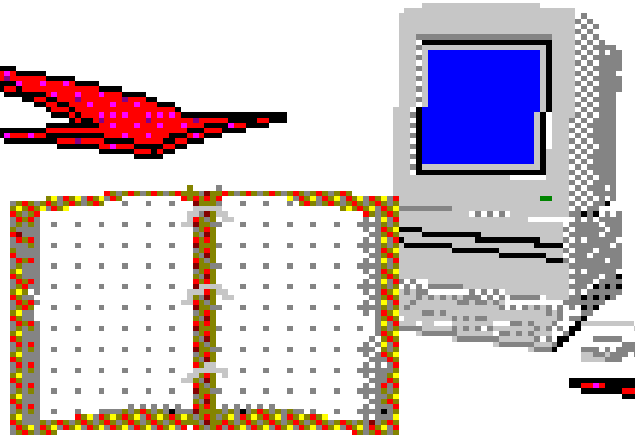
- Quality assurance, in its broadest sense,
  - is any action taken to prevent quality problems from occurring.
- In practice, this means devising systems for carrying out tasks which directly affect product quality.
- A simple example of quality assurance is a cooking recipe.
- A recipe is a system for preparing a particular dish.

- It describes the ingredients and utensils necessary to
  - prepare the food
  - the method of cooking it
  - how to test when it is ready
  - how to store it
  - how to serve it
- Cooking to a recipe produces better and more consistent results.

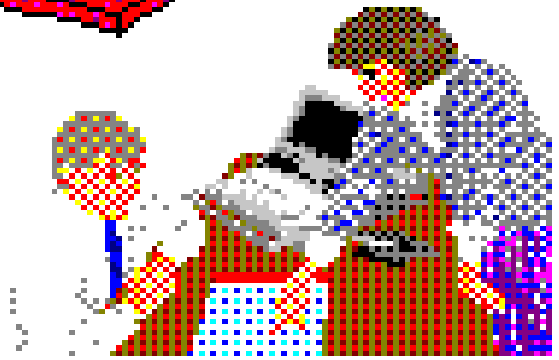
- To implement systems for an organization
  - you need to carry out three basic steps:
    - first develop the system;
    - second, document it (this takes the form of policies, procedures, and reference information)
    - third, inform, instruct, and train staff to use it.
  - This process is illustrated below.



carry out system analysis and development



document policies, procedures, and reference information



inform, instruct and train staff

- Systems of various kinds are, of course, already an integral part of all organizations.
- But in most cases they do not thoroughly address quality as a separate and important issue.
- This changes when an organization embraces and pursues quality assurance.
- Quality assurance does not only apply to products.
- Services, and even "non-production" activities such as administration and sales, benefit from a quality assurance approach.

Quality Assurance standards

- Quality Assurance Standards are published documents which describe in detail what systems should be used by a company to manage quality.

- the QA standards issued by various bodies.

Name of QA standard	***Issuing body***	***Applies to***
ISO 9001: Quality Systems - Model for quality assurance etc.	International Organization for standardization	General supplier qualification
Code of Good Manufacturing Practice (GMP)	Australian Health Authorities	Pharmaceuticals and sterile products
Testing Laboratory Certification standard	National Assoc. of Testing Laboratories (NATA)(Aust)	Qualification of testing laboratories
API Q1 Quality Program	American Petroleum Institute	Suppliers to the US petroleum industry
Mil-Q-9858	US Dept. of Defense	Suppliers to the US Defense Forces

- These Standards exist because many large organizations will not buy from suppliers who cannot give them assurance that they have systems which support quality.
- These large organizations include Government Defense Departments, Health Departments, car manufacturers such as Ford,
- Toyota, and General Motors, and Aerospace companies such as Boeing and Lockheed.

- Until the mid 1980's these large organizations published their own standards or codes for
  - suppliers to follow, and their staff would audit supplier companies regularly to make sure they followed the code.
  - It was not unusual for a supplier to be audited separately by a number of larger customers, all with their own quality system codes.

- In some instances suppliers hosted 30 or 40 quality system audits a year from all their major customers.
- To reduce the number of audits to which individual suppliers were subjected, the International Organization for Standards (ISO) published a series of standards in 1987 known as ISO 9000.
- Most large purchasing organizations accepted this worldwide standard and ceased to issue their own codes.
- They also ceased carrying out their own audits and accepted the findings of independent audit companies engaged by supplier companies to check their systems against the ISO 9000 standards.
- This allowed supplier companies to reduce the number of audits to two or three per year.

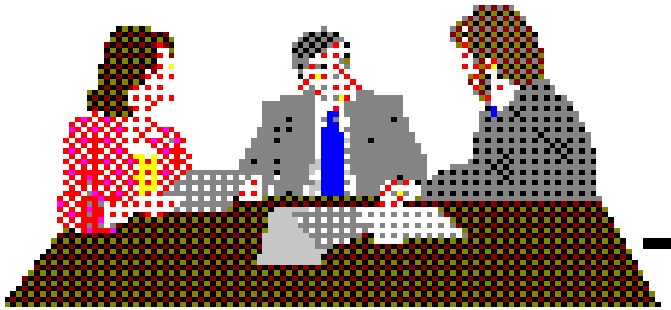
- Some of the independent audit companies operating in Australia are
  - Lloyds Quality Assurance Services
  - Quality Assurance Services (QAS)
  - Bureau Veritas
  - Benchmark Certification
  - SGS QA Services
  - National Assocation of Testing Authorities (NATA)

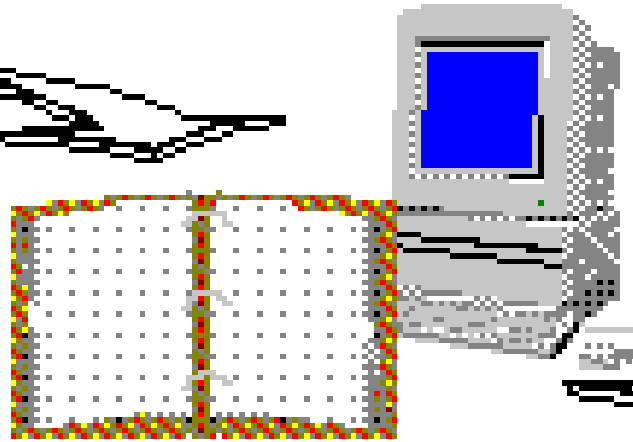
The ISO 9000 series of QA standards

- ISO 9000 is the name of a series of QA standards recognized by over 200 countries around the world
- adopted as their national standards for QA.
- In Australia this series has been named the AS 3900 series
  - but this will change in mid 1995 to the AS/NZ/ISO 9000 series to identify it more closely with the international standard.
  - AS 3900 and ISO 9000 have identical contents.

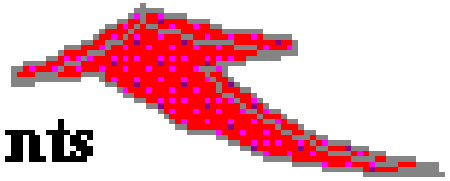
- The most important document in the ISO 9000 series is ISO 9001.
- This is the code against which audits are actually carried out
  - two other documents
  - ISO 9002 and ISO 9003
  - can also be audited against but these are 'cut down' versions of ISO 9001 for companies which do not need to comply with the entire code.
- All the other documents in the ISO 9000 series provide guidelines and explanations for how to apply ISO 9001.

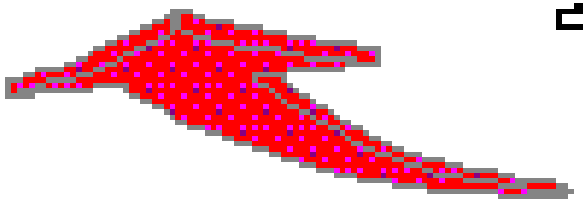
- The principal features of ISO 9001 are that it, takes the basic principle of QA (the need for documented systems to support QA), and
- adds requirements to control system documentation to make sure it is kept up-to-date
  - requires companies to carry out their own internal audits of their QA system to make sure it is working properly
  - requires the QA system to be constantly monitored to ensure that it is effective, and that changes are constantly



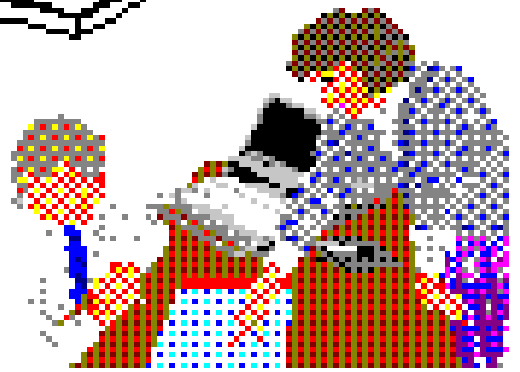


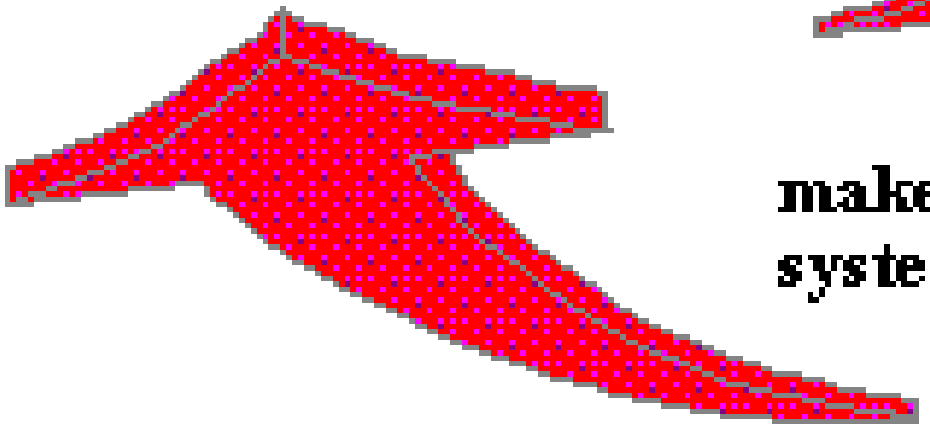
keep documents
in line with current
management thinking





make sure that
systems actually work





fix problems, look for their causes in the system,
and change the system

- In addition, ISO 9001 requires organizations to include documented systems in their QA system to cover all aspects of:
  - basic quality control (inspection, testing, test records, traceability, etc.)
  - a product's life cycle from the time negotiations start with the customer, through the design process, purchasing of raw materials, production, storage, and final delivery

When is QA appropriate

- The basic principle of QA - working out the best course of action before hand and communicating it reliably to all those concerned - should be applied whenever a planned process is complex, has implications for other processes, or has wide or repetitious application.
- Beyond this, the decision to follow the specifications in a comprehensive published QA standard rests on your organization's answers to the following questions:

- Is your organization prepared to invest the time to follow the formal discipline required?
- Does the law require your organization's compliance with a specific standard (pharmaceutical manufacturers must comply with the Code of GMP)?
- Do your customers insist on your organization's compliance with a standard (many large companies and
- Government Agencies and Departments have a policy of preference for suppliers with QA Certification)?

How to implement a QA system

- You can implement quality assurance in a general way by identifying the tasks, processes, or
- systems critical to the business and writing clear guidelines and instructions for staff.
- Use these guidelines and instructions for training and day-to-day reference.

- For the tasks, processes and systems covered, this will reduce:
  - the number of errors
  - waste of time and materials associated with errors
  - the number of customer complaints
  - the number of problems to fix
  - the time spent on giving day-to-day instructions
  - the time needed to improve processes and systems (by establishing a stable base)

10 best practices for an effective testing & QA implementation

By Jose Vargas and Julio Córdoba, Financial Services Division of Fortune 50 Organization

- After years of polishing and fine-tuning a division-wide testing & QA effort,
- we thought it would be a good idea to share the top ten lessons learned for what we now consider as the key to a successful outcome.
- We hope you find this short list useful as a source of validation

1) Process:

- It is critical that the organization defines a process that is robust and certified by experts in order to initiate the software assurance quality culture.
- The process will serve as a guideline that may evolve over time.
- Most importantly, it should be made official and should be followed through. Improvements will be made until a mature process is established.

2) Managerial Commitment:

- Managerial commitment should stem from the CIO to ensure alignment from each of the development managers,
- as well as from the development areas of each country.
- Everyone must be aware of the value that is added by testing & QA to the business.
- The process, therefore, must account for the value of the solutions that it offers to the organization.

3) Personal Experience:

- ❖Hiring someone as a tester that lacks necessary experience is a common mistake.
- ❖It is vital to acknowledge that the position requires experience in both the business and in software development in general.

4) Deliverables:

- ✓As part of the software development and testing processes,
- ✓it is necessary to define deliverables, such as requirements, a testing plan, and testing cases.
- ✓These will guarantee that testers can effectively follow-up throughout the project from the software quality perspective.

5) Tool Usage:

- Both the use of tools for tracking and managing defects
- as well as the creation of test cases and execution, are essential for increasing the maturity of the testing & QA process.
- The process may begin without tools, but they are a requisite for increasing execution maturity.

6) Metrics:

- Developing and creating metrics to track the software quality in its current state, as well as to compare the improvement with previous versions,
  - will help increase the value and maturity of the testing process (e.g. the number of components with errors in the software/the total number of components in the software; or
  - the number of errors detected in the testing phase/total number of errors detected).

7) Testing Environment:

- Implementation of appropriate testing environments that allow developers to
  - reproduce the system execution in production environments is crucial to
    - the creation and execution of the corresponding test cases.

8) Test Data:

- The testing environment required for day-to-day operation should provide or
- ensure availability of the necessary data to enable the corresponding test execution.
- Even if you have developed the appropriate testing environments, developers need to access specific data required to execute the associated test cases.

9) Change Management:

- Like any other production environment, the testing environment should
  - properly track changes in configuration
  - ensuring not only controlled results, but that the tests are run in environments that closely resemble those of the real production environment.

10) Developer Awareness:

- It is critical to have an awareness process that includes management commitment at each and every business unit and for associated developers.
- The goal is to demonstrate that testing activities add value to their daily work.

Performance Improvement and Outcomes Monitoring

- A program executive director was talking with a member of her clinical staff one afternoon.
- In the course of the conversation, she asked the supervising counselor, “So tell me, how's your group doing?”
- The supervising counselor replied, “Oh, they're doing really great.”
- The director then asked, “How do you know?”
- This question stumped both the director and counselor because, as in many programs,
  - they relied on intuitive assessments of clinical performance
    - they had no objective way of monitoring performance.

- Without objective indicators of performance,
- it is difficult to know how effective a treatment program is, whether its performance is improving or worsening.
- This chapter examines approaches for measuring and improving the performance of outpatient treatment (OT) and intensive outpatient treatment (IOT) programs, using objective performance data.

- Performance improvement, which is a set of processes used to improve a clinic's outcomes, need not be complex or expensive.
- Providers need to consider how they can integrate commonsense performance improvement into their daily treatment activities.
- Some providers may not realize that they probably are collecting data already that can be used to conduct performance improvement.

- Performance improvement and outcomes monitoring are becoming required elements in health service delivery.
- Outcomes monitoring has long been important to industry and health care because it provides an excellent and efficient mechanism for improving productivity and care (Mecca 1998).
- Performance improvement can increase revenues by improving service delivery, reducing costs, and increasing client satisfaction (Deming 1986).

- An emphasis on performance improvement ought not to be considered a burden.
- The viability of the substance abuse treatment field depends on establishing the effectiveness of its services.
- Performance improvement has a critical mission: to use objective information to improve outcomes continually by
- Identifying opportunities for improvement
- Testing innovations
- Reporting the results to the relevant stakeholders

- Program and management staffs should consider making performance improvement a central element of their program's administrative plan.
- This chapter focuses on
- Types of instruments and measures that are useful for providers in improving treatment outcomes
- How to establish an ongoing performance improvement program for staff and the clinic as a whole
- How to involve program staff in a collaborative and positive way as an outcomes improvement plan is being designed and implemented
- Positive actions that can be taken in response to performance evaluation findings